Click Here for Adderall: Fixing Telehealth Advertising and Services To Prevent Stimulant Misuse

By Morgan Stevens | December 5, 2022

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INTRODUCTION

Prescription stimulant consumption in the United States has increased significantly in recent years.[1] These medications treat a range of conditions, the most common being attention deficit hyperactivity disorder (ADHD), a medical condition characterized by inattentiveness, hyperactivity, and impulsivity.[2] In patients both with and without ADHD, the medication may improve concentration and productivity, leading many to seek out stimulant drugs without a legitimate medical need.[3] In the past couple of decades, consumption of stimulant medication has surged, following a pattern similar to the opioid epidemic.[4] Increases in consumption of stimulant medications continued during the COVID-19 pandemic, when some telehealth companies took advantage of loosened regulations to offer prescriptions for stimulants with little medical oversight or appropriate care. However, despite increases in the consumption and availability of stimulant medications, stimulant misuse and overprescription face less scrutiny than other Schedule II controlled substances, such as opioids.[5]

During the COVID-19 pandemic, policymakers rightly removed barriers to seeking mental health treatment via telehealth services.[6] Telehealth services allowed patients to seek medical care remotely, such as from their home or workplace, and enabled patients to more easily obtain prescription stimulant medications.[7] While many health care providers began offering telehealth services during the pandemic, or expanded existing operations, there have also been a number of new telehealth companies that have used these new telehealth policies to offer prescription stimulants to individuals even when not medically necessary.[8] Individuals seeking these drugs can easily find online telehealth providers that offer remote medical treatment for ADHD, making it possible to obtain prescription stimulants with only a few clicks.[9] These providers not only endanger the health and safety of individuals who obtain these drugs for non-medical purposes, but also threaten to delegitimize valid uses of telehealth services for mental health.[10]

Moreover, many telehealth companies have used advertising loopholes to aggressively market stimulant medications to users on social media without the typical disclosures found in pharmaceutical ads.[11] For example, companies offering stimulant medications for ADHD treatment have advertised on social media platforms with pictures or videos extolling the benefits of ADHD medications.[12] The advertisements suggest that medication is the key to resolving symptoms common to the general population, including "being able to have a quiet mind" or "being able to focus," that may not necessarily be indicative of ADHD.[13] While these advertisements may lead some ADHD patients to seek out an evaluation and receive an accurate diagnosis, they do not disclose potential risks of taking these medications.

Telehealth companies can post advertisements for prescription drugs without including any warnings or information about side effects due to technicalities in pharmaceutical advertising laws and regulations.[14] There are generally three types of prescription drug advertisements: product claim advertisements, reminder advertisements, and help-seeking advertisements. The Food and Drug Administration (FDA), alongside the Federal Trade Commission (FTC) in certain circumstances, regulates product claim advertisements and reminder advertisements, and requires both to adhere to strict content standards depending on their nature.[15] However, if an advertisement simply references a condition but does not suggest a specific drug, it is considered a help-seeking advertisement and falls under the purview of the Federal Trade Commission .[16] As such, help-seeking ads are subject to the FTC's truth-in-advertising laws instead of the FDA's pharmaceutical advertising regulations, and do not have to contain the same disclosures or elements as other prescription drug advertisements.[17]

Many telehealth companies have turned to help-seeking advertisements to market their mental health services, including writing prescriptions for

medications that can treat certain conditions.[18] The advertisements often feature or discuss medication to mitigate the symptoms of ADHD without naming a specific drug.[19] Stimulant medications are a well-known treatment for ADHD, so advertisements for ADHD medications or treatment do not necessarily have to name a specific drug to draw interest in a prescription for stimulant medications.[20] Telehealth companies' use of help-seeking advertisements for ADHD medications essentially allows them to promote access to prescription stimulant medications without making viewers aware of the associated side effects or risks.

Moreover, should a telehealth company post an advertisement violating the FDA's regulations, the agency's ability to pursue legal action is limited by its narrow scope. Federal law regulates advertisements from packers, distributors, and other actors responsible for producing medication. Telehealth companies do not fall under the definition of a regulated entity because they are typically structured as technology platforms that connect patients with medical providers.[21] As such, they are not held to the same advertising standards as many others.

Both federal and state policymakers have enacted various mechanisms to monitor prescription drug trends, retail sales of stimulant medications, and drug misuse; however, these mechanisms do not provide policymakers with comprehensive or timely data to quickly combat drug misuse. On a federal level, the U.S. Drug Enforcement Administration (DEA) publishes quarterly reports of retail sales of stimulant medications in the ARCOS database.[22] However, the DEA only reports the amount of stimulants sold.[23] The reported data does not show the number of prescriptions, dosage amounts, or prescriber information.[24] The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) also conducts an annual survey, known as the National Survey on Drug Use and Health (NSDUH), to collect data on drug misuse, including misuse of stimulant medications.[25]

State Prescription Drug Monitoring Program (PDMPs) databases collect more information.[26] PDMPs track prescriptions for controlled substances at an individual level, allowing for prescribers to review a patient's prescription history before issuing a prescription for stimulant medications. Some states allow patients to apply for and review their prescription histories; however, further public disclosure of the data to policymakers, researchers, and other designated medical providers or officials is limited. Through PDMPs, state authorities can monitor prescribing trends across the population and inform efforts to improve public health.[27]

Telehealth enables the provision of medical care to patients who may otherwise not receive treatment and policymakers should support this mission. To that end, policymakers should both make permanent many of the COVID-19 era policies that allow medical providers to see patients remotely; and enact provisions allowing for the practice of telemedicine

over state lines. However, policymakers should take further steps to ensure that telehealth providers offer and abide by the same standard of care as in-person treatment. Delays in data reporting and a lack of interoperability between state and federal databases make it difficult to know the effect of some companies' mental telehealth services on prescription stimulant drug misuse or overprescription.[28] Policymakers and medical researchers need better data to truly know the extent of this problem. In pursuit of this objective, state policymakers should standardize and improve data collection and reporting efforts by requiring prescribers to check a patient's PDMP before prescribing any Schedule II medication and entering into data-sharing agreements with other states. States should also conduct regular reviews of PDMP data to identify telehealth providers with higher prescription rates than their peers and require that they receive additional education and training. On the federal level, policymakers should revise the NSDUH survey to include questions on malingering, or the feigning of symptoms to obtain a lawful prescription. The survey could then provide a more comprehensive picture of unnecessary stimulant medication consumption in the United States.

Further, federal policymakers should close advertising loopholes by disallowing telehealth platforms and third-party actors from advertising medications without disclosing the side effects and nature of treatment. Finally, the DEA, the Department of Health and Human Services' Office of the Inspector General, and state law enforcement agencies should conduct random audits of telehealth companies to ensure that they are not operating as digital pill mills by providing patients with medically unnecessary controlled substances.

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

As Schedule II controlled substances, Adderall, Ritalin, and prescription stimulant medications pose a high potential for abuse that may lead to psychological or physical dependence.[29] However, despite their classification, dispensing of stimulant prescriptions has risen dramatically in recent years, far outpacing estimated increases in the prevalence of ADHD.[30]

ADHD is an early onset neurobehavioral disorder marked by persistent symptoms related to inattentiveness, hyperactivity, executive dysfunction, or impulsivity, including overlooking or missing important details, finding it difficult to organize tasks, or being easily distracted or forgetful.[31] Symptoms of the condition are thought to be caused by dysregulation of dopamine and norepinephrine, neurotransmitters associated with memory, alertness, and the brain's reward system.[32]

Adult patients can receive a diagnosis from a psychiatrist or primary care provider, who will likely collect the patient's medical history and ask a series of questions about symptoms found in the Diagnostic and Statistical

Manual of Mental Disorders-V (DSM-V), a set of guidelines on mental health conditions and diagnostic tools from the American Psychiatric Association.[33] Doctors may also ask for information from external parties, like a patient's family members, friends, or employer. Adult patients meet the diagnostic criteria for ADHD if they report a certain number of persistent symptoms that significantly interfere with life activities and experienced the symptoms before the age of 12.[34]

It is unclear how many adults in the United States have ADHD because of subjectivity in the diagnostic process, recent changes to the DSM-V, and outdated data.[35] First, by its nature as a psychiatric condition, the diagnostic test for ADHD cannot always provide accurate results.[36] Unlike objective diagnostic tools like the COVID-19 PCR test, medical providers must rely on their best judgment and patient-reported answers to inform a diagnosis.[37] This subjectivity increases the possibility of misdiagnosis, underdiagnosis, and overdiagnosis of ADHD.

Second, the American Psychiatric Association updated the DSM-V in 2013 to be more inclusive of adult ADHD.[38] The 2013 update broadened the diagnostic criteria for adult ADHD found in the DSM-IV by raising the age by which patients had to first experience symptoms and lowering the number of symptoms required.[39] If patients with ADHD sought treatment before the update and failed to obtain a diagnosis because of the previous criteria, they may not know that they qualify under the new criteria.[40]

Finally, the National Institute for Mental Health (NIMH) states that the estimated prevalence of current ADHD in adults aged 18 to 44 years is 4.4 percent.[41] However, this figure is from the National Comorbidity Survey Replication, a survey conducted from 2001 to 2003 with criteria from the DSM-IV.[42] Various factors have likely resulted in higher rates of diagnoses and a wider prevalence than 4.4 percent. For example, the DSM-V contains more inclusive diagnostic criteria that more adults in 2003 would have met and the enactment of the Affordable Care Act in 2010 led to many individuals gaining healthcare coverage. With insurance, more patients can see a medical provider and receive an evaluation for ADHD. Finally, discussions of ADHD on social media have helped raise awareness about the condition and lessen stigma against it.[43] These factors could result in more individuals seeking an evaluation for ADHD.

Most epidemiological studies discussing adult ADHD in the United States similarly rely on criteria found in the DSM-IV to estimate prevalence. In a 2014 study, researchers in Brazil performed diagnostic evaluations on 18- and 19-year-old individuals in Brazil.[44] They found that 3.6 percent of participants met the diagnostic criteria found in the DSM-V, whereas only 2.8 percent of participants met the criteria in the DSM-IV.[45] Their results suggest that diagnostic criteria in DSM-V would result in an increase in the known prevalence of adult ADHD.[46]

ADHD Treatments

Patients can manage symptoms of ADHD with stimulant medications, non-stimulant medications, or behavioral therapy.[47] Common stimulant medications consist of amphetamines, methamphetamines, methylphenidate, dexmethylphenidate, lisdexamfetamine, dextroamphetamine, or a combination of amphetamine and dextroamphetamine.[48] The most commonly prescribed stimulants with these compounds are popularly known as Adderall, Vyvanse, Concerta, and Ritalin.[49] Stimulant medications increase the amount of dopamine and norepinephrine in the brain by blocking their reuptake and, in some medications, increasing their release.[50] In patients with ADHD, stimulants improve concentration, energy, alertness, and functionality reduced by patients' symptoms.[51]

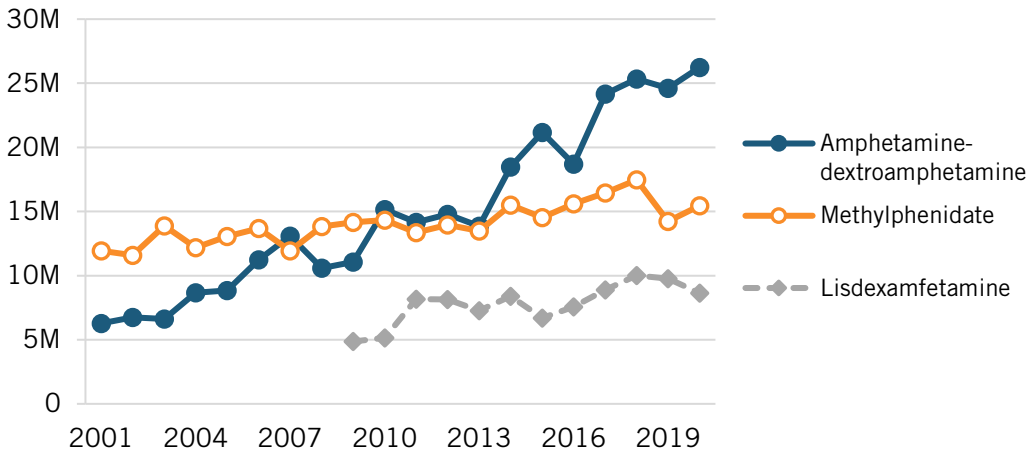
Stimulant medications can cause a number of side effects, including unintentional weight loss, insomnia, psychosis, anger, paranoia, heart attacks, seizures, and sudden death.[52] Further, they pose a high risk of misuse.[53] For this reason, the FDA requires most stimulants to display a boxed warning, the highest safety-related warning the FDA can require, about their misuse potential.[54] The FDA also requires amphetamines to post the same level of warning for adverse cardiovascular events.[55]

Before the COVID-19 pandemic, patients with ADHD had to undergo an in-person evaluation before receiving a prescription for stimulant medications. However, regulatory changes as a result of the COVID-19 pandemic allowed telehealth providers to prescribe stimulant medications without an in-person visit.

Prescription Rates

As shown in figure 1, prescriptions of stimulant medications, including amphetamine-dextroamphetamine, lisdexamfetamine, and methylphenidate, have increased significantly in the past two decades. According to the U.S. Agency for Healthcare Research and Quality's Medical Expenditure Panel Survey (MEPS), total purchases of amphetamine-dextroamphetamine stimulants increased from 5,981,000 in 2001 to 26,243,000 in 2020, while purchases of methylphenidate increased from 11,531,000 in 2001 to 15,449,000 in 2020.[56] The DEA's ARCOS data reflects similar increases, with retail sales of amphetamines increasing from 4.2 million grams in 2001 to 25.2 million grams in 2021 and retail sales of methylphenidate increasing from 10.1 million grams to 17.2 million grams.[57]

Figure 1: Total prescription stimulant medication purchases in the United States, 2001 to 2020[58]



New research from Iqvia Holdings, a U.S.-based pharmaceutical research company, shows that prescription rates for Adderall in the United States have accelerated since the beginning of the COVID-19 pandemic.[59] Dispensed Adderall prescriptions increased to 41.4 million in 2021, a 10.4 percent increase from 2020.[60] This increase follows a decade of similar growth. In a 2020 study, researchers at Johns Hopkins University and George Washington University matched MEPS data with population records to determine the total number of filled stimulant prescriptions.[61] They found that an estimated 4.1 million adults in the United States filled at least one prescription for amphetamine or methylphenidate stimulants in 2018, up from 2.3 million adults in 2013.[62]

A significant number of these increases have come from prescriptions to women.[63] According to the Centers for Disease Control and Population, the percentage of women in the United States aged 15 to 44 years old who are enrolled in a private health insurance plan, and filled a prescription for ADHD medications increased 344 percent from 2003 to 2015.[64] Women aged 25 to 29 constituted the largest increase, with a 700 percent increase in the same time frame.[65] Prescriptions for non-stimulant medication atomoxetine for women remained largely unchanged during the same time frame.[66] The report did not offer a reason for the increase in diagnoses; however, rising awareness of adult ADHD, changes in the DSM-V, and the frequent underdiagnosis of ADHD in women likely led to more women receiving diagnoses and prescriptions.[67]

NON-MEDICAL USE OF PRESCRIPTION STIMULANTS

Stimulant medications can enhance concentration, improve productivity, and suppress users' appetites. For this reason, some patients with and without prescriptions take stimulant medications in ways that differ from their intended medical use.[68]

Stimulant Misuse

In the NSDUH, stimulant misuse is defined as "use in any way not directed by a doctor, including use without a prescription of one's own; use in greater amounts, more often, or longer than told to take a drug; or use in any other way not directed by a doctor."[69] For patients with a valid prescription, non-medical use may consist of taking the medication at a higher or lower dosage than instructed by their doctor or mixing the proper dose with drugs known to enhance the effects of stimulant medications.[70] For individuals without a valid prescription, misuse consists of any use of the medication.

In the 2020 National Survey on Drug Use and Health, 4.8 million U.S. adults reported misuse of a stimulant medication in the past year.[71] Researchers at SAMHSA and the National Institute on Drug Abuse (NIDA) used data from the 2015 and 2016 NSDUHs to estimate the prevalence of misuse across the United States.[72] The team determined that approximately 5 million adults misuse prescription stimulants out of a population of 16 million adults who use prescription stimulants.[73] Patients' most commonly reported motivations were to be alert, study, get high, adjust the effects of other drugs, or experiment with the medication.[74]

Misuse for both parties may also consist of alternative administration routes.[75] Prescription stimulant medications largely come in the form of pills or tablets that patients swallow.[76] However, individuals engaging in stimulant misuse may instead consume the medication nasally, intravenously, or rectally.[77] Researchers with SUNY Upstate Medical University, Syracuse University, the University of Pennsylvania, Connecticut Clinical Research, Attention MD, and the Icahn School of Medicine conducted a meta-analysis of existing literature to estimate rates of misuse.[78] The team determined that, out of a population of 5 million adults in the United States who misused prescription stimulants, around 550,000 to 2 million people snorted the stimulants, 50,000 to 300,000 smoked the stimulants, and 50,000 to 550,000 injected the stimulants.[79]

Individuals without prescriptions can obtain medication from friends and family members with a prescription, Internet pharmacies, dealers on social media, street-based drug markets, or theft.[80] In a 2005 survey of 4,297 adults, 7 percent reported using ADHD medication nonmedically.[81] For those who used the drugs without an ADHD diagnosis or prescription, 66 percent reported receiving the medication from a friend or family member, 35 percent reported stealing stimulants from a friend or family member, and 5 percent reported acquiring medication from an Internet pharmacy.[82]

Individuals misusing stimulant medications can face serious consequences. First, federal and state laws prohibit the distribution or possession of controlled substances without prior authorization.[83] Individuals found guilty of either crime can face substantial fines or prison time.[84]

Second, many individuals turn to dealers on social media or rogue online pharmacies to acquire prescription medications.[85] However, some medications sold online are counterfeits that have been made to look like actual prescription medications.[86] Counterfeit stimulants have been laced with deadly amounts of fentanyl. In 2021 alone, the DEA seized over 20 million fake prescription pills laced with fentanyl, more than the past two years combined.[87] Subsequent lab tests confirmed that two out of every five pills laced with fentanyl contained a lethal dose.[88] In a survey of 1,449 13- to 24-year-olds in the United States in 2021, only 27 percent of teenagers and 50 percent of young adults were aware that counterfeit pills could contain fentanyl.[89]

Third, misuse of stimulant medication is associated with poor medical outcomes. In a 2019 study, researchers at SUNY Upstate Medical University and Massachusetts General Hospital found that individuals who snorted stimulants faced a risk of death 13 times higher than individuals with unintentional oral exposure, such as an individual who mistakenly ingested the medication or took more than prescribed, while individuals engaging in intravenous misuse faced a risk of death 22 times higher.[90]

Malingering

Because of the dangers and difficulty of obtaining stimulant medications, some individuals have instead feigned ADHD symptoms to a doctor to receive their own diagnosis and prescription.[91] This practice, known as malingering, is incredibly difficult to detect because the diagnostic process involves self-reported symptoms that can be found online beforehand.[92] In a 2012 study reviewing the prevalence of malingering, researchers at Louisiana State University found that most questionnaires designed to detect malingering during the diagnostic process failed to do so.[93]

According to the NSDUH, misuse of prescription stimulants slightly declined from 2015 to 2020.[94] Among people aged 12 or older, 2 percent reported misuse in 2015 while only 1.8 percent reported misuse in 2020.[95] However, the survey does not include questions on malingering and previous studies on the topic report both a lack of clarity and varying numbers. While there are several reasons why prescription rates have increased, such as changes to the DSM-V and the Affordable Care Act, policymakers cannot rule out malingering as a contributing factor.

EXISTING TOOLS AND LAWS TO PREVENT STIMULANT MISUSE

Both federal and state policymakers have enacted laws regulating how medical providers prescribe and dispense stimulant medications.[96] In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act, which included the Controlled Substances Act.[97] The law labeled certain drugs with one of five schedules, ranging from Schedule I, the most dangerous and restricted, to Schedule V, the most accessible, according to their addictive properties and potential for misuse.[98]

Given the drugs' high potential for abuse or psychological or physical dependence, the DEA has labeled stimulant medications as Schedule II controlled substances, in the same class as opioids, methamphetamines, and cocaine.[99] This limits prescription dispensing in a number of ways. On a federal level, prescribers must register with the DEA and ensure that the medication is taken for a legitimate medical purpose.[100]

State policymakers have enacted further regulations governing the prescription and monitoring of controlled substances. Laws vary by state, with some allowing nurse practitioners to prescribe controlled substances, others requiring prescription refills within a certain window of time, and more limiting prescriptions to a 30-day supply.[101]

Policymakers and medical professionals have a variety of data-capturing tools to curb the overprescription or illicit trading of stimulant medications. States can use Prescription Drug Monitoring Programs (PDMPs) to monitor the prescription of stimulant medications. PDMPs are databases that track prescriptions of controlled substances, including stimulant medications. They enable medical providers and pharmacists to check a patient's prescription history before prescribing or dispensing medication. Such practices can help prevent patients from obtaining multiple prescriptions from different doctors or pharmacies, allow oversight of prescribing practices of health care providers, and ensure that patients receive their correct prescription. Currently, 49 states, the District of Columbia, and 3 U.S. territories have PDMPs.[102] Missouri, the last state without a PDMP, passed a law in 2021 to create a PDMP, which is expected to go online in March 2023.[103]

However, the effectiveness of PDMPs for prescription stimulant misuse is stunted by a series of shortcomings. First, not all states share PDMP data with each other to keep patients from doctor or pharmacy shopping over state lines. States can share this data through the PMP InterConnect, a communications exchange platform run by the National Association of Boards of Pharmacy, or RxCheck, a similar platform created by the U.S. Bureau of Justice Assistance (BJA).[104] However, utilizing two separate platforms can create inconsistencies in data-sharing efforts and overload providers and pharmacists.[105] For example, the BJA and CDC require states that receive federal funding to both maintain a connection with RxCheck and respond to other states' requests for data using the platform the requestor used.[106] If a state uses PMP InterConnect to request data, the responding state must use PMP InterConnect to send the information back. This requirement essentially forces states to either maintain connections to two data-sharing platforms or forsake use of prescription data in states with a different platform.

Second, states require dispensers to enter prescriptions into PDMPs at varying intervals. While most states require daily reporting, five states allow for less frequent reporting.[107] Of those five states, one state requires

dispensers to report sales within seven days and two states require dispensers to report sales within two weeks.[108] These delays in reporting prevent medical professionals from accessing a patient's recent prescription history when prescribing or dispensing new medication. As a result, patients hoping to receive more medication than medically necessary may have an opportunity to visit multiple doctors and receive prescriptions without detection.

Third, states have different enrollment, reporting, and consultation requirements for prescribers and pharmacists. Some states do not require pharmacists to enroll in their PDMP while others do not require medical providers to review PDMP data before a patient receives medication.[109] For example, in the District of Columbia, prescribers and pharmacists are not required to check a patient's PDMP data before prescribing or dispensing Schedule II stimulants.[110]

Finally, states provide medical researchers and public health officials with varying levels of access. For example, of the 54 operational PDMPs in the United States, only 52 authorize use for epidemiologists, 29 authorize use for state health departments, and 32 authorize use for researchers.[111] By unnecessarily restricting use of PDMPs to prescribers, states prevent public health officials and researchers from identifying and mitigating widespread drug misuse in a timely fashion.

On the federal level, the Drug Enforcement Agency (DEA) uses the Automation of Reports and Consolidated Orders System (ARCOS), an automated reporting system that tracks medication from manufacturers or distributors to a point of sale or distribution, such as a retail pharmacy.[112] The system essentially enables the federal government to monitor total retail sales of stimulant medications. Additionally, SAMHSA conducts a yearly survey known as the National Survey on Drug Use and Health to collect data on drug use and misuse in the United States and reports on rates of misuse, use disorders, and the receipt of mental health services by age group.[113] However, the effectiveness of both these data sources faces similar limits, as both release only limited data in comparison to what they collect.

HOW COVID-19 CREATED A TELEHEALTH STARTUP ECONOMY

The COVID-19 pandemic led to a number of regulatory changes that allowed medical providers to offer more remote services than before, including prescribing stimulant medications.[114] These changes, along with social distancing measures, led to massive growth in the telehealth industry as both new and existing health care companies sought to expand their patient base and market share.[115]

Pandemic-Related Changes to Telehealth

In response to the COVID-19 pandemic, federal and state policymakers enacted a series of legislative and regulatory measures to expand access to telehealth services. On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) issued a public health emergency in response to the COVID-19 pandemic.[116] This declaration triggered a clause in the Ryan Haight Online Pharmacy Consumer Protection Act that allows telehealth providers to write prescriptions for controlled substances.[117] In 2008, Congress enacted the Ryan Haight Online Pharmacy Consumer Protection Act, an amendment to the Controlled Substances Act, that prohibits medical providers from issuing a prescription for a controlled substance by means of the Internet without first conducting an in-person medical evaluation of the patient or receiving temporary authorization from the patient's main provider.[118] However, the law includes a clause that allows providers to write prescriptions for new telehealth patients during a public health emergency.[119] Thus, as long as practitioners issued prescriptions for a legitimate medical purpose in the course of their usual professional practice, conducted the appointment using an audio-visual, real-time, two-way interactive communication system, and acted in accordance with applicable state and federal laws, the public emergency declaration allows them to prescribe controlled substances.[120]

In March 2020, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020.[121] The law authorized the Secretary of Health and Human Services to temporarily waive certain Medicare restrictions.[122] Shortly afterwards, HHS Secretary Azar issued a series of waivers that expanded Medicare beneficiaries' access to telehealth services by removing geographic and site of service limitations and permitted more medical providers to bill for telehealth services.[123] The Office for Civil Rights (OCR) at HHS also issued a notification of enforcement discretion and guidance allowing medical providers to conduct telehealth visits over popular online communications applications like Skype, Zoom, and Facebook Messenger video chat without fear of HIPAA noncompliance.[124]

Later that month, Congress passed the Coronavirus Aid, Relief, and Economic Security Act of 2020.[125] The law further expanded telehealth services by temporarily allowing Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to provide telehealth services to Medicare beneficiaries, instead of simply enabling their treatment from remote providers.[126]

Finally, Congress made Medicare waivers related to behavioral health services, including ADHD treatments, permanent in the Consolidated Appropriations Act of 2021.[127] However, Congress included a provision that patients using telehealth for mental health services must receive at least

one in-person service within the six-month period prior to receiving telehealth services.[128] Under the public health emergency declaration, that requirement has been waived, but it will become active again after the declaration expires and a 151-day grace period has passed.[129]

All 50 states and the District of Columbia similarly expanded access to telehealth services under Medicaid in response to the pandemic.[130] States have broad authority to set parameters for the use of telehealth under Medicaid. As such, policies on delivering behavioral care, including treatment for ADHD, via telehealth under Medicaid vary widely by state.[131] For example, states permit different covered services, payment rates, providers, care locations, and more. These differences largely enabled Medicaid enrollees to receive treatment for ADHD via telehealth during the pandemic. However, some changes are temporary, and many states have not yet reported whether they will make them permanent.[132]

State policymakers also introduced emergency waivers at the start of the COVID-19 pandemic that allowed medical providers to conduct appointments over common communications platforms.[133] Further, many states amended their licensure requirements so that medical providers could offer care or apply for temporary licensure.[134] These changes allowed medical providers to conduct appointments across state lines, including through telehealth appointments. However, most states have since let their waivers expire.[135] HHS has renewed the public health emergency 11 times, most recently in October 2022, but at some point, HHS will let the declaration expire.[136]

Telehealth Companies Offering Prescription Stimulants Online

Telehealth enables patients to receive medical care remotely, benefitting many patients including those living in rural areas, those without sufficient transportation, those without childcare, and others.[137] In addition to traditional healthcare providers creating or expanding their telehealth services during the COVID-19 pandemic, a number of companies exclusively providing telehealth services began offering comprehensive online treatments for a range of conditions they were previously unable to treat remotely as a result of relaxed healthcare regulations. For some telehealth companies, these new services consisted of comprehensive online treatments for ADHD, including electronic prescriptions of stimulant medications.

As shown in Table 1, there are a number of telehealth companies that offer ADHD treatment, including Cerebral, Done, Klarity, Ahead, and Circle Medical, that prescribe controlled substances to patients, including stimulant medications.[138] Some, including Cerebral and Circle Medical, offered ADHD treatments in addition to a range of other psychiatric or primary care services.[139] Others, like Carbon Health, make clear that they do not offer online prescriptions as part of their mental health services.

Table 1: Telehealth companies that offer ADHD treatment

	Cerebral	Done Health	Klarity	Ahead	Circle Medical	Carbon Health
Funding	$462M	Seed	Seed	$9M	$26.5M	$522.5M
Employees	1,001-5,000	11-50	11-50	1-10	11-50	501-1,000
Year Founded	2020	2019	2021	2017	2015	2015
Status	Open	Open	Open	Closed (6/2022)	Open	Open
Prescribes Stimulants	Yes (until 5/2022)	Yes	Yes	Yes	Yes	No
Under Inquiry	DOJ and FTC	DEA				

Utilization of telehealth services increased significantly at the beginning of the COVID-19 pandemic.[140] From March 2019 to March 2020, privately billed medical claim lines for telehealth services increased by over 4,300 percent.[141] In 2020, fee-for-service telehealth visits for Medicare beneficiaries increased 63-fold.[142] And, total venture capital investment in digital health companies in the United States in the first half of 2021 beat total investment for all of 2020 and reached nearly twice the amount of funds invested in 2019.[143] This growth was especially prominent for providers offering mental health services.[144] Telehealth claims for such services rose from 170,000 in February 2020 to 4.6 million in December 2020.[145] While utilization of telehealth services has since leveled off, many U.S. adults still choose to receive medical care via telehealth services.[146] In 2021, 37 percent of U.S. adults had used telemedicine within the last 12 months.[147] Moreover, 22.8 percent of U.S. adults surveyed from July 28, 2022 to August 8, 2022 reported attending an appointment with a health professional over video or phone in the past four weeks.[148]

TELEHEALTH COMPANIES' OVERPRESCRIPTION AND SUBSTANDARD CARE DURING THE COVID-19 PANDEMIC

In pursuit of rapid growth, some telehealth companies prioritized customer retention and satisfaction over ensuring that patients received appropriate, high-quality care.[149] Telehealth companies like Cerebral and Done have aggressively advertised prescriptions for ADHD treatment, including stimulant medications, on social media platforms and ignored consumer protection standards.[150] Moreover, the companies heavily prescribed

stimulant medication to new patients, often claiming that the large majority of their patients should receive a prescription.[151]

Overprescription of Stimulant Medications

Some companies operating in the telehealth space have not met the standards of in-person psychiatric care. The diagnostic process for ADHD typically involves a lengthy evaluation in which a medical provider will review a patient's clinical history, discuss reported symptoms, and may ask for information from the patient's friends and family.[152] Some companies, such as Cerebral and Done, instead evaluated patients during 30-minute appointments before reaching a diagnosis and prescribing stimulant medications.[153]

An investigation by *The Wall Street Journal* found that Cerebral intended to center its operations around ADHD treatments to increase patient retention.[154] The company encouraged practitioners to prescribe stimulant medications, often contacting them about specific cases "where medication regimens may not be optimized."[155] In its efforts for growth, Cerebral conducted operations in a manner inconsistent with providing a high standard of care, including hiring a doctor who had been reprimanded for lax opioid prescribing practices and had agreed not to renew his license.[156] The company also asked patients if they would be interested in receiving a prescription for controlled substances when signing up.[157]

Indeed, the company seems to have tried to capitalize on a market demand for stimulant medication. A *Bloomberg* article stated that Cerebral's chief medical officer David Mou decreed in a meeting with other managers that 95 percent of patients who saw a Cerebral nurse should receive a prescription, citing two former employees familiar with the meeting.[158] The company has denied the claims, stating that the figure referred to the percentage of patients who have received an appropriate diagnosis first, but refused to offer a more specific figure, other than suggesting more than half of patients receive a prescription.[159]

Similar to Cerebral, Done's online reviews and employee testimonials point to suspect business practices.[160] Former employees with Done accused the company of pressuring prescribers to diagnose ADHD and prescribe stimulant medications.[161] One employee described a "Best Practices for Done Platform Use" guidance document that advised prescribers to consider doing a medication trial even when a patient did not meet diagnostic criteria for ADHD.[162] One nurse practitioner admitted to managing 2,300 patients with Done and claimed that virtually every patient of hers had ADHD and was on stimulant medication.[163] Worse, during their investigations, *The Wall Street Journal* reporters reviewed emails sent by Done's clinical president David Brody. In one of them, he commented on a case study of a patient with ADHD and a history of methamphetamine-related arrests, and noted that the patient would receive stimulant medications under Done's philosophy.[164]

Further, the company employed several prescribers who issued refill prescriptions without an appointment.[165] According to *The Wall Street Journal*, Done announced that patients would not have to schedule a follow-up visit to renew their prescription or increase their dosage.[166] Instead, patients could just fill out an online form with their request.[167]

As evidenced by their Schedule II classification, stimulant medications have a high potential for abuse that could lead to psychological or physical dependence.[168] Further, their popular reputation as a study drug that could boost productivity and professional success can render stimulant medications highly desirable to many individuals.[169] While Cerebral, Done, and other telehealth platforms that offer access to stimulant medications have surely been a boon to many with ADHD diagnoses, their lax rules and prescribing standards have created easy opportunities for those with and without ADHD to access prescription stimulants.

To be clear, other parties in the medical field and federal regulators have taken notice of telehealth platforms offering prescription stimulants with little regard for patients' needs or wellbeing. The DEA began rejecting Cerebral providers' applications for licenses to prescribe controlled substances in the fall of 2021.[170] Later, in May 2022, the company received a grand jury subpoena from the U.S. attorney's office for the Eastern District of New York.[171] As of October 2022, both Cerebral and Done are under investigation for possible violations of the Controlled Substances Act; however, Done has released a statement claiming that reports of a DEA investigation are false and demanding that *The Wall Street Journal* retract, delete, or eliminate its articles.[172]

Further, in May 2022, both Walmart and CVS announced that they would stop filling prescriptions ordered by practitioners at Cerebral and Done.[173] Walmart cited the results of their audit and compliance process as the reason behind their decision, while CVS stated that they were unable to resolve differences with the two telehealth platforms.[174] By the nature of their business model, pharmacies have an economic interest in dispensing and receiving payment for as much medication as possible.[175] Refusing to dispense prescriptions from Cerebral and Done providers means that both Walmart and CVS are voluntarily rejecting the revenue from monthly prescriptions for hundreds of thousands of patients. Both companies likely wouldn't do so unless there were significant legal risks involved.

As a result of the increased scrutiny, in early May 2022, Cerebral announced that they would stop prescribing controlled substances that treat ADHD to new patients.[176] Shortly afterwards, the company announced that they would stop the prescription of most controlled substances and would either help patients taper down from the medication or seek care elsewhere.[177] However, Done is still offering ADHD treatments and prescription stimulant medications to patients. The company has since called for the DEA to create a special registration designation that would

make COVID-19 regulatory changes related to the prescription of controlled substances permanent.[178]

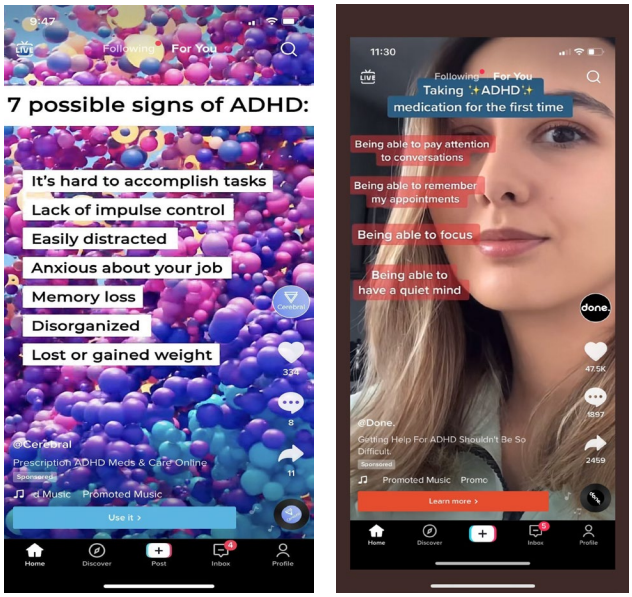
Inappropriate Online Advertising

Some telehealth companies offering prescription stimulants, including Cerebral, Done, and Klarity, have heavily marketed their services online.[179] All three companies have posted advertisements on social media platforms, such as Instagram and TikTok.[180] Cerebral and Done have also partnered with celebrity spokespersons to promote their services.[181] While many of their advertisements contain basic, conventional information, such as their price structure or evaluation methods, some online advertisements promote stimulant drugs without disclosing risks, list misleading information about ADHD, and market their services to those seeking stimulant medications.[182]

First, some online ads promote access to ADHD medication without providing relevant information or disclaimers about the potential risks of taking these drugs. Unlike advertisements that name specific drugs, these advertisements—classified by the FDA as "help-seeking ads"— discuss a condition or ailment but do not reference a specific medical treatment for it.[183] Instead, these ads will list a number of symptoms caused by ADHD and encourage viewers to visit a medical professional for treatment if they experience the symptoms.[184]

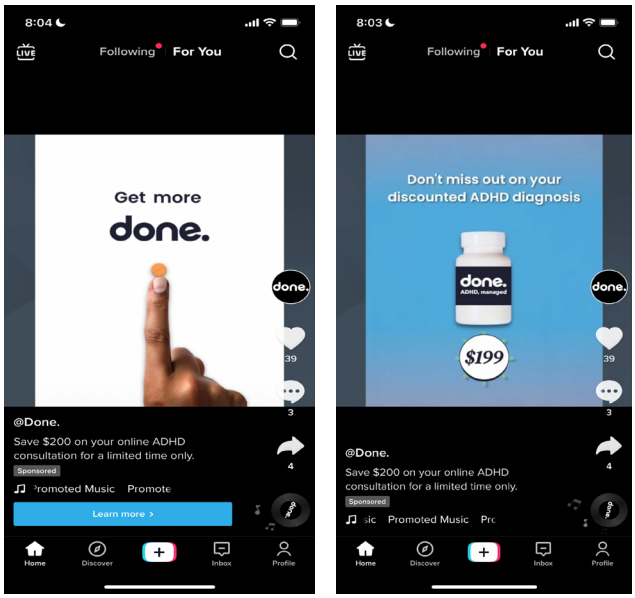
However, many of the symptoms listed in advertisements from Cerebral and Done are common to the human condition and may not indicate that an individual has ADHD.[185] For example, one of Done's ads on social media showed nameless pills or boxes overlaid with words like "Taking ADHD medication for the first time/Being able to pay attention to conversations/Being able to remember my appointments/Being able to focus/Being able to have a quiet mind." One of Cerebral's advertisements suggested that patients who were "easily distracted or anxious about [their] job" should consider treatment for ADHD. In relaying information about ADHD symptoms without providing additional context, these ads risk misleading viewers into thinking they have ADHD and should take medications to treat this condition, without understanding the risks. Viewers may identify with one or more of the common symptoms presented in the advertisement and seek out medical treatment for the condition.[186] This could then result in some viewers receiving an inaccurate diagnosis and medically unnecessary treatment. Both Cerebral and Done promote monthly membership plans, where subscribers sign up for medication management plans, which means the companies have a financial incentive to enroll as many individuals as possible.

Figure 2: TikTok advertisements from Cerebral and Done



Second, many of the advertisements seem designed to help those seeking out controlled substances obtain easy access to these drugs. For example, in one of Done's TikTok videos, the company replied to a user comment asking how to get diagnosed with ADHD and discussed common fears or concerns with the diagnostic process.[187] The caption for the video contained a number of hashtags, including #adhdmeds.[188] In another instance, Cerebral posted a TikTok of a patient dancing around with a package from the company, waving to her counselor, and holding a bottle of medication but offered little information about the diagnostic process or stimulant medications' side effects.[189]

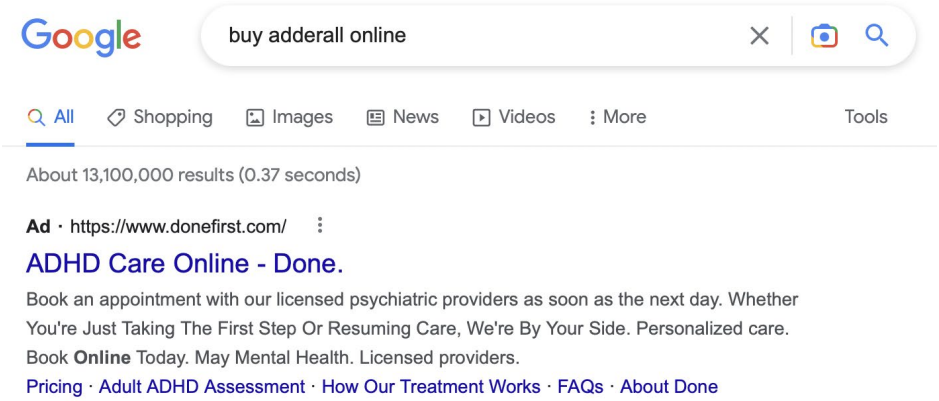
Figure 3: TikTok advertisements from Done



While these ads do not display the name of the medication, stimulant drugs are a popular and well-known method of treating ADHD symptoms.[190] Withholding mentions of specific medications in ADHD advertisements does little to prevent users who are curious about these drugs, or actively seeking them out, from understanding that these advertisements are offering an avenue to obtain a prescription for stimulant medications. When combined with high prescription rates from Cerebral and Done, the advertisements essentially raise awareness of an opportunity to malinger.

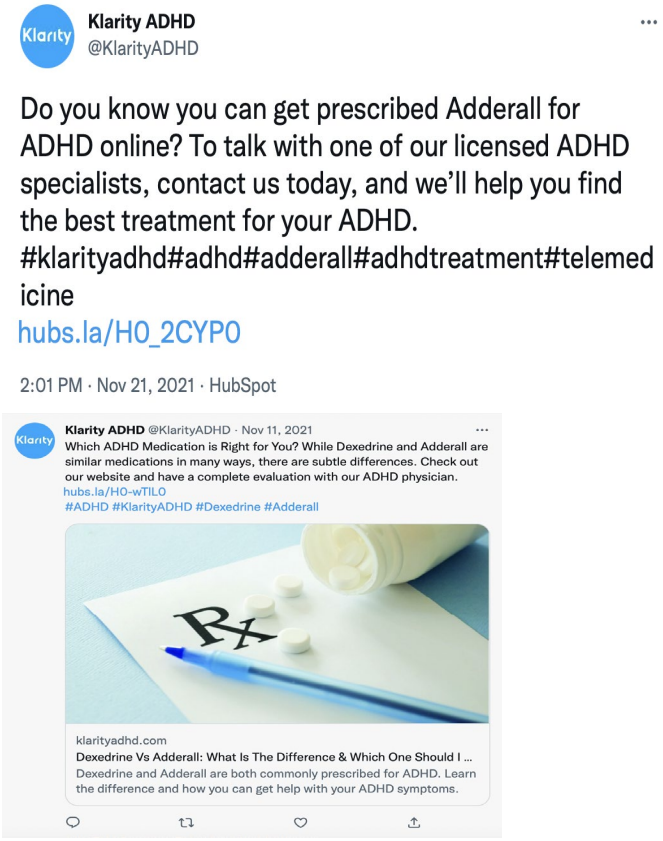
Finally, Done, Cerebral, and Klarity have all used more brazen advertisements to promote their services that directly offer or discuss stimulant medications. Both Done and Cerebral have advertised their services on Google Ads. Though Cerebral has since removed the ads, Internet users who searched online for "ADHD," "buy Adderall," or a related term before the company faced increased scrutiny may have seen an advertisement for Cerebral's services as one of the first results.[191] As of October 2022, searches for "ADHD," "Adderall," "buy Adderall online," and related terms still result in advertisements for Done's services.

Figure 4: Google advertisement from Done



Moreover, a Twitter account linked to Klarity's webpage posted a tweet asking if users were aware that patients with ADHD can receive a prescription for Adderall online.[192] Another asks users which ADHD medication would better suit them and proceeds to compare Adderall and Dexedrine, another prescription stimulant classified as a Schedule II controlled substance.[193]

Figure 5: Tweets from Klarity



The FDA and FTC regulate two of three types of prescription drug advertisements: product claim advertisements and reminder advertisements.[194] The first is an advertisement that both names a drug and lists associated risks and benefits.[195] Product claim advertisements face extensive requirements, such as to name the drug and its generic and list-approved uses, the most significant risks, a brief summary about the drug, and more.[196] The second, reminder advertisements, name the drug but cannot provide information about its uses.[197] Reminder advertisements are meant to promote drugs to individuals already familiar with their uses and the conditions they can treat.[198] Only the FTC regulates the third type, help-seeking advertisements.[199] As a result, help-seeking advertisements must abide by the agency's truth-in-advertising standards; however, they are not subject to the FDA's regulations for other prescription drug advertisements.

However, should a telehealth company post a product claim advertisement or reminder advertisement, it is unclear whether the FDA or FTC could pursue enforcement actions against the company. The FDA's regulations on pharmaceutical advertisements and promotions pertain to drug distributors, manufacturers, packers, and their representatives, and the American Medical Association's Code of Ethics prohibits prescribers from

false or misleading advertising.[200] However, telehealth companies are not distributors, manufacturers, packers, pharmaceutical representatives, or prescribers. They instead operate as platforms that connect prescribers with patients.[201] The same regulations for pharmaceutical advertisements and promotions that govern the pharmaceutical industry do not apply to their marketing efforts.[202] For example, Klarity posted a tweet that said, "Do you know you can get prescribed Adderall for ADHD online?"[203] Under the FDA's pharmaceutical advertising regulations, the tweet may constitute a product claim advertisement since it names a specific drug and lists the condition it treats. However, because Klarity is a telehealth platform, not a distributor, manufacturer, or other regulated entity, the FDA may not be able to pursue any enforcement action against the company.

RECOMMENDATIONS

Some telehealth providers offering mental health services have likely played a role in the massive increase in stimulant medication prescriptions during the COVID-19 pandemic. Policymakers should focus on improving oversight over these providers, and penalizing those violating the law, rather than seeking any retribution for the telehealth industry overall. Policymakers should protect telehealth platforms and their ability to provide care to patients remotely while ensuring that both in-person and virtual medical providers uphold high standards of care. To this end, there are several steps that policymakers could take to identify bad or negligent actors responsible for unnecessary prescriptions.

1. Make permanent the temporary regulatory changes that have enabled telehealth to flourish

Telehealth services have enabled patients to receive care for a variety of conditions, including mental health services, and policymakers should ensure that legitimate providers can still offer services remotely. However, eventually, federal and state policymakers will need to let the public health emergency declarations that have allowed healthcare providers to deliver services online expire. Therefore, federal and state policymakers should make the regulatory changes that enabled patients to receive medical care via telehealth during the COVID-19 pandemic permanent. From dropping certain Medicaid requirements to allowing the prescription of controlled substances without an initial in-person evaluation, many of the changes enabled patients to receive medical care they otherwise would have been unable to access. Policymakers should permanently extend these policies to ensure that patients can continue any medical treatments via telehealth after the public health emergency declaration has expired.

First, Congress should permanently extend Medicare telehealth flexibilities. The Advancing Telehealth Beyond COVID–19 Act of 2021, a bipartisan bill introduced by Rep. Liz Cheney (R-WY), would temporarily extend certain Medicare telehealth flexibilities, such as permitting federally qualified

health centers and rural health clinics to continue to serve as the distant site, until the end of 2024.[204] Ideally, Congress should make many of the flexibilities permanent; however, a two-year extension still provides enough time to enact a comprehensive legislative package for telehealth. The bill has passed the House but, as of October 2022, has yet to pass the Senate.[205] Senators in the 117th Congress or Congressmen and Congresswomen in the 118th Congress should extend Medicare flexibilities.

Second, the DEA should promulgate a rule allowing for the prescription of controlled substances via the Internet without requiring an in-person visit beforehand. In the Ryan Haight Act of 2008, Congress directed the DEA to set up a special registration that telemedicine providers could apply for to prescribe controlled substances.[206] Congress reiterated this requirement in the SUPPORT for Patients and Communities Act of 2018, which required the Attorney General to work with HHS to promulgate the rule.[207] To date, the DEA has not set up a special registration process for telemedicine providers to prescribe controlled substances; however, they should move quickly to do so to ensure that patients receiving controlled substances via telehealth can continue their treatment once the public health emergency declaration expires.[208]

Finally, all 50 states and the District of Columbia enacted flexibilities for the provision of telehealth under Medicaid in response to the COVID-19 pandemic.[209] Though the extent of the flexibilities varied by state, many of the new policies enabled patients to receive behavioral care via telehealth.[210] States should make these flexibilities, such as expanding originating sites and allowing telehealth for behavioral care, permanent.

2. Allow providers to practice across state lines

Further, policymakers should expand the number of providers that patients can see to receive mental health services. With telehealth, patients can receive remote medical care from providers in different locations. State policymakers should join licensing compacts that enable medical providers to practice across state lines. State licensing compacts allow providers from certain states to apply for licenses in participating states under an expedited and cheaper process if they meet certain restrictions. For example, 40 states and 1 territory have either partially or fully joined the Interstate Medical Licensure Compact, an agreement between states that allows physicians to receive expedited licensure in a participating state if they meet certain requirements.[211] Under such agreements, providers can then offer their services to patients in other states. In turn, this gives patients more medical providers to choose from when seeking out care and enables patients to receive the best services from their preferred provider, regardless of location.

Moreover, Congress should amend the Controlled Substances Act to permit authorized providers to prescribe controlled substances to patients in other

states. Under the Controlled Substances Act, providers must obtain DEA registration in the states where they are prescribing controlled substances, with limited exceptions.[212] Congress should amend this to allow providers to obtain a single, national license before writing a prescription for controlled substances.

3. Reform federal and state databases and reporting requirements.

The DEA should modify reporting requirements for the ARCOS database. Currently, the DEA requires distributors and manufacturers to report total retail sales of Schedule II controlled substances on a monthly or quarterly basis; however, such lag times result in delayed data on controlled substances transactions and prevents the agency from responding to drug misuse in a timely manner.[213] The DEA should revise the reporting schedules to require distributors and manufacturers to report transactions in real time. This change would enable the agency to identify the overprescription or diversion of controlled substances more quickly than is currently possible.

Moreover, the DEA should publish more timely data. Expeditious access to the data could give policymakers and researchers a clearer picture of problematic drug trends and an opportunity to stymie their further development. Cerebral, Done, and other telehealth companies have offered prescriptions for controlled substances for only a few years. If regulators had known that retail sales began increasing shortly after telehealth companies started offering prescriptions for stimulant medications, they could have started investigating each company's prescription practices sooner.

Finally, SAMHSA should collect data on malingering in the National Survey on Drug Use and Health. Currently, the survey does not include questions on malingering, leaving policymakers unaware of the extent to which patients fraudulently display symptoms of ADHD to receive a prescription for stimulant medications.[214] Collecting data on malingering rates could help policymakers address the overprescription of stimulant medications.

Federal efforts to improve data collection and reporting should match policies on the state level to reform PDMPs. PDMPs provide data on a patient's prescription history and can be a useful tool for identifying patients who visit multiple doctors in an effort to acquire as much medication as possible.[215]

First, state policymakers should require all prescribers and pharmacists to enroll in and utilize their state's PDMP. States should require prescribers and pharmacists to review a patient's information before prescribing or dispensing a Schedule II controlled substance. By requiring providers to review a patient's prescription history, policymakers can help ensure that patients are receiving medically appropriate medication and deter doctor or pharmacy shopping.

Second, state policymakers should require pharmacists to report the sale of Schedule II controlled substances to PDMPs at the point of sale. Currently, a few states allow pharmacists to enter data on prescriptions at later points in time. However, this delay provides patients with an opportunity to seek additional prescriptions of the medication elsewhere. Policymakers should enact more timely reporting requirements so that other prescribers and pharmacists can review a patient's most recent prescription history before dispensing medication.

Third, the BJA and CDC should remove grant stipulations and allow states to share data with the platform of their choosing. Such requirements unnecessarily impede data-sharing efforts and can deter states from pursuing important grants. BJA should instead remove the stipulations while refining RxCheck to make it a more useful platform than PMP InterConnect.

Finally, states should allow public health officials and researchers access to PDMP data. Public health officials and researchers can use the data to monitor trends in population drug use and inform policymakers' efforts to prevent misuse, diversion, or overprescription.

4. Law enforcement agencies should regularly audit telehealth platforms.

While telehealth might make it easier for individuals to obtain access to Schedule II stimulants, it also makes it easier for law enforcement agencies to investigate these providers.

The DEA, the Department of Health and Human Services' Office of the Inspector General, and state law enforcement agencies should regularly audit telehealth companies to ensure that they are providing appropriate care to their patients and not operating as digital pill mills offering medically unnecessary controlled substances. Investigators can take advantage of telehealth's virtual nature to audit companies in multiple locations at various times, allowing more insight into their operations than might otherwise be possible.

Moreover, state attorneys general and law enforcement agencies should regularly review data from state PDMPs to identify providers with abnormally high prescription rates and ensure that such providers receive adequate training on appropriate medical care and clinical guidelines for controlled substances.

5. The FTC and FDA should clarify and improve its guidelines for advertising by telehealth platforms offering controlled substances.

The FDA and FTC should update regulatory guidelines to prevent telehealth platforms from posting pharmaceutical advertisements that offer medications to combat common human concerns, such as Done's

advertisement claiming ADHD medication provides patients with a quiet mind, or Cerebral's advertisement suggesting ADHD medication can treat job anxiety, without disclosing side effects of common treatments. To date, neither agency has offered sufficient guidance on telehealth companies' advertisements. As a result, it is unclear if telehealth companies would face the same consequences for inappropriate advertising as manufacturers, distributors, or other actors involved in the supply chain for stimulant medications. The FDA and FTC should issue new guidelines that clarify jurisdiction and requirements for telehealth advertising and ensure telehealth providers fall within their scope.

Moreover, the FTC should strengthen guidelines for help-seeking advertisements. Many telehealth companies use help-seeking advertisements to promote their services. However, in promoting treatment for ADHD, these advertisements list symptoms common to many individuals without ADHD, such as job anxiety, memory loss, or weight gain. This content may cause some consumers to mistakenly believe they have a condition and seek out medically unnecessary treatment. The FTC should clarify appropriate content for help-seeking advertisements and inform telehealth companies as to when more information or certain disclosures must be included.

Finally, the FTC should clarify guidelines to explain what is required of advertising agencies and endorsing figures, such as social media influencers, when promoting pharmaceutical products. Telehealth companies, such as Cerebral and Done, may turn to advertising agencies to create effective advertising strategies or celebrity spokespersons to promote their services. However, medications require more disclosures than many other products or services featured in advertising campaigns or influencers' posts. The FTC should clarify third parties' responsibilities when advertising medications to ensure that consumers receive an appropriate amount of information.

CONCLUSION

Regulatory changes from the COVID-19 pandemic led to the development of a telehealth startup economy. These new companies enabled patients to receive medical care from the comfort of their home and provided medical benefits that would have otherwise been unavailable, but some telehealth providers have exploited these changes to the detriment of patients. Given telehealth's benefits and ease of access, policymakers should continue the regulatory changes that allowed companies to flourish. However, they should work to ensure that remote patients receive the same standard of care as they would during in-person appointments. By enacting permanent regulatory changes, improving state and federal data requirements, expanding licensing options, auditing medical providers, and clarifying telehealth guidelines, policymakers can both protect patients from malpractice and boost the development of telehealth.

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