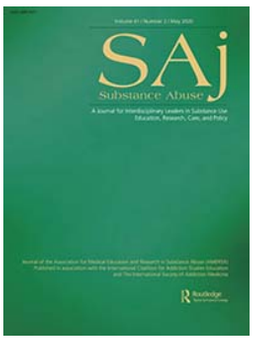

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EDITORIAL



# Opioid use disorder and the COVID 19 pandemic: A call to sustain regulatory easements and further expand access to treatment

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**ABSTRACT**

We highlight the critical roles that pharmacists have related to sustaining and advancing the changes being made in the face of the current COVID-19 pandemic to ensure that patients have more seamless and less complex access to treatment. Discussed herein is how the current COVID-19 pandemic is impacting persons with substance use disorders, barriers that persist, and the opportunities that arise as regulations around treatments for this population are eased.

**KEYWORDS**

Pandemic; opioid use disorder; pharmacists; buprenorphine; methadone; regulations; policy

Individuals who comprise the editorial board of *Substance Abuse* and the Board of Directors and membership of the parent organization, the Association for Multidisciplinary Education in Substance use and Addiction (AMERSA) are representative of the various professionals focusing on substance use-related education, research, practice, and policy. Among the AMERSA membership are a growing number of pharmacists. We highlight the critical roles that pharmacists have related to sustaining and advancing the changes being made in the face of the current COVID-19 pandemic to ensure that patients have more seamless and less complex access to treatment. Discussed herein is how the current COVID-19 pandemic is particularly impacting persons with opioid use disorder, barriers that persist, and the opportunities that arise as regulations around treatments for this population are eased.

In times of crisis, the current regulations that exist in the substance use treatment world intensify the barriers that already exist for patients because of over regulation and policies in the U.S. In the face of the COVID-19 pandemic, providers have been challenged to address the needs of patients with opioid use disorder in the context of long-standing rules and regulations around medications such as methadone and buprenorphine. An additional area of concern is how to operationalize physical/social distancing when face-to-face group treatment is a dominant modality and in-person 12-Step and other mutual support groups are such an important part of recovery support. Even before March 12, 2020 when the World Health Organization announced the COVID-19 outbreak, health care providers and advocates were calling for the removal of barriers to treatment for persons with substance use disorder.[1–4] While some obstacles are being temporarily removed,[5] there are opportunities to demonstrate the impacts of telehealth for initiating and monitoring patients on buprenorphine, the flexibilities for take home medication for opioid use disorder treatment, and the expanded access to virtual support groups through online meetings.[6]

Yet these expansions will be utterly insufficient to care for the people with opioid use disorder who are in treatment, let alone those in need of and who will seek out treatment in the coming weeks and months as there is a shift in drug markets and people begin to experience withdrawal symptoms. Presently, projections for a COVID-19 vaccine are at least 12–18 months into the future; there is no effective screening test for coronavirus in sight; and when a test does become available, conducting testing to a volume sufficient to meet the country's needs is questionable. The social distancing strategy is likely the best intervention tool for the short term (next few months) as well as intermittently in the longer term (next few years), to be deployed again when outbreaks occur across the country. Based on what is known today, the epidemiology of COVID-19 suggests that changes in regulations and the flexibility afforded thus far during this public health emergency not only need to be made permanent, but further expansions are immediately necessary.

Since opioid treatment is highly regulated, when confronted with a crisis, providing care to persons with opioid use disorder becomes more of an emergency. For example, after the 2012 Hurricane Sandy, interviews of 300 New York City residents who injected drugs were conducted to understand how that natural disaster impacted their medical treatment.[7] Concerning was that of those on methadone or buprenorphine, only 30.1% were able to obtain sufficient

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take-home doses of those medications.[7] Post Hurricane Sandy interviews were conducted with providers and administrators that offer pharmacological treatment for opioid use disorder using methadone and/or buprenorphine in public clinics and in community practices accepting Medicaid.[8] Methadone providers reported more barriers to continuity of care (i.e. poor communication with regulatory agencies, clinic relocation problems, lack of emergency preparedness strategies, and dosage and patient status verification difficulties) than buprenorphine providers (i.e. buprenorphine clinic relocation, lack of emergency preparedness strategies, and dose verification).[8] Those barriers were similar to the ones documented following the 9/11 attacks and Hurricane Katrina. In reviewing the legal challenges for substance use treatment during disasters, Rutkow et al. suggested strategies for the future including: clarification about the status of critical professionals who participate in emergency responses outside of their home states, addressing federal regulations that restrict access to treatment during disasters, and sharing of information such as treatment status and dosing information.[9] Nearly a decade has passed since the 9/11 disaster with two natural disasters following with few, if any changes to regulations and, not surprisingly significant disruptions in treatment of persons with OUD with the current pandemic. Will this be the time for permanent changes to regulations that remove barriers to OUD treatment for a highly vulnerable population?

A major oversight in the regulatory expansions is the failure to consider the enormous capacity of pharmacies, places that remain open and are considered essential to overall pandemic response in addition to being sources of substance use treatment as well as medication provision. The over 224,000 pharmacists in the United States[10] in 60,000 community locations represent a group of highly educated professionals with expertise in the safe use of medications. These professionals are responsible to dispense medications to patients, counsel patients, and work collaboratively with patients and their health care team in medication management and detection of adverse events. Pharmacies have long dealt with the topics and resources of harm reduction and addiction medicine. Sale of nonprescription syringes complement access to sterile injection materials in geographic areas to support community syringe service programs. Medications to treat substance use disorder like buprenorphine and naltrexone are regularly dispensed and all the safeguards for storage and dispensing of controlled substances are accepted practice. Pharmacists also have a role in dispelling misinformation about medications that may be ineffective or could even worsen coronavirus disease.

Moreover, community pharmacies stock and distribute naloxone, educating patients and first responders about the signs and symptoms of opioid overdose and how to administer this life-saving medication. The results of a survey of pharmacists in Massachusetts and Rhode Island revealed that nearly 18% had responded to or witnessed a suspected overdose on-site at their practice location.[11] Pharmacists who are on the frontline caring for patients have skills which are highly underutilized and clearly could be expanded beyond the current pandemic, and sustained through adequate reimbursement for delivering disease state management services. On March 18th, 2020, the American Pharmacists' Association House of Delegates validated their support of medications for OUD as first-line treatments to be maintained in pharmacies and paid for equitably by insurers to maximize patient access.[12]

A March 19, 2020 directive by the Substance Abuse and Mental Health Administration (SAMHSA) exempted opioid treatment programs from the requirement to perform an in-person physical examination for consideration of buprenorphine treatment, but not for methadone treatment.[13] Compton and colleagues suggested that pharmacies of the future should have an expanded role in opioid-related treatment, including dispensing methadone.[14] Calcaterra and colleagues provided a review of international (Canada, Australia, and United Kingdom [UK]) pharmacy-based methadone and presented a vision of integrated primary-care and pharmacy prescribed, dispensed, and managed methadone for OUD, consistent with how other chronic diseases are managed.[15] Given the current call for social distancing and the need to manage the flow of patients in methadone clinics, the UK model could be an exemplar for a revolution in pharmacy addiction care. That is, in the UK, dispensing of methadone (and buprenorphine) can be undertaken at a registered pharmacy. A study by Strang and colleagues demonstrated that in Scotland and England, the addition of pharmacists supervising the consumption of the medications combined with other safety protocols prevented the increase of methadone-related deaths as prescribing of these opioid-related medications increased.[16]

If the U.S. implemented such a model for methadone, patients with opioid use disorder could receive the same treatment as others who are taking prescribed medications, an approach that could also help mitigate the stigma experienced by this population and free the patient from the confines of a heavily regulated and controlled care environment. Indeed, pharmacies already maintain stock and dispense methadone for pain. During this unprecedented time, Americans are encouraged to stock up on their medications, yet such options are not available to persons with an opioid use disorder managed effectively with buprenorphine or methadone. Leavander and Wakeman pointed out that the current coronavirus mitigation measures fall short of what is needed and "it will not be a matter of whether an outbreak will occur at an opioid treatment program, but when."[17]

A March 2019 publication called for the deregulation of buprenorphine for opioid use disorder treatment based on safety, access, the nature of misuse, and the need to mainstream treatment.[2] The authors presented multiple reasons for deregulation and called for the removal of the requirement for physicians, physician assistants (PA), and advanced practice nurses (APN) to complete the 8- to 24-hour educational training to obtain authorization to prescribe buprenorphine for the treatment of opioid use disorder from the Drug Enforcement Agency. To date, there is no evidence to support the additional 16-hour requirement for PAs and APNs versus the 8-hour requirement for physicians and, in

fact the greater amount of time may be an additional barrier for patients being able to access this treatment. A more sweeping approach would be to remove the requirement for the waiver entirely, as proposed by Frank and colleagues.[18] Their argument for eliminating the wavier, formulated in response to the worst drug overdose crisis in U.S. history is even more salient at a time of the worst pandemic in modern history. In the face of the opioid public health emergency, now overshadowed by the COVID-19 pandemic, calls for expanding the number of providers who can prescribe buprenorphine are even more pressing.[19–22] Further, the need for leaders of transformative change in the treatment of this population is even more critical for saving lives.

In summary, providers who work on the front lines treating persons with substance use disorders have made compelling cases for addressing the burdensome regulations that stand in the way of improving the patient care experience, improving the health of a population that is among the most vulnerable, and reducing per capita health care costs. Similar calls, even in past natural disasters, have gone unheeded. Today, restrictions in care and associated stigma experienced by persons with substance use call for immediate recommendations for system changes. As regulations are lifted to provide essential treatment and support to those with substance use disorders, it timely for healthcare researchers to examine the impacts, benefits, and unintended consequences of these special exemptions, thus informing which easements should remain permanently in place. Pharmacists stand ready with colleagues from other disciplines to lead change in systems that will further remove barriers to treatment for our patients.

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