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Post-Pandemic Access to Healthcare: Legal Implications of Telehealth Treatment with Buprenorphine for Opioid Use Disorder

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Post-Pandemic Access to Healthcare: Legal Implications of Telehealth Treatment with Buprenorphine for Opioid Use Disorder

I. Introduction

The future of healthcare and health law in the United States was rewritten in March of 2020 when President Trump declared a Public Health Emergency (or "PHE") in response to the COVID-19 pandemic. The PHE allowed for extraordinary measures to be taken to aid the people and the economy in a transition to quarantine. As the country finally reaches the end of the pandemic and transitions to a state of longed-for normalcy, pandemic era emergency measures allowed by the PHE are suddenly faced with an uncertain future. The measures taken at the forefront of the pandemic in the healthcare sector were unprecedented, considering there had not been a global health crisis like this for nearly 100 years. Those who were chronically ill or required in-person treatments now faced a world gone entirely remote. How can there be a remote option for anyone whose life depends on the intimate, in-person care only a doctor can provide? One of the most drastic changes was a shift from almost entirely in-person healthcare to telehealth, which meant that healthcare providers were forced to change the way they practiced medicine for the foreseeable future.

The declaration of the PHE allowed for the Department of Health and Human Services ("DHHS") to waive in-person healthcare requirements to allow for the usage of telehealth services.[1] There were many logistical issues, including how to prescribe medications and diagnose certain ailments without in-person evaluations. It was cases that were not per se "emergencies" but still grappled with life and death that discerned the need for innovation. Addiction treatments were

[1] Telehealth Insurance Coverage. "Telehealth Insurance Coverage," n.d. https://www.medicare.gov/coverage/telehealth.

one of the medical issues that required immediate changes, namely waivers on strict treatment and prescription regulations under HIPAA.[2] Expectedly, this opened the door to a plethora of legal questions and concerns.[3]

II. Background

At the beginning of the pandemic, The HHS Office of Civil Rights allowed providers to administer telehealth addiction treatment without the burden of penalties for noncompliance.[4] The medication Buprenorphine was one of the medications whose regulations were waived under these novel pandemic measures. Buprenorphine is classified as a Schedule III drug used for medication-assisted treatment ("MAT") to treat Opioid Use Disorder (also referred to as "OUD" or "SUD") and has become a bastion in combating the opioid crisis.[5] It is specifically known to "lower physical dependency on other opioids and reduces withdrawal symptoms, drug cravings, and morbidity and mortality for patients with OUD while also providing lower euphoric effects compared to other opioids."[6] However, it was notoriously difficult for doctors to prescribe the medication due to a series of onerous in-person treatment requirements and approval processes.[7] One of these requirements, called "X-Waivers", were a series of special licensing requirements

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[2] "Supporting Access to Telehealth for Addiction Treatment". AMERICAN SOCIETY OF ADDICTION MEDICINE. https://www.asam.org/quality-care/clinical-recommendations/covid/supporting-access-to-telehealth-for-addiction-services. (Sept 19, 2020).

[3] Tyler D. Wolf. "Telemedicine and Malpractice: Creating Uniformity at the National Level ." WILLIAM AND MARY LAW REVIEW (April 2020). https://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=3862&context=wmlr.

[4] *Id.* at 1508.

[5] "Buprenorphine." SAMHSA, March 21, 2023. https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine. Buprenorphine can also be considered a "MOUD" or medication for opioid use disorder.; DEA. "Drug Scheduling," n.d. https://www.dea.gov/drug-information/drug-scheduling. Drug, substances, and other chemical schedule classifications are based off of a number of factors, including the drug's medical use and risk of dependency. Schedule I drugs, such as heroin and marijuana, have no accepted medical use and a high risk of dependency. Schedule III drugs have a low to moderate risk of dependency and are medically accepted.

[6] "SAMSHA *supra* note 5.*; see also* "Medications for Opioid Use Disorder Save Lives", NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE. (2019) *https://nap.nationalacademies.org/catalog/25310/medications-for-opioid-use-disorder-save-lives*.

[7] ASAM, *supra* note 2.

that doctors needed to have in order to prescribe buprenorphine and were particularly difficult to obtain.[8] Heavy regulation resulted from the reality that Buprenorphine, an opioid itself, can be dangerous if misused. Further, the 2008 Ryan Haight Act in amendment to the 1970 Controlled Substances Act was passed in response to the rise in illegal online prescriptions of opioids and directly impacted how drugs like Buprenorphine were administered.[9] This legislation was key in forcing the arduous in-person evaluations for OUD patients to be prescribed buprenorphine.[10]

It became clear that the heavy regulations on Buprenorphine were no longer workable during the pandemic when telehealth became the new standard. The Substance Abuse and Mental Health Services Administration (or "SAMHSA") and the Drug Enforcement Administration (or "DEA") subsequently standardized Opioid Treatment Program (or "OTP") guidance to waive prior necessary prerequisites of lengthy in-person evaluations.[11] These were a direct countermeasure to the Ryan Haight Act which had previously limited the use of telehealth practices to treat OUD patients.[12] The waivers presented immediate benefits and expanded treatment access to those suffering from OUDs, especially the poor and those in isolated regions formerly lacking approved

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[8] NIDA. "Buprenorphine misuse decreased among U.S. adults with opioid use disorder from 2015-2019." NATIONAL INSTITUTE ON DRUG ABUSE. (2021) https://nida.nih.gov/news-events/news-releases/2021/10/buprenorphine-misuse-decreased-among-us-adults-with-opioid-use-disorder-from-2015-2019. October 15, 2021 Accessed May 2, 2023.; Noah Weiland. "More Doctors Can Now Prescribe a Key Opioid Treatment. Will It Help?" THE NEW YORK TIMES. (March 3, 2023). https://www.nytimes.com/2023/03/03/us/politics/buprenorphine-opioid-addiction-treatment.html

[8] *Id.*

[9] Morgan Godvin, "Buprenorphine Access: Telehealth Revolution Faces Uncertain Future", FILTER, (Oct. 25, 2022). https://filtermag.org/buprenorphine-telehealth-pandemic/;

[10] *Id.* at 12891.

[11] *Id.*; Godvin, *supra* note 9.; Section 1834(m) of the Social Security Act restricts the usage of telehealth services unless such care is provided at an approved site—a provision that has traditionally been used in rural communities, this was also waived. American Bar Association. https://www.americanbar.org/groups/business_law/publications/blt/2022/04/telehealth/

[12] Godvin, *supra* note 9.; Drug Enforcement Administration. "Expansion of Induction of Buprenorphine via Telemedicine Encounter" FEDERAL REGISTER 88 no. 12890 (March 1, 2023). https://www.govinfo.gov/content/pkg/FR-2023-03-01/pdf/2023-04217.pdf

physicians.[13] It was this feasible access to buprenorphine that began to expose critical pre-pandemic gaps in healthcare for those dealing with addiction.[14]

The benefits of treating OUDs through telehealth became apparent with the recent removal of the X-Waiver in the Consolidated Appropriations Act of 2023.[15] Its removal dramatically expanded the pool of doctors eligible to treat OUDs.[16] While this was a step in the right direction, the newest DEA guidelines on telemedicine treatment of OUDs could present another barrier that might render this move diminutive.[17] As of February 2023, the DEA's proposed guidelines would place new restrictions on PHE-era waivers for telehealth-only treatment of OUDs. The allotted supply of buprenorphine for OUD patients would be decreased to only 30 days' worth, and patients would have to revert back to in-person appointments to renew prescriptions after the initial 30 day prescription is used.[18] Of course, these guidelines drew mixed reviews across the political aisle and from medical professionals who are concerned over the potential impacts they would have on OUD patients.

It is important to consider that providing specialized treatment and buprenorphine prescriptions through a screen or telephone call without in-person consultations also pose legal implications of medical malpractice, issues of informed consent, data security and regulatory

[13] Wang L, Weiss J, Ryan EB, Waldman J, Rubin S, Griffin JL. Telemedicine increases access to buprenorphine initiation during the COVID-19 pandemic. J SUBST. ABUSE TREAT. (2021).
[14] Drug Enforcement Administration *supra* note 10.
[15] Weiland, *supra* note 8.; Consolidated Appropriations Act, 2023 Pub. L. 117-328 § 1262. The 2023 Consolidated Appropriations Act was a 1.7 trillion dollar spending bill to aid in funding a number of priority foreign and domestic policy issues. Section 1262 removed the federal requirement for practitioners to have a waiver to prescribe medications such as buprenorphine for OUDs.
[16] *Id.*
[17] *Id.*
[18] See Drug Enforcement Administration. "DEA Announces Proposed Rules for Permanent Telemedicine Flexibilities" (Washington D.C., 2023) https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities.; Ryan Hampton. "The DEA's new telehealth rules are medical malpractice for people with opioid addiction" THE HILL. (March 14, 2023) https://thehill.com/opinion/congress-blog/3900597-the-deas-new-telehealth-rules-are-medical-malpractice-for-people-with-opioid-addiction/.

compliance.[19] This Note will analyze whether the benefits of telehealth treatment outweigh the potential legal consequences enough to make these measures permanent, and what the current and future administrations should do to protect doctors and patients in a post-covid world. I will examine these issues through the lens of the impact to those with OUDs, and will analyze whether SAMSHA and DEA waivers for buprenorphine prescriptions should continue with less restrictive guidelines than currently proffered by the DEA's proposals.

III. Legal Problems Presented by Telehealth

Because of the abrupt and sudden nature of the pandemic, healthcare workers were forced to take on a new method of providing care with little to no easement period for adjustment.[20] Attorneys and doctors were quick to identify a number of legal concerns. What is the standard of care? At what point is the physician-patient relationship established?[21] A lack of uniformity regarding healthcare laws prompted such questions and subsequently faced few answers at the start of the pandemic.[22]

A. Medical Malpractice

Concerns of medical malpractice, with a specific focus on addiction treatment, are at the forefront of problems presented in telehealth. Generally, to establish a prima facie medical malpractice claim, there must have existed a contractual doctor-patient relationship and the action of the doctor constituted a breach in their professional and customary duty of care.

[19] Renata Solimini, F.P. Busardo, F., Busardò, Fillipo Gibelli. "Ethical and Legal Challenges of Telemedicine in the Era of the COVID-19 Pandemic." MEDICINA (2021).
[20] "Telehealth". AMERICAN BAR ASSOCIATION (2022). https://www.americanbar.org/groups/business_law/publications/blt/2022/04/telehealth/
[21] Wolf. *supra* note 3.
[22] *Id.*

While the standard of care is considered to be identical to in-person treatments, courts have recognized the unique situations that telehealth presents in terms of where treatment is provided and how thoroughly services are rendered.[23] A New York court in *Snyder v. State of New York* examined whether a physician deviated from the standard of care for telehealth services when the patient presented symptoms of a heart attack and was advised to take Tylenol rather than receive an EKG reading. The court's brief examination into the consideration of a higher standard of care for telehealth gives a glimpse into how it presents an obvious weakness in providing an identical standard of care to in-person treatments.[24] Without a uniform or even greater standard of care, telehealth's limitations will likely continue to present itself in similar cases as *Snyder*.[25]

There are few medical malpractice cases involving addiction treatment via telehealth, but there are some general issues of which to be aware. Lawyers typically warn doctors to beware of patients using different names via telehealth, since taking away the in-person aspect makes it harder for physicians to confirm their identity.[26] The concern is that OUD patients may see telehealth as a scapegoat to get doctors to prescribe opioids under another name.

It is especially important for physicians to be cognizant of the risks that buprenorphine presents as a Schedule III drug. A doctor's failure to administer their duty of care in prescribing buprenorphine could lead to a patient's misuse and/or accidental overdose. Telehealth presents a barrier to the physical body, making it challenging to diagnose an addict on their physical symptoms. Doctors should be having consistent meetings with their patients to minimize the risk

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[23] Doug Mann. "How Do Telemedicine Lawsuits Work?" DYER, GAROFALO, MANN & SCHULTZ (March 29, 2023). https://ohiotiger.com/blog/how-do-telemedicine-lawsuits-work/; *Snyder v. State*, 70 Misc. 3d 801, 817 (N.Y. Ct. Cl. 2020).
[24] *Id.*
[25] Wolf. *supra* note 3.
[26] "Telemedicine Malpractice." GILMAN & BEDIGIAN, (Jan. 7, 2021). https://www.gilmanbedigian.com/telemedicine-malpractice/

of drug abuse and maximize the efficacy of this essential drug. These simple measures can save medical professionals from malpractice suits, but more importantly save more OUD patient's lives.

B. Informed Consent

Although informed consent laws vary by state, HHS provides general guidelines for telehealth. Online counseling requires physicians to describe what to expect out of the visit, ensure that the patient is in a private setting where others are unable to hear their medical records, and acquire consent if there is to be anyone else observing the evaluation.[27] It is acceptable to require patients to use appropriate technology and secure their own privacy during each appointment.[28] If a patient is new, it may be more difficult to get all of their detailed medical history over a phone or video call. It is essential that doctors disclose some of the risks of not being able to do the evaluation and collect their information as they would in person.[29] Overall, it is important to disclose to the patient all of the things that can and cannot be done over a telehealth visit, methods of billing, and how to obtain medical records.[30]

There are extra steps needed for addiction medicine to ensure the patients are informed and prepared for OUD treatment. According to SAMSHA's "Buprenorphine Quick Start Guide", there are addiction-specific steps for doctors to guarantee patients are fully informed during their visits. Physicians should inform patients of all risks and benefits of buprenorphine, especially disclosing that discontinuing poses a risk for relapse, using alcohol and other depressants increases the risk of overdose, and it should not be used by pregnant women.[31] All of this is conjoined with the

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[27] U.S. Department of Health and Human Services. "Obtaining Informed Consent". (June 29, 2022). https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/obtaining-informed-consent
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] Substance Abuse and Mental Health Services Administration. "Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings." (2021). https://store.samhsa.gov/sites/default/files/pep21-06-01-002.pdf.

custom practice of providing informed consent through telehealth detailed above. Due to these in-depth requirements, many physicians have opted to treat OUD patients with whom they have an existing relationship.[32]

Existing case law contextualizes the slightly higher standard that physicians must meet in obtaining informed consent for buprenorphine. A Kentucky court recently examined in *Hall v. Kenton Cnty* whether a pregnant inmate provided informed consent for receiving a prescription change to buprenorphine.[33] The court stated that, "the duty to obtain informed consent to a change in medical care – and here, specifically the prescription of buprenorphine – rests with the licensed, prescribing physician."[34] The physician must explain the risks and benefits, and most importantly in this case, must have been informed on the risks to pregnant women.[35] The doctor made a unilateral switch to buprenorphine for the patient, leading the court to conclude that the doctor was deliberately indifferent to the standards of informed consent by not knowing and not informing the patient of potential buprenorphine risks to pregnant women.[36]

Given that informed consent standards for telehealth and addiction treatments are clearly higher, it is critical that physicians keep these risks in mind to avoid potential malpractice claims. Informed consent will very likely become more important as buprenorphine waivers are rolled back and patients will be required to book in-person appointments to continue treatment. Doctors will not only have to update their patients with the newest DEA guidelines, but they themselves will be required to keep up with changes to avoid potential lawsuits.

C. Privacy and Data Security

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[32] Erin Jackson. "Obtaining Informed Consent in Telehealth." JACKSON LLP HEALTHCARE LAWYERS (June 14, 2022) https://jacksonllp.com/informed-consent-in-telehealth-and-telemedicine/.
[33] *Hall v. Kenton Cnty.*, No. 2:19-00054 (WOB-CJS), 2022 U.S. Dist. LEXIS 117619 (E.D. Ky. July 5, 2022).
[34] *Id.* at 28.
[35] *Id.*
[36] *Id.*

Issues of privacy and data security must be addressed for telehealth to continue being a valuable resource in the post-pandemic era.[37] The initial concern was the lack of privacy that many patients experienced due to a number of factors – homelessness, age, and inpatient rehabilitation presenting just a few complicating factors.[38] Situational setbacks posed risks of sharing sensitive information to unauthorized parties in violation of HIPAA standards. More importantly, telehealth is not immune from data security and privacy breaches, leaving patients' sensitive information even more vulnerable to third-party interception.[39] Cyberattacks are becoming more frequent and approximately four out of five doctors have been exposed to some form of cyberattack according to the American Medical Association.[40] These issues still exist three years into the pandemic, but there are steps that physicians have taken to maximize privacy and protect their patients.

A possible solution to issues of privacy is related to that higher standard of getting informed consent.[41] Providers should inform patients at the onset that their privacy, security, and well-being are of utmost importance in their telehealth visits.[42] This means making sure that patients are comfortable in their setting at the time of the appointment, and being flexible to each patient's respective level of comfort regarding video chat consultations.[43] Informing a patient about whether their meeting is being recorded or overseen by other physicians is also of utmost importance to ensure transparency.[44] For those who are homeless or using drugs, physicians can work with

[37] "Solutions for Challenges in Telehealth Privacy and Security." JOURNAL OF AHIMA (Jan 30, 2023). https://journal.ahima.org/page/solutions-for-challenges-in-telehealth-privacy-and-security.
[38] *Id.*
[39] IHI Team. "How to Protect Patient Privacy During Telemedicine Visits" INSTITUTE FOR HEALTHCARE IMPROVEMENT (Apr. 28, 2022). https://www.ihi.org/communities/blogs/how-to-protect-patient-privacy-during-telemedicine-visits
[40] American Medical Association. "Cybersecurity 101: What You Need to Know" https://www.ama-assn.org/system/files/2020-06/ama-telehealth-quick-guide-appendix-d3-cybersecurity-101.pdf
[41] *Id.*
[42] *Id.*
[43] IHI, *supra* note 39.
[44] AMA, *supra* note 40.

community-based organizations to set up private spaces for those who do not have access to them.[45]

Avoiding cybersecurity breaches is a complex issue that is more difficult to regulate, but there are safeguards available to physicians to maximize protection of patient data. Passwords should be set up for all virtual visits to protect against unwanted hackers in a setting such as Zoom or Microsoft Teams.[46] All medical offices should be up to date on antivirus software and should only be allowed to access secured websites under a private wi-fi network.[47] These measures mitigate the interruptions to practice operations that nearly two thirds of physicians have experienced due to data breaches.[48] Data encryption is another proven safeguard that entails "converting sensitive and confidential patient data into a coded language that can only be accessed by authorized individuals with a decryption key."[49] By implementing encryption into medical practices, doctors can comply with updated regulations and ensuring secure data sharing amongst office personnel.[50]

The Legislative Analysis and Public Policy Association, in a review of substance abuse disorders and telehealth services, analyzed the benefits and future considerations of this practice. Interestingly, privacy was framed to be less of a concern when accounting for the public policy considerations of combating the opioid epidemic.[51] The HIPAA requirements waived by the HHS at the onset of the PHE allowed for practitioners, in good faith, to administer treatment to opioid

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[45] IHI, *supra* note 39.
[46] AHIMA, *supra* note 37.
[47] *Id.*
[48] AMA, *supra* note 40.
[49] AIMultiple. "Data Encryption in Healthcare: Importance, Benefits & Use Cases," n.d. https://research.aimultiple.com/data-encryption-in-healthcare/.
[50] *Id.*
[51] Legislative Analysis and Public Policy Association. "Telehealth and Substance Use Disorder Services in the Era of COVID-10: Review and Recommendations" LAPPA (June 2022). https://www.whitehouse.gov/wp-content/uploads/2022/06/Telehealth-and-Substance-Use-Disorder-Services-in-the-Era-of-COVID-19-FINAL.pdf

users over FaceTime, Facebook Messenger, Google Hangouts, Zoom and Skype.[52] Those in the OUD treatment field, while acknowledging that the risk of privacy breaches was increased, measured that risk against the pressing need for those with OUDs to have more feasible methods of accessing treatment. Simply put, "the more choices patients have regarding the platforms they can use to engage their providers, the more likely they will be to seek health care."[53]

A recent Wall Street Journal article detailed the Federal Trade Commission's crackdown on the data-sharing practices of telehealth apps that allegedly shared patient information with advertising agencies.[54] The issue here was that patients were willingly inputting their data into these apps, which creates a go-around for violating HIPAA standards. Professor Nicholson Price from the University of Michigan Law School told the Wall Street Journal, "'HIPAA really doesn't reach apps or places where patients share their own information,' he said. 'So that's generally not preventing companies or app developers from sharing or selling or licensing this sort of data.'"[55] These practices not only drew the attention of the FTC, but of lawmakers across the aisle who became skeptical of the privacy practices of telehealth apps.[56] Since the onset of the pandemic, the FTC has pursued legal action against several companies including BetterHealth, GoodRx Holdings, and Kochava Inc. for disclosing patient's health data to social media companies and advertisers to frame marketing campaigns.[57]

It is critical for all these reasons that guards are not being put down by medical professionals to protect their patient's privacy. It is also immensely important for consumers to do

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[52] *Id.* at 21.
[53] *Id.*
[54] Patience Haggin. "Telehealth Apps Sharing Consumer Data Draw FTC Crackdown." WALL STREET JOURNAL (April 14, 2023). https://www.wsj.com/articles/telehealth-apps-sharing-consumer-data-draw-ftc-crackdown-1f4775e3.
[55] *Id.*
[56] *Id.*
[57] *Id.*

research on the apps in which they are putting their sensitive data considering the difficulty government agencies have had in regulating them. OUD patients and treating physicians should be especially careful with data privacy as there are different regulations for confidentiality under SAMSHA.[58]

IV. Risk Analysis: Benefits and Drawbacks of DEA's Proposed Regulations on Telehealth Buprenorphine Prescriptions

It is clear that prescribing buprenorphine treatment through telehealth has beneficial effects on opioid users. Buprenorphine, while an opioid itself, is known to mitigate the symptoms of OUD when used in a controlled treatment plan. As a medication for OUD, or MOUD, buprenorphine has been proven to "drastically reduce overdose and overall mortality rates, reduce serious co-occurring conditions, improve retention rates in treatment, and improve quality of life for people with OUD."[59] However, they can be dangerous if misused or prescribed incorrectly, leaving a heavy burden on physicians to make sure that they are correctly treating their OUD patients. The DEA guidelines, at an attempt to address these implications, have drawn a number of concerns from medical professionals. The portion that drew the most criticism is that the telehealth allowance for OUD treatment will be limited to a 30-day supply of buprenorphine before patients will have to return to in-person examinations from their doctor.

Critics of the DEA's recent guidelines say that the guidelines themselves are medical malpractice.[60] The risk of relapse because of a limited buprenorphine prescription without the

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[58] Substance Abuse Confidentiality Regulations. "Substance Abuse Confidentiality Regulations," SAMSHA (June 17, 2022). https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs.
[59] Lindsay A. Pearce et al., "Opioid Agonist Treatment and Risk of Mortality During Opioid Overdose Public Health Emergency: Population Based Retrospective Cohort Study" BRIT MED .J., (Mar. 31, 2020)
[60] Hampton, *supra* note 18; Richard Frank MD, Pushpa Raja, MD, Haiden A. Huskamp, PhD, Alisa B. Busch, MD, Michael L. Barnett, MD, Ateev Mehrotra, MD to The Honorable Merrick B. Garland, (March 21, 2023). *Comments in response to RIN 1117-AB78: Expansion of Induction of Buprenorphine Via a Telemedicine Encounter.* https://www.brookings.edu/wp-content/uploads/2023/03/DEA-response-3-21-23-FINAL.pdf

guarantee of an in-person doctor's visit is incredibly high for those suffering with addiction disorders.[61] This reality, faced with study after study about the benefits of remotely accessible buprenorphine treatment, has lead leading physicians to challenge the guidelines as "overly restrictive and would likely create more harm than benefit."[62] On the other hand, supporters of the guidelines are adamant that an in-person evaluation in conjunction with telehealth practices is crucial for physicians as part of their due diligence to fully examine their patient's needs.[63] This section will examine whether the DEA's newest guidelines correctly assess the risks and benefits of expanded buprenorphine access in telehealth. I will also address the impact of the guidelines on physicians, and what should happen moving forward to increase access to treatment.

A. Benefits of Expanded Buprenorphine Access

Promising data coming out of the pandemic shows that buprenorphine not only appears to be pivotal against the opioid crisis, but that its expanded access does not pose a danger to those with OUDs. Buprenorphine-related deaths did increase after the PHE waivers, but they were still in significantly smaller numbers within overall opioid deaths. However, many buprenorphine-related deaths involved either situations where the medication was accessed illegally and not under the supervision of a treating physician or in combination with other opioids.[64]

Telehealth buprenorphine waivers increased access to care and broke down socioeconomic barriers to treatment access that were previously mainstays in the opioid epidemic.[65] Physicians

[61] Hampton, *supra* note 18.
[62] *Id.*; Frank to Garland *supra* note 60.
[63] Godvin, *supra* note 9.
[64] Lev Facher. "Buprenorphine Deaths Did Not Increase despite Wider Access during Pandemic, Study Shows." STAT NEWS, (Jan 20, 2023). https://www.statnews.com/2023/01/20/buprenorphine-deaths-did-not-increase-despite-wider-access-during-pandemic-study-shows/.
[65] Noa Krawczyk, PhD, Bianca D. Rivera, MPH, Carla King, MPH , Bridget C.E. Dooling, JD. "Pandemic telehealth flexibilities for buprenorphine treatment: A synthesis of evidence and policy implications for expanding opioid use disorder care in the U.S." https://www.medrxiv.org/content/medrxiv/early/2023/03/17/2023.03.16.23287373.full.pdf

were finally able to feasibly initiate treatment for the homeless, those in rural areas, and marginalized ethnic groups created a route to accessing OUD treatment that was never available before the pandemic.[66] In a multi-state survey on experiences with OUD telehealth treatment, patients were satisfied with the choice of modality offered after the pandemic because it allowed them a flexibility that was not previously offered by the healthcare sector.[67] In another study, community clinics in the Bronx, New York were analyzed to examine OUD treatment outcomes before and during the pandemic, and showed that patient retention for buprenorphine treatment was greater than before the pandemic.[68] Several other studies have found that the waivers lead to increased retention rates in community-based services programs.[69] It is clear that the waivers had tangible benefits on the opioid crisis and exposed gaps in healthcare in historically minority and isolated regions across the country.

However, both physicians and patients have identified some drawbacks of the practice. Each side has presented issues with struggling to build a doctor-patient rapport over video chat, feeling unimportant or rushed, and lacking a privacy that an in-person visit can provide.[70] While these considerations are nonetheless important, especially with implications of potential

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[66] *Id.*; K. M Ward, A. Scheim, , J. Wang, B. Cocchiaro, K. Singley, & A. M. Roth. "Impact of reduced restrictions on buprenorphine prescribing during COVID-19 among patients in a community-based treatment program." DRUG AND ALCOHOL DEPENDENCE REPORTS (2022) https://doi.org/10.1016/j.dadr.2022.100055.

[67] Brendan Saloner, Noa Krawczyk, Keisha Solomon, Sean T. Allen, Miles Morris, Katherine Haney, and Susan G. Sherman. "Experiences with Substance Use Disorder Treatment during the COVID-19 Pandemic: Findings from a Multistate Survey." PUBMED CENTRAL (PMC), (Nov 19, 2021). https://doi.org/10.1016/j.drugpo.2021.103537.

[68] C. Cunningham, O., Khalid, L., Deng, Y., Torres-Lockhart, K., Masyukova, M., Thomas, S., Zhang, C., & Lu, T. "A comparison of office-based buprenorphine treatment outcomes in Bronx community clinics before versus during the COVID-19 pandemic." JOURNAL OF SUBSTANCE ABUSE TREATMENT, *135*, 108641 (2022). https://doi.org/10.1016/j.jsat.2021.108641.

[69] K. Ward, M., Scheim, A., Wang, J., Cocchiaro, B., Singley, K., & Roth, A. M. "Impact of reduced restrictions on buprenorphine prescribing during COVID-19 among patients in a community-based treatment program." DRUG AND ALCOHOL DEPENDENCE REPORTS, (2022). https://doi.org/10.1016/j.dadr.2022.100055; https://ps.psychiatryonline.org/doi/10.1176/appi.ps.202100088.

[70] K. Mattocks. M., Moore, D. T., Wischik, D. L., Lazar, C. M., & Rosen, M. I. "Understanding opportunities and challenges with telemedicine-delivered buprenorphine during the COVID-19 pandemic." JOURNAL OF SUBSTANCE ABUSE TREATMENT (2022). https://doi.org/10.1016/j.jsat.2022.108777.

malpractice and informed consent, it is clear from many studies and surveys that outcomes in OUD treatments with expanded access to buprenorphine did not worsen the opioid crisis and may have actually, at the very least, set out a promising solution.

B. DEA's Guidelines: Striking the Right Balance under Ryan Haight Act Restrictions

There existed seven exceptions to the Ryan Haight Act that aided in creating COVID-19 telehealth waivers:

> "The seven exceptions are: 1) treatment in a hospital or clinic; 2) treatment in the physical presence of a DEA-registered practitioner; 3) treatment by Indian Health Service or Tribal practitioners; 4) treatment during a public health emergency as declared by the Secretary of Health and Human Services; 5) treatment by a practitioner who has obtained a "special registration"; 6) treatment by Department of Veterans Affairs practitioners during a medical emergency; and 7) other circumstances specified by regulation. *See* 21 C.F.R. § 1300.04(i)(1)-(7)."

Exception number four to the Ryan Haight Act allowed for in-person telehealth waivers during a PHE. Now, at the end of the PHE, the newest DEA guidelines will force patients who are currently taking buprenorphine to receive an in-person examination in order to continue treatment, even if they have been receiving treatment on an exclusively telemedical basis.[71] While this is an expansion of the Ryan Haight Act, it is a restriction on the COVID-era telehealth waivers that many patients became accustomed to during the course of their treatment.[72]

The DEA's proposed rules would fall under exception seven to the Act, specifically "other circumstances specified by regulation."[73] The proposed rule, 21 U.S.C. § 802(54)(G), also defines the term "telemedicine prescription", which is a "term of art" and only applies to very specific controlled substance prescriptions (including buprenorphine).[74] The term is said to be confusing,

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[71] "DEA's Proposed Rules on Telemedicine Controlled Substances Prescribing after the PHE Ends." FOLEY & LARDNER LLP (2023). https://www.foley.com/en/insights/publications/2023/02/deas-telemedicine-controlled-substances-phe-ends.
[72] *Id.*
[73] *See* 21 C.F.R. § 1300.04(i)(1)-(7).
[74] Foley and Lardner, *supra* note 71.

as it seems to encompass all prescriptions under telemedicine.[75] There is also a "qualifying telemedicine referral" exception that allows another method of receiving prescriptions beyond the 30 day limit, which is:

> "a referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred." [76]

Unsurprisingly, legal professionals urge the DEA to clarify their proposed rules as to not make its conditions too arduous and confusing for physicians to follow.[77] They also urge the DEA to clarify that these proposals are for specific restrictions on controlled substances only, as the terms are general and lack specificity.[78]

In terms of buprenorphine, going from lenient regulations to abrupt restrictions on administering OUD treatment can have major effects on patients. It is important to note that physicians will still be allowed to prescribe buprenorphine before an in-person evaluation. The difference will be that telemedicine-exclusive treatment will no longer be allowed and further prescriptions will be contingent on an in-person evaluation. Supporters of such restrictions believe that, "[t]he required medical evaluation can enhance treatment by enabling the practitioner to conduct tests which make sure that buprenorphine is safe and appropriate for the patient."[79] In other words, some believe it is crucial for doctors to get a better understanding of their patients' medical needs through an in-person evaluation. Republican lawmakers have argued that removal

[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] Godvin, *supra* note 9.

of the X-waiver will produce a large number of poorly trained physicians who are inept to treat these disorders.[80] Others expressed concerns of buprenorphine misuse and illegal sales.[81] The Ryan Haight Act was implemented to avoid such outcomes, which makes these concerns valid and grounded in legislative precedent.

On the other hand, many lawmakers, organizations, and advocates question whether removing the telehealth-only option for buprenorphine will cause more harm than good to patients who became dependent on telehealth treatment.[82] "The American Society of Addiction Medicine wrote in its comment letter that it is 'extremely concerned' about the 'disproportionate weight' the DEA is giving concerns about buprenorphine diversion 'even when it may mean reducing appropriate access to [opioid use disorder] treatment that benefits public health and safety.'"[83] Democratic House Representatives Anne McLane Kuster and Frank Pallone, Jr. both voiced concerns that the 30-day deadline may cause detrimental lapses in treatment because there is no guarantee of an in-person evaluation within that time frame.[84] A number of organizations, including Blue Cross Blue Shield, have expressed their concerns about the 30-day limit and proposed the idea of a six-month supply in line with the length of the average course of treatment.[85] Other organizations like the National Health Law Program have urged the DEA to maintain PHE-era waivers and roll back the proposed 30-day requirements. The American Telemedicine Association expressed concerns that this will be so restrictive as to negatively impact progress made in the opioid crisis.[86] Finally, there are also legal considerations of the referral program of

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[80] Weiland, *supra* note 8.
[81] *Id.*
[82] Foley & Lardner, *supra* note 71.
[83] Roll Call. "DEA Proposal Sparks Concerns about Access to Telehealth," (April 10, 2023). https://www.rollcall.com/2023/04/10/dea-proposal-sparks-concerns-about-access-to-telehealth/.
[84] *Id.*
[85] *Id.*
[86] \Holland & Knight. "DEA Proposes New Telehealth Prescribing Rules (March 7, 2023). https://www.hklaw.com/en/insights/publications/2023/03/dea-proposes-new-telehealth-prescribing-rules.

whether it is fair, balanced, and not burdensome to both doctors and patients.[87] While the guidelines offer another route to receive telehealth treatment, the referral program would still force an in-person evaluation at some point before that can happen.[88]

The DEA's guidelines, in an attempt to maintain the benefits that telehealth has promulgated across the nation in battling the opioid crisis, may fall short of this goal. On the one hand, it is clear that the flexibility allowed under PHE waivers decreased disparities in healthcare access for OUD treatments. It is clear that the 30-day limit may present a high risk for buprenorphine patients if they are not able to receive in-person treatment in time. For those reasons, it is critical that the DEA take a second inquiry into the appropriate time frame with the assistance of medical professionals. On the other hand, buprenorphine can be dangerous if misused or prescribed by a doctor who is not completely informed on their patient's history. These concerns became exacerbated with the removal of X-Waivers, and may require regulation to counteract potential consequences. The current state of the opioid crisis garnered enough desperation to relinquish a strict requirement in the X-Waiver only to be faced with guidelines that would directly disadvantage those seeking continuous treatment. It is necessary that the DEA addresses glaring issues with the guidelines through the knowledge of leading medical professionals in the field moving forward.

C. Impact of the Removal of X-Waivers on OUD Treating Physicians

An important consideration is the willingness and preparedness of physicians to treat OUDs with buprenorphine following removal of X-waivers.[89] Prior to the 2023 Consolidated

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[87] Foley & Lardner, *supra* note 71.
[88] *Id.*
[89] AMERICAN COLLEGE OF EMERGENCY PHYSICIANS (Jan 13, 2023). https://www.acep.org/news/acep-newsroom-articles/x-waiver-no-longer-required-to-treat-opioid-use-disorder/. On January 12, 2023, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) issued guidance on the removal of the X-waiver, which had been a barrier for physicians to treat OUDs.

Appropriations Act which included a provision removing the X-Waivers, physicians were required to obtain a special registration to administer buprenorphine.[90] The disparities in access to healthcare created by the waiver were stark – "only approximately 5 percent of U.S. physicians obtained a waiver…Over 40 percent of counties did not have a single waivered subscriber, a deficit that increased to 60 percent for rural counties."[91] Additionally, the number of patients whom physicians were able to treat was capped at 30 patients for the first year following waiver approval, and 100 after a second process of approval.[92] In 2016, SAMSHA increased that number was increased to 275, but was followed by years of increasingly frequent opioid overdose deaths.[93] The start of the pandemic and rapid changes in healthcare exposed a problem that lied behind the walls of highly regulated and minimally available addiction treatments.

Now, the removal of the waiver means that any physician registered under the DEA regulations to prescribe Schedule III drugs can administer buprenorphine as OUD treatment. The removal was initiated under a promise that better access to OUD treatment would be the result, but experts are concerned that the benefits may be diminutive and much more complicated than it appears.

Important in the long-term is beating the stigma of OUD and encouraging more prescribers to practice addiction treatment healthcare.[94] However, experts are concerned that removal of the waiver will not incentivize physicians to treat OUDs on its intended scale in the short-term. Jason

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[90] Network for Public Health Law. "Removal of 'X-Waiver' Promises Increased and More Equitable Access to Opioid Use Disorder Treatment - Network for Public Health Law,". (March 2, 2023). https://www.networkforphl.org/news-insights/removal-of-x-waiver-promises-increased-and-more-equitable-access-to-opioid-use-disorder-treatment/.

[91] *Id.*

[92] Chris Larson. "It's Not 'Magic': Ending the X-Waiver Alone Unlikely to Fix MAT's Access Problem" BEHAVIORAL HEALTH BUSINESS. (March 3, 2023). https://bhbusiness.com/2023/03/03/its-not-magic-ending-the-x-waiver-alone-unlikely-to-fix-mats-access-problem/.

[93] *Id.*

[94] *Id.*

Kletter, president of Baymark Health Services – known for being a leading provider in evidence-based MAT programs and OUD treatments across the country – explained that physicians, "don't want to work with that population for whatever reason", and could be because of the "stigma — not wanting to have 'those patients' in waiting rooms — hesitancy to treat a complicated disease such as substance use disorder (SUD), and/or worries about the intensive support needed to ensure recovery."[95] However, there remains an optimism that in the long term, the removal of administrative boundaries will create a more competent OUD treatment network.[96] A compelling statement about the move explains its emblematic meaning – "the move is a powerful symbolic move by the government to show that it, as the ultimate regulatory body over buprenorphine, no longer attaches skepticism and stigma to using MAT in primary care settings. That signal may prompt additional changes in the future."[97]

For now, the removal of the X-Waiver serves as a promising first step to overriding the damaging social stigma of OUDs and educating the public on addiction treatments that are now readily available on a larger scale. It is imperative that SAMSHA and the DEA require some form of training or continuous education to ensure that physicians are adequately equipped to treat OUDs through telehealth without running into potential legal trouble. Removal of the waivers can open the door to hasty vetting of physicians who may not be apt to treat OUDs or handle the prescribing of buprenorphine. Avoiding this outcome is as important as improving OUD patients' access to healthcare considering how dangerous buprenorphine can be if misused.

V. How Lawyers can Support Increased Access to Medication-Assisted Treatment

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[95] *Id.*; *see also* Baymark Health Services. https://baymark.com/.
[96] *Id.*
[97] *Id.*

In an effort to combat OUD stigmas, the Department of Justice released in 2022 guidance on how the Americans with Disabilities Act ("ADA") should protect OUD patients in treatment or recovery programs, including those taking buprenorphine.[98] Those with OUDs face challenges not only in accessing healthcare, but in the workplace and in government services and programs.[99] Removing discriminatory barriers to individuals suffering from OUDs is a major step in prevention and mitigation of the worsening opioid epidemic.[100] Civil Rights lawyers and activists can play a major role in reducing the crisis by taking on successful discrimination cases. This section will examine the various areas of the law where lawyers can advocate for those who suffer with OUDs.

A. ADA Considerations

The ADA is a civil rights law that ensures people with disabilities have the opportunity to work without facing discrimination in the workplace.[101] In recent years, civil rights commissions, including the Equal Employment Opportunity Commission, have taken on a number of cases involving discrimination of those with OUDs actively being treated with medication due to the harmful stigma around drug addiction.[102]

Cross-sector collaboration can be key in enhancing ADA provisions to protect OUD patients from discrimination. One analysis by the Network for Public Health Law examines medical-legal partnerships ("MLP") and how they can be used to overcome social determinants of

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[98] Department of Justice. "Justice Department Issues Guidance on Protections for People with Opioid Use Disorder under the Americans with Disabilities Act," (April 5, 2022). https://www.justice.gov/opa/pr/justice-department-issues-guidance-protections-people-opioid-use-disorder-under-americans.
[99] *Id.*
[100] *Id.*
[101] Kelly K. Dineen & Elizabeth Pendo, "Engaging Disability Rights Law to Address the Distinct Harms at the Intersection of Race and Disability for People with Substance Use Disorder", 50 J. L. MED AND ETHICS 38, 39 (2022).; 42 U.S.C. §§ 12101–12213. ("The ADA's broad reach prohibits discrimination based on disability in employment (Title I); public programs, services, and activities (Title II); public transportation and places of public accommodations (Title III);and telecommunications (Title IV).")
[102] Dineen, *supra* note 101.

health that cause OUD.[103] An MLP "is a collaborative intervention that embeds civil legal aid professionals in health care settings to address seemingly intractable social problems that contribute to poor health outcomes and health disparities."[104] MLPs can prevent discrimination against OUD patients in housing, employment, and other sectors, which directly correlates to the DOJ's goal with their issued ADA guidance.[105] Lawyers, lawmakers, and activists should be in active support of the implementation of MLPs to mitigate the social stigma of those seeking treatment.

B. Criminal Justice and Prison Reform

Lawyers and lawmakers should also be in active support of reforming the criminal legal system for OUD patients given the current hostility and stigma toward those who suffer from drug addiction. There have been documented instances where OUD patients sought buprenorphine or methadone illegally in hopes of treating themselves and were subsequently arrested for illegal drug possession. The Network for Public Health Law explains that the decriminalization of illegal buprenorphine possession is necessary because most offenders are looking to merely treat themselves.[106] While this is a valid cause, it is vital to remember that buprenorphine is extremely dangerous if used improperly and can lead to overdose. It is much more important to focus on the permanency of telehealth and buprenorphine waivers than it is to decriminalize possession of this potentially dangerous drug so physicians can administer proper dosages for patients in a controlled setting. Waivers for telehealth, removal of X-Waivers, and more physicians being able to prescribe

[103] The Network for Public Health Law. "A Cross-Sector Approach to Removing Legal and Policy Barriers to Opioid Agonist Treatment" (December 2020). https://www.networkforphl.org/wp-content/uploads/2020/12/Cross-Sector-Approach-to-Removing-Barriers-to-OAT.pdf

[104] 4 Regenstein, M., Trott, J., Williamson, A., & Theiss, J. "Addressing social determinants of health through medical-legal partnerships." HEALTH AFFAIRS, (2018) https://doi.org/10.1377/hlthaff.2017.1264.

[105] The Network for Public Health Law, *supra* note 103 at 5.

[106] The Network for Public Health Law, *supra* note 103 at 14.

buprenorphine should disincentivize those with OUDs to seek buprenorphine illegally because access would be expanded. State and local governments can also ensure telehealth success by creating programs to provide subsidies for electronics and internet access to underfunded communities.[107]

Relatedly, in the context of prison reform, it is essential that incarcerated people – two thirds of which have substance abuse disorders – have access to MAT as well. The case *P.G. v Jefferson County* in New York highlighted how withholding methadone treatment in prison violated a prisoner's rights under the ADA and the Fourteenth Amendment Equal Protection Clause.[108] Plaintiff here successfully contended that OUD is a chronic brain disease and that they have the right to be administered treatment for that chronic illness just as every other person who requires medication in the prison.[109] While defendants tried to argue that the plaintiff had no right to be prescribed methadone, the court acknowledged the plaintiff's right to receive the benefits of the prison's medical services and to not receive disparate treatment under Title II of the ADA.[110]

Implementing meaningful programs to treat OUDs in prison can lead to better outcomes post-incarceration. The Network for Public Health Law exemplified a model program in Rhode Island, "where the state began providing opioid agonist treatment in its unified jail and prison system in 2016. This program was credited with dramatically reducing overdose deaths for people after release."[111] Buprenorphine waivers and increased access to telehealth can break down some of the barriers that incarcerated patients seeking treatment face. Now, a broader network of physicians can reach incarcerated people if prisons are short staffed or do not have enough

[107] *Id.*
[108] *P.G. v. Jefferson Cnty.,* No. 5:21-CV-388, 2021 U.S. Dist. LEXIS 170593 (N.D.N.Y. Sep. 7, 2021).
[109] *Id.* at 10-14.
[110] *Id.*
[111] The Network for Public Health Law, *supra* note 103 at 16.

prescribers able to administer buprenorphine. Taking on civil rights cases like *Jefferson* and lobbying for telehealth waivers allows lawyers to make trailblazing impacts in this crisis.

C. Continuing Legal Education

It may also be helpful for legal professionals and Judges to be educated in substance abuse disorders considering the barriers that the criminal legal system creates for defendants suffering from OUDs. The Legal Action Center has an MAT Advocacy Toolkit that helps patients and attorneys understand the benefits of MAT and advocate for their rights in court. Attorneys may not know the importance of buprenorphine and other MAT treatments, and therefore not know how to advocate for their client in court to get a successful outcome.[112] The National Center for State Courts also has a list of opioid and drug-related materials to educate Judges and defense attorneys.[113]

D. Mobile OUD Treatment

The ability to bring treatment to patients, whether over telehealth or other delivery methods, can further increase patient access to healthcare and mitigate barriers to transportation. The DEA allowed physicians to offer mobile care from a specific location during the PHE, and proposed regulations that would allow them to implement mobile delivery.[114] If passed, government entities would be able to facilitate mobile delivery of treatment. Because buprenorphine is regulated considerably less than other types of MAT, it could easily be permitted in mobile delivery services if this practice becomes permissible under the law.[115] In addition, the removal of X-Waivers opens the door to more physicians who are able to provide these mobile treatments. The move to telehealth in combination with mobile delivery of treatments could be

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[112] *Id.*
[113] *Id.*
[114] The Network for Public Health Law X-Waiver Removal, *supra* note 90 at 25.
[115] *Id.*

groundbreaking for the homeless and others that cannot afford transportation who are suffering from OUDs. Mobile treatment can also be a midway consensus for those who believe that OUD treatment should require in-person evaluations rather than happen exclusively through telehealth.

VI. Conclusion

Access to healthcare is a notoriously difficult challenge for many Americans – but it is a treacherous reality for chronically ill patients suffering from a stigmatized and socially unacceptable illness. The pandemic changed the course of healthcare forever by exposing major gaps for those with OUD. Telehealth showed a possible route toward expanding access to millions of people unable to receive in-person treatment due to a plethora of social, financial, and personal barriers.

The removal of X-Waivers and consistent lobbying for deregulation of buprenorphine shows a bipartisan political movement centered on a real solution to the opioid crisis. The DEA's recent guidelines on the thirty day requirement may not only be ill-informed, but dangerous to those in treatment and recovery. Understanding buprenorphine's benefits is the key to regulations that are reasonable without being too constricting. Essentially, the benefit of X-Waivers becomes moot at the DEA's attempt to roll back telehealth allowances. Lawyers and activists should continue to educate themselves on the benefits of increased access to buprenorphine and to push federal and state governments to a compromise. It certainly cannot be a free for all, but the regulations cannot burden a population of people who can seriously benefit from permanent telehealth visits.

The end of the PHE means the end of many emergency measures taken at the forefront that many Americans have become accustomed to since. While the pandemic is essentially over, the

opioid crisis continues to worsen and solutions are scarce. These tangible and workable methods of treating OUDs as a product of the PHE were a blessing in disguise. This could be the solution to America's real, ongoing pandemic with collaboration, cooperation, and willingness to ignite change on the forefront of healthcare.