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Policies and Regulations Surrounding Opioid Use Disorder During COVID-19

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While policy makers and public health agencies have been grappling with how to recuperate from the devastating effects of the COVID-19 pandemic, a different epidemic has continued to silently ravage communities across the United States. In October 2017, the Trump Administration officially declared the opioid crisis a "public health emergency."[1] Individuals with Opioid Use Disorder ("OUD") continue to struggle with addiction to opioids such as prescription pain relievers, heroin, and synthetic opioids such as fentanyl. In the 12 months ending in May 2020, over 81,000 drug overdose deaths occurred in the United States—an 18.2 percent increase from the prior 12-month period.[2] This is a particularly grim reality in rural communities. In 2019, the five states with the highest rates of death due to drug overdoses were West Virginia, Delaware, Maryland, Pennsylvania, and Ohio.[3] While the Center for Disease Control ("CDC") has not reported official data for 2020, current preliminary data suggests that opioid overdose deaths in 2020 will be the highest on record.

Traditional policies addressing OUD have stigmatized, criminalized, and isolated People Who Use Drugs ("PWUD"), leading to unnecessarily high overdose rates and poorer health outcomes. While the suffering and death of those struggling with OUD is a reason enough to expend resources to mitigate the negative effects of this crisis, the effects of OUD ripple through society. Increases in injection drug use has contributed to the spread of preventable infectious diseases such as HIV and Hepatitis C.[4] The economic burden that results from opioid misuse is also significant—the CDC has estimated the opioid crisis costs the United States $78.5 billion

[1] *Ongoing emergencies & disasters*, CENTER FOR MEDICARE & MEDICAID SERVICES (Jan. 23, 2020) https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Ongoing-emergencies

[2] *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTES OF HEALTH; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, (March 11, 2021), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis

[3] *Opioid Overdose: Drug Overdose Deaths*, CENTER FOR DISEASE CONTROL AND PREVENTION, (March 22, 2021), https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[4] *Supra*, n. 2.

per year, which includes "the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement."[5] The policies and regulations surrounding OUD that have shifted during the COVID-19 pandemic have been largely beneficial to patients suffering from OUD. Ensuring these policies are permanently implemented in a post-COVID-19 world will be a critical step for rural communities in their effort to combat this crisis, improving health outcomes, and mitigate the social stigmatization surrounding OUD.

OUD ravages urban and rural communities alike. Part I of this paper will provide a brief overview of what it means to live with OUD. Part II will disscuss the economic and sociological history of substance abuse in Rural America, as demonstrated through two case studies. Part III will discuss the challenges for PWUD that compounded when COVID-19 arrived on our shores. Finally, Part IV will provide an assessment of four categories of policies and regulations surrounding substance abuse as they were before the COVID-19 pandemic, during the COVID-19 pandemic, and how policy makers should frame them in a post-COVID-19 world. These policy categories include a waiver program creating a route by which providers can expand their prescription of medically assisted treatments ("MATs") for OUD (the "DEA X Waiver"), Opioid Treatment Program regulations, Medicaid coverage and reimbursement, and telehealth.

I. What is Opioid Use Disorder and How is it Treated?

Opioid Use Disorder is a complex,[6] chronic mental disorder characterized by, among other things, a problematic pattern of taking large amounts of opioids or taking them for a longer period than prescribed.[7] Opioids attach to pain and pleasure receptors in the brain and release

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[5] *Id*.
[6] The full picture of OUD is extraordinarily nuanced and beyond the scope of this paper. Part I provides a very simplified, basic overview of the OUD landscape.
[7] *Opioid Use Disorder*, AMERICAN PSYCHIATRIC ASSOCIATION, (November 2018) https://www.psychiatry.org/patients-families/addiction/opioid-use-disorder/opioid-use-disorder

large amounts of dopamine throughout the body.[8] Addiction can manifest in a short amount of time, as little as four to eight weeks.[9] While the chemical structure of opioids are all very similar, specific opioids vary in source and potency.[10] In 2018, 32 percent of all opioid overdose deaths involved prescription opioids such as morphine, codeine, oxycodone, and hydrocodone.[11] While one study approximated that one-third of PWUD started by using heroin, many individuals become addicted to opioids by way of a prescription and transition to using illicit and/or synthetic substances such as heroin and fentanyl when it is more easily available.[12] One study by the American Medical Association found that about 45 percent of people who use heroin started with an addiction to prescription opioids.[13] Fentanyl, a synthetic opioid, is 50 to 100 time more potent than morphine and causes more overdose deaths than any other type of opioid.[14] While fentanyl can be obtained by prescription, the illegally used fentanyl most associated with overdoses is created in labs and sold on the black market—often to be mixed with other drugs such as heroin, cocaine, and methamphetamine.[15] While some PWUD intentionally seek fentanyl, often PWUDs do not realize the drugs they are taking contain fentanyl, as dealers often cut other drugs with fentanyl to make their supply go farther.[16]

OUD is traditionally combatted with Medication Assisted Treatment, or MAT. MAT involves a combination of FDA approved medications and patient counseling. As with many

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[8] *Prescription Opioids DrugFacts*, NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF HEALTH; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, (May 27, 2020), https://www.drugabuse.gov/publications/drugfacts/prescription-opioids
[9] *Supra*, n. 7.
[10] *Supra*, n.. 8.
[11] *Opioid Overdose: Overdose Death Maps*, CENTER FOR DISEASE CONTROL AND PREVENTION, (November 20, 2020), https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html
[12] *Supra*, n. 8.
[13] *Supra*, n. 7.
[14] *Opioid Overdose: Synthetic Opioid Overdose*, CENTER FOR DISEASE CONTROL AND PREVENTION, (March 19, 2020) https://www.cdc.gov/drugoverdose/data/fentanyl.html
[15] *Fentanyl DrugFacts*, NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF HEALTH; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, (February 28, 2019), https://www.drugabuse.gov/publications/drugfacts/fentanyl
[16] *Id*.

chronic illnesses, there is no "one size fits all" approach to OUD treatment.[17] There are three FDA approved medications that are often used in some combination by those being treated for OUD—Buprenorphine, Methadone, and Naltrexone.[18] Methadone has strict federal regulations surrounding its distribution, but Buprenorphine and Naltrexone may be prescribed in the outpatient clinical setting.[19] Buprenorphine has a small potential for abuse—several studies have shown its administration in "non-opioid dependent individuals produce[] the euphoric effects typically associated with opioids."[20] In opioid-dependent individuals, however, Buprenorphine has been shown to blunt the reinforcing effect of opioids and thus has a relatively low risk for abuse among those utilizing it as MAT.[21] Naltrexone has no potential for abuse and can be prescribed by anyone who is licensed to prescribe medication.[22] While each has a slightly different effect and purpose, overall these medications are prescribed to patients to reduce cravings, reduce withdrawal symptoms, and to blunt the effects of opioids.[23] Under federal law,[24] individuals in MAT are required to combine medication with some sort of counseling—outpatient or inpatient—such as addiction counseling, contingency management, recovery coaching, and other mental health services.[25] While the overall goal of MAT is long-term remission and recovery, some individuals continue to use opioids while in treatment, though less

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[17] *Medications for Opioid Use Disorder*, 27, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, 2020 file:///C:/Users/19725/Downloads/PEP20-02-01-006_508.pdf

[18] *MAT Medications, Counseling, and Related Conditions*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions#opioid-dependency-medications (last visited March 21, 2021).

[19] Michael L. Barnett, et al., *In Rural Areas, Buprenorphine Waiver Adoption Since 2017 Driven By Nurse Practitioners And Physician Assistants*, 38, HEALTH AFF., 2048, 2048-56 (2019).

[20] Michael A. Yokell, et al., 4 *Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review*, CURR DRUG ABUSE REV., 4 (Mar. 1, 2011) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3154701/

[21] *Id*.

[22] *Mandatory Medicaid State Plan Coverage of Medication-Assisted Treatment*, CENTER FOR MEDICARE & MEDICAID SERVICES, (Dec. 30, 2020) https://www.medicaid.gov/federal-policy-guidance/downloads/sho20005.pdf

[23] *Supra*, n. 17.

[24] See 42 C.F.R. § 8.12.

[25] *Supra*, n. 17 at 29.

frequently or in smaller amounts.[26] MAT gives PWUD the time and space to make life changes associated with recovery while reducing their risk of overdose death.[27] Several studies examining the effectiveness of MAT have concluded it is superior to treatments such as abstinence only treatment—MAT has been shown to "reduce the amount of illicit and nonprescribed opioids used by patients, decrease[] criminal activity, and help[] to reduce the transmission of HIV among [PWUD] and the occurrence of high-risk injection practices."[28] Despite the science-based evidence that overwhelmingly suggests MAT is the gold standard in treating OUD, the stigma surrounding OUD leads many healthcare providers to underutilize available treatments.[29] Only about 21.5 percent of people with OUD received any sort of MAT treatment from 2009-2013.[30] Increasing access to MAT and reducing the stigma surrounding it is vital to reduce the rate of fatal overdose.

II. The Economic and Sociological History of Substance Abuse in Rural America

For a lot of Americans, the thought of Rural America elicits mental images of backward, poor, white folks as reductively illustrated in J.D. Vance's *Hillbilly Elegy*. It is easy to frame poverty and addiction as a moral failing of individuals, but the real root of OUD in rural America is a complex, multi-faceted, problem that cannot be fully detailed within the scope of this paper. While rural communities across the U.S. all have particularized sociological and economic factors that contribute to their collective OUD susceptibility, there is a general common denominator among many: deindustrialization led to an economic void, which caused the remaining sources of work to be mostly labor intensive, which led to high levels of depression,

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[26] *Id.* at 32.
[27] *Id.*
[28] *Supra*, n. 20.
[29] *Medication-Assisted Treatment for Opioid Addiction: Myths and Facts*, LEGAL ACTION CENTER, https://www.lac.org/assets/files/Myth-Fact-for-MAT.pdf (last visited March 21, 2021)
[30] *Supra*, n. 17 at 34.

poverty, and pain, which caused individuals to seek coping mechanisms—often in the form of opioids.[31] This snowball effect—compounded with a lack of healthcare infrastructure, lack of informational access, and stigma—leads to high rates of opioid misuse and overdose deaths.

A recent study conducted in McKeesport, Pennsylvania illustrates how macro-economic phenomena such as deindustrialization and lack of community healthcare access can create an environment prone to overdose risk. Located 12 miles southeast from the center of the prosperous city of Pittsburgh, McKeesport was once a thriving regional economy dependent on steel production.[32] When steel mills closed en-masse in the 1980s, McKeesport and other neighboring towns in the Monongahela River Valley experienced devastation.[33] Over 150,000 factory workers were laid off, and cities lost "'90% of everything'—residents, jobs and businesses."[34] McKeesport has lost over 35 percent of its population, approximately 18 percent of its buildings stand vacant, and approximately 30 percent of its residents were living under the poverty line as of 2013.[35] Many study participants named the lack of employment opportunities in the area as the catalyst for widespread opioid usage.[36] One study participant noted "If you don't work at Eat 'n' Park, CVS, or Family Dollar, you don't work."[37] Because of this lack of employment, participants noted, there are high rates of depression among the communities' population and in turn, high rates of drug selling and using.[38]

Of the 50 study participants, roughly 76 percent of them reported they had a family member, friend, or acquaintance who recently overdosed on opioids and 46 percent of them reported a

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[31] Interview with Fred Wells Brason II, Project Lazarus in Moravian Falls, N.C. (Oct. 25, 2017) https://www.ruralhealthinfo.org/assets/842-2848/fred-wells-brason-interview-transcript.pdf
[32] Katherine McLean, *"There's nothing here": Deindustrialization as risk environment for overdose*, 29, INT'L. J. OF DRUG POL'Y, 19, 19-26 (2016).
[33] *Id*.
[34] *Id*.
[35] *Id*.
[36] *Id*.
[37] *Id*.
[38] *Id*.

personal history of overdose.[39] A common hoped-for solution among study participants was the introduction of a major employer that would create jobs in the area.[40] The lack of healthcare infrastructure compounds the problem: there is only one substance use treatment facility in town and one needle exchange/naloxone distribution program in the whole county—1 hour from McKeesport.[41] By contrast, the treatment facilities in Pittsburgh are integrated.[42] While only 16 miles away, the cost of getting to those facilities—approximately one to two hours and eight dollars in bus fare—"render it essentially inaccessible" to most McKeesport residents who desperately need those services.[43] Study participants also noted the community police officers' perceived indifference to the problem, explaining that it would be likely for a police officer to not want to "waste" Narcan on someone they've revived before.[44] The McKeesport study illustrates how "a vacuum of opportunity, social support, and hope" can create an environment that is prone to widespread drug use and overdose deaths.[45]

The term "Deaths of Despair," as coined by the prominent economist Angus Deaton, has been used to describe overdose deaths that stem from the social, behavioral, and economic factors—a perfect descriptor of the phenomena occurring in Southern West Virginia.[46] With an average life expectancy 7 years below that of the healthiest state in the country,[47] communities in Southern West Virginia have seen this despair with the abandonment of coal mining.[48] West

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[39] *Id*.
[40] *Id*.
[41] *Id*.
[42] *Id*.
[43] *Id*.
[44] *Id*.
[45] *Id*.
[46] ANNE CASE & ANGUS DEATON, DEATHS OF DESPAIR AND THE FUTURE OF CAPITALISM, 40, (Princeton University Press, eds., 1st ed. 2020).
[47] Kelly Gooch, *50 States ranked from healthiest to unhealthiest*, BECKER'S HOSPITAL REVIEW, (Sept. 3, 2020) https://www.beckershospitalreview.com/rankings-and-ratings/50-states-ranked-from-healthiest-to-unhealthiest.html (last visited Mar. 23, 2021).
[48] Elizabeth Arias, Ph.D. et al., *U.S. State Life Tables, 2018*, 70, NATIONAL VITAL STATISTICS REPORTS, 1, 3 (Mar. 11, 2021) https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-1-508.pdf

Virginia is the second largest coal producer in the United States after Wyoming,[49] and in the 1950s the coal sector employed over 125,000 West Virginians.[50] Coal mining has been on the decline as conversations about decarbonization come to the national stage. In 2015 in Boone County, West Virginia, just 2,000 people made up the 20 percent of the total work force that is tied to coal mining.[51] Adjusting for inflation, the jobs that do exist pay substantially less than they used to thanks to successful anti-union efforts by coal companies.[52]

The loss of revenue from coal extraction has led to spending cuts—in 2015 Boone County had to close three of its 10 elementary schools.[53] It has also led to more pain, both physical and emotional. While mining coal is not a job free of physical pain, some workers have transitioned to even more labor-intensive positions, which brings injury.[54] Angus Deaton has suggested that transitioning from a laborious job such as coal extraction to a low-wage job in fast-food or retail could bring about an equal amount of pain—albeit emotional: "Lower earnings are associated with more pain," he says, "and it is entirely possible that the pain comes not from what happens at work but from the loss of status and meanings as a worker, or from the loss of the social structure that was supported by a well-paying job in a union town."[55] It is not arbitrary that Boone County, the second most coal reliant county in the U.S., leads the U.S. in per-capital opioid-related costs at a whopping $206.5 million per year for the mere 23,645 people that live

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[49] *West Virginia State Energy Profile*, U.S. ENERGY INFORMATION ADMINISTRATION, (Oct. 20, 2020), https://www.eia.gov/state/print.php?sid=WV

[50] James A. Haught, *A short history of mining – and its decline – in West Virginia*, THE REGISTER HERALD, (Mar. 30, 2017) https://www.register-herald.com/opinion/columns/a-short-history-of-mining----and-its-decline----in/article_4c968cfd-8d8b-51c7-bccb-77e186ea61f7.html

[51] Adele C. Morris, et al., *The Risk of Fiscal Collapse in Coal-Reliant Communities*, 18, COLUMBIA CENTER ON GLOBAL ENERGY POLICY (July 2019) https://www.brookings.edu/wp-content/uploads/2019/05/Morris_Kaufman_Doshi_RiskofFiscalCollapseinCoalReliantCommunities-CGEP_Report_FINAL.pdf

[52] Eric Scheuch, *Life After Coal: The Decline and Rise of West Virginia Coal Country*, COLUMBIA UNIVERSITY EARTH INSTITUTE, (Aug. 7, 2020) https://blogs.ei.columbia.edu/2020/08/07/coal-rise-decline-west-virginia/

[53] *Supra*, n. 51.

[54] *Supra*, n. 31.

[55] *Supra*, n. 46 at 92.

there—deindustrialization has been directly linked to this phenomenon.[56] Like in McKeesport, there is one substance abuse treatment center in all of Boone County.[57] The residents of Boone County have even more limited options for transportation. There are exactly two busses that stop three times per day at a spot within walking distance to the treatment center.[58] While there have been conversations within the state legislature about the ecological and economic imperative of transitioning away from fossil fuels and toward investment in a diversified economy[59], the slow-moving wheels of government has facilitated the existence of an environment that fuels depression, pain, and opioid abuse.

III. COVID-19's Impact on People Who Use Drugs in Rural Communities

"Epidemics don't smolder during pandemics—they *ignite*."[60] COVID-19 struck "at a moment when our national response to the opioid crisis was beginning to coalesce…[and] COVID-19 threatens to dramatically overshadow and reverse this progress."[61] In the early days of the pandemic, in May of 2020, the Overdose Detection Mapping Application Program showed that since the first reported case of COVID-19, fatal overdoses increased an estimated 11.4 percent and nonfatal overdoses increased an estimated 18.4 percent when compared to the same

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[56] Eric Eyre, *Report: Boone County Leads US in per-capita opioid-related costs*, CHARLESTON GAZETTE-MAIL, (Mar. 21, 2018) https://www.wvgazettemail.com/news/health/wv_drug_abuse/report-boone-county-leads-us-in-per-capita-opioid-related-costs/article_ebca6051-eb47-5a22-b566-8929b4ad7d9c.html

[57] *Southern West Virginia Substance Abuse Treatment Services*, WEST VIRGINIA ATTORNEY GENERAL'S OFFICE, https://ago.wv.gov/consumerprotection/Fighting%20Substance%20Abuse/Documents/Region%201%20Substance%20Abuse%20Resources%20Handout.pdf (last visited Mar. 23, 2021).

[58] TriRiver Transit, Tririver.org. (Wharton and Clothier lines stop near Lick Creek Service Center, which is near the Prestera Treatment Center.).

[59] Brittany Patterson, *Amid Climate Debate and Coal's Decline, West Virginia Considers a 'Just Transition',* THE ALLEGHENY FRONT (Feb. 21, 2020) https://www.alleghenyfront.org/just-transition-amid-climate-debate-and-coals-decline-west-virginia-considers-its-future/

[60] Utsha G. Khatri & Jeanmarie Perrone, *Opioid Use Disorder and COVID-19: Crashing of the Crises*, J. ADDICT MED. (May 2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7236857/

[61] G. Caleb Alexander, *An Epidemic in the Midst of a Pandemic: Opioid Use Disorder and COVID-19*, ANNALS OF INTERNAL MED., (Jul. 7, 2020) https://www.acpjournals.org/doi/full/10.7326/M20-1141

time period during the previous year.[62] On May 10th, 2020, the Herald Mail Media reported out of Martinsburg, West Virginia that more people had died so far that year from overdose than from COVID-19 in the area.[63] In June 2020, the Charleston Gazette-Mail reported that Kanawha County, West Virginia had experienced a 400 percent increase in the number of people overdosing.[64]

Rural communities have always been socially distant. They have more geographic space per person, and people tend to live farther apart. While wide open spaces may intuitively be the ideal condition to slow the spread of COVID-19, social distancing requirements compounded by the barriers rural communities already face to OUD treatment has exacerbated the opioid crisis exponentially.[65] COVID-19 has affected the opioid epidemic in myriad ways. The physical conditions caused by frequent drug use, such as hypoxemia (slowed breathing), pulmonary hypertension, and cardiomyopathy (heart disease) can cause people who contract COVID-19 to experience severe or life-threatening symptoms.[66] PWUD are more likely to be low-income and more likely to experience housing insecurity, which could make it challenging to shelter in place or follow social distancing guidelines.[67]

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[62] Aliese Alter & Christopher Yeager, *The Consequences of COVID-19 on the Overdose Epidemic: Overdoses are Increasing*, OVERDOSE DETECTION MAPPING APPLICATION PROGRAM, (May 13, 2020) https://files.constantcontact.com/a923b952701/dbf0b5a5-f730-4a6f-a786-47097f1eea78.pdf

[63] Matthew Umstead, *Overdose deaths outpacing COVID-19 deaths in the Tri-State area*, HERALD MAIL MEDIA, (May 10, 2020) https://www.heraldmailmedia.com/news/special/coronavirus/overdose-deaths-outpacing-covid-19-deaths-in-tri-state-area/article_a36e41cf-8c97-5881-9aed-0668b24b67c2.htmlhttps://www.kentucky.com/news/coronavirus/article242926656.html

[64] Caity Coyne, *'How are we going to keep people alive?' Behind the pandemic, overdoses are rising across West Virginia*, CHARLESTON GAZETTE-MAIL, June 20, 2020 https://www.wvgazettemail.com/coronavirus/how-are-we-going-to-keep-people-alive-behind-the-pandemic-overdoses-are-rising-across/article_6df7f23b-ef35-54fc-94e3-360662f5a123.html

[65] Wiley D. Jenkins, et al., *COVID-19 During the Opioid Epidemic – Exacerbation of Stigma and Vulnerabilities*, J. RURAL HEALTH, (April 2020) https://www.researchgate.net/profile/Jerel-Ezell/publication/340587696_COVID-19_During_the_Opioid_Epidemic_-_Exacerbation_of_Stigma_and_Vulnerabilities/links/5ebace6892851c11a864d063/COVID-19-During-the-Opioid-Epidemic-Exacerbation-of-Stigma-and-Vulnerabilities.pdf

[66] Nora D. Volkow, *Collision of the COVID-19 and Addiction Epidemics*, ANNALS OF INTERNAL MED. (Jul. 7, 2020) https://www.acpjournals.org/doi/full/10.7326/M20-1212

[67] *Supra*, n. 65.

Before the pandemic, many PWUD—particularly in rural communities—often sought care in emergency departments when faced with overdose or other mental health episodes.[68] The reliance on emergency medicine among PWUD could stem from multiple factors, including lack of access to information regarding treatment programs, and the general lack of trust in health care providers.[69] The critical illnesses caused by COVID-19 caused emergency departments to overflow and demanded all of their time and resources.[70] As a result, "seemingly overnight, any condition that [was] not immediately life threatening" became less of a priority, and people suffering from OUD were put on the back burner.[71]

Since both drug procurement and seeking harm reduction tools require social contact, social distancing requirements presented a unique conflict for PWUD. People who use alone have a greater risk of overdose—if something goes wrong there is no one available to intervene. However, social distancing requirements encourage people to use alone to decrease their risk of exposure to COVID-19.[72] PWUD may be conflicted about whether to use alone in order to decrease their risk of exposure to COVID-19 or to use with others to reduce the risk of fatal overdose.[73] Social distancing requirements may increase anxiety, depression, stress, and loneliness, which may trigger relapse among some PWUD.[74] Social distancing may also cause a lack of ability to purchase drugs, which may lead to withdrawal.[75] OTP requirements further

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[68] *Id*.
[69] *Id*.
[70] *Supra*, n. 60.
[71] *Id*.
[72] *Supra*, n. 65.
[73] *Id*.
[74] Fernando Alfonso III, *The Pandemic is triggering opioid relapses across Appalachia*, CNN (May 14, 2020), https://www.cnn.com/2020/05/14/health/opioids-addiction-appalachia-coronavirus-trnd/index.html
[75] *Supra*, n. 65.

exacerbate the social distancing conundrum—those that must travel to methadone clinics daily or weekly put people with OUD at an even greater risk of contracting COVID-19.[76]

The drug supply-chain is also causing increased overdoses rates. The Journal of Appalachian Health reported "[c]losed borders and restricted travel have interrupted the heroin supply from Mexico to the U.S.…[and there are] drug shortages, reduction in purity, and increased prices." This has caused drug dealers to utilize whatever is cheapest and easiest to obtain, and they may dilute drugs with more potent drugs, such as fentanyl, that will make their supply last longer.[77] Indeed, during the first 30 days of the pandemic, one study reported a 35.6 percent increase in the fentanyl positivity rate from the same time period the year before among a group of tested specimens.[78] Fentanyl, a substance 50 to 100 times more potent than morphine, dramatically increases risk of overdose, especially if the user is unaware their substance of choice includes fentanyl.[79]

The new challenges brought on by COVID-19 are compounded by the pre-existing health care access barriers and economic despair. As previously noted, 88.6 percent of rural counties lack sufficient OTP access.[80] During the pandemic, many clinics shut their doors and rapidly transitioned to telehealth-based services.[81] While telehealth-based services can provide a meaningful substitute for in person MAT, many rural patients do not have access to reliable

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[76] Margaret Miller, et al., *Rural Appalachia Battling the Intersection of Two Crises: COVID-19 and Substance Use Disorder*, 2, J. APPALACHIAN HEALTH, 86-91, (2020) https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1084&context=jah
[77] *Supra*, n. 61, cmt. 1.
[78] *Id*.
[79] *Fentanyl Drug Facts*, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/publications/drugfacts/fentanyl#:~:text=The%20high%20potency%20of%20fentanyl,to%20reverse%20a%20fentanyl%20overdose (Accessed March 31, 2021)
[80] *Opioid Use Disorder: Challenges and Opportunities in Rural Communities*, PEW, (Feb. 7, 2019) https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2019/02/opioid-use-disorder-challenges-and-opportunities-in-rural-communities
[81] *Supra*, n. 60.

internet or phone services.[82] This also leads to a lack of access to credible information surrounding COVID-19 precautions and OUD safety.[83] To fill the information gap as well as the gap in healthcare access, many non-profits and grassroots organizations have taken it upon themselves to create community-based harm reduction programs—many of them mobile. Harm reduction—programs and policies that aim to minimize the negative health, social, and legal impacts associated with drug use—offers an alternative or sometimes supplemental approach for people seeking to end their relationship with drugs.[84] Organizations like Holler Health Justice, Virginia Harm Reduction Coalition, and others like them offer direct community services such as fentanyl test strips, at-home HIV tests, naloxone, and safe syringe exchanges.[85] Rural communities often rely on these integral services that attempt to bridge the access gap—in fall of 2019, Queer Appalachia, a harm reduction coalition, handed out over 2,000 doses of naloxone.[86] Unfortunately, many of these grassroots harm reduction programs that attempt to fill the healthcare gap have closed their doors due to government mandated social distancing requirements, further exacerbating the OUD problem in rural communities.[87]

IV. Assessment of Policies and Regulations Surrounding Substance Abuse: Before, During, and After COVID-19.

When COVID-19 began to ravage communities, it became clear that PWUD and those suffering from OUD would suffer. Both the federal and state governments initiated swift policy changes to mitigate the devastation. This section will discuss four major policy areas that frame how rural providers think about and deliver substance abuse treatment: the DEA X Waiver,

[82] *Supra*, n. 76.
[83] *Supra*, n. 65.
[84] *What is Harm Reduction?*, HARM REDUCTION INTERNATIONAL, https://www.hri.global/what-is-harm-reduction, (accessed Mar. 21, 2021).
[85] *Harm Reduction*, HOLLER HEALTH JUSTICE, https://www.hollerhealthjustice.org/harm-reduction, (last accessed Mar. 27, 2021).
[86] *QA Harm Reduction*, QUEER APPALACHIA, https://www.queerappalachia.com/harm-reduction (last accessed Mar. 27, 2021).
[87] *Supra*, n. 65.

Opioid Treatment Program regulations, Medicaid reimbursement for OUD treatment, and telehealth. To provide context for the impact COVID-19 had on the opioid crisis in rural areas, each subsection will review pre-COVID-19 policies and regulations regarding each of these policy areas. Each subsection will then discuss any emergency or regulatory changes undertaken in these policy areas as a response to COVID-19. Finally, each subsection will discuss the implications of these changed policies remaining in a post-COVID-19 world.

A. DEA X Waiver

The X Waiver is a DEA-issued licensed that allows physicians to prescribe buprenorphine to a set number of patients. Many health policy experts were hopeful that COVID-19 would compel the Department of Health and Human Services ("DHHS") to do away with the X Waiver, as there is widespread agreement among OUD treatment specialists that it acts only as a barrier to effective treatment. Part 1 of this subsection will discuss the evolution of the X-Wavier and its effect on rural communities. Part 2 will discuss the regulatory changes that almost came to fruition and the importance of the continued advocacy for those changes.

1. Pre-COVID Regulations

As illustrated through the discussion of McKeesport and Boone County, rural areas in the U.S. suffer from a significant lack of certified opioid treatment programs and a lack of healthcare infrastructure in general. Prior to the year 2000, MAT was only available through federally approved Opioid Treatment Programs. In 2000, the Drug Addiction Treatment Act (DATA 2000) provided a remedial step by allowing physicians to register with the Drug Enforcement Administration (DEA) to obtain a license that allows them to prescribe buprenorphine in any

setting in which they are allowed to practice.[88] To obtain the X Waiver, Physicians must complete special training for the treatment and management of patients with OUD, or otherwise hold a specialty board certification in addiction psychiatry.[89] The Substance Abuse and Mental Health Services Administration (SAMHSA) will issue the license and the first year a physician has their X Waiver, they are permitted to treat and manage no more than 30 patients at a time.[90] Physicians may increase their patient volume to 100 after the first year.[91]

Even with this relaxation of regulation, there is a shortage of MAT providers, especially in rural areas. Many rural physicians cite a lack of mentorship as a reason to not incorporate it into their practice, highlighting the shortage of addiction medicine-trained providers in their area.[92] There is, however, no shortage of prescription opioids being pumped into rural populations. In the 1990s, the pharmaceutical industry, which had previously assured providers and patients that opioids were not addictive, pushed providers to prescribe these drugs to their patients.[93] Between 1999 and 2015, this industry-wide push to sell prescription opioids led to a 325 percent increase in drug overdoses in rural areas.[94] Ironically, there are no federal requirements physicians must comply with when prescribing opioids for pain management. However, each state does impose minimal continuing education requirements on physicians in order for them to remain licensed to prescribe controlled substances for pain management purposes.[95]

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[88] *Process to Obtain Buprenorphine Waiver on DEA License*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, https://chcams.org/wp-content/uploads/2018/08/DATA-2000-Waiver-Process.pdf, (last visited March 21, 2021).
[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] *Medication-Assisted Treatment for Opioid Use Disorder in a Rural Family Medicine Practice*, J. PRIMARY CARE CMTY. HEALTH, (Jun. 6, 2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7278292/
[93] *Id*.
[94] *Id*.
[95] *State Requirements for Pain Management CME*, NEJM KNOWLEDGE, (April 9, 2020) https://knowledgeplus.nejm.org/cme-moc/pain-management-and-opioids-cme/state-requirements-for-pain-management-cme/

Despite broad efforts to expand access to buprenorphine, as of 2016 more than 60 percent of rural counties in the United States lacked a physician with an X Waiver to prescribe it.[96] A 2016 study conducted by the University of Washington Rural Health Research Center found that of the rural physicians that had an X Waiver, approximately 90 percent had utilized the waiver to treat OUD, but only half were accepting new patients.[97] Further, rural physicians reported treating, on average, only 8.8 patients of their allotted 30 and an average of 56.9 if their allotment was 100.[98]

Enter, CARA. In 2016, President Obama expanded buprenorphine prescribing privileges beyond only physicians to qualifying nurse practitioners (NPs) and physician assistants (PAs) by signing the Comprehensive Addiction and Recovery Act (CARA) into law.[99] NPs and PAs also must complete training, and may treat up to 30 patients at one time.[100] CARA also increased the number of patients a physician can treat at one time from 100 to 275 when other criteria are met.[101] One study published in December of 2019 estimates that after the passage of CARA, "the number of waivered clinician per 100,000 population in rural areas increased by 111 percent," with PAs and NPs accounting for more than half of that increase.[102]

While this rapid increase seemed promising, rural clinicians continued to face barriers in maximizing the full potential of their X Waiver. Scope-of-practice policies vary state to state, and some states such as West Virginia and Tennessee require physician supervision for an NP or a PA to prescribe medication.[103] CARA was expanded once again in 2018 by the SUPPORT Act to expand prescription privileges to Clinical Nurse Specialists, Certified Registered Nurse

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[96] C. Holly A. Andrilla, et al., *Prescribing Practices of Rural Physicians Waivered to Prescribe Buprenorphine*, 54, AM. J. PREVENTATIVE MED., S208, S208-S214 (Supp. 2018).
[97] *Id.*
[98] *Id.*
[99] *Supra*, n. 88.
[100] *Id.*
[101] C. Holly A. Andrilla, et al., *Overcoming Barriers to Prescribing Buprenorphine for the Treatment of Opioid Use Disorder: Recommendations from Rural Physicians*, 35, J. RURAL HEALTH, 113, 113-21, (2018).
[102] *Supra*, n. 19.
[103] *Id.*

Anesthetists, and Certified Nurse-Midwifes.[104] In a 2018 study funded by the Federal Office of Rural Health Policy, some clinicians simply reported simply not having the time or resources to confidently incorporate MAT into their practices—as it requires unique prescribing schedules, appointment structures, paperwork, and record keeping to ensure DEA compliance.[105] Lack of mental and psychosocial support partnerships in rural communities also contribute to the underutilization of the X Waiver—while some physicians are willing to provide counseling themselves, others do not have the time or resources to do so.[106] Without community partners that specialize in the behavioral side of MAT, prescribing buprenorphine can be feared to be futile.[107] Finally, many rural prescribers reported resistance to the X Waiver from within their own practices due to the social stigma surrounding substance use disorders.[108]

2. The Argument for X-Waiver Removal

Unfortunately, no regulatory changes to the X Waiver have come to fruition yet. On January 14, 2021, the DHHS announced that it would be removing the X Waiver training requirement for physicians who wanted to prescribe buprenorphine.[109] The new policy would have allowed any physician that has a DEA prescriber license to treat up to 30 patients no matter what, exempting hospital-based physicians from the patient cap.[110] Physicians who wished to treat more than 30 patients, nurse practitioners, and physician assistants would still be required to undergo training and obtain the X Waiver.[111] Even though some rural providers are hesitant or uninterested in

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[104] *Statutes, Regulations, and Guidelines*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Oct. 7, 2020) https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines
[105] *Supra*, n. 101.
[106] *Id*.
[107] *Id*.
[108] *Id*.
[109] Richard Bottner, *When the X-Waiver gets X'ed: Implications for hospitalists*, THE HOSPITALIST, (Feb. 17, 2021), https://www.the-hospitalist.org/hospitalist/article/236059/neurology/when-x-waiver-gets-xed-implications-hospitalists
[110] Lev Facher, *Trump administration will let nearly all doctors prescribe addiction medicine buprenorphine*, STAT, (Jan. 14, 2021) https://www.statnews.com/2021/01/14/trump-admin-nearly-all-doctors-buprenorphine/
[111] *Id*.

incorporating MAT into their practice, this change would have drastically increased rural communities' ability to access live-saving MAT. Unfortunately, the Biden administration froze the training requirement removal pending a 60-day review, citing procedural factors and concerns that DHHS "may not have the authority to void requirements mandated by Congress."[112] The 60-day review timeline has come and gone, and it is not clear at this time if the Biden Administration will issue the guidelines as announced by the Trump Administration. The abolishment of the X Waiver requirement would have been an invaluable tool for rural providers over the past year amidst the COVID-19 pandemic, providing more flexibility for PWUD to obtain a prescription from a physician closer to them, thereby mitigating unnecessary travel and COVID-19 exposure.[113]

Even if the COVID-19 pandemic never happened, the abolition of the X Waiver was a change urged and welcomed by organizations such as the American Medical Association,[114] the National Council for Behavioral Health, and over 140 other organizations comprising medical professionals and policy experts alike.[115] A recent article published by Filter, a non-profit organization dedicated to advocating for compassionate approaches to drug policy, captured what it would mean to PWUD if the X Waiver was abolished. It argues the X Waiver acts as a double standard and perpetuates stigma surrounding OUD.[116] It points out the puzzling fact that physicians are able to prescribe opioids that lead people down the path of addiction with little training and no special license, but to prescribe the cure to the disease they may have caused, the

[112] *Supra*, n. 109.
[113] Louise Vincent, *MAT Treatment Recommendations*, SHOOTING BLIND, THE NORTH CAROLINA SURVIVORS UNION BLOG, (Apr. 9, 2020), http://ncurbansurvivorunion.org/2020/04/09/mat-treatment-recommendations/
[114] Leah Kuntz, *Dropping the X-Waiver for Buprenorphine*, PSYCHIATRIC TIMES, (Jan. 18, 2021) https://www.psychiatrictimes.com/view/dropping-the-x-waiver-for-buprenorphine
[115] Aaron Ferguson, et al., *As People Who Use Drugs, We Urge Biden to End the Buprenorphine X-Waiver*, FILTER MAGAZINE, (Mar. 3, 2021), https://filtermag.org/buprenorphine-x-waiver-biden/
[116] *Id*.

physician requires special training.[117] "The double standard here *is* stigma," Filter argues, "[r]egardless of how it is sliced, applying a different set of rules to addiction treatment drugs than to the rest of medicine will only serve to vilify people in need and keep addiction health care on the fringe."[118]

B. Opioid Treatment Programs

Another vital resource that is drastically lacking in rural America are SAMSHA accredited Opioid Treatment Programs (OTPs). OTPs are heavily regulated methadone clinics that often require patients to attend every day for treatment. The social distancing requirements that accompanied the onset of the COVID-19 pandemic forced SAMHSA to rethink their OTP policies to ensure the safety of patients and clinicians alike. Part 1 of this subsection will discuss the regulations surrounding OTPs before COVID-19. Part 2 will discuss the emergency regulatory changes initiated amidst the pandemic, and part 3 will argue for these regulatory changes to become permanent.

1. Pre-COVID Regulations

OTPs must ensure they comply with federal regulations set out in 42 C.F.R. § 8. Of particular importance is § 8.12, the standards governing patient admission criteria, required services, recordkeeping, medication dispensing, and maintenance treatment.[119] § 8.12 requires patients to have been suffering from opioid addiction for at least one year prior to admission for treatment, unless the individual has a documented history of opioid use disorder.[120] Patients must also undergo a preliminary physical evaluation before admission to any OTP, and there are special

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[117] *Id.*
[118] *Id.*
[119] 42 C.F.R. § 8.12.
[120] *Federal Guidelines for Opioid Treatment Programs*, Substance Abuse and Mental Health Services Administration, 23-4, (Jan. 2015), file:///C:/Users/19725/Downloads/pep15-fedguideotp.pdf

requirements for pregnant patients.[121] OTPs provide integrated counseling services as well as referral services to education, employment services, and vocational rehabilitation.[122] All patients in OTPs are subject to at least eight random drug tests per year while they are in treatment.[123] Before COVID-19, all OTP patients were required to receive and ingest all doses of methadone[124] under the supervision of the OTP prescriber, except for doses they may take home for the days the clinic is closed.[125] Patients may have been deemed eligible for unsupervised use, subject to the evaluation of the following factors: absence of recent abuse of drugs, regularity of clinic attendance, absence of serious behavioral problems at the clinic, absence of known recent criminal activity, stability of the patient's home environment and social relationships, the length of time in treatment, availability of safe and adequate medication storage in the patient's home, and whether the benefit of decreasing the frequency of clinic attendance outweighs the potential risks of diversion.[126] If it was found that a patient was eligible for unsupervised treatment, during the first 90 days of treatment a patient was able to take one dose per week unsupervised, and in the second 90 days of treatment a patients was able take two doses per week unsupervised.[127] If an OTP wanted to deviate from this standard for an individual patient, they were required to submit a request to SAMHSA for approval.[128] Dose control is partly predicated on the notion that PWUD will sell or share their doses to others, a practice known as dose diversion.

OTPs are a vital component of OUD treatment and unsurprisingly, rural areas are lacking in OTPs. According to a study by the Pew Charitable Trusts, 88.6 percent of rural counties lack

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[121] *Id.* at 31-2.
[122] *Id.* at 41.
[123] *Id.* at 46.
[124] This part of the regulation is not applicable to buprenorphine.
[125] *Supra*, n. 7.
[126] *Id.* at 56.
[127] *Id.*
[128] *Id.* at 57.

sufficient OTP capacity.[129] Rural OTPs that do exist report patient transportation to be a substantial barrier for individuals.[130] A study by Yale researchers found that on average, OTP patients in Indiana, Kentucky, Ohio, Virginia and West Virginia must travel between 37-49 minutes to their nearest OTP center—assuming they have access to a vehicle or they can reply on friends or family for transportation.[131] Public transportation is most often non-existent in rural communities.

2. Emergency Regulations in Response to COVID-19

At the beginning of the COVID-19 pandemic, SAMHSA instituted sweeping policy change surrounding OTP guidance. On March 16, 2020 SAMHSA issued guidance permitting states to request a temporary blanket exception for all stable patients in an OTP to receive 28 days of take-home doses, eliminating the requirement for everyday travel to an OTP clinic.[132] Less stable patients were able to request up to 14 days of doses, provided the OTP believed they could safely handle that level of take-home medication.[133] In April of 2020, pursuant to 42 C.F.R. § 8.11(h), SAMHSA also granted emergency exemptions to OTPs, removing the requirement for OTPs to conduct in-person evaluations for physical evaluations prior to beginning a patient on a buprenorphine treatment plan.[134] New patients seeking methadone treatment were still required to undergo an in person medical evaluation.[135] Existing patients were able to continue with

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[129] *Supra*, n. 80.
[130] Jean Hilliard, *Travel Distance To Opioid Addiction Treatment Places Strain On Rural America*, ADDICTION CENTER, (Oct. 22, 2019), https://www.addictioncenter.com/news/2019/10/opioid-treatment-rural-addiction/
[131] *Id.*
[132] *Opioid Treatment Program (OTP) Guidance*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Mar. 16, 2020), https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf
[133] *Id.*
[134] *FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Apr. 21, 2020) https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf
[135] *Id.*

treatment with both buprenorphine and methadone via telehealth, and physicians could continue to provide prescriptions remotely.[136]

3. The Argument for Permanent Regulatory Relaxation

Many are calling for this to become a permanent modification to 42 C.F.R. § 8.12, as daily OTP attendance can "interrupt daily routines and serve as a barrier to treatment engagement."[137] In rural communities, this take-home allowance could be especially meaningful—rural patients often have to travel very far, every day, to receive their dose. Saving money and time on transportation could free up daily valuable time and allow for more self-enrichment, employment, or relaxation.

While the full effect of regulation relaxation cannot be realized so soon after its implementation, preliminary data suggest the relaxation of OTP regulations have not necessarily had a negative effect on patients and their treatment goals. A study conducted among three OTP clinics in central North Carolina during the summer of 2020 found that of the 91.6 percent of patients receiving take-home doses, 93 percent were taking their methadone as prescribed.[138] Only 7 percent of those patients reported selling or sharing their doses. Additionally, study participants often indicated they diverted doses not for profit, but to help someone else that could not otherwise access MAT.[139] This data suggests that dose diversion may not be as big of a problem as it has been perceived to be.[140] The study did find considerable variation among the

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[136] *Id.*
[137] Giliane Joseph, et al., *Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID-19*, 122 J. SUBSTANCE ABUSE TREATMENT, (March 2021) https://www.sciencedirect.com/science/article/pii/S0740547220304761?casa_token=WBz1tMy7h1IAAAAA:Wg7GS0onc6pK0nmOkxRaqT8Es2SQDK_zLFuZ2CE2t-rtIBqqJXJ_R-SAt99ttxN8iI5JyrEq9pRl
[138] Mary C. Figgatt, et a., *Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19*, J. SUBSTANCE ABUSE TREATMENT, (April 2021) https://www.sciencedirect.com/science/article/pii/S0740547221000027
[139] *Id.*
[140] *Id.*

three clinics regarding the type of patient receiving take-home doses, however, and contends this may suggest a need for a greater understanding of how clinics actually implemented SAMHSA directives during the pandemic.[141]

One OTP in the Bronx reported that between March 8 and March 22, 2020 it reduced the proportion of patients who came daily from 47.2 percent to 9.4 percent.[142] The OTP also ceased requiring mandatory toxicology screenings.[143] It experienced six nonfatal overdoses and zero fatal overdoses between March 16 and May 31, 2020.[144] When compared with the previous three months, these numbers indicate this method is safe—between January 1 and March 15, 2020, this OTP experienced two nonfatal overdoses and one fatal overdose.[145] While the structure of the daily routine of going to the clinic is beneficial for some patients, for others it hinders them from achieving their full potential. Keeping these SAMHSA policies in place post-COVID-19 and allowing patients to have more control over their treatment plan will allow for PWUD to experience more autonomy on their journey to recovery.

C. Medicaid Reimbursement for OUD

Medicaid has proven instrumental in delivering MAT to individuals with OUD—in 2017 adults with Medicaid were nearly twice as likely to receive treatment than those with private insurance or those who are uninsured.[146] Still, Medicaid reimbursement often acts as a significant barrier to rural providers of OUD treatment. Part 1 of this subsection will discuss what Medicaid coverage for OUD looked like before COVID-19. Part 2 will discuss the legislative changes that

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141 *Id*.
142 *Supra*, n. 137.
143 *Id*.
144 *Id*.
145 *Id*.
146 Kendal Orgera, et al., *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment*, KFF, (May 24, 2019) https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/

occurred during the pandemic. Part 3 will discuss how COVID-19 has strengthened the case for Medicaid expansion of OUD coverage and how such expansion will benefit rural communities.

1. Pre-COVID-19 Medicaid Coverage for OUD

Since the passage of the Affordable Care Act, 39 states and Washington, D.C. have adopted Medicaid expansion that allowed states to provide expanded OUD treatment for Medicaid recipients with mental health and substance use disorder services.[147] In 2017, 48 percent of all non-elderly adults with OUD were low income (income below 200 percent of the federal poverty level), and 55 percent of those low-income adults that suffered from OUD were insured through Medicaid.[148] While standards of OUD care vary across those states that have adopted Medicaid expansion, all state Medicaid programs cover at least one MAT medication and most cover all three.[149] State Medicaid programs vary widely in terms of the intensity, duration, and kind of counseling support they cover.[150] Some states have obtained Section 1115 waivers—waivers from the DHHS that allow states to test new ways to deliver and pay for healthcare services in Medicaid—to expand OUD treatment options to include expanded community benefits, including "supportive housing, supported employment, and peer recovery coaching."[151] Medicaid recently revised guidance on a long standing policy called the Institutions for Mental Disease (IMD) Exclusion, by which states were ineligible for federal funds to pay for inpatient mental healthcare at residential treatment facilities with more than 16 beds.[152] Medicaid now allows states to seek Section 1115 waivers for IMD services, and the Center for Medicare and

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[147] *Status of State Action on the Medicaid Expansion Decision*, KFF, (updated Mar. 26, 2021) https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
[148] *Supra*, n. 146.
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Id. See also*, *The Medicaid IMD Exclusion: An Overview and Opportunities for Reform*, LEGAL ACTION CENTER https://www.lac.org/assets/files/IMD_exclusion_fact_sheet.pdf (last accessed Apr. 5, 2021)

Medicaid Services (CMS) has approved waiver requests in over 20 states to provide OUD treatment in IMD facilities.[153] The SUPPORT Act also allows states to use federal funds for adults receiving IMD SUD services for up to 30 days per year.[154]

While innovation in Medicaid delivery improves health outcomes, many rural physicians report Medicaid reimbursement as a barrier to providing MAT services.[155] In the 2018 Federal Office of Rural Health Policy study, the majority of rural physicians reported their state's Medicaid reimbursement amount was too low compared to the time and effort required to provide adequate treatment.[156] While some physicians were able to "take the financial hit," provide the treatment, and collect the Medicaid reimbursement, others could not.[157] Some decided to accept cash only, and some reported accepting cash in conjunction with private insurance on a sliding fee scale to try to make up for the Medicaid reimbursement deficiencies.[158]

2. Legislative Changes to Medicaid Amidst COVID-19

While the SUPPORT Act was passed in 2018, provision 1006(b) did not kick in until October 2020—the provision requiring all state Medicaid programs to cover all FDA approved MAT drugs, counseling services and behavioral therapy.[159] There is an exception for states that certify that implementing that provision "would not be feasible by reason of a shortage of qualified providers of medication-assisted treatment, or facilities providing such treatment."[160] This provision will sunset in September 2025, but many are calling for it to stay. A recent study

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[153] *Supra*, n. 146.
[154] *Id*.
[155] *Supra*, n. 101.
[156] *Id*.
[157] *Id*.
[158] *Id*.
[159] Mary Beth Musumeci, *Federal Legislation to Address the Opioid Crisis: Medicaid Provision in the SUPPORT Act*, KFF, (Oct. 5, 2018), https://www.kff.org/medicaid/issue-brief/federal-legislation-to-address-the-opioid-crisis-medicaid-provisions-in-the-support-act/
[160] *Supra*, n. 22.

from Rhode Island, a state that expanded Medicaid to cover MAT in 2014, has reported that over a six-year observation period, the state had great progress in treating OUD with MAT among Medicaid patients than non-Medicaid enrollees, suggesting expanded eligibility is integral in combatting OUD.[161]

In March, 2021, Congress passed the American Rescue Plan Act (ARPA), creating a five-year Medicaid coverage option with enhanced federal funding assistance for states to develop "community-based mobile mental health and substance use disorder crisis intervention services and appropriates $15 million for planning grants to assist states with developing a state plan amendment or waiver request."[162] ARPA also earmarked $420 million for community behavior health clinics, $100 million for behavioral health workforce education and training, and $8.5 billion in payments to eligible rural Medicare and Medicaid providers.[163] This creates a strong financial incentive for states that have yet to expand their Medicaid programs to do so.[164] Notably, the federal matching funds provision requires that community based services must use those federal funds "to supplement rather than supplant their current spending on these services."[165] This incentive, coupled with the millions reserved for grants, give states the opportunity to ramp up their OUD treatment infrastructure and move toward a more complete coverage continuum for OUD patients.[166] Rural states would be prudent to use these funds toward behavioral health workforce education and training and increasing payments to providers.

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[161] Larry Bean, *Study: Medicaid expansion improves access to medication-assisted treatment for opioid use disorder*, FEDERAL RESERVE BANK OF BOSTON, (Mar. 17, 2021) https://www.bostonfed.org/news-and-events/news/2021/03/boston-fed-study-medicaid-expansion-increases-treatment-for-opioid-use-disorder.aspx
[162] Morgan Lewis, et al., *The American Rescue Plan Act and Healthcare Providers—A First Look*, JDSUPRA, (Mar. 17, 2021) https://www.jdsupra.com/legalnews/the-american-rescue-plan-act-and-3766554/
[163] *Id.*
[164] Anna Bailey, *States Can Use Rescue Plan's Medicaid Funding to Strengthen Substance Use Care*, CENTER ON BUDGET AND POLICY PRIORITIES, (Mar. 18, 2021) https://www.cbpp.org/blog/states-can-use-rescue-plans-medicaid-funding-to-strengthen-substance-use-care
[165] *Id.*
[166] *Id.*

On average, rural counties have 1.8 licensed behavioral health providers per 1,000 Medicaid enrollees, compared with 6.4 in urban counties.[167] In the 2018 Federal Office of Rural Health Policy study, the majority of rural physicians reported their state's Medicaid reimbursement amount was too low compared to the time and effort required to provide adequate treatment.[168]

3. How COVID-19 has Strengthened the Case for Medicaid Expansion of OUD Coverage

The COVID-19 pandemic has highlighted the pitfalls and coverage gaps in the U.S. Healthcare system, and the case for Medicaid expansion has never been stronger. Among the 14 states that have yet to expand, five of them have extraordinarily high opioid overdose rates—four of which are mostly rural in character.[169] The convergence of the pandemic and the opioid epidemic has led several organizations to advocate for states to adopt additional innovative initiatives that would expand their state's Medicaid enrollees' access to MAT.

In November of 2019, Manatt Health released a Toolkit for State Medicaid Leaders to provide implementation guidance on OUD Medicaid expansion.[170] One way for states to increase access to MAT is to abolish prior authorization requirements that impede Medicaid enrollee's access to MAT. One study has shown that prior authorization can actually increase dose diversion among OUD patients, the very thing prior authorization purported to protect against.[171] Manatt health has pointed to New Hampshire as an example of how to implement this: in New

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[167] James Maxwell, et al., *Battling The Mental Health Crisis Among The Underserved Through State Medicaid Reforms*, HEALTH AFFAIRS, (Feb. 10, 2020) https://www.healthaffairs.org/do/10.1377/hblog20200205.346125/full/
[168] *Supra*, n. 101.
[169] *Compare Opioid Summaries by State*, NATIONAL INSTITUTE ON DRUG ABUSE, (Apr. 16, 2020), https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state *with Finishing the Job of Medicaid Expansion*, STATE HEALTH AND VALUE STRATEGIES, (Jan. 26, 2021) https://www.shvs.org/finishing-the-job-of-medicaid-expansion/, (Wisconsin, Tennessee, North Carolina, South Carolina, and Florida have yet to expand Medicaid and all have over 15 opioid-involved overdose deaths per 100,000 people).
[170] Patricia Boozang, et al., *Using Medicaid to Advance Evidence-Based Treatment of Substance Use Disorders*, MANATT HEALTH, (Nov. 2019) http://www.manatt.com/Manatt/media/Media/PDF/White%20Papers/AV-Medicaid-Opioid-Toolkit-November-2019.pdf
[171] *Id.* at 8.

Hampshire's Medicaid managed care contract, managed care organizations must cover any OUD treatment identified as necessary by a clinician and consistent with professional standards without prior authorization or utilization management.[172] The contract also "precludes prior authorization for urine drug screenings—an important ancillary service needed for MAT—unless screens exceed 30 per month." [173] "Prior authorization does nothing to improve the quality of care," explains Dr. Tiffany Lu, a Buprenorphine treatment specialist, "but most certainly delays access to treatment and contributes to the epidemic of overdose deaths."[174] Removal of prior authorization requirements in rural areas could save thousands of lives—there is often a small window of time someone suffering from OUD is willing to seek help, and prior authorization requirements compounded with transportation and healthcare infrastructure barriers could make that window even smaller.

Section 1115 waivers and Medicaid expansion can be used in myriad ways to expand access to MAT, the scope of which is beyond the purview of this paper. It will be important for rural communities to utilize ARPA funds in a way that maximizes their full potential of achieving OUD treatment equity.

D. Telehealth

Telehealth refers to using the internet and other communication technologies to provide health treatment in real time.[175] The utilization of telehealth to treat OUD has many positive qualities—it can allow patients access to quality treatment without barriers caused by

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[172] *Supra*, n. 170 at 12.
[173] *Id*.
[174] Tracie Gardner & Christine Khaikin, *Removing Prior Authorization Requirements for All Addiction Medication will Save Lives and Reduce Health Care Costs to New York*, LEGAL ACTION CENTER, (Dec. 6, 2019) https://www.lac.org/news/removing-prior-authorization-requirements-for-all-addiction-medication-will-save-lives-and-reduce-health-care-costs-to-new-york
[175] *Telehealth in State Substance Use Disorder (SUD) Services*, THE NATIONAL ASSOCIATION OF STATE ALCOHOL AND DRUG ABUSE DIRECTORS, Inc. (Jun. 2009) https://nasadad.org/wp-content/uploads/2015/03/Telehealth-in-State-Substance-Use-Disorder-SUD-Services-2009.pdf

transportation, physical disabilities, or social stigmas that may prevent patients from seeking care.[176] It has been shown to be equally as effective as face-to-face interaction—an early study conducted in 2009 found that subjects in an internet-based outpatient program were twice as likely to complete the program than those in traditional treatment.[177] But for Telehealth, many more lives could have been lost to OUD during COVID-19. Initial studies have shown that it is possible to keep OUD patients engaged in treatment and counseling virtually, and one study found a small overall increase in patient engagement during their transition to telehealth.[178] The patchwork of state and federal policies that govern telehealth is nuanced—the entirety of which is outside the scope of this paper. However, a brief explanation of three aspects telehealth regulation are critical in understanding the future of OUD telehealth treatment in the United States—federal privacy regulations, reimbursement barriers, and licensure requirements. Each subsection will discuss, pre-COVID-19 regulations, emergency regulations in response to COVID-19, if any, and what the future of telehealth OUD services should look like.

1. Privacy Regulations

The Health Insurance Portability and Accountability Act (HIPAA) and 42 C.F.R. Part 2 regulate covered entities participating in OUD telehealth practices.[179] HIPAA requires all healthcare providers that electronically transmit health information to adequately safeguard all patient personal health information.[180] While all healthcare providers must ensure their patient information storage practices are HIPAA compliant, 42 C.F.R. Part 2 affords OUD patients that

[176] *Id.*
[177] *Id.*
[178] James R. Langabeer, II, et al., *Telehealth sustains patient engagement in OUD treatment during COVID-19*, J. SUBSTANCE ABUSE TREATMENT, (Nov. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685137/
[179] *HIPAA and Telehealth*, CENTER FOR CONNECTED HEALTH POLICY, https://www.telehealthpolicy.us/sites/default/files/2018-09/HIPAA%20and%20Telehealth.pdf (accessed Mar. 21, 2021)
[180] *Id.*

receive federally-assisted SUD treatment an added layer of privacy.[181] Under 42 C.F.R. Part 2, patient records are not to be disclosed to anyone without written patient consent, even with a subpoena.[182] HIPAA does not contain any provision that explains how a covered entity may utilize telehealth services while remaining HIPAA compliant, and there is no accreditation system that verifies whether a telehealth platform adequately protects patient health information under HIPAA.[183] As a result, OTP centers and other OUD providers commonly face multiple barriers in providing telehealth services and ensuring their HIPAA compliance. Firstly, it is the provider's responsibility to ensure their wireless connection is secure enough to "guard against unauthorized access to electron protected health information that is being transmitted over an electronic communications network."[184] Additionally, provider must have an appropriate agreement with the business association that maintains their tele-platform to ensure that third party entity is bound to protect personal health information.[185] Non-compliance with HIPAA can bring about a range of federal penalties, from a $100 fine for a disclosure made in error up to a $250,000 fine and 10 years in prison for malicious use of records.[186] While these requirements discussed barely scratch the surface of what it means to be fully HIPAA compliant, a recent study from the University of Michigan School of Public Health found that among surveyed OUD providers, legal compliance was the strongest barrier in their successful implementation of telehealth services.[187] In many rural areas, these technological and legal challenges are

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[181] Todd Molfenter, et al., *Trends in Telemedicine use in addiction treatment*, 10 Addiction Sci. & Clinical Prac., (2015) https://link.springer.com/article/10.1186/s13722-015-0035-4
[182] Bill Connors, et al., *The 42 C.F.R.Part 2 and NHIN Conundrum*, 29, BEHAV. HEALTHCARE, 52, 52-3 https://www.proquest.com/docview/228083721?accountid=13793
[183] *Supra*, n. 181.
[184] *Supra*, n. 179.
[185] *Id*.
[186] Becky Sutherland Cornett, *The HIPAA Privacy Rule in Everyday Life*, THE ASHA LEADER, (Feb. 1, 2002), https://leader.pubs.asha.org/doi/full/10.1044/leader.OTP.07022002.2#:~:text=There%20are%20specific%20federal%20penalties,for%20malicious%20use%20of%20records.
[187] Cory Page, et al., *Access to Treatment for Opioid Use Disorder: A Survey of Addiction Medicine Physicians on Telemedicine and Medication-Assisted Treatment*, UNIV. MICH. SCH. OF PUB. HEALTH BEHAV. HEALTH WORKFORCE RSCH. CTR., (December 2019), https://www.behavioralhealthworkforce.org/wp-content/uploads/2020/08/Access-to-

compounded by broadband capacity and access, as many rural areas have limited access to broadband that supports telehealth platforms and many individuals in rural areas do not have access to even basic broadband.[188]

On March 17, 2020, DHHS announced that they will "exercise enforcement discretion and will waive potential penalties for HIPAA violations against health care providers that serve patients in good faith through every day communications technologies during the COVID-19 nationwide public health emergency."[189] This allowed providers the flexibility to use non-traditional platforms such as FaceTime or Skype to engage patients. SAMHSA issued separate guidelines regarding 42 C.F.R. Part 2, and stated that "[t]he prohibitions on use and disclosure of patient identifying information under 42 C.F.R. Part 2 would not apply [when providers are offering telephonic consultations to patients] to the extent that, as determined by the provider(s), a medical emergency exists."[190] In this context, the normal requirement to obtain informed consent may be waived—for example, if a hospital needed more clinical information about an unconscious patient.[191] As mentioned, SAMHSA also allowed telehealth prescriptions of buprenorphine without an initial in-person consultation, a result of DHHS waiving that provision of the Ryan Haight Act that traditionally required such in-person examination.[192] Some lawmakers are pushing to make this a permanent change. In June of 2020, two senators

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Treatment-for-Opioid-Use-Disorder_A-Survey-of-Addiction-Medicine-Physicians-on-Telemedicine-and-Medication-Assisted-Treatment_Full.pdf

[188] *In Brief: Rural Behavioral Health: Telehealth Challenges and Opportunities*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Nov. 2016) https://store.samhsa.gov/product/In-Brief-Rural-Behavioral-Health-Telehealth-Challenges-and-Opportunities/SMA16-4989 (click: download)

[189] *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communication During the COVID1-9 Nationwide Public Health Emergency*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, (Mar. 17 2020) https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html

[190] *COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf, (last accessed Mar. 21, 2021)

[191] *Supra*, n. 61.

[192] Corey S. Davis, *Continuing increased access to buprenorphine in the United States via telemedicine after COVID-19*, INT. J. DRUG POL'Y, (Aug. 15, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428767/

introduced the Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, calling for treatment to be initiated after a telehealth consultation.[193] While this would be a step in the right direction, rural providers will still face barriers. The TREATS Act calls for utilization of audiovisual platforms, leaving those in "digital deserts" out of the picture.[194] Policy experts have suggested that expanding this allowance to audio-only telehealth visits could help bridge the gap faced by the third of rural Americans that don't have home broadband access.[195]

2. Reimbursement Barriers

The variety of state telehealth laws make it difficult to provide a complete picture of what types of OUD treatment are covered and how much is reimbursed through public or private insurance. Reimbursement presents two separate but related issues—whether the service in question will be covered at all, and, if so, whether it will be paid at parity with live visits. The Brookings Institute notes that "no two states have the same regulations when it comes to coverage and payment…and range from having no telehealth parity laws that specify which telehealth services are covered and their reimbursement rate, to having full coverage and payment parity for telehealth services."[196] Private insurance regulations are important, and 37 states have telehealth laws that require insurance companies to reimburse providers for care they deliver via telemedicine at the same rate, or at parity.[197] Part a will discuss how Medicaid

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[193] Utsha Khatri, et al., *These Key Telehealth Policy Changes Would Improve Buprenorphine Access while Advancing Health Equity*, HEALTH AFFAIRS, (Sept. 11, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200910.498716/full/

[194] *Id.*

[195] *Id.*

[196] Nicol Turner Lee, et al., *Removing regulatory barriers to telehealth before and after COVID-19*, THE BROOKINGS INSTITUTE, (May 6, 2020), https://www.brookings.edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/

[197] *Private payer reimbursement for telemedicine*, CHIRON, https://chironhealth.com/telemedicine/reimbursement/private-payer/ (last accessed Mar. 21, 2021).

approached coverage right before the pandemic and the emergency regulations CMS enacted as a response to COVID-19. Part b will discuss parity issues, both before and during COVID-19.

a. Coverage

Medicare and Medicaid coverage have a huge impact on the accessibility of OUD care. As mandated by the SUPPORT Act, on January 1, 2020, CMS expanded Medicare coverage to Medicare Part B recipients to include payment for OUD treatment, including MAT and counseling services.[198] Each state's Medicaid program differs in what types of telehealth modalities Medicaid will cover and the fee reimbursement rate for those services. For example, a recent study by the Center for Connected Health Policy reported that in 2019, every state's Medicaid program reimbursed providers for live video services, but only 22 states reimbursed for remote patient monitoring.[199] Patient monitoring is a huge part of OUD treatment—as mentioned, patients using OTP services are monitored daily. Monitoring includes ensuring the security of the patient's medication within their home, ensuring patient compliance with dosing instructions, as well as keeping abreast of the patient's phycological and psychological states throughout treatment.[200] As of 2019, four of the five states with the highest overdose rates did not have remote patient monitoring reimbursement for Medicaid recipients.[201]

Shortly after the onset of COVID-19, CMS issued a statement announcing that Medicare will expand coverage to broader circumstances, "allowing clinicians to provide a wider range of

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[198] *Opioid Treatment Programs*, CTR. FOR MEDICARE AND MEDICAID SERV., (updated Mar. 16, 2021) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program
[199] *State Telehealth Medicaid Fee-For-Service Policy, A Historical Analysis of Telehealth: 2013-2019*, Center for Connected Health Policy, (Jan. 2020) https://www.cchpca.org/sites/default/files/2020-01/Historical%20State%20Telehealth%20Medicaid%20Fee%20For%20Service%20Policy%20Report%20FINAL.pdf
[200] *Supra*, n. 120 at 57.
[201] *Supra*, n. 199; see also *Supra*, n. 3.

services without having the travel to a healthcare facility."[202] CMS also allowed state Medicaid programs to reimburse providers for telehealth services in the same manner as they would for face-to-face services.[203] Many states have done so—Virginia, for example, expanded Medicaid coverage to include audio-only OUD services.[204]

b. Parity

If a telehealth service is covered under Medicaid, the issue then becomes whether the service is reimbursed at parity with in person services. There is no federal parity law for Medicaid telehealth services—states can set their own rates for telehealth services and they do not have to be at parity with in person services, absent a state law to the contrary.[205]

Shortly after the onset of COVID-19, CMS stated that "No federal approval is needed for state Medicaid programs to reimburse providers for telehealth services in the same manner or at the same rate that states pay for face-to-face services."[206] At least 45 states have amended their Medicaid programs to offer reimbursement to telehealth providers at payment parity.[207] Notably, North Carolina has extended its Medicaid coverage, including payment parity, to licensed clinical addiction specialists and peer counselors.[208] The Center for Connected Health Policy has

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[202] *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*, FEDERATION OF STATE MEDICAL BOARDS, (Mar. 16, 2021) https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf

[203] *Current State Laws & Reimbursement Policies*, CENTER FOR CONNECTED HEALTH POLICY, https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies?jurisdiction=76&category=All&topic=All (last accessed Mar. 26, 2021)

[204] Jocelyn Guyer & Karen A. Scott, *State Strategies For Helping Individuals With Opioid Use Disorder Through The COVID-19 Epidemic*, HEALTH AFFAIRS, (May 2, 2020) https://www.healthaffairs.org/do/10.1377/hblog20200429.476954/full/

[205] Calder Lynch, *CMS Informational Bulletin*, CTR. FOR MEDICARE AND MEDICAID SERV., (Apr. 2, 2020) https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib040220.pdf

[206] *Supra*, n. 203.

[207] *Supra*, n. 204.

[208] *Id*.

an interactive map that shows updated Medicaid reimbursement rates by state—a helpful tool for policy makers exploring ways to improve Medicaid financed OUD delivery.[209]

3. Licensure Requirements

In addition to HIPAA and reimbursement barriers, generally, in order for a provider to engage in telehealth with a patient, that provider "must be licensed in the state where the patient is located at the time of treatment."[210] There has been incremental progress—as of May 2020, nine states have special licenses to allow out of state providers to deliver telehealth services to their residents.[211] Medicaid traditionally predicated their coverage of telehealth on where the patient is physically located during the delivery of services, typically requiring that they be located in a physician's office, hospital or health center.[212] As of 2019, 29 states now allow the patient to be at home when they receive services.[213] Traditionally, states also have geographic restrictions on how far a patient has to be from the provider in order to qualify for Medicaid covered telehealth services. This has changed in recent years and as of 2019 only 4 states still have geographic limitations.[214]

CMS has made key changes to licensing and site of service requirements amidst the pandemic. Notably, Medicare recipients allow all beneficiaries to access telehealth from their home.[215] Additionally, the DEA granted exceptions to the requirements that "require DEA-

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[209] *Supra*, n. 203.
[210] Andis Robeznieks, *Key changes made to telehealth guidelines to boost COVID-19 care*, AM. MED. ASS'N. (Mar. 19, 2020) https://www.ama-assn.org/practice-management/digital/key-changes-made-telehealth-guidelines-boost-covid-19-care
[211] *Report to Congress: Reducing Barriers to Furnishing Substance Use Disorder (SUD) Services Using Telehealth and Remote Patient Monitoring for Pediatric Populations Under Medicaid*, THE OFF. OF THE ASSISTANT SEC'Y FOR PLAN. AND EVALUATION, 32, (May 15, 2020) https://www.medicaid.gov/medicaid/benefits/downloads/rtc-reducing-barriers-may-2020.pdf
[212] *Supra*, n. 199.
[213] *Id*.
[214] *Id*.
[215] Gabriela Weigel, et al., *Opportunities and Barriers for Telemedicine in the U.S. During the COVID-19 Emergency and Beyond*, KFF, (May 11, 2020) https://www.kff.org/womens-health-policy/issue-brief/opportunities-and-barriers-for-telemedicine-in-the-u-s-during-the-covid-19-emergency-and-beyond/

registered practitioners to obtain additional registrations with the D[E]A in each state where the dispensing (including prescribing and administration) occur, for the duration of the public health emergency."[216] As of March 16, 2021, 41 states have waived their in-state licensure requirements for telehealth, and many states have [217] This allows clinicians to treat patients virtually no matter their geographic location, provided the healthcare professional has an equivalent license in another state.[218] In a recent study done in western communities in North Carolina demonstrates how abolishment of telehealth geographic restrictions can benefit rural communities.[219] The overall average distance patients traveled to the studied clinic did not significantly change during the study period, but the patients utilizing telehealth lived farther away from the clinic than the patients who continued with in-person visits.[220] Additionally, the study reported an increase in the number of patients from rural communities being treated by the clinic overall, suggesting that telehealth indeed increases access.[221]

Despite the evidence that MAT reduces risk of death among patients with OUD as much as 50 percent, access to buprenorphine and methadone remains out of reach for many individuals in rural communities—through traditional face to face service or via telehealth.[222] Many of these progressive policies are set to expire at the end of the COVID-19 public health emergency, a notion that frightens many OUD experts. A recent article in the International Journal of Drug

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[216] *Caring for Patients During the COVID-19 Pandemic*, AMERICAN SOCIETY OF ADDICTION MEDICINE, https://www.asam.org/docs/default-source/covid-19/telehealth-guidance.pdf?sfvrsn=9c6e53c2_2 (last accessed Mar. 28, 2021)
[217] *Supra*, n. 202.
[218] *Supporting Access to Telehealth for Addiction Services: Regulatory Overview and General Practice Considerations*, AMERICAN SOCIETY OF ADDICTION MEDICINE, https://www.asam.org/Quality-Science/covid-19-coronavirus/supporting-access-to-telehealth-for-addiction-services (last accessed Mar. 28, 2021)
[219] Phillip Hughes, et al., *An examination of telehealth policy impacts on initial rural opioid use disorder treatment patterns during the COVID-19 pandemic*, J. RURAL HEALTH, (Mar. 15, 2021) https://onlinelibrary.wiley.com/doi/full/10.1111/jrh.12570?casa_token=lEcyxVomjNEAAAAA%3AjWAfMeHoXjDSA--t7WBfecgFPpX-F99EZpQKk1Mct_IjRj2pI7vqZ58LlcmqdESlc1HG911BUOv2CmjlIg
[220] *Id*.
[221] *Id*.
[222] *Supra*, n. 192.

Policy contends that while legislation solidifying these changes is paramount, the DHHS Secretary is authorized to extend waivers and regulation relaxations through *any* public health emergency and should exercise that authority for the duration of the opioid crisis.[223] There is much to do regarding telehealth access in rural areas, given the gaps in rural broadband capabilities. Investing in those infrastructures will also be integral in bridging gaps in OUD care.

V. Conclusion

It is difficult to fully assess the impact of the OUD policies and regulations adopted during COVID-19 at this juncture, but preliminary data suggest promising progress. Rural and urban communities alike have been ravaged by the collision of COVID-19 and OUD, and that collision has forced a paradigmatic shift in the way clinicians, policy experts, and lawmakers think about delivering OUD treatment. Going forward policy makers should prioritize analysis of the impact these policy changes have had to strengthen the argument for their permanence. Since the overall goal is to improve health outcomes and increase community access to MAT and harm reduction, if future studies reveal these policy changes have the opposite effect, they should be revaluated. In addition to permanent policy reform, rural communities require a revitalization of their OUD healthcare infrastructure systems, including more OTPs, more physicians and clinicians to prescribe and manage MAT, and expanded access to broadband as the country reckons with the possibility of permanent transitions to telehealth services for some OUD patients. State Medicaid programs will be an integral tool in connecting OUD patients to needed care, and states with large rural communities that suffer from high rates of OUD should prioritize using ARPA funds to help bridge that gap.

[223] *Supra*, n. 192.