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Amending the Ryan Haight Act: Elevating Telemedicine Law to New Heights

Dillon Vaughn

Texas A&M University School of Law (Student), dillon123@tamu.edu

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AMENDING THE RYAN HAIGHT ACT: ELEVATING TELEMEDICINE LAW TO NEW HEIGHTS

By: Dillon Vaughn*

ABSTRACT

The Ryan Haight Act has established excessive restrictions on controlled substance prescribing through telemedicine by first requiring an in-person exam. If the Act is not amended, many individuals in need of medication will go without proper medical care. While other agencies and states have made moves to expand telehealth, the DEA has dragged its feet on making any significant changes. This Comment argues that the federal government should amend the Ryan Haight Act, allowing telemedicine providers to prescribe controlled substances without an in-person exam. This amendment would focus on the standard of care while requiring stringent documentation by physicians who perform telemedicine services. If this change occurs, patients who have barriers to accessing medical treatment will have the opportunity to get the proper care they need.

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I. INTRODUCTION

The federal Ryan Haight Online Pharmacy Consumer Protection Act places excessive limitations on telemedicine providers. The Act requires an in-person examination before prescribing a controlled substance.¹ But an evaluation through audiovisual communication technology can be performed that accomplishes the same result at a reduced cost to both parties. Individuals who have difficulty meeting with a physician in person because of barriers to access health care, whether geographic or due to a lack of transportation, can benefit from a change in the law that allows physicians to prescribe controlled substances through telemedicine without forcing the patient to visit a brick and mortar doctor's office first. This Comment argues that there is a way to reform telemedicine prescribing laws that would not be overly permissive, but would allow telemedicine providers to use advancements in technology for the benefit of the healthcare industry as a whole. This Comment also brings to light the unintended consequences the Ryan Haight Act has placed upon individuals with substance abuse disorders who are in need of medication-assisted treatment.

Telemedicine is a descriptive term that is commonly used interchangeably with "telehealth," and both terms will be used interchangeably throughout this Comment.² Telemedicine services are delivered through various devices such as telephone consultations, remote cardiac monitoring, or doctor appointments held through a video conference.³ The flexibility that telemedicine allows would give unprecedented access to healthcare services in areas that need significant development to eliminate barriers to treatment.⁴

1. 21 U.S.C. § 829(e)(2)(A)(i) (2012).

2. Kayla R. Bryant, *Health Law Daily Wrap Up, STRATEGIC PERSPECTIVES: States Fail to Fully Use Telemedicine to Fight Public Health Crises*, WOLTERS KLUWER (Sept. 28, 2018), <https://www.alston.com/-/media/files/insights/publications/2018/10/wolters-kluwer-health-law-daily-wrap.pdf> [<https://perma.cc/WX6A-J3MJ>].

3. *See id.*

4. *Id.*

II. THE FOUNDATION FOR THE RYAN HAIGHT ACT

Clayton Fuchs developed a business plan in the late 1990s which allowed for the use of his pharmacy license to start an online pharmacy.⁵ The issue with his business plan was that the online pharmacy, Friendly Pharmacy, allowed customers to simply visit its website, easily complete an online profile, and order any prescription drug of their choice.⁶ Then, Fuchs's online pharmacy would forward the order to a physician who lived in Texas to fill the prescription without ever speaking to or physically examining any of the patients.⁷ The online pharmacy filled nearly every order placed.⁸

There is no doubt that taking advantage of the system this way is not ethical or legal and should be eliminated. Fuchs's online pharmacy, and other online pharmacies like his, was the reason for the Ryan Haight Online Pharmacy Consumer Protection Act's name. Ryan Haight was a seventeen-year-old boy who, while in his home, began buying prescription drugs from Fuchs's online pharmacy.⁹ Ryan purchased Vicodin and other drugs from the online pharmacy, and in 2001, he died of an overdose from these drugs.¹⁰ All of Ryan's drugs were prescribed without any communication with a physician whatsoever.¹¹ Ryan's story eventually led to the amendment of the Controlled Substances Act in 2009, named the Ryan Haight Online Pharmacy Consumer Protection Act.¹²

A. *What the Ryan Haight Online Pharmacy Consumer Protection Act Requires*

The Ryan Haight Act was passed to regulate rogue pharmacies—pharmacies like the one in the story above—from overprescribing controlled substances online.¹³ However, although the Act does successfully regulate these dangerous rogue pharmacies, it also negatively affects legitimate healthcare providers that use telemedicine to prescribe controlled substances for the true benefit of their patients.¹⁴

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

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.* at 546.

10. *Id.*

11. *See id.* at 545–46.

12. *Id.*

13. Nathaniel M. Lacktman, *Telemedicine Prescribing and Controlled Substance Laws*, FOLEY & LARDNER (Apr. 3, 2017), <https://www.foley.com/en/insights/publications/2017/04/telemedicine-prescribing-and-controlled-substances> [<https://perma.cc/CN35-UDMQ>].

14. Nathaniel M. Lacktman, *Prescribing Controlled Substances Without an In-Person Exam: The Practice of Telemedicine Under the Ryan Haight Act*, BECKER'S HEALTHCARE (Apr. 19, 2017), <https://www.beckershospitalreview.com/healthcare-in->

The Ryan Haight Act prohibits prescribing a controlled substance “as determined under the Federal Food, Drug, and Cosmetic Act . . . delivered, distributed, or dispensed by means of the Internet without a valid prescription.”¹⁵ A valid prescription is one that is issued for a legitimate medical purpose in the course of professional practice by (1) a practitioner that has conducted at least one in-person medical evaluation of the patient, or (2) a covering practitioner.¹⁶ Therefore, to comply with federal law, a practitioner prescribing a controlled substance through telemedicine must have already evaluated the patient in person or have a covering practitioner evaluate the patient. A covering practitioner is a practitioner who conducts a medical evaluation at the request of a practitioner who (1) has conducted at least one in-person evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous twenty-four months, and (2) is currently unavailable to conduct the evaluation.¹⁷

B. *Problems with the Ryan Haight Act*

While the Ryan Haight Act has helped to reduce the number of up-and-running rogue online pharmacies in the United States, the Act has also produced negative results for legitimate telehealth providers. For example, the exceptions that were carved out in the Ryan Haight Act for legitimate telehealth providers have not been acted upon by the Drug Enforcement Agency (“DEA”). One exception states that the attorney general can issue a special registration to a practitioner to engage in the practice of telemedicine.¹⁸ To receive the special registration, a practitioner must (1) have a legitimate need for the special registration, and (2) be registered in the state in which the patient is located when receiving treatment through telemedicine.¹⁹

No practitioner has been given the special registration to date,²⁰ in fact, the DEA has not even opened the special registration process.²¹ In 2015, the American Telemedicine Association (“ATA”) sent a letter to the DEA requesting that the DEA open the special registration process, to allow psychiatrists and physicians to prescribe controlled substances through telemedicine without the requirement of an in-

formation-technology/prescribing-controlled-substances-without-an-in-person-exam-the-practice-of-telemedicine-under-the-ryan-haight-act.html [https://perma.cc/F3F7-4PTU].

15. 21 U.S.C. § 829(e)(1) (2012).

16. *Id.* § 829(e)(2)(A)(i)–(ii).

17. *Id.* § 829(e)(2)(C)(i)–(ii).

18. 21 U.S.C. § 831(h) (2012).

19. *Id.* § 831(h)(1)(A)–(B).

20. Mohana Ravindranath, *Doubts Surround Pending DEA Telemedicine Rule*, AM. TELEMEDICINE ASS’N, <https://www.americantelemed.org/industry-news/doubts-surround-pending-dea-telemedicine-rule/> (last visited Sept. 21, 2019) [https://perma.cc/U9P4-TV SX].

21. *Id.*

person exam.²² The letter stated that “the [current] interpretation of the [Ryan Haight] Act’s general prohibition of prescribing controlled substances by means of the internet has become overly restrictive.”²³ In 2016, the DEA responded that it planned to issue a rule to activate the special registration process that would allow physicians to prescribe controlled substances through telemedicine without an in-person exam, but this rule has not been released.²⁴ As a result of the DEA’s reluctance to open the special registration, recent legislation was passed by the federal government to force the opening of the special registration process.²⁵

Therefore, as a result of the Ryan Haight Act being passed, almost all telemedicine providers that prescribed controlled substances over the internet without first performing an in-person exam have become obsolete or are being run illegally. Due to restrictions of the Act, the federal government is failing to use telemedicine services to their full potential—like getting medical help to underserved and in-need individuals across the United States.

C. *Telemedicine Classification of Online Pharmacies*

Not every online pharmacy is alike; online pharmacies are typically split up into three classifications.²⁶ Knowing the different classifications of online pharmacies helps to detect what problems certain pharmacies may present.²⁷ First, there are “traditional online pharmacies,” which function similarly to “traditional brick and mortar pharmacies” and are “often an online extension” of brick and mortar pharmacies.²⁸ These traditional online pharmacies require a prescription from a physician before an order will be processed for a customer and are simply an additional way in which patients can fill their existing prescription.²⁹ These pharmacies are not the type that the Ryan Haight Act seeks to regulate.³⁰

22. Lacktman, *supra* note 13.

23. *Id.*

24. *Id.*

25. Jacqueline N. Acosta & Nathaniel M. Lacktman, *President Signs New Law Allowing Telemedicine Prescribing of Controlled Substances: DEA Special Registration to Go Live*, FOLEY & LARDNER (Oct. 25, 2018), <https://www.healthcarelawtoday.com/2018/10/25/president-signs-new-law-allowing-telemedicine-prescribing-of-controlled-substances-dea-special-registration-to-go-live/> [https://perma.cc/X2AP-BN6D].

26. Bob Schultz, *Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem*, 16 SAN DIEGO INT’L L. J. 381, 385 (2015).

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.* at 385–86.

The second classification of online pharmacies is “prescribing-based site pharmacies.”³¹ These pharmacies provide prescriptions and medication to those who visit the website.³² To receive a prescription from this type of online pharmacy, a customer will typically have a consultation that consists of not much more than a questionnaire.³³ Afterwards, a doctor will review the results of the “consultation” and will write the prescription.³⁴ There is no physical examination in this type of online pharmacy.

The third classification of online pharmacies is “rogue online pharmacies.”³⁵ These pharmacies are the most dangerous to consumers because they sell prescription medication without receiving a valid prescription, performing an “online consultation,” or conducting any type of examination to determine if there is a need for the medication.³⁶ All a consumer is required to do to receive medication from a rogue online pharmacy is fill out an order form in which the consumer selects the desired medication and quantity of that medication, then merely pay for the medication.³⁷ Rogue online pharmacies generally operate illegally because licensed practitioners must distribute pharmaceuticals in accordance with a valid prescription, and this type of medication-dispensing does not legally meet the standard of a valid prescription.³⁸

D. *State Law Interaction with Federal Law*

Many states have passed legislation in recent years that deals directly with telemedicine and how a patient–practitioner relationship may be formed. A number of states have developed laws making telemedicine less restrictive, which would allow a patient–practitioner relationship to be formed without a prior in-person examination. But some states have passed laws with similar demands to the Ryan Haight Act, requiring an in-person exam of some type.³⁹

For example, Texas passed legislation in 2017 making its telemedicine laws less restrictive, which aligns with many of the legislators’ views that those in rural areas need to have a better opportunity to receive health care and that telemedicine is one way to accomplish this goal.⁴⁰ The new Texas law no longer requires an in-person meeting between practitioner and patient before performing

31. *Id.* at 386.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 387.

36. *Id.*

37. *Id.*

38. *Id.*

39. Kimberly Lovett Rockwell, *The Promise of Telemedicine*, 96 MICH. B. J. 38, 40 (2017).

40. TEX. OCC. CODE § 111.005.

treatment through telemedicine.⁴¹ The Texas Occupations Code describes ways to establish the practitioner–patient relationship. One way to establish this relationship is through practitioner compliance with the proper standard of care and providing “telemedicine medical services through the use of . . . synchronous audiovisual interaction between the practitioner and the patient.”⁴² An example of a synchronous audiovisual interaction is one that is conducted through real-time video conversations, much like Skype, WebEx, or FaceTime.⁴³

In contrast, the Georgia Administrative Code has placed very restrictive regulations on Georgia’s telemedicine providers.⁴⁴ Georgia’s regulation states that the Medical Board can take disciplinary action against a practitioner who is “providing treatment via electronic or other means unless a history and physical examination of the patient has been performed by a Georgia licensee.”⁴⁵ Georgia does not allow “[p]rescribing controlled substances and/or dangerous drugs for a patient based solely on a consultation via electronic means with the patient”⁴⁶

Additionally, Alaska has an interesting set of laws regarding telemedicine that takes federal law into consideration.⁴⁷ The Alaska statute states that a physician may not be disciplined for prescribing a prescription:

drug that is not a controlled substance to a person without conducting a physical examination if (1) the physician or another licensed health care provider or physician in the physician’s group practice is available to provide follow-up care; and (2) the physician requests that the person consent to sending a copy of all records of the encounter to the person’s primary care provider . . . and, if the patient consents, the physician send the records to the person’s primary care provider.⁴⁸

Thus, Alaska has complied with the Ryan Haight Act in that it does not allow controlled substance prescribing at all without a prior in-person exam, but the Alaska statute opens up the opportunity for practitioners to prescribe other drugs without first providing an in-person exam.⁴⁹ In fact, all Alaska requires is that a physician is “available” for follow-up care.⁵⁰

41. *Id.*

42. *Id.*

43. *Asynchronous vs. Synchronous Video Communications: What’s The Difference?*, PANOPTO (June 2, 2019), <https://www.panopto.com/blog/asynchronous-vs-synchronous-video-communications-whats-the-difference/> [https://perma.cc/9PLC-FNEL].

44. GA. COMP. R. & REGS. R. 360-3-.02.

45. *Id.*

46. *Id.*

47. ALASKA STAT. § 08.64.364 (2018).

48. *Id.*

49. *Id.*

50. *Id.*

This is a small sample of just three states in the United States that have very different laws. The variance between state laws shows that the practice of telemedicine is very difficult because one state may allow telemedicine prescribing without an in-person exam, while a different state requires a prior in-person examination by an in-state licensee. Moreover, there are states like Alaska, which has essentially created a quasi-requirement that a practitioner must be available for a follow-up. Even though there is patchwork legislation among the states and physicians would have to be conscientious of the law in the state or states they are practicing in, the federal government should give states the freedom to make their own choice of law when it comes to telemedicine prescribing.

The Supremacy Clause of the United States Constitution states that federal law trumps state laws that are in conflict with said federal law.⁵¹ Therefore, a practitioner must currently look to both the state telemedicine laws as well as the federal. But, if choice of telemedicine law was given to each state, larger states could choose to allow telemedicine prescribing without an in-person exam so that individuals who have barriers to accessing a qualified physician can get proper medication, while smaller states would have the choice to keep their telemedicine laws more restrictive.

III. NEWLY ENACTED FEDERAL LEGISLATION

A. *What the Legislation Says*

For those with substance abuse issues and mental health disorders, the Ryan Haight Act has had the effect of cutting off medication-assisted treatment, which often utilizes medication labeled a controlled substance and is thus subject to the Ryan Haight Act.⁵² Congress did not realize the Ryan Haight Act would have these unintended consequences when it passed the Act over ten years ago. The negative result that the Ryan Haight Act has placed upon legitimate telemedicine providers and individuals in need of medication has been noticed. Recently passed legislation could alleviate some of the problem by allowing certain telemedicine providers to prescribe controlled substances without the requirement of an in-person examination.⁵³ This legislation would open up the DEA's special registration process mentioned previously.

The "SUPPORT for Patients and Communities Act," which was signed into law by President Donald Trump in October 2018, contains a chapter labeled "Special Registration for Telemedicine Clarification

51. U.S. CONST. art. VI, § 2.

52. Bryant, *supra* note 2, at 2.

53. Acosta & Lactman, *supra* note 25.

Act of 2018.”⁵⁴ This chapter establishes regulations that relate to the special registration exception of the Ryan Haight Act. It states that:

Not later than [one] year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying . . . the limited circumstances in which a special registration under this subsection may be issued; and . . . the procedure for obtaining a special registration under this subsection.⁵⁵

The proposed legislation originally required that the DEA promulgate final regulations within ninety days of enacting the legislation, but the DEA responded that this requirement would be burdensome and should be lengthened.⁵⁶ In response to the DEA, Congress extended the requirement to allow the DEA to promulgate final regulations within one year of enactment.⁵⁷ This change in the time requirement to promulgate this new rule can benefit both the DEA and practitioners hoping to receive the special registration.⁵⁸ With the original ninety-day requirement, the DEA would have published a rule without giving the public time for notice and comment.⁵⁹ This would have given the DEA the ability to put into force a rule that ultimately may not help the current issue in telemedicine prescribing.⁶⁰ But, by changing the time requirement to one year, the DEA can propose the rule and give the healthcare providers, prescribers, and patients who care most about this issue ample time to comment.⁶¹ This gives the DEA the proper duration and ability to consider the public’s view on the rule and tailor the rule accordingly.⁶²

Although this legislation has the potential to bring about positive change in the telemedicine industry by getting medical treatment to those who may not be reached otherwise, there are still many uncertainties in how this legislation will play out and ultimately affect the telemedicine landscape.

B. *Problems with the Legislation*

While great progress may come from the Special Registration for Telemedicine Clarification Act of 2018, some loopholes remain by

54. *Id.*

55. *Id.*

56. Bradley S. Davidsen & Daniel Kim, *Law Urging DEA to Promulgate Rules for “Special Registration” Likely This Summer*, LEXOLOGY (June 18, 2018), <https://www.lexology.com/library/detail.aspx?g=0f383547-cfe7-431e-b756-78b739d91aec> [<https://perma.cc/5ZBY-PLBY>].

57. *Id.*

58. Acosta & Lacktman, *supra* note 25.

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

which the DEA could effectively inhibit the number of providers receiving special registration.

First, a potential issue is the scope of the promulgated regulation, which could be written either very broadly or very narrowly. Congressman Greg Walden described a possible narrow rule as one that would grant the special registration “for emergency situations, like the lack of access to an in-person specialist.”⁶³ Additionally, Congressman Buddy Carter stated that the original purpose of the special registration was for “legitimate emergency situations.”⁶⁴ This interpretation differs from the language of the Ryan Haight Act. The special registration exception’s original language states the exception may be given to a practitioner who “demonstrates a legitimate need for the special registration.”⁶⁵ A plain reading of this language seems broader than the description Congressmen Walden and Carter read into the exception. This alone could be an issue because many legitimate practitioners believe that as a result of this new legislation, they will have the opportunity to receive the special registration. But, in reality, the newly promulgated rule could be written so narrowly that it would be nearly impossible to receive the special registration from the DEA.

The ATA has written the DEA a letter offering recommendations on the special registration process presented in this legislation. This letter offers five recommendations for the DEA, stating that the DEA should (1) update the current DEA registrations process to specify between traditional and telehealth prescribing privileges, (2) allow sites and prescribers to register for telehealth, (3) allow for a comment period for the public within the one-year timeline allowed before the special registration activation, (4) ensure that the special registration is not restricted to just one discipline, and (5) allow telehealth providers to apply for the registration in multiple states at once.⁶⁶ The ATA stated that “[t]he telehealth community has long advocated for activation of special registration to relieve the regulatory impasse that confronts many telehealth prescribers.”⁶⁷ The DEA should follow these recommendations offered by the ATA because the ATA can foresee the positive impact that the special registration could have on telemedicine. The ATA has explained that the special registration would “combat the opioid crisis, but also provide the broad range of medical disciplines an avenue to expand access to quality care.”⁶⁸

63. Davidsen & Kim, *supra* note 56.

64. *Id.*

65. 21 U.S.C. § 831 (2012).

66. *ATA Sends Recommendation Regarding the Special Registration Process for Telehealth Under the Ryan Haight Act to the DEA*, AM. TELEMEDICINE ASS’N (Jan. 12, 2019), <https://thesource.americantelemed.org/blogs/jessica-washington/2019/01/12/ata-sends-recommendations-regarding-the-special-re> [https://perma.cc/4CUU-XH2A].

67. *Id.*

68. *Id.*

Second, as previously discussed, many states like Alaska and Texas are revising legislation that allows a practitioner to perform telemedicine services without a prior in-person exam. While these states are maintaining pace with technology, the federal law makes some of this legislation obsolete because federal law preempts state law. Therefore, while this update to the special registration law would be progress toward resolving the issue of getting medication to those in need who do not have the means to meet with a practitioner in person, the overall issue requires a more comprehensive solution.

Since the passage of the Ryan Haight Act in 2008, there have been technological advancements that can not only help the DEA track controlled substance prescribing, but can also assist legitimate telehealth practitioners to create the practitioner–patient relationship by using a modern audiovisual medium. Such technological advancements must be taken into account by the federal government, and changes should be made by the federal government to help legitimate telehealth practitioners get medication to those in need.

This issue is analogous to changes in the marijuana laws that are being seen around the country. States are legalizing the sale and possession of marijuana,⁶⁹ much like they are legalizing the use of telemedicine services without requiring an in-person exam. But while states are legalizing the ability to prescribe controlled substances without an in-person exam, it is still a federal crime to do so—much like the sale or possession of marijuana has been legalized by some state laws but remains illegal at the federal level.⁷⁰ Therefore, until the federal laws governing telemedicine services become less restrictive, there will remain a federal penalty that may be enforced by the federal government. But if the federal statutes follow what a number of states have done, there will likely be a boom in both the marijuana and telemedicine industries.

Therefore, while the Special Registration for Telemedicine Clarification Act of 2018 has the structure to potentially be very beneficial to legitimate telemedicine providers who want to help unreached communities through telemedicine services, the DEA could still promulgate a regulation that makes receiving the special registration almost impossible. This type of regulation would not have much of a positive effect on the telemedicine industry or those who could benefit from telemedicine services.

69. See *Recreational Weed States – States That Have Legalized Weed*, WORLD POPULATION REV. (Oct. 7, 2019), <http://worldpopulationreview.com/states/recreational-weed-states/> [<https://perma.cc/BJQ2-Z73A>].

70. 21 U.S.C. § 812(c) (2012); *Id.* §§ 841–844 (2012).

IV. MEDICARE REIMBURSEMENT

While the DEA continues to drag its feet, other agencies are making significant progress toward expanding telehealth. By publishing several new rules, the Centers for Medicare and Medicaid Services (“CMS”) has made it possible for Medicare users to have access to healthcare services provided remotely by telehealth methods.⁷¹

A. *Change in Law for Reimbursement of Telehealth Services*

CMS officials stated that the rule, effective as of January 1, 2019, was promulgated to support access to health care using telecommunications technology.⁷² Medicare will now reimburse providers for new uses of technology-based services.⁷³ This demonstrates that CMS believes telehealth services can provide increased access to low-cost and high-quality health services and that CMS will allow for more flexibility to use these services by reimbursing a broader range of services.⁷⁴ CMS administrator Seema Verma supports the rules expanding Medicare and said that “[t]his provides opportunities for patients around communicating with providers remotely . . . [t]his is an historic change in terms of increasing access and it’s also a great example of some of the efforts that we’re trying to make around supporting innovation.”⁷⁵ Verma spoke about how access to care is an issue around the country, in both rural and urban areas, and that CMS hopes to use technology to provide better access.⁷⁶

1. Remote Evaluations and Virtual Check-Ins

Two key updates in CMS’s rules are (1) the reimbursement for the evaluation of pre-recorded patient information, and (2) brief communication technology-based services (virtual check-in).⁷⁷ The new rules permit the use of store-and-forward asynchronous telemedicine technologies that include pre-recorded still or video images submitted only

71. HOGAN LOVELLS, MEDICARE EXPANDS PAYMENT FOR AND COVERAGE OF TELEHEALTH AND SIMILAR SERVICES 1 (2018), https://www.hoganlovells.com/~media/hogan-lovels/pdf/2018/2018_11_07_health_alert_medicare_further_expands_payment_for_and_coverage_of_telehealth_and_similar_services.pdf [https://perma.cc/36BE-YXHB] [hereinafter *Medicare Further Expands Payment for and Coverage of Telehealth and Similar Services*].

72. Heather Landi, *BREAKING: CMS Publishes CY 2019 Physician Fee Schedule/QPP Final Rule*, HEALTHCARE INNOVATION (Nov. 2, 2018), <https://www.healthcare-informatics.com/article/payment/breaking-cms-publishes-cy-2019-physician-fee-scheduleqpp-final-rule> [https://perma.cc/4CUU-XH2A].

73. *Id.*

74. *Medicare Further Expands Payment for and Coverage of Telehealth and Similar Services*, *supra* note 71.

75. Landi, *supra* note 72.

76. *Id.*

77. *Medicare Further Expands Payment for and Coverage of Telehealth and Similar Services*, *supra* note 71, at 2.

by the patient.⁷⁸ The patient cannot give information solely through filling out a questionnaire.⁷⁹ After the information is given and the practitioner reviews the image or video, the practitioner must respond within twenty-four hours. The response does not have to be over an asynchronous forum and may be delivered by phone call, e-mail, or another form of communication.⁸⁰ CMS has put limits on this reimbursement by stating the reimbursement is only available to established patients.⁸¹ An established patient is one “who has received professional services from the physician or qualified healthcare professional or another physician or qualified healthcare professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past [three] years.”⁸² While there are gaps in this new rule from CMS, reimbursing for asynchronous image review is a promising step toward bringing Medicare reimbursement to virtual care services.⁸³

2. Telehealth to Treat Substance Abuse Disorders

A provision passed as a part of the SUPPORT for Patients and Communities Act expands the ability of practitioners to be reimbursed for telehealth treatment of substance abuse disorders.⁸⁴ The change eliminates many of the geographic restrictions that are applied to most telehealth services for treatment of individuals diagnosed with substance abuse or mental health disorders.⁸⁵ The patient’s home has been included as an originating site, allowing for telehealth treatment to be performed with the patient remaining in his or her house, but without the added charge of a facility fee.⁸⁶

B. What is a “Telehealth Service”

What is recognized as a “telehealth service” under Medicare is very important in determining whether a practitioner will be reimbursed. Under Medicare, “telehealth services” are those in which practitioners typically conduct in-person examinations, but “are instead furnished using interactive, real-time telecommunication technology.”⁸⁷ While the CMS rule changes have presented positive moves toward ex-

78. Nathaniel M. Lactman, *Understanding Medicare’s New Remote Evaluation of Pre-Recorded Patient Information (Asynchronous Telemedicine)*, FOLEY & LARDNER (Nov. 6, 2018), <https://www.foley.com/en/insights/publications/2018/11/understanding-medicare-new-remote-evaluation-of-p> [<https://perma.cc/W3F2-HLEJ>].

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. Nathaniel M. Lactman & Olivia King, *Medicare Proposes (and Rejects) New Telehealth Services for 2019*, FOLEY & LARDNER (Aug. 7, 2018), <https://www.health>

panding telehealth services, CMS continues to require an in-person exam before reimbursing for telehealth services, except if certain requirements are met.⁸⁸ CMS has stated that “it is critical that the initial hospital visit by the admitting practitioner be conducted in person to ensure that the practitioner . . . comprehensively assesses the patient’s condition upon admission to the hospital”⁸⁹

However, there are conditions that must be met for a practitioner to use telehealth services as a substitute for an in-person exam.⁹⁰ Those conditions require that:

(1) [t]he beneficiary is located in a qualifying rural area; (2) [t]he beneficiary is located at one of eight qualifying originating sites; (3) [t]he services are provided by one of ten distant site practitioners eligible to furnish and receive Medicare payment for telehealth services; (4) [t]he beneficiary and distant site practitioner communicate via an interactive audio and video telecommunications system that permits real-time communication between them; and (5) [t]he Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) code for the service itself is named on the list of covered Medicare telehealth services.⁹¹

These requirements are specific, but it is evident that CMS is willing to allow an exception to the in-person requirement when the circumstances warrant it. For example, as stated above, CMS is now allowing patients who have been diagnosed with substance abuse or mental health disorders to use their home originating site to qualify to receive telehealth services, as well as removing the geographic requirements to qualify for telehealth services.⁹² This allows a practitioner to get needed care to those with certain mental disorders without having to perform an in-person exam and without requiring the patient to be in the presence of another practitioner.⁹³

The rule changes CMS promulgated recognize the comfort patients and healthcare providers have with using communication technology and the value it brings to the healthcare industry.⁹⁴ CMS has realized the increased demand for convenient telehealth services, and CMS has responded by giving those impacted access to an expanded range of reimbursable services.⁹⁵

carelawtoday.com/2018/08/07/medicare-proposes-and-rejects-new-telehealth-services-for-2019/ [https://perma.cc/EN7T-4F4M].

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Medicare Further Expands Payment for and Coverage of Telehealth and Similar Services*, *supra* note 71, at 3.

93. *Id.*

94. *Id.*

95. *Id.*

V. NEEDED REFORM OF TELEMEDICINE

A. *Who Can Benefit from Changes*

The expansion of telemedicine services can benefit a very wide range of individuals, but the main focus of much of current legislation and those who practice medicine can be grouped into three populations: (1) those with substance abuse disorders, (2) those with legitimate mental health issues, and (3) individuals who live in rural areas and do not have the means to travel long distances to reach a health-care professional.

1. Individuals with Substance Abuse Disorders

An expansion of telehealth services is needed and can bring serious improvements to the opioid crisis by bringing medical services directly to the homes of those with substance abuse issues. Senator Brian Schatz from Hawaii has been a longtime advocate for telehealth services.⁹⁶ He stated that “[o]pioid addiction is a national epidemic, and we need a comprehensive approach to address it.”⁹⁷ In the United States, over 100 Americans die as a result of a drug overdose every day.⁹⁸ Although the deaths involving prescription painkillers have begun to level off, the data on fatalities involving heroin and illicitly-manufactured fentanyl has been astounding, showing that the number of deaths quintupled between 2010 and 2016.⁹⁹ The opioid crisis led to the passage of the SUPPORT for Patients and Communities Act, which seeks a way to get individuals with substance abuse disorders the help they need.¹⁰⁰

Treatment for substance use disorders usually involves an approach that includes behavioral counseling and medication-assisted treatment (“MAT”).¹⁰¹ For opioid addiction, MAT uses medications such as methadone, naltrexone, and buprenorphine, which work by blocking the effects of narcotics and/or by reducing withdrawal risk or symptoms.¹⁰² Using these MAT medications is controversial because people who are not addicted to opioids can experience euphoria when using these drugs.¹⁰³ But the National Institutes of Health stated that individuals who have developed a high tolerance for opioids do not

96. Eric Wicklund, *Congress Takes Aim at Opioid Crisis with Telehealth Expansion*, MHEALTH INTELLIGENCE (Oct. 4, 2018), <https://mhealthintelligence.com/news/congress-takes-aim-at-opioid-crisis-with-telehealth-expansion> [https://perma.cc/C3M5-CDTR].

97. *Id.*

98. Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 139 (2018).

99. *Id.* at 139–40.

100. Wicklund, *supra* note 96.

101. Bryant, *supra* note 2, at 2.

102. *Id.*

103. *Id.*

experience this euphoria and that these MAT drugs are essential for patients to function well enough to participate in other treatments.¹⁰⁴

The Ryan Haight Act was put into place to stop the illegal prescribing of controlled substances that were not medically necessary, but it has effectively blocked a channel for those struggling with substance abuse disorders to get treatments.¹⁰⁵ MAT drugs are controlled substances and as such are restricted by the Ryan Haight Act.¹⁰⁶ Therefore, individuals with substance abuse disorders who are not able to see a physician to start MAT will not receive the treatment necessary to cure their illnesses.¹⁰⁷ The Ryan Haight Act effectively eliminated substance abuse treatment via telemedicine.¹⁰⁸ And because of a lack of qualified physicians in opioid-use treatment, many individuals with substance abuse disorders go untreated.¹⁰⁹ Barriers to accessing health care result in untreated patients and overworked providers, illuminating the fact that telemedicine reform is needed.¹¹⁰

2. Those with Legitimate Mental Health Issues

Individuals with legitimate mental health issues can greatly benefit from having access to medication that can help them treat their conditions. The United States is currently facing a mental health crisis, with one in five adults experiencing some type of mental health issue.¹¹¹ Over 43 million Americans experienced a mental health issue in 2017, and of these 43 million, 4% suffer from a mental health issue so severe it has a serious impact on their daily life activities.¹¹² These mental health issues include post-traumatic stress disorder, anxiety disorders, major depression, bipolar disorder, and schizophrenia.¹¹³ The United States loses almost \$1 trillion per year in mental health care costs and lost wages resulting from mental health issues.¹¹⁴ The expansion of telemedicine to treat mental health issues in the United States will not only help individual citizens, but the economy as well.

3. Individuals Living in Rural and Low-Income Areas

A major issue for those with mental health and/or substance abuse issues is the lack of access to mental health care. One of the most

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. Allison N. Winnike & Bobby Joe Dale III, *Rewiring Mental Health: Legal and Regulatory Solutions for the Effective Implementation of Telepsychiatry and Telemental Health Care*, 17 HOUS. J. HEALTH L. & POL'Y 21, 25 (2017).

112. *Id.* at 26.

113. *Id.*

114. *Id.* at 28.

vulnerable populations in the United States that has little access to mental health care or substance abuse treatment include those living in rural or urban low-income areas.¹¹⁵ The issue for these groups is the long geographic distances one must travel to meet with a healthcare professional that is qualified to treat them.¹¹⁶ Mental health professional scarcity is a contributing factor to the long distances a patient must travel to meet with a healthcare provider. In the United States, nearly 60% of people living in rural areas live in one of the over 3,900 mental health professional shortage areas.¹¹⁷ Telemedicine has the ability to reduce the number of Americans living with mental health and substance abuse issues by getting medication to individuals living in rural and low-income areas that would otherwise not have access to care.

4. The Elderly

Additionally, the elderly population as a whole—especially those living in rural areas—could benefit from an expansion of telemedicine services.¹¹⁸ It is estimated that one in four elderly individuals has some form of mental illness.¹¹⁹ Much of the elderly population lacks adequate transportation to access competent health care.¹²⁰ These issues must be addressed in some way. Telemedicine gives those that live in rural areas or have limited mobility a drastic improvement in their ability to access healthcare services, thereby closing the gap between those in need and practitioners that can provide help.¹²¹ The expanded use of telemedicine could be a tool used in providing what the Centers for Disease Control and Prevention (“CDC”) have determined are the ten “essential public health services.”¹²² There have been concerns with insurance coverage, but as stated above, CMS has made changes that show it is beginning to see the benefits of using technological advancements to reach individuals who have barriers to health care, especially individuals fighting mental illness.¹²³ Now it is the federal government’s turn to rise to the occasion and do the same.

There is a vast range of unreached individuals who are barred from receiving proper health care. Expanding access to medication to those with substance abuse disorders, mental health diseases, and individuals living in rural areas would be a great step toward reaching these

115. *Id.* at 38–39.

116. *Id.* at 39.

117. *Id.* at 38.

118. *Id.* at 34.

119. *Id.*

120. *Id.*

121. Bryant, *supra* note 2, at 1.

122. *Id.*

123. *Medicare Further Expands Payment for and Coverage of Telehealth and Similar Services*, *supra* note 71.

classifications of individuals with poor health care. Telemedicine is a powerful means by which access to care can be greatly improved.

B. *What Changes Should be Made*

Changes to the federal Ryan Haight Act should be made to mitigate mental health and substance abuse issues, while also helping individuals in rural locations access quality health care. Without being overly permissive, there are a number of ways in which Congress can pass legislation that will help alleviate the issue of lack of health care while still regulating controlled substance prescribing. Changes in telemedicine laws would help the law catch up with innovation because we now have modern technology that allows a physician to evaluate a patient over an audiovisual communication. Such technology was not available when the Ryan Haight Act was passed in 2008.

The American Medical Association (“AMA”) has noted in its Ethics Opinion 1.2.12 that “innovation in technology, including information technology, is redefining how people perceive time and distance.”¹²⁴ The Opinion goes on to say that innovation is “reshaping how individuals interact with and relate to others, including when, where, and how patients and physicians engage with one another.”¹²⁵ This Ethics Opinion is titled “Ethical Practice in Telemedicine,” and observes that telehealth has the ability to offer multiple methods of delivering care, but that patients “need to be able to trust that physicians will place patient welfare above other interests.”¹²⁶ The AMA expects physicians to uphold the normal standards of professionalism required in an in-person exam by following ethical guidelines and the applicable law.¹²⁷

While the AMA Ethics Opinion supports following the law, which requires an in-person examination before prescribing controlled substances, the ethical standards set out in the Ethics Opinion could be complied with if the law was changed to allow controlled substance prescribing through telemedicine.¹²⁸ For example, the AMA believes that healthcare institutions and professional organizations should monitor the telehealth landscape by supporting refinement and development of telehealth technologies to ensure that the services are safe for patients and that physicians are delivering quality care.¹²⁹ Such institutions should advocate for policies and initiatives that promote access to telehealth services for those who can benefit.¹³⁰

124. *Code of Medical Ethics Opinion 1.2.12*, AM. MED. ASS'N, <https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine> (last visited Nov. 2, 2019) [<https://perma.cc/U64G-HB28>].

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

Additionally, the AMA encourages physicians to identify negative consequences as technologies evolve while still spreading the news of both positive and negative outcomes of telehealth.¹³¹ This desire to promote accessibility for those who could benefit from telehealth can be achieved by amending the Ryan Haight Act. The correct regulations for prescribing controlled substances would support the development of telehealth technologies while ensuring a safe service for patients through a proper monitoring system and an audiovisual medium.

1. Federal Changes and Regulation

Like CMS, Congress needs to take steps to recognize innovations in communication technologies. There are ways in which treatment through audiovisual communication technology can be effectively substituted for an in-person exam. Like CMS creating exceptions for those with substance abuse issues, Congress should make similar exceptions for qualifying classes of individuals. Francesca Ozinal, of the law firm Epstein Becker & Green, stated that she believes Congress should amend the Ryan Haight Act to focus more on the proper standard of care for the patient rather than requiring an in-person exam.¹³² Physicians have a legal and ethical obligation to follow the proper standard of care for each patient.¹³³ There are many situations in which the standard of care can be met by using an audiovisual medium rather than requiring an in-person exam.

However, controlled substance prescribing should not be a free-for-all that allows any online pharmacy to prescribe medication to any person who merely fills out a questionnaire. There should be laws enacted that allow the DEA to regulate controlled substance prescribing so legitimate telemedicine providers can provide beneficial treatment to those in need. A step in the right direction for federal law would be to emphasize the use of telemedicine in rural and low-income urban areas because they are most impacted by the current restrictions. Adding a geographic layer to the law would put a sensible restriction on prescribing controlled substances, rather than completely banning prescribing a controlled substance without an in-person exam. As shown above, many Americans have barriers that prevent them from getting to a qualified practitioner who can give them the treatment and prescriptions they need. Allowing individuals living in remote geographic areas to consult a practitioner through audiovisual technology and obtain a prescription could be a huge step toward fixing the provider shortage. Such change would also create progress toward

131. *Id.*

132. Bryant, *supra* note 2, at 1–2.

133. *Id.*

limiting the number of individuals suffering from mental illness or substance abuse issues in the United States today.

There are many ways in which the DEA can regulate controlled substance prescribing without the burden currently placed on telemedicine providers. First, there should be a required meeting between the patient and a qualified practitioner through an audiovisual communication technology, to substitute for an in-person exam, so that the patient and practitioner actually have a one-on-one encounter. This should be an absolute requirement, and no controlled substance should be prescribed before this evaluation occurs. This type of required interaction would likely have prevented the issue in the case of Ryan Haight. Because Ryan Haight was only required to complete an online questionnaire before receiving prescription drugs, there was no face-to-face meeting with a physician in any form, either in-person or through an audiovisual communication technology.¹³⁴

Second, to properly regulate controlled substance prescribing, the DEA must require an extensive documenting process. This would help the DEA track what controlled substances are being prescribed, as well as when and where they are being prescribed. A database for telemedicine providers to report their prescribing quantities and proof of evaluation would be an efficient way to keep track of prescribing and would force practitioners to operate legally and legitimately.

Additionally, the DEA should keep an eye out for geographic areas in which more than the projected amount of controlled substances is being prescribed. Such monitoring would be essential, because although a requirement of a face-to-face meeting through an audiovisual communication technology would help to legitimize telemedicine prescribing, there will likely continue to be corrupt physicians who attempt to take advantage of the system. Therefore, if the DEA were to see a spike in controlled substance prescribing by a certain practitioner or in a geographical area, it could perform an investigation to ensure there is no illegal activity. This step would help monitor controlled substance prescribing as a whole because physicians who have performed an in-person exam may overprescribe as well.

If these steps were taken, the probability of another tragedy like the one in the case of Ryan Haight would be nearly completely eliminated, and health care would reach those in desperate need of it. Additionally, these suggestions would help the DEA monitor what controlled substances are being prescribed while still letting legitimate telemedicine providers make a living by helping those in need, so long as they follow the proper steps and standard of care.

134. Lipman, *supra* note 5, at 545.

2. Deference to State Laws

Additionally, federal law should defer to the states, allowing them to decide how strict their telemedicine laws should be. The federal law should be a way to regulate controlled substances as a whole, but state legislatures should decide if their particular state has need for a physician to prescribe controlled substances through telemedicine without an in-person examination. This deference would be a practical way of continuing to solve the issue at hand. Smaller, more populous states—that do not have as big of a challenge in getting their residents health care—may still decide that they do want practitioners to conduct an in-person exam before prescribing any drug through telemedicine. But larger, less populous states may decide that many of their residents have barriers to proper health care, whether they be geographic or financial. As such, they may want to allow controlled substance prescribing through telemedicine, so long as statutory requirements are met for establishing a practitioner–patient relationship. The latter mirrors Texas’ approach¹³⁵ as a state where there are both rural communities and individuals suffering with substance abuse and mental health issues who need additional help to access health care. Texas, as well as many other states, has put laws into effect that allow for the practitioner–patient relationship to be formed by way of an audiovisual technology. Now, the federal government should step in and do its part by amending the Ryan Haight Act.

VI. CONCLUSION

The Ryan Haight Act should be amended because it overly restricts legitimate telemedicine providers, and since its enactment, technology has been developed that can help regulate telemedicine prescribing more effectively. Future regulation should be done in a way that still strictly monitors the telemedicine industry, but also provides medical treatment to individuals who can more easily be reached through telemedicine. Additionally, the Ryan Haight Act has prevented individuals from getting treatment they need—a consequence unintended by Congress when it passed the Act.

The Special Registration for Telemedicine Clarification Act of 2018 has the potential to be a great step toward improving telemedicine laws, but the uncertainty of the law could lead to little real benefit to the telemedicine industry and the patients who lack access to care.

Congress should amend the Ryan Haight Act to mirror the laws that many states have been adopting, specifically so telemedicine providers can use audiovisual mediums to provide legitimate health care to individuals in need without the requirement of a prior in-person exam. This type of legislation would not only help to eliminate the

135. *See* TEX. OCC. CODE § 111.005.

opioid crisis, but would give healthcare access to those who have geographic barriers and individuals who struggle with mental health issues. With the correct type of regulation, online prescribers and pharmacies can have a positive effect on healthcare, not the negative effect seen in the tragic story of Ryan Haight.