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Editorial

Continuing increased access to buprenorphine in the United States via telemedicine after COVID-19

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Introduction

In response to the concurrent opioid overdose and COVID-19 epidemics, the United States (US) Drug Enforcement Administration (DEA) and other federal agencies have taken steps to temporarily remove some legal and regulatory barriers to buprenorphine treatment for opioid use disorder (OUD). These changes have the potential to improve access to this lifesaving medication, particularly among those most at risk. However, most of these changes will revert after the COVID-19 crisis ends. In this Commentary, we briefly describe the importance of increased access to buprenorphine for OUD treatment, current US legal and regulatory modifications that increase access to buprenorphine via telemedicine, and available avenues for making those changes permanent.

Buprenorphine for opioid use disorder

Treatment with buprenorphine, a medication for opioid use disorder (MOUD), reduces the risk of death among people with OUD by as much as 50 percent (Sordo et al., 2017). Although buprenorphine treatment has increased over the past decade, it is often not available when and where it is most needed (Olfson, Zhang, Schoenbaum, & King, 2020). Federal laws that make buprenorphine for OUD difficult to access for many patients, including those most at-risk for overdose death, are a key driver of the persistent gap between treatment need and availability (Davis & Carr, 2019).

These legal restrictions are many and varied. Perhaps most importantly, US federal law prohibits physicians and other providers from prescribing buprenorphine for OUD unless they've obtained a federal "waiver" to do so (Fiscella, Wakeman, & Beletsky, 2019). To obtain this waiver, most physicians must complete an eight-hour training; nonphysician prescribers must complete 24 hours. US federal law also limits the number of concurrent patients waivered prescribers may treat (Davis & Carr, 2017).

Access to buprenorphine is limited by other laws as well. Chief among these is the Ryan Haight Act, which permits controlled substances to be initially prescribed in most cases only after the prescriber has conducted an in-person examination of the potential patient ("21 U.S.C," 2020). This requirement, while well intentioned, can create a potentially insurmountable barrier for individuals who would benefit from buprenorphine treatment but are unable to meet with a waivered provider in person, and disproportionately impacts individuals with OUD in rural areas, those without reliable transportation, and individuals with disabilities (Andrilla, Coulthard, & Larson, 2017).

While use of buprenorphine has modestly increased in recent years, due in part to the Medicaid expansion permitted by the Affordable Care Act, (Olfson, Zhang, Schoenbaum, & King, 2020; Sharp et al., 2018) there remain significant gaps and inequities in treatment access and availability by geographic location and race(Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Currently, only approximately five percent of US physicians are waivered to provide buprenorphine, (Olfson et al., 2020) and more than half of rural counties lack a waivered buprenorphine provider (Andrilla, Moore, Patterson, & Larson, 2019). The restrictive regulatory regime can also impact buprenorphine dispensing. For example, a recent survey of pharmacies in a rural area with high opioid overdose rates found that 80% limited buprenorphine dispensing, often because of concerns regarding potential violations of federal law (Cooper et al., 2020).

Further, despite similar prevalence of OUD among Black and white adults, Black patients have significantly lower odds of being prescribed buprenorphine at outpatient visits (Lagisetty, Ross, Bohnert, Clay, & Maust, 2019). These inequities are in no small part due to structural healthcare resource allocation. Majority white counties are more likely to have increased availability of buprenorphine, while majority Black and Hispanic/Latino counties are more likely to have facilities providing methadone (Goedel et al., 2020).

Telemedicine is one strategy to address gaps in provider availability and access inequities. While there are not yet studies evaluating the use of telemedicine for starting buprenorphine treatment, telemedicine-delivered buprenorphine for maintenance treatment has demonstrated comparable patient retention, medication adherence, and obstetric outcomes compared to in-person care (Eibl et al., 2017; Guille et al., 2020; Zheng et al., 2017). While the potential of telemedicine to improve addiction treatment access has been recognized for years, only with the advent of COVID-19 have changes been made to reduce some regulatory barriers to evidence-based treatment for OUD (Yang, Weintraub, & Haffajee, 2018).

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Removal of some barriers to MOUD during COVID-19

During the COVID-19 pandemic, telemedicine has been broadly expanded across medical specialties as a result of changes to payment, privacy, and licensing regulations (Shachar, Engel, & Elwyn, 2020). Some barriers to the delivery of buprenorphine treatment by telemedicine have also been temporarily lifted. Most notably, the Secretary of Health and Human Services (HHS) has, in coordination with the Attorney General, used his statutory authority to waive the Ryan Haight Act's in-person examination requirement for the duration of the federally-declared COVID-19 emergency, thereby permitting the initial consultation for buprenorphine treatment to be held via telemedicine.

While this authority was initially limited to communication conducted via an "audio-visual, real-time, two-way interactive communication system," DEA has recently used its enforcement discretion to authorize telephone consultation as well (Prevoznik, 2020). This innovation is key, as it permits "tele-bupe" services such as those that have been created in areas such as California, New York City, Philadelphia, and Rhode Island. These services permit an individual with OUD to quickly and easily contact a waivered provider who conducts a phone consultation and, where medically indicated, prescribes buprenorphine and schedules appropriate follow-up.

To further improve access to treatment during COVID-19, the DEA has also waived, in some circumstances, a requirement that a DEA-registered provider obtain a separate DEA registration in each state in which they practice (McDermott, 2020). Since DEA deems the provider to be practicing in the state in which the patient is located, this change may further improve the ability of providers to prescribe buprenorphine via telemedicine, particularly in rural areas. All of these changes are currently set to expire with resolution of the COVID-19 public health emergency.

Permanently reducing barriers to buprenorphine

The opioid crisis was declared a US public health emergency in 2017 (Hargan, 2017). Despite repeated calls prior to the COVID-19 pandemic for the federal government to remove unnecessary restrictions to MOUD to prevent overdose and other opioid-use related harms, buprenorphine prescribing regulations have not been fundamentally improved (Stancliff, Greene, & Zucker, 2019). Congress has made incremental amendments, such as increasing the number of patients a buprenorphine waivered provider can treat and expanding the pool of prescribers who can become waivered to include advanced practice clinicians (Davis, 2019). However, buprenorphine for OUD remains more difficult to access than nearly all other medications, including opioid analgesics, illicit opioids, and buprenorphine when prescribed for pain (Davis & Carr, 2019).

Many of the barriers to buprenorphine treatment existed before the COVID-19 crisis and will persist after it is resolved. Indeed, disruptions caused by the coronavirus will make the overdose crisis even more acute. There are two primary ways the federal government can ensure that increased access to buprenorphine via telemedicine remains accessible after the COVID-19 emergency has passed: 1) legislative action and 2) regulatory change and use of regulatory discretion. On the legislative front, Congress can modify existing law to remove the waiver requirement and amend the Ryan Haight Act to permit waivered providers to prescribe buprenorphine for OUD treatment without an initial in-person visit where medically indicated.

Federal agencies, however, need not wait for Congress to remove barriers to buprenorphine therapy by telemedicine. The HHS Secretary is authorized by existing law to waive the Ryan Haight Act's restrictions for providers practicing telemedicine during any public health emergency. He can and should extend the current waiver to initiate buprenorphine via telemedicine for the duration of the opioid public health emergency. DEA, which enforces the Act, should continue exercising its discretion to permit those consultations to take place via telephone where necessary.

DEA can pursue other avenues as well. When the Ryan Haight Act was passed in 2008, it permitted the Justice Department to create a "special registration" that would permit controlled substances to be prescribed via telemedicine more broadly. The specifics were left up to the DEA to designate via regulation. When it failed to do so after nearly a decade, in October 2018 Congress passed a law requiring that they be created within a year. DEA should quickly move to create regulations that permit the initial prescription of buprenorphine for OUD treatment via telemedicine without an initial in-person evaluation where necessary.

Finally, DEA has wide latitude to grant exceptions to many controlled substance regulations at any time, for any reason (2020). It has used this authority to waive the requirement that providers obtain a separate registration in each state in which they practice but has done so only for the duration of the coronavirus pandemic. There is no legal or regulatory reason for this change to expire when that pandemic is contained, and it should be continued indefinitely to enable the responsible prescribing of buprenorphine via telemedicine.

While change at the federal level is necessary, it will not be sufficient to meaningfully increase access to buprenorphine treatment. States also impose a variety of restrictions on the practice of telemedicine, some of which are similar to those in the Ryan Haight Act (Park, Erikson, Han, & Iyer, 2018). Like the federal government, many states have modified those restrictions in light of the COVID-19 emergency (Augenstein, Marks, Morgan, & Peng, 2020). As with the federal government, state restrictions that reduce access to buprenorphine should be permanently removed.

The primary concern offered by those skeptical of increased access to buprenorphine is diversion – that is, use of the medication by someone other than the person to whom it was prescribed. That concern is misguided. Studies evaluating the use of non-prescribed buprenorphine have demonstrated that it is primarily used for the purpose for which it was intended – helping people with OUD to reduce use of other opioids and to treat symptoms of withdrawal (Chilcoat, Amick, Sherwood, & Dunn, 2019). Further, research shows that, among adults with OUD, greater frequency of non-prescribed buprenorphine use is significantly associated with lower risk of overdose (Carlson, Daniulaityte, Silverstein, Nahhas, & Martins, 2020).

There is increasing recognition that the causes of the epidemic of opioid use disorder and related harm are many and varied, and efforts to address them – particularly those that seek to dismantle structural racism and economic inequality - should be redoubled (Dasgupta, Beletsky, & Ciccarone, 2017). We strongly endorse that view. Simultaneously, the federal government should act quickly to facilitate the use of evidence-based treatment for OUD. Congress and federal agencies can and should act now to ensure that the increased access to buprenorphine treatment currently available does not disappear with the coronavirus.

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Declarations of Interest

None.

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