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The impact of COVID-19 on opioid treatment programs in the United States

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ABSTRACT

Background: The COVID-19 pandemic had the potential to severely disrupt the delivery of methadone and buprenorphine, as social distancing and other public health regulations made in-person services difficult to maintain. Federal and state regulators changed requirements regarding the dispensing of medication and inperson counseling at opioid treatment programs. Understanding staff and patient reactions to these changes can help determine whether they should be maintained.

Methods: We interviewed 25 directors of OTP programs located throughout the United States. Note takers wrote summaries of each interview which were coded for topics and themes covered in the interview guide, including changes to clinic practices, take-home medications, telehealth, patient and staff reactions to new COVID-related protocols, and financial concerns for programs.

Results: Most programs rapidly incorporated new regulatory requirements, and directors were generally positive about the impact of increased take-home doses of medication and increased reliance on telehealth. Some directors voiced concerns about these changes, and some reported that patients missed the daily clinical contact with staff. Directors also suggested that more time was needed to assess the full impact of these changes. Financial impacts varied, although many directors were quick to point out that the ongoing opioid epidemic has delivered a steady stream of new patients, thus offsetting potential financial losses.

Conclusions: Overall, this study demonstrated the generally positive view of OTP directors to the regulatory changes necessitated by the COVID-19 pandemic. More time is needed to fully evaluate the impact of these changes on clinical outcomes.

1. Introduction

Similar to other disasters such as hurricanes (Matusow et al., 2018; McClure et al., 2014) the coronavirus pandemic (COVID-19) and its associated medical and social distancing protocols have confronted opioid treatment programs (OTPs) with multiple challenges, leading to policy changes that substantially altered the manner in which agonist medications are dispensed and counseling is conducted. In response to the pandemic, on March 16, 2020 the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) permitted states to request blanket exceptions for dispensing agonist medication (up to 28 days take-home doses for stable OTP patients and up to 14 days for less stable patients (SAMHSA, 2020). The pandemic has also spurred the introduction and expansion of telephonic and telehealth services.

OTPs play a vital role in treating patients with an opioid use disorder

(OUD) since they are the only programs in the U.S. that can dispense methadone. OTPs are also noteworthy for providing counseling and other services to a population that often presents with a variety of medical and psychosocial challenges (SAMHSA, 2013; Stein & Friedmann, 2002). However, access and retention in OTPs has traditionally been compromised by waiting lists for treatment entry, limited geographic coverage, and stringent regulations such as daily onsite dispensing of medication for many patients (Kleinman, 2020; National Rural Health Association, 2017; Rosenblum et al., 2011). The COVID-19 pandemic has produced a natural experiment in which these barriers to OTP access and retention have been altered or suspended. One important question is whether the changes resulting from COVID-19 protocols (e.g., expansion of take-home medication and introduction of telehealth services) may have helped to improve OTP practices, increased the number of patients treated with agonist medications, and reduced the

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burden and stigma that has long been associated with agonist treatment. On the other hand, there is concern that such changes may have a detrimental impact such as increased diversion and overdose, and frustration with telehealth services for those who may have limited access to a phone or a video platform, or access to a private space to use such services.

Research findings addressing these questions have begun to emerge and indicate a decline in clinic visits, a significant increase in take-home doses, modest or no increase in diversion, and no increase in fatal overdose (Figgatt et al., 2021; Joseph et al., 2021; McIlveen et al., 2021). (Figgatt et al., 2021; Joseph et al., 2021).

Of particular relevance is whether and how these changes in regulations and OTP practices can be sustained once the pandemic has ended. While the emerging studies provide data to support the continued relaxation of requirements for take-home medications and the expansion of telehealth among OTPs, little is known about the perspective of the OTPs themselves. The aim of our study is to understand how OTPs adapted to structural, behavioral and regulatory changes, implemented due to the COVID-19 pandemic, including the reactions of staff to these changes. This paper focuses on OTP clinic directors' perspectives of the regulatory changes instituted during the early part of the pandemic in the U.S.

2. Methods

2.1. Participants.

We conducted qualitative interviews with the directors of 25 methadone treatment programs located throughout the United States. Participants were recruited through Stop Stigma Now (SSN), an organization dedicated to reducing the stigma associated with medication assisted treatment (MAT). The President of SSN emailed letters to OTP directors describing the project, and those who were interested were contacted by the interview team to schedule an interview. Several directors of large agencies recommended interviewing individuals who oversaw specific programs, some described smaller programs, and several provided information about multiple programs under their supervision.

2.2. Interviews

Interviews were conducted, using Zoom, by two individuals with extensive experience with OUD treatments, including a retired physician and a SUD treatment evaluation researcher. A semi-structured interview protocol covered the following domains: general program information, pre-COVID-19 program activities, onset of COVID-19, adaptations to COVID-19, and lessons for the future. At least one, and sometimes two, note takers attended each interview and took detailed notes during the interview. The note takers captured some verbatim quotes, and the final notes contained both narrative summaries of interviewee statements as well as verbatim quotes. These notes were summarized by one note taker, reviewed by the interviewer, and sent directly to the interviewee, who had the opportunity to correct or clarify any information recorded. Final versions of these notes were used as data, and were coded and analyzed as described below.

2.3. Coding

After all interviews were completed, and notes were finalized, a team of three coders (the two note takers and an additional researcher from SSN) reviewed the notes and developed a set of 14 general topics based upon the content recorded in the notes (clinic environment, diversion, federal-state reactions, finances, future changes, ongoing challenges, onset of COVID, patient reactions, pre-COVID initiatives, patient and staff infections, staff reactions, take-home medications, telehealth, and toxicology). Each set of notes was then coded for these topics by two

coders, with disagreements resolved through discussion and consensus. This resulted in separate documents that contained all notes across all interviews that corresponded to each topic. Two coders then reviewed the notes corresponding to each topic, identified specific themes for each topic, and coded the themes in each topic document, with disagreements again resolved through discussion and consensus.

This paper presents analyses of themes from three of these topics most relevant to the regulatory changes instituted early in the pandemic: take-home medications, telehealth, and finances, all of which were impacted by changes in federal, state and local regulations that instituted new protocols and procedures due to the COVID-19 pandemic. In addition to narrative examples and direct quotes from the interviewees, which focus on the experiences of staff and patients in each of these areas, we summarized whether interviewees were positive, negative or mixed/neutral regarding their experience with increased take-home medications and telehealth. We also include a theme that was identified in the "Future Changes" topic, which we have labeled "too soon to tell." This reflects interviewees' caution regarding the immediate assessment of the impact of regulatory changes due to the COVID-19 pandemic. Finally, we highlight stigmatizing language that was used by some interviewees, as well as statements that reflect an understanding of the stigma that patients face and concrete efforts to address this stigma.

3. Results

While most interviewees oversaw a single clinic, several worked in health systems with multiple programs or oversaw larger treatment networks. Eleven programs were located in major cities, while the rest were located in smaller communities, including some rural locations. Across the four regions of the U.S., eight programs were located in the Northeast, eight in the South, six in the Midwest and three in the West. Programs varied in size; directors oversaw anywhere from one to 37 clinics (12 were responsible for more than one clinic), treating from 80 to more than 16,000 patients at the time of their interview (the median census was 720). All programs provided methadone according to state regulations, in clinical settings that, prior to the pandemic, required regular in-person visits.

Several prominent themes were highlighted in the interviewees' responses. In general, interviewees thought that there were substantial benefits to these regulatory changes, and cautiously hoped that the changes might continue once the COVID-19 pandemic has passed. However, some interviewees highlighted negative impacts of these changes, while others suggested that more time was needed to fully assess the impacts of these changes. Themes related to take-home medications, telehealth, and the financial impact of these regulatory changes, with supporting narrative data, are described below, followed by a selection of quotes that reflect the stigma associated with OUD and

3.1. Regulatory changes/take-home medications

Federal and state regulatory authorities relaxed requirements for take-home doses of medication and face-to-face clinical contact. Respondents were generally appreciative of this new flexibility, and clinics reacted quickly to implement new procedures and protocols to protect patients and staff. However, some directors were uncomfortable with the rapid pace of these changes, and some reported negative experiences, as described below. Many clinics shifted to every other day, weekly, or monthly schedules for patients, resulting in less crowded clinics that made social distancing possible. In most cases, patients who already received some take-home medication were put on less restrictive schedules, while patients who were homeless or could not safely store their bottles were kept on six-day schedules. Some OTPs implemented and maintained expanded take-homes for patients who provided negative drug screens, picked up their medication and attended counseling

sessions as required, and returned empty bottles. Other clinics required a set number of weeks or months of "stability" to maintain take-home medication. Patients considered high risk "still had to come in every day for fear that something would happen to them or to the medication." (Program located in the Midwest,10,000 patients).

The majority of comments related to take-home doses of medication were positive, with 16 (64%) expressing positive views and/or a desire for these relaxed regulations to continue, and only seven (28%) expressing a negative view. Respondents reported that most patients were doing well with take-home medications, including one who reported that patients who once tested positive were now testing negative, perhaps due to a new sense of responsibility. Another stated, "Patients we never would have put on once a month or twice a month have done really well with this." (Northeast, 5743 patients). One respondent reported that "patients felt like it [coming to the clinic] was one less thing they had to worry about." (Northeast, 900 patients) and another stated that "Now it shows that you can work hard and this is your reward." (Midwest, 156 patients).

Other OTP directors suggested that things had gone better than they had anticipated. One respondent reported that "As pro patient and pro responsibility as I am, it has been better than expected." (Midwest, 1100 patients) Challenges that did arise were not surprising to some directors. One respondent stated that "giving privileges too quickly along with the isolation, we weren't surprised with the handful of problems we had." (South, 1586 patients) Another said that "we've always been control freaks" but that when they let go, patients rose to the challenge. (Northeast, 16,000 patients) Respondents hoped that extended take-home medications would be allowed to continue; "It would be fantastic if we could always give these patients extended take-homes... We pray that everything goes great so that the patients can continue." (Midwest, 10,000 patients).

There were, however, some negative reactions to the increased takehome doses of medication. One interviewee reported that they use "more take-homes than we were comfortable with" (Northeast, 220 patients) based on guidelines issued by their state, and another described their discomfort with take-home medications as, "Powerful medications in the wrong hand that can kill...very anxiety causing." (Northeast, 16,000 patients). Some respondents were strongly opposed to take-home medication, with one interviewee reporting "giving people take-home [doses] is giving them what they want." (Midwest, 208 patients). Another thought that increased take-home doses would ultimately be problematic; "I don't want to be discussing the methadone epidemic in five years." (South, 1586 patients).

Several programs increased take-home doses but then returned to their previous dosing protocols. One clinic instituted two-week take-home protocols but observed a significant number of relapses. They reacted by returning to their old protocols; "We took away take-homes so that we have eyes on them." (South, 215 patients) Another interviewee, whose program, which increased take-home medication and saw no increase of medication in the community, was more positive. "This gets back to the overregulation, which I believe is just another demonstration of stigma." (Northeast, 3000 patients) One clinic provided naloxone prescriptions to all patients receiving increased take-home medication.

Not all changes were well-received by all patients. Some OTP directors reported that a small but significant minority of patients preferred to pick up their medication and attend counseling sessions in person. "Some of them really enjoy it [less frequent attendance] but some of them miss coming in all the time...Sometimes we're the only nice people they see all day." (West, 211 patients) and did not want take-home. "Some of them wanted to see us every day." (West, patient numbers not reported) Some patients had trouble sticking with the routine necessary to self-administer medication at home, and several clinics required patients to maintain their counseling schedule or answer their phone when called in order to keep receiving take-home doses.

3.2. Regulatory changes/telehealth

Similar to their responses to changes in take-home doses of

medication, respondents were generally supportive of the regulatory changes allowing for increased use of telehealth, with 13 (52%) having a positive reaction and seven (28%) reacting negatively. Some interviewees had mixed feelings about the allowance of remote, rather than in-person, counseling sessions, and some also noted significant logistical challenges and negative impacts on the quality of counseling that could be provided.

Respondents reported that both staff and patients liked telehealth sessions. One respondent, whose clinic used telephone counseling only, reported that a lot of patients love it: "it's way more convenient, they don't want to come in, they're tired of their counselors." (Midwest, 208 patients). Another said, "I really hope telemedicine is here to stay." (South, 217 patients). Respondents also reported that telehealth allowed them to maintain their caseload. "Due to telephonic services our utilization is through the roof. Individuals absolutely love it. We've never had our show rate be as high as it is now" for groups, individual counseling, medication management, and doctor's appointments. (Northeast, 3000 patients). One respondent pointed out that clinics and patients in rural areas especially benefitted from telehealth because of the elimination of the substantial travel time necessary to visit clinics in person.

Some respondents highlighted challenges with telehealth. Many patients do not have access to computers, and even telephone counseling can be challenging for unstable or older patients. "Sometimes it is a little difficult to get in touch with clients on the phone." (West, 211 patients). Often patients would not recognize clinic phone numbers, or would miss scheduled appointments. Some clinics allowed patients to use clinic offices to call their counselors, who were working remotely. One respondent commented that patients were not compliant; "Once they got their bottles they weren't really interested in taking calls from their counselors." (Midwest, 1075 patients) The quality of telehealth counseling sessions was also a concern for some respondents. Respondents commented that, "there's no substitute for human interaction." (Midwest, 208 patients), and "just the connection is missing." (West, 211 patients) One respondent stated, "telehealth system seems to be leading to alienate the traditional relationship between client and counselor." (Northeast, 212 patients).

There appeared to be more ambivalence regarding groups compared with individual counseling with the implementation of telehealth. One director reported low attendance and even no-shows during telehealth groups and another noted that, "[a] lot of patients can't wait for [inperson] groups to come back" (Midwest, 208 patients) But other OTP directors observed positive features with telehealth groups. One reported a 15% increase in group attendance since starting to use telehealth, while another noted that some patients who weren't comfortable attending inperson groups have been more comfortable in telephonic groups.

3.3. Finances

One area of concern related to both take-home doses of medication and the provision of telehealth was the financial impact of these regulatory changes. In many states, prior to the COVID-19 pandemic, the methadone reimbursement system was based on daily (or at least frequent) in-person visits to receive both medication and counseling. As pandemic regulations changed, some (but not all) states allowed for different reimbursement plans based on changes to clinic visit requirements. In others, changes were not implemented and this posed a challenge. Respondents, who were responsible for the fiscal aspects of their clinics, saw this as a business issue. "We are in the behavioral health business." (Northeast, 212 patients).

Clinic costs increased in some areas (e.g., the need to buy Personal Protective Equipment (PPE) and technology for telehealth) and decreased in others (lower staffing costs due to decreased in-person services). One respondent reported that "The costs have gone up and the reimbursements have gone down." (South, 1586 patients). Even when reimbursement was allowed for telehealth, it was often difficult to reach patients for these sessions, and therefore reimbursement

decreased

More often, however, respondents reported that financial impacts were either minor or offset by other revenue gains. Bundling, in which states paid clinics a fixed rate for comprehensive services – a practice that existed in some states prior to the pandemic – meant that reimbursement was unaffected by decreased clinic visits; "If medication goes out the door, we collect the bundled rate." (Midwest, 1100 patients). Other respondents highlighted the fact that the opioid epidemic continued, and even worsened, during the COVID-19 pandemic, and revenue from new patients offset the loss of revenue from regulatory changes. One respondent stated, that "there is always a steady source of revenue in treating these clients." (Northeast, 152 patients). Further, while visits decreased for stable patients, new patients were often seen more frequently.

3.4. Too soon to tell

A number of interviewees highlighted the fact that public health restrictions implemented to limit the spread of COVID-19 would not last indefinitely, and that it would therefore be important to monitor the impact of these regulatory changes as these restrictions were relaxed and both patients and staff adjusted to whatever protocols were in place post-pandemic. One interviewee pointed out that the COVID-19 pandemic was still continuing – "we're not out of the woods yet." (Midwest, 4000 patients) – and that adjustments were still being made. Another highlighted the fact that the regulations associated with methadone treatment have been controversial for a long time, stating "it is too early to know what changes are going to come about to change the treatment mindset of the last 50 years." (Northeast, 212 patients) Another stated, "Methadone rules haven't changed for a long time. It's time we looked at that." (Northeast, 900 patients).

Other respondents expressed some concerns with the regulatory changes, emphasizing the need to look at the impact of these changes scientifically, and not rush to judgment. One interviewee reported, "Regulations tend to start with good intents but by the time they get down to where the rubber meets the road they become bad things...I'm hoping we don't get sweeping, global regulations. Those tend to do more harm than good." (South, 1586 patients). Another interviewee stated, "We don't know how patients are going to react to extended take-homes when they are not in shelter in place... I prefer to see change with some actual evidence behind it." (Northeast, 930 patients).

3.5. Stigma associated with OUD and MAT

Although we did not include stigma as a topic or directly ask any stigma-related questions, issues relating to stigma appeared both directly and indirectly throughout the interviews. As seen in the quotes presented above, some interviewees used narrative reflecting the underlying stigma associated with OUD and MAT, sometimes characterizing patients in ways that suggest implicit discomfort and an "us and them" view of opioid users. For example, as presented above, two interviewees (both in the Midwest, one with 1075 patients and the other with 208 patients) indicated that patients were only interested in getting their medication, and not interested in speaking with their counselors. Several interviewees were not comfortable with take-home medication, with one referring to the opportunity to receive take-home medication as "giving them [patients] what they want" (Midwest, 208 patients) and another referring to methadone as "powerful medications in the wrong hand" (Northeast, 16,000 patients). Another interviewee described the decision to stop providing take-home medication with the words "so that we have eyes on them." (South, 215 patients).

Other interviewees, however, directly noted the stigma that patients experience. One (Northeast, 3000 patients) thought that methadone was overregulated, and that this reflected the underlying stigma associated with OUD and MAT. Another suggested that clinics should be careful, because liberally giving out take-home doses might lead to problems

that will ultimately increase stigma (South, 1586 patients). This same Director believes that clinicians should be able to treat OUD like any other medical condition, which would reduce stigma. Another interviewee said that their clinic allowed take-home doses up to the post-COVID state and federal limits and viewed this as a way to reduce stigma (Midwest, 1100 patients).

Several interviewees described concrete aspects of stigma that directly affect their patients, and ways to counter that stigma. One noted that the clinic was on a main street, and that the stigma associated with OUD and MAT stops some potential patients from coming to the clinic (Midwest, 200 patients). Another clinic provides ongoing training to staff in the ED and inpatient units of the hospital with which they are affiliated (Northeast, 152 patients); they report that they are making progress but that stigma has not yet been eliminated. One clinic had been planning an anti-stigma event for the community that was unfortunately canceled due to the COVID-19 pandemic (South, 220 patients).

4. Discussion

We interviewed directors of 25 OTP programs across the United States, finding that they reported a range of reactions among their staff and patients to the regulatory changes allowing increased take-home medication doses and permitting telehealth clinical visits that were instituted early in the COVID-19 pandemic. Directors also reported a range of financial impacts, largely based on the size of their programs and specific state-level regulations. While stigma was not directly addressed during the interviews, several directors used stigmatizing language to describe patients, while others talked directly about steps they were taking to reduce the stigma associated with OUD and MAT. Although we sampled across all regions of the U.S., we were unable to determine specific regional differences, most likely due to the variety of programs within each region and the strong impact of state-level regulations, which were not consistent within geographic regions.

The public health requirements of the COVID-19 pandemic to limit physical contact and the associated federal waivers expanding medication take-home options and telehealth interactions, have created dramatic changes for OTPs. Rapid changes in medication and counseling protocols were implemented to meet these requirements. The limited pre-pandemic options regarding take-home medications and frequent in-person clinic attendance, long-standing burdens of treatment participation and obstacles to enrollment in treatment, can now be examined under the aegis of an emergency, providing some preliminary guidance for possible regulatory change.

This study demonstrated some variety in reactions of patients and staff to these changes who generally, according to the program directors interviewed, were positive about the option to selectively give more take-home doses and to permit more interaction with patients via telehealth, though there were some exceptions. OTP directors made specific comments suggesting that employing less restrictive protocols would benefit patients by reducing the burden and stigma associated with being a methadone patient, an observation that others have made (e.g., Frank, 2021). Some respondents were cautious about drawing conclusions prematurely, and recommended additional experience with the emergency regulations and collecting more systematic outcome data before drawing conclusions about the advisability of retaining some or all of the emergency-inspired changes. Unfortunately, it is not clear how long these changes will remain in place, and thus how much data will be collected before federal and state governments might decide to revise, or revert to pre-pandemic, OTP regulations.

Clinics reacted very quickly to make the necessary changes, and (after an initial adjustment period and some confusion when regulatory changes were first introduced) many program directors were pleasantly surprised by how well these changes were received by both staff and patients. Although not described above, many of these changes were innovative and highly creative – providing doses in cars, developing contactless visit protocols, meeting a wide range of technology needs for

patients and staff (e.g., providing basic cell phones for patients, providing Zoom accounts for staff),(Frank, 2021) and repurposing rooms in their clinics to meet the new requirements. No clinic reported any interruption in providing medication, and only brief disruptions to individual counseling sessions. There appeared to be greater problems with group counseling with some directors reporting comparably greater difficulties implementing telehealth group counseling and patients' acceptance of this modality (although other OTP directors reported a positive response by patients).

Financial impacts varied by state, and larger treatment programs were better insulated from these impacts than smaller programs. Study data showed that OTPs are highly vulnerable to fiscal disruption while also being highly adaptable (perhaps due to years if not decades of underfunding) to disruptions. Several interviewees reported taking on additional clinical responsibilities to reduce expenses. Many reported that the ongoing opioid epidemic, driven by the consequences of the COVID-19 pandemic (social isolation, economic disruption, trauma, despair), has resulted in an ongoing supply of new OTP treatment admissions. This has helped sustain those programs whose revenues depended heavily on frequency of clinic visits. Nevertheless, the financial underpinnings of the methadone treatment system are long overdue for reform and stabilization.

The COVID-19 pandemic evolved over the course of the spring, summer and fall of 2020, and different regions of the U.S. were impacted in different ways and at different times. While our study had wide geographic representation throughout the country, interviews were conducted between June and August, and reflected the views of program directors at that time only. It is possible that, had interviews been conducted earlier or later, findings might have been different. Also, the data presented in this paper represents a subset of the overall interview topics and content. Subsequent data analyses may reveal additional important findings.

There are a number of limitations that should be noted. First, we selected interviewees based upon their personal and professional connections to SSN and its senior members, and thus this is not a representative sample of U.S. OTP programs (although our sample did include programs across the U.S.). It is possible that program directors connected to SSN had more favorable views of regulatory changes than the overall population of OTP program directors in the U.S. While interviewees were assured of confidentiality, and only the authors knew of the information provided by specific interviewees, it is unclear whether or to what extent respondents tailored their answers. Also, we decided not to record the interviews; this limited our ability to present direct quotes from the program directors. While one or two note takers were present at each interview, the number of direct quotes were limited. In taking notes, a possible unintentional bias may have resulted from the note takers having captured more negative statements, in an effort to capture the range of sentiments and because negative comments tended to be more detailed. We also did not interview patients, and therefore were unable to confirm staff perceptions of patient reactions to the topics we discussed. Finally, our study focused on OTPs (where methadone is the most frequent medication dispensed), and thus did not capture the perspectives of programs that exclusively provide other medications for OUD.

Several issues suggested by the data raise concerns. Negative remarks were made by a few interviewees regarding more flexible takehomes, often using language that reflected an "us vs. them" view of patients. Stigmatizing attitudes towards patients exist among OTP directors, and these need to be identified and reduced. Fortunately, other directors described their clinics in a way that reflected an understanding of the stigma their patients experience, and several described active efforts to reduce stigma among hospital staff and the greater community. Another issue concerns the fact that regulatory changes which permit variation in policy implementation seem most desirable. While most patients relished greater take-home allowances, some who were judged suitable clinically and given appropriate take-home doses came back

into the clinic and returned the medication, demonstrating insight into their own ability to manage these changes.

Future research will help to answer ongoing questions that were raised by the present study. Quantitative data can illustrate the extent to which methadone delivery and counseling changed, and how these changes varied over time and location. Further qualitative studies might reveal different reactions based upon the time that interviews were conducted and the state of the pandemic in the locations where the interviews took place. Finally, data collected going forward can further document the impact of the COVID-19 pandemic on people who use drugs and the programs that serve them, and the perspective of front-line treatment providers of regulatory changes over time.

5. Conclusion

In summary, this study demonstrated the generally positive view of OTP program directors to the regulatory changes necessitated by the COVID-19 pandemic. While more time is needed to fully evaluate the impact of increased take-home doses and the expansion of telehealth, the rapid and innovative responses of OTPs to the changing regulations put into place to manage the pandemic has initially had positive results. More data, including comprehensive quantitative data on relapse rates, overdose and medication diversion is needed. It is important that regulations be extended to allow these data to be collected, analyzed and disseminated. Equally important, regulatory and clinical policy studies should be implemented incorporating promising adaptations engendered by the pandemic.

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CRediT authorship contribution statement

All authors made a substantive contribution to both the study and the manuscript.

Conflict of Interest

No conflict declared.

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