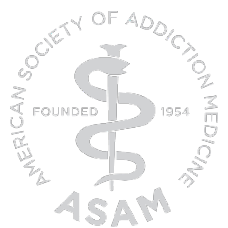
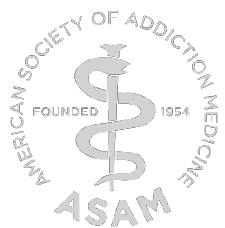




ASAM American Society *of*
Addiction Medicine



ASAM, founded in 1954, is a professional medical society representing over 7,400 physicians, clinicians and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction.



Optimizing Telehealth Access to Addiction Care

ASAM Public Policy Statement*



**This policy statement is endorsed by the American College of Academic Addiction Medicine, the American College of Medical Toxicology, and the American Osteopathic Academy of Addiction Medicine.*

AGENDA

01 – **Background**

02 – Recommendations



ASAM Supports Policies That Increase Telehealth Access to Evidence-Based Addiction Care

- **ASAM is deeply committed to ensuring every person with substance use disorder (SUD) has access to high-quality, full-spectrum addiction care and to closing the addiction treatment gap.**
 - This includes advocating for optimizing telehealth access and utilizing it to advance health equity in addiction medicine.
- **ASAM strongly supports policies that increase telehealth access to evidence-based addiction care, including the use of addiction medications.**

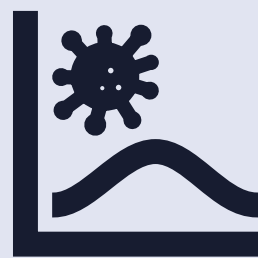


If policymakers and the medical community are not careful, however, telehealth policy related to addiction care may exacerbate existing health disparities, if complex or relatively expensive technologies are required to meet the standard of care.

COVID-19 Pandemic Was a Turning Point for Telehealth Access to Addiction Care

Telehealth for addiction care grew more slowly than it did for other types of medical care before the onset of COVID-19 and was limited by longstanding obstacles including lack of clinician comfort with telehealth, laws and regulations, reimbursement restrictions, and licensing requirements.

The COVID-19 pandemic catalyzed sweeping changes that brought telehealth beyond where it was previously underutilized or prohibited.



- Telehealth became a valuable tool for more addiction clinicians, providing greater access and convenience for patients, and was associated with improved addiction treatment retention and lower odds of medically treated overdose.

Telehealth Terms and Definitions and Toxicology Testing

Synchronous telehealth is live, real-time interaction between patient and clinician; asynchronous telehealth is often called “store and forward,” and allows patients and clinicians to share information before or after appointments.

- Telehealth modalities include audio-visual and audio-only, which are both synchronous communications.



Ancillary services, such as drug testing (toxicology), are often provided asynchronously with telehealth-delivered addiction care.

Some ancillary services are more easily provided with remote technology, such as oral fluid-based or monitored breathalyzer tests.

Laws and Regulations Have Limited the Use of Telehealth to Prescribe Controlled Medications

The Ryan Haight Online Pharmacy Consumer Protection Act (the Ryan Haight Act) of 2008 was intended to curb internet pharmacies.



- With limited exceptions, the Ryan Haight Act requires an in-person medical evaluation prior to a clinician's prescription of a controlled medication.

There are seven “practice of telemedicine” exceptions to the Ryan Haight Act’s in-person evaluation requirement; one relates to a declared public health emergency (PHE).

Those Legal and Regulatory Limits Contribute to Significant Geographic Variability in People with Opioid Use Disorder's (OUD) Access to Addiction Medications

<14%

People with OUD receive addiction medications nationally.

- People who are racially or ethnically minoritized with OUD are less likely to be offered the standard of care, especially buprenorphine, and are more likely to live in communities with a higher prevalence of methadone-based care.

While it is a highly effective opioid agonist treatment for OUD, methadone's availability is largely limited to highly regulated opioid treatment programs (OTPs) with strict requirements.

Improved telehealth access to addiction medication, including buprenorphine, has the potential to reduce disparities and increase access to care overall.

Emergency Federal Actions Increased Telehealth Access to Addiction Medications During the COVID-19 PHE



The Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) allowed temporary regulatory flexibility for the initiation of buprenorphine for OUD by audio-only telephone, including at OTPs.

- In March 2022, the DEA announced it “was working to make temporary regulations allowing medication-assisted treatment to be prescribed by telemedicine permanent.”

SAMHSA announced a one-year, post-PHE extension of its OTP exemption for an in-person physical evaluation for buprenorphine treatment for OUD, which has provided more time for SAMHSA to promulgate regulations to make this OTP flexibility permanent.



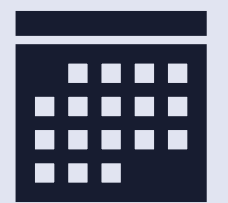
- SAMHSA still requires an in-person evaluation of a person with OUD to initiate methadone at OTPs.

Stakeholders Have Long Awaited Actions by Federal Agencies to Implement Regulations That Would Increase Telehealth Access to Addiction Medications

In 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (the SUPPORT Act) directed the U.S. Attorney General, in consultation with the Secretary of Health and Human Services (HHS), to issue final regulations to implement the “special registration” “practice of telemedicine” exception under the Ryan Haight Act.

While no such regulations have been promulgated to date, in March 2022, the DEA submitted a proposed rule to the Office of Information and Regulatory Affairs (OIRA), indicating those proposed regulations were under review at the Office of Management and Budget (OMB).

The Unified Agenda has noted an expected notice of proposed rulemaking (NPRM) for August 2022.



Federal agencies’ delay in the Ryan Haight Act-related rulemaking may be associated with an environment that is increasingly impeding clinicians’ medical discretion to treat patients with OUD with addiction medication.

The DEA's Actions During the COVID-19 PHE Have Allowed Telehealth-Initiated Prescribing of Controlled Medications Beyond Buprenorphine for OUD

During this time, the U.S. Justice Department, and the Federal Trade Commission (FTC) have initiated investigations of at least one telehealth provider with clinicians prescribing controlled medications for mental health conditions.

- Payers and pharmacies have ceased relations with certain telehealth companies with clinicians prescribing controlled medications.



The HHS Office of the Inspector General (OIG) has advised clinicians of potentially fraudulent telehealth arrangements, such as those that paid clinicians “a fee that correlated with the volume of federally reimbursable items or services ordered or prescribed.”

- Some national pharmacy chains may be becoming increasingly cautious about dispensing any controlled medication prescribed through telehealth for patients who have not had an in-person visit.

Therefore, telehealth-based prescriptions for controlled medications may now be subject to increased scrutiny by pharmacists, including buprenorphine for OUD. In some cases, pharmacists may be refusing to dispense buprenorphine prescribed through telehealth or requiring verbal confirmation from the prescriber.

- Some pharmacists' discomfort dispensing buprenorphine may be due to concerns about potential diversion (and may be partially alleviated with increased communication with prescribers).

A Lack of Broadband Access Constrains At Least 21 million People's Access to Audio-visual Telehealth in the U.S.

Infrastructure barriers often limit the digital inclusion of individuals who are marginalized and minoritized, including barriers to technology, device ownership, and digital literacy.

- Socioeconomic factors, including age, limited English proficiency, and social isolation have a disparate impact across communities and affect people's ability to engage with addiction medicine by telehealth.
- Black and lower-income people are more likely to engage in audio-only, rather than audio-visual visits, compared to White and higher-income people.

Investments in infrastructure, individual technological capacity, and telehealth readiness are a public health policy problem.

- The U.S. Congress has promoted digital inclusion through broadband infrastructure investment and initiatives to increase digital access and expand digital literacy.
- Federal agencies are also acting to reduce barriers to digital inclusion, for example, by promoting practices at the state and local levels to combat digital discrimination like 'red-lining.'



Poor Payment Parity and Questions Regarding Interstate Licensing Limited Telehealth for Addiction Care Prior to the COVID-19 Pandemic

During the COVID-19 pandemic, payers' temporary establishment of payment parity between telehealth and in-person care removed an extensive disincentive to the provision of telehealth-delivered addiction care.

The Centers for Medicare and Medicaid Services (CMS) has now permanently expanded the definition of telehealth services under Medicare that are eligible for reimbursement to include audio-only services for the diagnosis, evaluation, or treatment of mental health disorders (including SUD) in established patients, which includes certain services offered at OTPs.

- CMS and SAMHSA have encouraged state Medicaid programs to expand telehealth for addiction care, although state Medicaid telehealth coverage is variable, particularly related to audio-visual and audio-only modalities.

During the COVID pandemic, nearly every state temporarily modified medical clinician licensure requirements or renewal policies, including requirements for the delivery of out-of-state (OOS) telehealth services, to enable licensure portability.

Licensure wait times can exacerbate workforce shortages, which are acute for addiction specialists.

- The Interstate Medical Licensure Compact (IMLC) creates a pathway to expedite already licensed physicians that seek to practice medicine in multiple states and strengthens public protection by facilitating state medical board sharing of investigative and disciplinary information.

Clinicians Had to Balance the Use of Telehealth with an Emerging and Evolving Standard of Care Due to Rapid Adoption of Telehealth During the COVID-19 Pandemic

- **Telehealth can be safe and effective for many mental health conditions, but research on telehealth-delivered addiction care is quite limited.**
 - Prior reviews have documented few, small, retrospective, telehealth-related studies on SUD care.
 - No randomized controlled trial has been published on telehealth-delivered addiction medications for SUD.



Although there are limitations in the methods of the prior studies, there are some indications that telehealth use for SUD care can be associated with comparable outcomes, treatment retention, and patient satisfaction.

Uncertainty Around the Use of Telehealth for Addiction Care and Privacy Regulations

During the COVID-19 pandemic, HHS' temporary pause of enforcement of privacy/Health Insurance Portability and Accountability Act (HIPAA) regulations enabled the use of additional internet platforms SAMHSA issued 42 CFR Part 2 regulations guidance to clinicians.



Federal agencies are currently working to harmonize HIPAA and 42 CFR Part 2 regulations, as required by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) of 2020.

- As a result, clinicians have significant uncertainty regarding their compliance with privacy/HIPAA regulations in this environment, particularly around storage of video and other electronic communication records.

Access to Addiction Care Depends on Health Plan Network Adequacy and Coverage

- **While telehealth can improve access to clinicians by eliminating geographic barriers to care, it does not solve insurance network adequacy problems.**
 - Health plans could limit their SUD care network to specific telehealth providers, unduly steer people only to those services (and away from their regular or other clinician), or exclusively limit patients to telehealth-based care.



These actions would inappropriately limit patient autonomy to choose the modality best suited to their needs.

Telehealth Accelerated Innovations in Care Models Lowered Thresholds to Accessing Addiction Care

For people with SUD, especially those with unstable housing, HIV or Hepatitis C infection, and/or criminal legal involvement, experiencing stigma within traditional healthcare systems can be a barrier to accessing care.

Increased use of telehealth can aid delivery of addiction care by increasing access to addiction specialists in unconventional settings and community-based care.



Integrating telehealth into less stigmatizing settings where persons who use drugs receive services, such as syringe services programs, has significant promise.

Establishing effective strategies to take full advantage of the opportunities provided by telehealth services can create opportunities to close the gaps in care for marginalized patient populations and help them achieve sustainable recovery.

AGENDA

01 – Background

02 – **Recommendations**



Recommendations

1

Federal agencies, states, and payers should standardize telehealth definitions and terminology.

2

Addiction medicine professionals should offer telehealth options to optimize access to addiction care.

3

Requirements for ancillary services, such as toxicology testing, should not be barriers to accessing addiction care via telehealth and may be delivered via telehealth in some circumstances.

4

Federal law should be amended to create a new telehealth evaluation alternative to the Ryan Haight Act's in-person medical evaluation requirement, which would permit the initial issuance of a prescription for a controlled medication approved by the Food and Drug Administration to treat SUD, using an audio-visual, real-time, and two-way interactive communication system and without any requirement for special registration. If and when the DEA issues final regulations to implement the "special registration" "practice of telemedicine" exception under the Ryan Haight Act, those regulations should be consistent with principles of broad access and low barriers to addiction care.

Recommendations

5

Regulatory flexibilities tied to the COVID-19 PHE are relevant to the opioid overdose crisis and should be extended under that PHE or other available authority. Federal agencies should continue to study the impact of the use of audio-only technology for buprenorphine treatment for OUD, including the impact on health inequities and outcomes.

a

DEA regulations should continue to allow for the initiation and maintenance of buprenorphine with audio-only technology during the opioid overdose crisis PHE, and SAMHSA regulations should continue to allow for same at OTPs. DEA and SAMHSA should work to make these flexibilities permanent, as appropriate, based on findings of further studies.

b

SAMHSA regulations should make permanent other OTP-related telehealth flexibilities implemented during the COVID-19 PHE.

c

SAMHSA and DEA regulations should allow for the initial medical evaluation for treatment of OUD with methadone by audio-visual telehealth technology.

d

Federal and state laws, regulations, and guidance related to telehealth-delivered addiction care should not add restrictions or barriers that could increase risk of abrupt discontinuation of addiction care.

Recommendations

6

States should align their telehealth policies with federal telehealth policies to the extent the latter allow for increased access to, and retention in, evidence-based addiction care.

7

States should adopt legislation to prohibit pharmacies, pharmacy benefit managers, and health insurers from interfering with a state-licensed pharmacist's corresponding responsibility under the federal Controlled Substances Act; such legislation should appropriately empower state medical or pharmacy boards to review and potentially veto corporate policies that limit or restrict controlled addiction medication prescriptions or their dispensing on basis of relation to telehealth, prior to the policies' implementation. Any such existing corporate policy should be suspended.

8

The use of audio-only and audio-visual telehealth modalities for addiction care should be studied to inform best practices, ensure better health outcomes, and advance health equity.

9

Federal and state governments should expand programs that reduce inequities in digital access for people with SUD, promote digital literacy, and make strategic investments in telehealth infrastructure, while acting decisively to prevent and eliminate digital discrimination.

Recommendations

10

Jurisdictions and institutions should ensure virtual interpretation services are provided to patients with non-English language preference to increase access to care.

11

Payers should cover telehealth-delivered addiction care *on the same basis and to the same extent they cover the provision of the same service through in-person care*, including prescribing through telehealth if such prescribing is permissible under applicable federal and state law.

a

Reimbursement rates for telehealth-delivered addiction care should be fair and equitable and account for facility fees to support telehealth services for beneficiaries who are unhoused or otherwise difficult-to-reach and treat populations and in need of telehealth services at a safe, confidential location.

b

Utilization management techniques on benefits provided through telehealth for addiction care should be fully consistent with standards of care and clinical practice that are generally recognized by federal agencies or medical societies with expertise in addiction treatment.

12

States should join the Interstate Medical Licensure Compact to increase access to addiction care, especially given the more widespread adoption of telehealth.



Recommendations

13

Further studies, including prospective clinical trials, are needed to measure and compare the effectiveness of different telehealth modalities (audio-visual and audio-only) for addiction care, focusing on utilization, quality of care, and impacts in real world healthcare systems. Studies should attempt to account for the fact that the alternative to telehealth-delivered addiction care is often no care.

14

Federal agencies should study the impact of pausing HIPAA enforcement against healthcare providers in connection with the good faith provision of telehealth during the COVID-19 PHE to inform long-term policy approaches that will protect patient privacy and confidentiality in telehealth care, without creating barriers to accessing care. Federal agencies should provide clear, user-friendly HIPAA telehealth guidance for the period following the COVID-19 PHE.

15

Telehealth should not supplant adequate in-person addiction care. Health plans should have adequate SUD provider networks that allow beneficiaries the option to access telehealth and in-person addiction care.

16

Tele-harm reduction services, including syringe services, should be studied, and expanded to the extent they improve health outcomes.

17

Policymakers, and to the extent applicable, payers, should support telehealth service expansion in jails and prisons to increase access to addiction treatment, including addiction medications.