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Medications for Opioid Use Disorder during COVID-19

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In response to the intersecting risks of COVID-19 and the worsening overdose crisis, key regulations governing opioid agonist therapies (OAT) have been loosened by Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Agency (DEA). These changes were desperately needed as opioid users are at heightened risk for both COVID-19 infection and overdose due to a host of medical, legal and structural reasons. This document outlines guidance provided to OAT prescribers, treatment programs and clinics.[1] It also covers, in collaboration with Legal Action Center, important changes concerning 42 CFR Part II and HIPAA and the expanded use of telehealth.

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1. Confidentiality and the use of telehealth

The National Consortium of Telehealth Resource Centers defines telehealth as "the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration."

- Some providers of telehealth for medication for opioid use disorder (MOUD) are required to comply with 42 CFR Part 2 (Part 2), which governs confidentiality of substance use disorder (SUD) treatment records. Nearly all are required to comply with HIPAA.
- 42 CFR Part 2 changes:
  - Part 2 normally requires that OAT patients provide written consent to allow their provider to collect and disclose identifying information and SUD treatment records to other medical providers.
  - Providing written consent, however, can be challenging during COVID-19, if people are sheltering in place and signatures cannot be obtained electronically or via regular mail.
  - To facilitate communication between OAT prescribers and other medical personnel during COVID-19, SAMHSA has provided guidance encouraging broader use of the "medical emergency" exception. This exception permits disclosure to medical personnel without written patient consent for a bona fide medical emergency, when written consent cannot be obtained.

1. There were no regulatory changes made in relation to naltrexone prescribing.

- SAMHSA guidance for COVID-19 emphasizes that telehealth providers may make their own determinations whether a bona fide medical emergency exists for purposes of providing needed treatment to patients. This guidance indicates that remote treatment during COVID-19 may satisfy the medical emergency exception if patients cannot sign a consent form remotely.
- Providers, however, may not use the medical emergency exception to override a patient's objection to the disclosure, or to make disclosures to third-party payers, court officials, or anyone other than medical personnel.
- Providers also must document certain information in their records after a disclosure under the medical emergency exception.

- HIPAA changes:
  - The Office for Civil Rights of the Department of Health and Human Services has stated that during the COVID-19 public health emergency, it will not enforce violations of HIPAA that arise out of good-faith use of telehealth, such as the use of non-compliant platforms like FaceTime, Zoom, and Skype for telehealth appointments. This does not apply to public-facing platforms like TikTok, Facebook Live, and Twitch, which should not be used.
  - Privacy and security violations of HIPAA may still be subject to enforcement by state Attorneys General and private parties.
- Note: telehealth policy and reimbursement varies further state-to-state.

2. Buprenorphine

- **Challenge:** COVID-19 risks associated with in-person visits for initial consultations and/or weekly or bi-monthly evaluations and prescription refills.
- **Virtual induction:** From the DEA's updated guidance, "practitioners may prescribe controlled substances to patients using telemedicine without first conducting an in-person evaluation during this public health emergency under 21 U.S.C. 802(54)(D). (As of March 31, 2020) the DEA notes that practitioners have further flexibility during the nationwide public health emergency to prescribe buprenorphine to new and existing patients with OUD via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine." With respect to using non-HIPAA compliant platforms, "the Office for Civil Rights (OCR) at the U.S Department of Health and Human Services (HHS) announced, effective immediately, that it will exercise its enforcement discretion and will waive potential penalties for HIPAA violations against health care providers that serve patients through everyday communications technologies during the COVID-19 nationwide public health emergency."
- **Increased take-home doses:** As per SAMHSA's updated guidance, "the state may request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder. The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication." More on SAMHSA's criteria for "stability" here.
- **Delivery:** Can be dispensed to a "trustworthy, patient-designated, uninfected member of the household" for delivery to the "ultimate user" or the OTP can prepare a "doorstep" delivery.
- **Limitations:** In most jurisdictions, there are not enough waivered providers to meet the demand. Even with eased regulations, access remains challenging.

3. Methadone

- **Challenge:** COVID-19 risks associated with in-person visits for initial consultations, daily observed dosing, counselling, drug testing, and/or weekly or bi-monthly evaluations and prescription refills.
- **Virtual induction:** SAMHSA still requires induction to be conducted in person.
- **Increased take-home doses:** As per SAMHSA's updated guidance "The state may request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder. The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication."
- **Delivery:** Can be dispensed to a "trustworthy, patient-designated, uninfected member of the household" for delivery to the "ultimate user" or the OTP can prepare a "doorstep" delivery.
- **Limitation:** In-person consultation still required to initiate treatment; most new patients will not meet the "stability" criteria for take-homes; excludes patients on short-term or interim treatment.