



Flexibilities in Controlled Substances Prescribing and Dispensing During the COVID-19 Pandemic

KEY POINTS

- The federal government issued a range of flexibilities around telehealth, medications for opioid use disorder, licensing, and emergency prescribing to improve access to controlled substances and medications for opioid use disorder during the COVID-19 pandemic.
 - States relaxed or suspended regulations to allow for the implementation of federally-issued flexibilities, and also issued unique flexibilities related to controlled substance prescribing.
 - Flexibilities allowing for the use of telehealth for controlled substance prescribing and medications for opioid use disorder were the most common flexibilities implemented by states.
 - This brief summarizes federal and state flexibilities around controlled substance prescribing in response to the COVID-19 pandemic, enabling analysis of the impacts on prescribing and patient access.
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INTRODUCTION

The COVID-19 pandemic had wide-ranging impacts on health care delivery, particularly services that require in-person interactions. For patients needing access to medications to treat pain or certain substance use disorders (SUDs), the COVID-19 pandemic presented particular challenges for continuity of treatment. Unlike other types of medications, controlled substances used to treat pain or SUD involve higher regulatory oversight and barriers to access, such as requirements for in-person physical examinations. These include opioid medications to treat pain as well as two effective treatments for opioid use disorder (OUD), buprenorphine and methadone. Since these medications could not simply be prescribed remotely, restrictions on in-person services to reduce spread of COVID-19 therefore created barriers to access needed medications.

To ensure continued access to controlled substance medications as well as minimize exposure to COVID-19 from in-person interactions, the federal Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) issued emergency policies changing controls under the Ryan Haight Act and the Controlled Substances Act on prescribing and dispensing controlled substances. These federal flexibilities allowed states to temporarily change or waive their policies without violating federal law. States also issued their own flexibilities related to opioid and other controlled substance prescribing. The variety of flexibilities issued across states provides an opportunity to examine impacts of different flexibilities and help inform policy decisions about whether sustaining or making permanent certain flexibilities outside the COVID-19 public health emergency (PHE) could remove barriers to accessing care and improve health outcomes. For example, several studies have already explored the types of policies implemented by states to

ensure access for treatment of opioid use disorder and their impacts on patient access during the early months of the COVID-19 pandemic.^{1,2,3}

This brief summarizes federal and state flexibilities related to controlled substance prescribing implemented in response to the COVID-19 PHE between March 2020 and July 2021. Details about individual flexibilities, including source documentation, can be found in the accompanying database.

METHODS

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services (HHS) contracted with Mathematica to conduct an environmental scan of policies and regulations issued by the federal government and states intended to reduce barriers to prescribing opioids and other controlled substances during the COVID-19 pandemic. Mathematica conducted the search from May to August 2021 using Google Search. The topic areas for flexibilities are listed in Table 1. For the purposes of this environmental scan, a flexibility was defined as a distinct policy action, such as a governor’s executive orders, guidance, regulation, or law, pertaining to easing a provision related to one of the topic areas listed in Table 1.

Table 1: Topic areas for opioid and controlled substance prescribing flexibilities

- Telehealth
- Controlled substance prescribing
- Medication-assisted treatment (specifically medications for opioid use disorder (MOUD), for the purposes of this issue brief)
- Emergency prescribing of controlled substances
- Refills, days supplied, and dosing for controlled substance prescriptions
- Licensing and registration requirements
- Naloxone co-prescribing

Federal flexibilities were identified by searching for relevant documents published by DEA and SAMHSA on the agencies’ websites. These included guidance documents issued by the agencies and documents answering frequently asked questions.

State flexibilities were identified using a search strategy based on the flexibility topic areas listed in Table 1. Two strategies guided the search for state flexibilities. The first strategy focused on identifying state flexibilities that related to the flexibility topic areas identified in Table 1. Search terms for flexibilities included “controlled substances”, “telehealth”, “telemedicine”, “medication assisted treatment”, “opioid”, “buprenorphine”, “methadone”, “naloxone”, “take home doses”, “opioid treatment program”, “narcotic treatment programs”, “e-prescribing”, “exceptions to emergency schedule II prescriptions”, “schedule II, III, IV, V prescriptions”,

¹ Guyer, J. and Scott, K. (2020). State Strategies For Helping Individuals With Opioid Use Disorder Through The COVID-19 Epidemic. *Health Affairs Blog*. Available at <https://www.healthaffairs.org/doi/10.1377/hblog20200429.476954/full/>. Accessed August 27, 2021.

² Andraka-Christou, B., Bouskill, K., Haffajee, R., Randall-Kosich, O., Golan, M., Totaram, R., Gordon, A., Stein, B. (2021). Common themes in early state policy responses to substance use disorder treatment during COVID-19. *American Journal of Drug and Alcohol Abuse* 47 (4), 486-496. doi: 10.1080/00952990.2021.1903023

³ Amram, O., Amiri, S., Panwala, V., Lutz, R., Joudrey, P., Socias, E. (2021). The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. *The American Journal of Drug and Alcohol Abuse* 47(6), 722-729. doi: 10.1080/00952990.2021.1979991

“days’ supply”, “dosing”, “early refills”, and “DEA registration”. In addition to the search terms used to describe flexibilities, the search strategy also included “COVID-19” and “policies”, “waivers”, or “guidance” to try to limit results to flexibilities related to the PHE. Resources provided by professional organizations that consolidated information for state-level flexibilities and contained links to state documentation^{4,5,6,7,8,9,10,11} were used to supplement the results of the search.

The second strategy for identifying state flexibilities utilized a second, broader search using the following combinations of terms: “[state]” and “COVID-19” and “controlled substance”. This search identified other state-specific flexibilities that the first search strategy might not have captured. Documents that described flexibilities included guidance for practitioners published on state agency and government websites (for example, web pages for the state medical board, pharmacy board, emergency management, public health department, health and social services department, Medicaid website, governor's office, and behavioral health authority), policy statements and executive orders, lists of frequently asked questions about flexibilities, and legislation. While this two-step approach was designed to be as thorough as possible, it is possible that the search did not identify all instances of flexibilities implemented by the states.

Flexibilities were included if they met the following criteria:

- Documentation showed evidence that the state made a policy or regulation change during the period of the COVID-19 PHE, whether it was specifically linked to the PHE or not.
- Documentation of the flexibility was publicly available.
- The flexibility’s language referenced controlled substance prescribing or dispensing.

The results of the federal and state searches were incorporated into a database that captures details about federal and state opioid and controlled substance flexibilities using information from publicly available documentation. The database includes information about the terms of the flexibility, reference to the original policy in federal or state laws, actions taken to enact or terminate flexibilities, dates of enactment and expiration when available, target patient population, and target providers. The scope of the search did not include determining whether states made flexibilities permanent, which would require a more substantial targeted search to find each state’s relevant legislation; however, where the search did identify this information, it is included in the database. The search did not involve legal databases, so technical or codified components were not tracked or verified. The database also includes high-level tags, including telehealth, controlled substances, buprenorphine, methadone, naloxone, opioids, licensing, linked services, refills, days’

⁴ Federation of State Medical Boards (2021). U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19. Available at <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>. Accessed August 12, 2021.

⁵ Center for Connected Health Policy (2021). Easing Prescribing Requirements. Available at <https://www.cchpca.org/topic/easing-prescribing-requirements/>. Accessed August 12, 2021.

⁶ American Psychiatric Association (2021). Practice Guidance for COVID-19. Available at <https://www.psychiatry.org/psychiatrists/covid-19-coronavirus/practice-guidance-for-covid-19>. Accessed August 12, 2021.

⁷ Kaiser Family Foundation (2021). State COVID-19 Data and Policy Actions. Available at <https://www.kff.org/report-section/state-covid-19-data-and-policy-actions-policy-actions/#policyactions>. Accessed August 12, 2021.

⁸ American Society for Addiction Medicine (2020). COVID-19 National and State Health Guidance. Available at <https://www.asam.org/Quality-Science/covid-19-coronavirus/national-and-state-guidance>. Accessed August 12, 2021.

⁹ National Council of State Boards of Nursing (2021). State Response to COVID-19 (APRNs). Available at https://www.ncsbn.org/State_COVID-19_Response.pdf. Accessed August 12, 2021.

¹⁰ American Psychological Association (2021). Telehealth Guidance by State During COVID-19. Available at <https://www.apaservices.org/practice/clinic/covid-19-telehealth-state-summary>. Accessed August 12, 2021.

¹¹ Healthcare Ready. COVID-19 Patient Resources – Prescriptions. Available at <https://healthcareready.org/covid19-patient-resources/meds/>. Accessed August 12, 2021.

supply, and e-prescribing. The database also includes current-as-of dates for each flexibility, reflecting when information was extracted and entered into the database. Documents often included multiple flexibilities, and in those cases, each flexibility is listed separately.

The search used in this study was limited in scope to the terms described above and may not include all flexibilities that pertain to controlled substance prescribing or delivery of MOUD. This search only identified state flexibilities for which documentation of state action could be found. This does not necessarily mean that the state did not implement a given flexibility, because not all flexibilities may have required state action to implement. Further discussion of the limitations is found at the end of the issue brief.

RESULTS

Federal Flexibilities

DEA and SAMHSA issued a range of flexibilities related to opioid and controlled substance prescribing. These flexibilities included the use of telehealth for prescribing or consultation related to controlled substances; increased take-home doses of medications for opioid use disorder¹² (MOUD); alternative delivery options for MOUD; exceptions for emergency oral prescriptions; and registration requirements. These federal flexibilities are listed in more detail in Table 2. All of the identified federal flexibilities were issued between March and July 2020. While some of the flexibilities below will expire when COVID-19 PHE issued by the U.S. Department of Health and Human Services¹³ ends, the documentation did not provide end dates for all of these flexibilities.

Table 2: Summary of opioid and controlled substance prescribing flexibilities issued by federal agencies, as of August 12, 2021

Flexibility category	Flexibility descriptions
Telehealth	DEA-registered practitioners may issue prescriptions for all schedule II-V controlled substances for whom they have not conducted an in-person medical evaluation, provided certain conditions are met.
	Practitioners may prescribe buprenorphine via telehealth for new and existing patients, waiving the requirement for an in-person physical evaluation for new patients.
	Practitioners may continue treating an existing patient of an opioid treatment program with methadone via telehealth.
Controlled substance dispensing	Health care providers may dispense controlled substances in provider parking lots.
Medications for opioid use disorder	Opioid treatment programs (OTPs) may utilize alternative delivery methods of take-home medications for patients quarantined due to COVID-19, including “doorstep” delivery in a locked box and delivery by a wider range of personnel.

¹² This issue brief uses the terminology “medications for opioid use disorder (MOUD)” throughout. The search conducted in 2021 used medication-assisted treatment, or MAT, rather than MOUD.

¹³ Pursuant to Section 319 of the Public Health Service Act.

	States may request a blanket exception for all stable patients in an OTP to receive up to 28 days of take-home medication. ¹⁴
	States may request a blanket exception for less stable patients in an OTP to receive up to 14 days of take-home medication, if the OTP believes these patients can safely handle this level of take-home medication. ¹⁵
	OTPs may regularly use of off-site locations to deliver take-home doses of methadone or buprenorphine without separate registration.
Licensing and registration requirements	Practitioners are not required to obtain separate Drug Enforcement Administration (DEA) registration to dispense controlled substances (including prescribing and administering) outside home state, including via telehealth.
Emergency prescribing	Practitioners have 15 days (as opposed to 7) to send a follow-up written prescription when orally prescribing schedule II controlled substances.
	Practitioners can send the follow-up written prescription via facsimile, photograph, or scan.

Note: Unless otherwise specified, these flexibilities are scheduled to end with the termination of the COVID-19 PHE. States could implement these flexibilities without additional policy action, to the extent that these flexibilities were allowable under state law.

State Flexibilities

State flexibilities were identified in 35 states. Many state flexibilities fell into similar categories as the federal flexibilities identified in Table 2, including state policy actions to allow implementation of the corresponding federal flexibility. Most of these flexibilities were issued between March and June 2020, but a small number of flexibilities were issued in 2021. Some state flexibilities have already expired; many were linked to the federal or state PHE.

Telehealth to prescribe controlled substances and MOUD

Telehealth-related flexibilities were generally aligned between federal and state flexibilities. Federal agencies issued specific flexibilities for the use of telehealth by schedule of controlled substances. State-issued flexibilities relating to telehealth often suspended regulations to align with the federal flexibilities. Telehealth flexibilities were the most common type of flexibilities enacted by states; 15 states took action to allow telehealth for the prescribing of controlled substances.

¹⁴ SAMHSA has extended this flexibility for one year after the end of the COVID-19 public health emergency and has indicated plans to publish a notice of proposed rulemaking to make this flexibility permanent. <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance#:~:text=On%20March%2016%2C%202020%2C%20SAMHSA,14%20days%20of%20Take%2DHome>

¹⁵ SAMHSA has extended this flexibility for one year after the end of the COVID-19 public health emergency and has indicated plans to publish a notice of proposed rulemaking to make this flexibility permanent. <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance#:~:text=On%20March%2016%2C%202020%2C%20SAMHSA,14%20days%20of%20Take%2DHome>

Medications for opioid use disorder

Federal regulations generally limit the number of take-home doses that an opioid treatment program (OTP) can provide based on the patient's time in treatment and other conditions such as recent drug use, consistency of clinic attendance, behavioral health problems, stability of home environment, recent criminal activity, and safe storage of take-home doses.¹⁶ The federal flexibilities allowed states to request blanket exceptions that permitted up to 14 days of take-home doses for less-stable clients and up to 28 days of take-home doses for stable clients. Although the search found evidence that OTPs in many states utilized these flexibilities, most states did not need to take any policy actions (i.e., suspending regulations) to implement these flexibilities. In fact, researchers have noted that the majority of states requested the required exemption from SAMHSA, despite a lack of public-facing documentation.¹⁷ Our study identified three states (Hawaii, Massachusetts, and Pennsylvania) that suspended or waived existing regulations to allow for implementation of this flexibility; however, the lack of documentation for other states does not mean that they did not use this flexibility.

Federal flexibilities also established alternative options for home delivery of MOUD. DEA also allowed controlled substances to be dispensed in prescriber parking lots. States did not issue any unique flexibilities relating to home delivery of MOUD, although some imposed additional requirements such as the inclusion of naloxone for doorstep deliveries. Other dispensing-related flexibilities issued by states included allowing other provider types, such as pharmacists and registered nurses, to prescribe, administer, or dispense MOUD.

Emergency oral prescribing for Schedule II controlled substances

The Controlled Substances Act does not allow pharmacists to dispense Schedule II controlled substances without a written or electronic prescription except in emergency situations, which are determined by the following: a provider deems that Schedule II controlled substances are medically necessary, alternatives to Schedule II medications are not available, and it is not possible for the provider to provide a written prescription.¹⁸ Under these circumstances, a prescription may be conveyed orally to pharmacists.

Federal flexibilities allowed 15 days for follow-up with submission of a written prescription by fax, photo, or scan for Schedule II prescriptions that are conveyed orally to pharmacists. States issued flexibilities to allow the implementation of these exceptions for oral Schedule II medications. Two states issued additional flexibilities regarding emergency oral prescribing: both Mississippi and New Jersey allowed 30 days' supply of oral Schedule II prescriptions.

Refills, days supplied, and dosing of controlled substances

Although there were not any federal flexibilities relating to refills or days supplied of controlled substances, several states issued unique flexibilities to address these issues. These included allowing state Medicaid programs to cover early refills or a larger number of days supplied and allowing mid-level providers or pharmacists to refill prescriptions for controlled substances under certain circumstances.

¹⁶ 42 CFR § 8.12(i)(2)

¹⁷ McIlveen, J., Hoffman, K., McCarty, D. (2022). State policy uptake does not require formal action: A comment on Nesoff et al. *Addiction*. doi: 10.1111/add.15886

¹⁸ McDermott, W. (2020). Practitioner Registrants and Pharmacists. Available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-021\)\(DEA073\)%20Oral%20CII%20for%20regular%20CII%20script%20\(Final\)%20+Esign%20a.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-021)(DEA073)%20Oral%20CII%20for%20regular%20CII%20script%20(Final)%20+Esign%20a.pdf). Accessed April 26, 2022.

Licensing requirements

The federal flexibility waived licensing requirements for DEA-registered practitioners to obtain additional DEA registrations for each additional state in which they dispense or prescribe controlled substances, including via telehealth. Several states issued similar flexibilities to waive state registration requirements.

DISCUSSION

This environmental scan focused on changes to controlled substance prescribing in response to the COVID-19 pandemic. The search identified a wide range of federal and state flexibilities related to the use of telehealth for controlled substance prescribing and medication management; prescriptions or take-home doses for a greater number of days; and strategies for access to MOUD when OTPs were closed, such as dispensing medication in clinic parking lots and home delivery. Although some states took action to allow implementation of federal flexibilities, it was beyond the scope of this study to determine if states that did not take action were able to implement the federal flexibilities within the constraints of their existing regulations. However, in addition to allowing for the implementation of federal flexibilities, states also implemented a range of unique flexibilities to enhance patient access. In some cases, variation in the types of flexibilities issued by states may indicate differing approaches for addressing these issues during COVID-19 and may have had implications for access to controlled substances and MOUD.¹⁹

Variations in the flexibilities issued by states also provide an opportunity to compare the impact of specific policy decisions. For example, some states have flexibilities that require payment parity for telehealth and in-person services, or that require parity with some restrictions.²⁰ Some states explicitly included audio-only telehealth as an option for their telehealth-related flexibilities, but others did not specify or did not include audio-only telehealth. A survey conducted between March and November 2020 found that 62 percent of substance use treatment facilities that provide MOUD reported frequently using telehealth, but states varied considerably in the frequency of use.²¹

Many flexibilities were specifically linked to federal or state PHEs. For state flexibilities that would be permissible under federal law, additional state action is required to make some flexibilities permanent, such as changes to state licensure codes and regulations. Many states terminated their public health emergencies in 2021 or 2022, meaning that many of these flexibilities have likely been rolled back. Similarly, although the federal flexibilities exist as long as the COVID-19 PHE remains in place, additional federal action is required to make flexibilities permanent. Without regulatory change, the termination of the COVID-19 PHE could result in reduced access to treatment, especially for those in medically underserved areas. However, federal agencies have signaled the extension of at least one COVID-19 flexibility – SAMHSA has already extended its flexibility regarding take-home dosing for one year beyond the end of the COVID-19 PHE,²² citing evidence that this

¹⁹ Guyer, J. and Scott, K. (2020). State Strategies For Helping Individuals With Opioid Use Disorder Through The COVID-19 Epidemic. *Health Affairs Blog*. Available at <https://www.healthaffairs.org/doi/10.1377/hblog20200429.476954/full/>. Accessed August 27, 2021.

²⁰ Augenstein, J., Marks, J., Peng, A., and Andrade, M. (2021). Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19. Available at <https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat>. Accessed August 27, 2021.

²¹ Karmali, R., Manteuffel, B., and Agufa, J. (2021). "Availability of Clinical, Counseling, and Ancillary Services in Facilities that Provide Medications for opioid use disorder for Opioid Use Disorder." Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, May 2021. Available at https://www.mathematica.org/-/media/publications/pdfs/health/2021/availability-of-services_final.pdf. Accessed August 27, 2021.

²² SAMHSA (2022). Methadone take-home flexibilities extension guidance. Available at: <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance>. Accessed April 21, 2022.

flexibility has enhanced and encouraged use of OTP services with few incidents of misuse or medication diversion,²³ and a notice of proposed rulemaking to make this flexibility permanent is expected later this year.²⁴ This example emphasizes the importance of exploring the ways in which policy changes enacted during COVID-19 might also be able to enhance patient access outside of the PHE.

LIMITATIONS

The search used in this study was limited in scope to the terms described in the Methods and may not include all flexibilities that pertain to controlled substance prescribing or delivery of MOUD. For example, the search strategy and database do not cover flexibilities specific to insurance coverage, billing, or prior authorizations for telehealth services.

This search only identified state flexibilities for which documentation of state action could be found. This does not necessarily mean that the state did not implement a given flexibility, because not all flexibilities may have required state action to implement. For example, certain emergency flexibilities may already be included in state policy for other emergency conditions, and a state did not need to issue an executive order or agency guidance about a state-implemented flexibility specific to the COVID-19 PHE. In addition, this search strategy specifically focused on identifying flexibilities established because of the COVID-19 PHE. Some states might have enacted legislation or released guidance related to controlled substance prescribing that did not explicitly reference COVID-19, which meant that the search did not capture them. Therefore, the lack of an entry in the database for a given flexibility should not be assumed to mean that the flexibility was not available in the state.

Furthermore, the search strategy did not include a targeted search of state legislation. Therefore, while the search captured some relevant legislation, the database is not comprehensive and does not reflect all pertinent legislation that may have been passed to prevent expiration of these flexibilities as states began to terminate their public health emergencies.

CONCLUSION

The federal government and states issued numerous flexibilities during the COVID-19 PHE related to controlled substance prescribing. These flexibilities may have improved access to care for some patients, but gaps in access to care could remain or be exacerbated when the COVID-19 PHE ends or when flexibilities are discontinued. Experiences with these flexibilities over the last two years may provide insight into their impact on quality of care and patient access.

²³ Amram, O., Amiri, S., Panwala, V., Lutz, R., Joudrey, P., Socias, E. (2021). The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. *The American Journal of Drug and Alcohol Abuse* 47(6), 722-729. doi: 10.1080/00952990.2021.1979991

²⁴ SAMHSA (2022). Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone in the Unified Regulatory Agenda. Available at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0930-AA39>.

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