

# Telemedicine and Opioid Use Disorder: Regulatory Changes and Evidence

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# Disclosures

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No conflicts of interest or relationships to disclose.

# Outline

- Describe regulatory changes concerning the provision of telemedicine-delivered care for opioid use disorder in the wake of the COVID pandemic.
- Review current evidence base for Telemedicine treatment of OUD.

# Case

- You are working from home via telehealth to maximize social distancing. Your next patient is a 64 year old man, new to your practice, with well-controlled HIV and moderate COPD, who has been using heroin for the past 18 months and is interested in treatment.

# Regulatory Changes

# Regulatory changes

## Timeline Relevant to Telehealth and COVID-19

<b>January 20, 2020</b> First Confirmed Case of COVID-19 in the U.S. (Washington)	<b>January 31, 2020</b> HHS Secretary declares Public Health Emergency (retro to Jan 27)	<b>March 11, 2020</b> WHO names Outbreak a Pandemic	<b>March 13, 2020</b> President declares a National Emergency
<b>March 13; March 17; April 30, 2020</b> CMS issues Regulatory Waivers	<b>March 16, 2020</b> DEA waives in-person exam requirement before Rx controlled sub.	<b>March 17, 2020</b> HHS OCR HIPAA Enforcement Discretion	<b>March 19, 2020</b> SAMHSA exempts OTPs from in-person exam for BUP Rx and dispensing
<b>March 30; April 30, 2020</b> Medicare Telehealth Coverage Interim Final Rules	<b>March 31, 2020</b> DEA Guidance on Phone for BUP Rx during PHE	<b>April 21, 2020</b> SAMHSA updates Guidance for Methadone and BUP during PHE	<b>April 26, 2020</b> HHS renews PHE (through July 25)

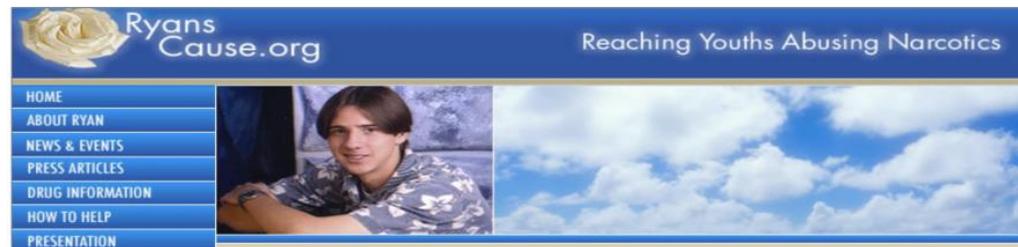


Opioid  
Response  
Network  
STR-TA

# Regulatory Changes: Controlled Substances

## BC: Before COVID

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 amended the controlled substance act.



- Requires, before the prescribing of a controlled substance, **at least one in-person medical evaluation** of the patient.
- There are seven “telehealth exceptions” to the above, but they are generally narrow and technical.

# Regulatory Changes: Controlled Substances

## AC: After COVID

- One exception is during a federally declared Public Health Emergency.
- DEA gave explicit guidance on March 16<sup>th</sup> that registered practitioners could prescribe controlled substances without an in-person examination if:
  - Prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice
  - **Communication conducted using an audio-visual, real-time, two-way interactive communication system.**
  - Acting in accordance with federal and state law.

# Regulatory Changes: Controlled Substances

## AC: After COVID

- On March 31, 2020, DEA provided additional guidance: During Public Health Emergency, authorized practitioners can prescribe buprenorphine to new and existing patients with OUD **via telephone** without first conducting an examination in-person or via Telemedicine if
  - Prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice
  - If an adequate evaluation can be accomplished via telephone.

# Regulatory Changes: CMS Reimbursement

- **BC:** For Medicare, patient had to live in a rural health professional shortage area and had to be seen at a local medical facility to get telehealth services. For Medicaid and commercial insurance, it was a patchwork.
- **AC:** CMS expands Telehealth. Removal of geographic and originating site restrictions (beneficiary can be in their home). Reimbursement same as in-person FFS rate. Phone visit rates increased. Expanded payable service codes (more than 90).

# Regulatory Changes: HIPAA

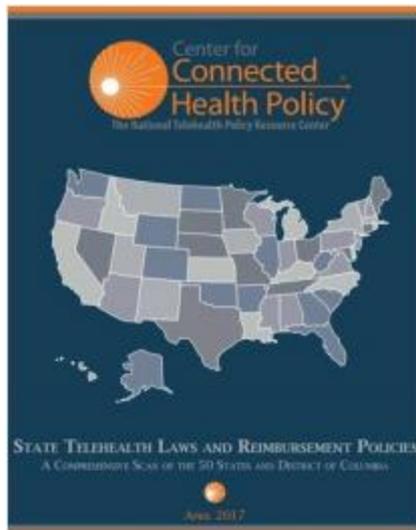
- **BC:** HIPAA compliant platform requires fully encrypted data transmission with contractual assurances that third parties will also followed rules around HIPAA (Business Associate Agreement)
- **AC:** On March 17<sup>th</sup>, HHS Office for Civil Rights: OCR will not impose penalties for nonadherence with regulatory requirements under HIPAA in connection with good faith provision of telehealth during public health emergency.

# Regulatory Changes: Others

- 42 CFR Part 2: SAMHSA issued guidance that restrictions on use and disclosure of patient identifying information would not apply in situations of a medical emergency determined by the clinician.
- SAMHSA allow Opioid Treatment Programs to provide up to 28 days of take-home medications for stable patients and up to 14 days for less stable patients.
- DEA granted an exception to the requirement that practitioners obtain additional registration with DEA in the additional state(s) where the dispensing (including prescribing and administering) occurs, for the duration of the public health emergency

# Regulatory Changes: State Laws

- State-specific laws may impact questions around controlled substance prescribing, reimbursement, security requirements, and licensure.
- Some states may have laws which are more stringent.



<https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies>



U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19  
(Out-of-state physicians; preexisting provider-patient relationships; audio-only requirements; etc.)

Last Updated: November 20, 2020

<https://www.fsmb.org/siteassets/advocacy/pdf/state-s-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>



# Evidence

# Telehealth for chronic disease management

- Numerous studies and reviews have examined the effectiveness of telemedicine-delivered psychotherapy and medication treatment for several mental health disorders, including depression, PTSD, dementia.
- Generally show no less effective vs. in-person treatment and associated with high patient satisfaction.<sup>1</sup>
- Interest in Telehealth for OUD, given the effectiveness of treatment and the poor penetrance of evidence based treatments, particularly in rural areas.
- Adoption of Telemedicine for SUD care has been limited (among patients with commercial insurance, less than 0.1% of all SUD visits from 2010-2017).<sup>2</sup>

# Telehealth for OUD: Systemic Review

- Systematic Review published in Journal of Substance Abuse Treatment in 2019: Examined manuscripts from 1998-2018. All SUDs. Meds and/or psychotherapy.
- 13 studies: 3 for tobacco, 5 for alcohol, 5 for OUD.

# OD: Psychotherapy

- 2 randomized studies focused on telemedicine for psychotherapy (for patients on methadone maintenance)
- Small sample sizes (37 and 59)
- No difference in number of sessions attended or percent of drug positive urines. No difference in patient or therapist ratings of therapeutic alliance.

# OD: Medication management

- 3 retrospective, non-randomized studies.
- In all studies, patient was at remote or rural clinic, and treating physician at distant site. Other components of care included urine toxicology screens and (often intensive) counseling.
- Large study (3733) in Ontario, Canada, among methadone patients found telemedicine group was more likely to be retained in treatment at one year than those receiving primarily in-person visits.
- Maryland study among buprenorphine patients: Greater than 50% retention with telemedicine (no comparison groups).
- West Virginia Study among 100 buprenorphine patients found no difference in time to abstinence or 90 and 365 day retention.

# Conclusions of systematic review

- Evidence for telemedicine is robust for certain chronic mental health disorders, but limited number of studies in SUDs.
- Some indicators of comparable therapeutic alliance and retention in care, though small sample sizes and no non-inferiority studies conducted.
- Need more data on telemedicine to people's homes and on quality and outcomes of telemedicine treatment.
- “Telemedicine-delivered treatments are a promising alternative” when in-person visits are not readily available.

# Remaining barriers

- Adhering to state laws
- Uncertainty about whether new regulations will last
- If, when, and how to use urine toxicology testing
- How to treat patients who may require a higher level of care
- Lack of clinical guidelines on high quality practices
- Patients without access to wifi/smartphone

# Take Home points

- Telemedicine-delivered care for opioid use disorder is understudied, but current evidence suggests similar efficacy in terms of retention in care and establishment of therapeutic relationship.
- A slew of emergency regulatory changes have made it easier to treat OUD via telehealth, including making it possible to prescribe buprenorphine to a new or existing patient via telehealth or telephone encounter.
- Barriers to uptake remain, but potential exists to expand safe access to treatment during a period of increased risk for people with substance use disorders.

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# Resources

- Pcssnow.org: Modules on Telehealth
- ASAM COVID-19 Task Force Recommendations
  - Supporting Access to Telehealth for Addiction Services
- SAMHSA COVID-19: <https://www.samhsa.gov/coronavirus>  
Drug Enforcement
- DEA COVID-19 Information Page:  
<https://www.dea.gov/diversion.usdoj.gov/coronavirus.html>

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