

DEA Proposed Rules: Telemedicine Prescribing of Controlled Substances

National Council for Mental Wellbeing
Emily Diehl, manager, federal policy



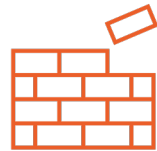


Public Policy Mission Statement

National Council advocates for assertive public policies that:



Ensure equitable access to high-quality services;



Build the capacity of mental health and substance use treatment organizations; and



Promote a greater understanding of mental wellbeing as a core component of comprehensive health and health care.



Assertive Public Policy Priorities for 2023

Strengthen the mental health and substance use workforce through initiatives aimed at improving reimbursement rates, supporting value-based contracting, removing barriers to employment and reimbursement, increasing workforce diversity, recruitment, and retention and creating a pipeline for the future workforce

Bolster substance use disorder prevention, care, and recovery by expanding access to medication-assisted treatment, overdose prevention, and recovery supports

Protect and grow funding for mental health and substance use programs, mental health awareness training programs such as Mental Health First Aid, and prevention and treatment initiatives including recovery and housing supports

Increase equitable access to high-quality services by expanding CCBHCs through initiatives that ensure ongoing SAMHSA grant support, define CCBHCs in the Social Security Act, and provide adequate funding for data collection

Promote comprehensive 988 implementation that ensures a robust crisis care continuum, including enhanced mobile crisis response, coordination with CCBHCs, sustainable funding, and a strong workforce

Elevate initiatives impacting justice-involved populations that focus on prevention from entering the system, pre-entry, care while in the system, re-entry and warm handoffs, and recidivism prevention

Support mental health and substance use disorder parity implementation and enforcement, including consideration of enforcement mechanisms

Expand access to mental health and substance use disorder services provided via telehealth, ensuring the provision of high-quality, effective care

Support youth and maternal mental health and substance use prevention and treatment, including school-based initiatives to support mental health awareness and increased coverage for prenatal and postnatal care

Address social determinants of health through improving access to supportive housing, including re-entry and recovery housing and additional community support



Telemedicine Regulations for Controlled Substances Pre-COVID-19

NATIONAL
COUNCIL
for Mental
Wellbeing



Ryan Haight Online Pharmacy Consumer Protection Act of 2008

- The Ryan Haight Act, enacted on October 15, 2008, amended the Controlled Substances Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the “internet”
- To prescribe a controlled substance through telemedicine, practitioners must:
 - Conduct at least one in-person medical evaluation of the patient; or
 - Be a “covering practitioner”
 - Practitioner conducting a telemedicine evaluation at the request of a practitioner who has conducted at least one in-person medical evaluation or telemedicine evaluation within the previous 24 months; and
 - Is temporarily unavailable to conduct the evaluation
 - Covering practitioner may prescribe controlled substance via telemedicine

Ryan Haight – Exceptions

- Includes seven “practice of telemedicine” exceptions to the in-person medical evaluation requirement:
 1. Treatment in a hospital or clinic;
 2. The patient is being treated by and in the physical presence of another practitioner;
 3. Treatment by Indian Health Service or Tribal practitioners;
 4. Treatment during a public health emergency as declared by the Secretary of Health and Human Services;
 5. Treatment by a practitioner who has obtained a “special registration”;
 6. Treatment by Department of Veterans Affairs practitioners during a medical emergency; and
 7. Other circumstances specified by regulation

<https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf>



Ryan Haight – Definitions and Records

- Defines “practice of telemedicine”
 - “The practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act.”
 - The Social Security Act references, but does not define, such telecommunications systems
- Recordkeeping
 - No specific recordkeeping requirements for practitioners utilizing telemedicine exception

Ryan Haight – Special Registration

- Ryan Haight included a “practice of telemedicine” exception for practitioners who have obtained a “special registration”
- Language indicated that the Attorney General *may* issue a special registration to engage in the practice of telemedicine if the practitioner:
 - Demonstrates a legitimate need for the special registration and
 - Is DEA-registered to prescribe controlled substances
- Requires the AG, with the concurrence of the Secretary of HHS, to promulgate regulations regarding the circumstances in which a special registration could be issued and the procedures for obtaining the registration
- The SUPPORT Act included a provision requiring the DEA to promulgate regulations by October 2019
- Also included in FY2023 Omnibus Appropriations Bill



Public Health Emergency



COVID-19 Flexibilities - Telemedicine

- In January 2020, DEA rolled back select provisions of Ryan Haight under the “practice of telemedicine” exception for “treatment during a public health emergency as declared by the Secretary of Health and Human Services”
- DEA-registered practitioners were eligible to issue prescriptions for Schedule II-V controlled substances without first conducting an in-person evaluation provided the following conditions were met:
 - Prescription is issued for legitimate medical purpose by practitioner acting in the usual course of his/her professional practice;
 - The telemedicine communication is conducted using an “audio-visual, real-time, two-way interactive communication system;” and
 - Practitioner is acting in accordance with applicable Federal and State Laws

[https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf)



COVID-19 Flexibilities - Buprenorphine

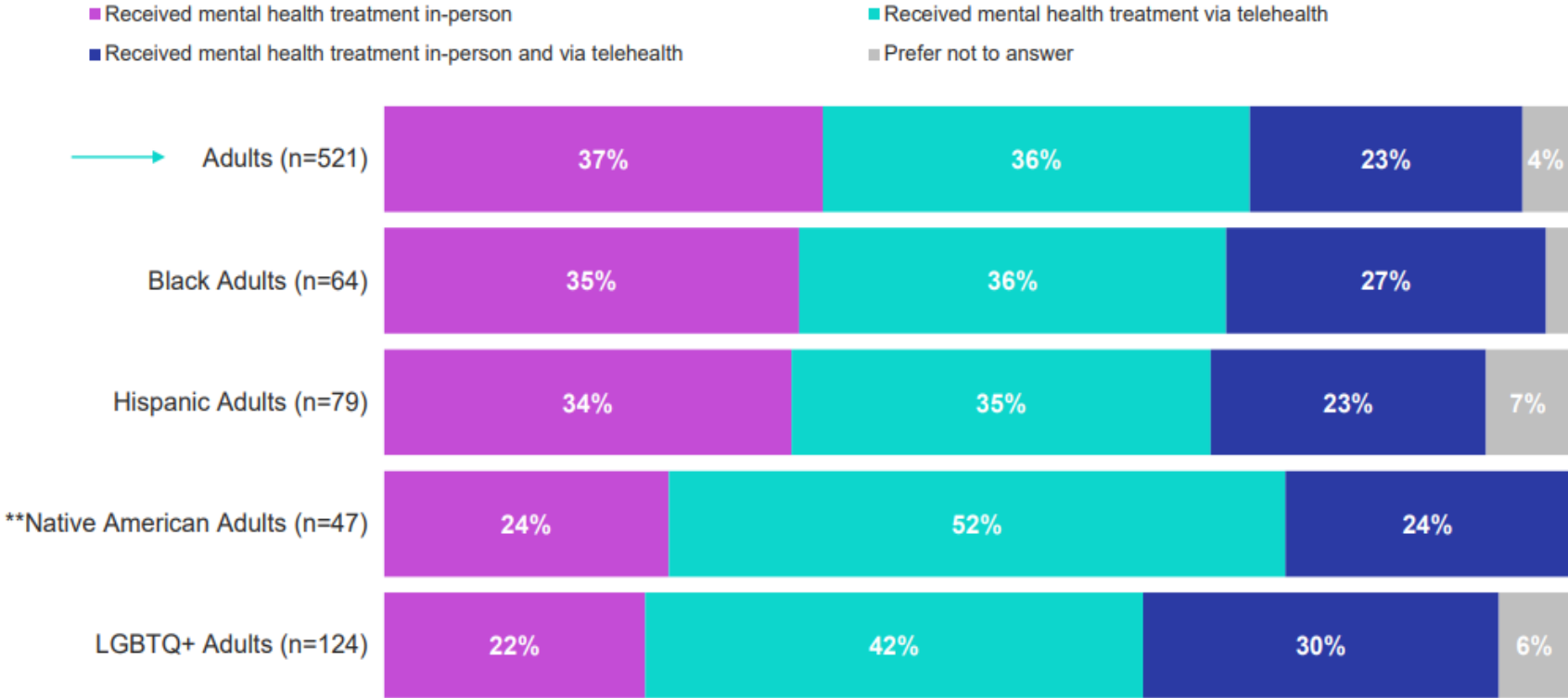
- In March 2020, DEA and SAMHSA released guidance on telemedicine prescriptions for buprenorphine
- Under the guidance, DATA-waivered practitioners and OTP practitioners could prescribe buprenorphine for maintenance or detoxification treatment following an evaluation using audio-visual or audio-only technology
- This applied to both existing and new patients

<https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>



Telehealth Utilization: Mental Health

ADULTS WHO RECEIVED TREATMENT FOR MENTAL HEALTH CONDITION

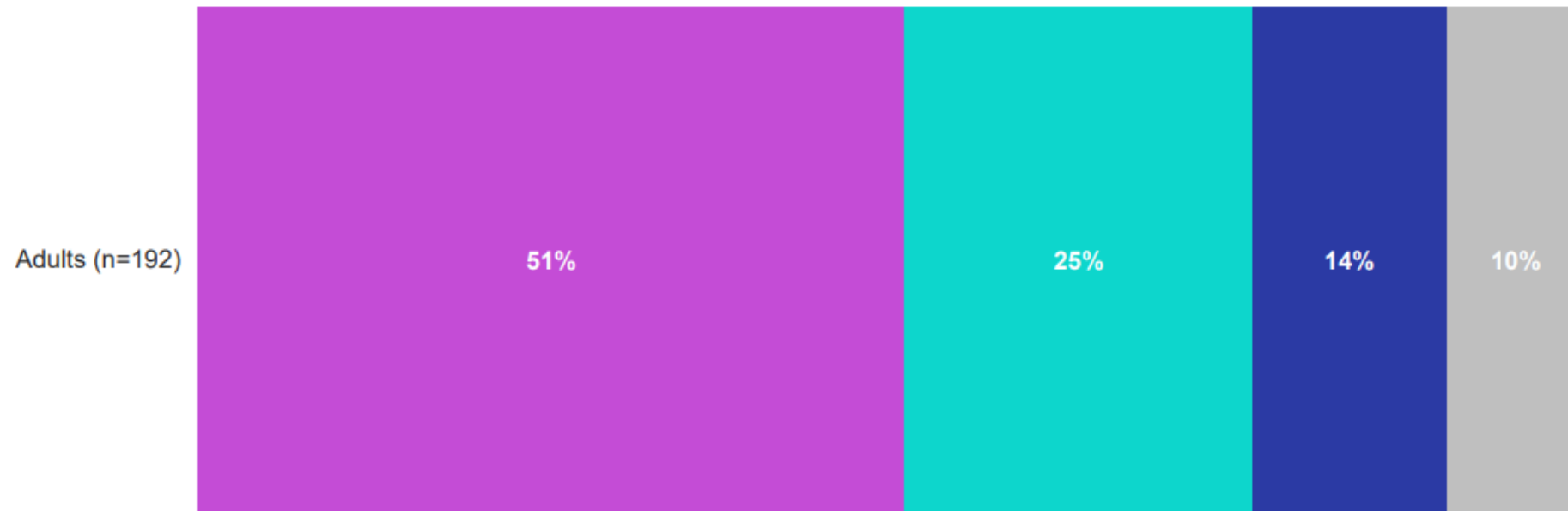


National Council survey, 2021

Telehealth Utilization: Substance Use

ADULTS WHO RECEIVED TREATMENT FOR SUBSTANCE USE CHALLENGES

- Received substance use treatment in-person
- Received substance use treatment in-person and via telehealth
- Received substance use treatment via telehealth
- Prefer not to answer



National Council survey, 2021

Telehealth Utilization

- Telehealth utilization has stabilized at levels 38X higher than before the pandemic, most significantly for mental health and substance use care.
- In April 2021, 58% of surveyed providers said they viewed telehealth more favorably now than pre-COVID.
- Most Certified Community Behavioral Health Clinics (CCBHCs) surveyed reported that they were better positioned to care for clients during the pandemic, given experience with and early implementation of telehealth.
 - Using telehealth to fill staffing gaps, expand service hours, and reach rural areas.
 - Pennsylvania CCBHCs saw a 63% increase in telehealth between the first and second year of the demonstration.
 - New Jersey CCBHCs reported that telehealth increased access to care and reduced “no show” rates.

<https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality>

- The PHE is currently extended through April 11, 2023
 - HHS Secretary has ability to declare a PHE for up to 90 days intervals
 - Congress and agencies must be given 48-hour notice
 - President Biden has [notified](#) Congress that he will end the PHE on May 11, 2023.
- January 2021: Acting HHS Secretary sent a [letter](#) to governors assuring a 60-day notice prior to ending the PHE

RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective January 11, 2023, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, and October 13, 2022, that a public health emergency exists and has existed since January 27, 2020, nationwide.

January 11, 2023

/s/

Date

Xavier Becerra



Proposed Rule: Telemedicine Prescribing of Controlled Substances

Proposed Rule: Telemedicine prescribing of controlled substances

- On February 24, 2023, the DEA released two Proposed Rules regarding the use of telemedicine for controlled substances
- How would prescribing controlled substances work under the proposed rule?
 - DEA-registered practitioner conducts a telemedicine exam of a patient who has never had a prior in-person exam
 - Revises DEA regulation in accordance with CMS regulations to require an interactive telecommunications system that includes audio-visual technology
 - For telemental health services, practitioners must be technically capable of providing audio-visual technology but if the patient is not capable of, or does not consent to, the use of video technology, practitioners can utilize audio-only technology
 - Mental health services must be provided “to a patient in their home”

Proposed Rule Cont'd

- Practitioner must review and consider PDMP for controlled substances prescribed to the patient in the last year
 - If practitioner is unable to access PDMP, the practitioner may issue the prescription for no more than a 7-day supply
 - The practitioner must subsequently obtain the PDMP data and conduct the review within 7 days of the telemedicine encounter; and
 - The practitioner must record the attempts to obtain the PDMP data.

Proposed Rule Cont'd

- Practitioner may issue a maximum 30-day supply for non-narcotic Schedule III-V controlled substances (including buprenorphine for maintenance and detoxification treatment)
 - Must be for legitimate medical purposes by practitioners acting in the usual course of professional practice
 - Prescribing practitioner must be located in the United States or a territory of the United States
 - Prescriber must be authorized to prescribe under state law where the practitioner is located *and* where the patient is located
 - Practitioner must include notation on prescription indicating it was issued via telemedicine

Proposed Rule Cont'd

- To prescribe beyond the 30-day supply, one of the following must occur:
 1. The prescribing telemedicine practitioner conducts an in-person exam of the patient
 2. The prescriber performs a synchronous audio-video telemedicine encounter with the patient while the patient is located in the physical presence of another DEA registered practitioner
 - Audio-only is prohibited for this exam, even for mental health disorders
 3. The prescriber receives a qualifying telemedicine referral from a DEA registered practitioner who has conducted an in-person exam of the patient
 - Under this scenario, the practitioner could prescribe Schedule II-V and narcotic controlled substances provided extensive documentation requirements are met
- If one of the above is met, the practitioner may continue prescribing without additional in-person exams



Proposed Rule – Recordkeeping

- Requires practitioners to maintain written or electronic logs for each prescription issued pursuant to a telemedicine encounter including:
 - Date prescription was issued
 - Full name and address of patient
 - Drug name, strength, dosage form, quantity, and directions for use
 - Address for practitioner and city and state of patient
 - Name, NPI, and copy of referral, if applicable
 - All efforts to access PDMP
- If prescriber performs a synchronous audio-video telemedicine encounter with the patient while the patient is located in the physical presence of another DEA registered practitioner:
 - Date and time of evaluation
 - NPI of DEA-registered practitioner present with patient
 - Address at which prescribing practitioner is located
 - Address at which DEA-registered practitioner is physically present with patient



Proposed Rule – Definitions

- Sec. 1300 defines “telemedicine relationship established during the COVID-19 public health emergency”
 - Applies to practitioners who have not conducted an in-person medical evaluation and
 - The practitioner has prescribed one or more controlled substances based on telemedicine encounters during the PHE
- This exception allows providers to continue prescribing Schedule II-V controlled substances for 180 days after the effective date of the Proposed Rule or the end of the PHE, whichever is later.



Proposed Rule: Telemedicine Prescribing of Buprenorphine

Proposed Rule: Telemedicine prescribing of buprenorphine

- In conjunction with the previous rule, DEA released a Proposed Rule regarding the prescribing of buprenorphine through telemedicine
- The rule regarding buprenorphine is identical to the prior rule with a few exceptions:
 - Clarifying the purpose of buprenorphine prescriptions
 - Addition of definitions for PDMPs and telemedicine encounters
 - Slightly different recordkeeping requirements
 - Audio-only provisions and recordkeeping requirements

Proposed Rule – Purpose of Buprenorphine

- Clarifies that all buprenorphine prescriptions may only be issued for maintenance or detoxification treatment and may not be issued for any other purpose
- Language states that prescriptions must be issued for a “Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment”
- Buprenorphine, at present, is the only Schedule III-V narcotic controlled substance approved by FDA for maintenance and detoxification treatment.



Proposed Rule – Definitions

- Defines prescription drug monitoring program (PDMP)
 - “A State controlled substance monitoring program, including a program supported by the Secretary of Health and Human Services”
- Defines telemedicine encounter
 - “Communication between a practitioner and a patient using an interactive telecommunications system”
 - Interactive telecommunications system
 - Revises DEA regulation in accordance with CMS regulations to require an interactive telecommunications system that includes audio-visual technology
 - For telemental health services, practitioners must be technically capable of providing audio-visual technology but if the patient is not capable of, or does not consent to, the use of video technology, practitioners can utilize audio-only technology
 - Mental health services must be provided “to a patient in their home”



Proposed Rule – Recordkeeping

- Persons required to keep records and file reports
 - Requires practitioners to maintain copies of all qualifying telemedicine referrals they issue
 - All records must be stored at the location practitioner provided for DEA-certification
 - In the case of an evaluation conducted via telemedicine while the patient is in the physical presence of a DEA-registered practitioner, both the prescribing practitioner and the physically present practitioner must store records at their respective locations
- Practitioners issuing buprenorphine prescriptions must indicate in records
 - Whether the telemedicine encounter was conducted using audio-video or audio-only technology
 - If conducted using audio-only, the patient's reason for requesting audio-only
 - All efforts to comply with PDMP
 - Name, DEA-registration number, and NPI of DEA-registered practitioner in physical presence of patient, if applicable
 - Name, NPI of referring practitioner, and copy of referral if prescription is the result of a qualifying telemedicine referral



Questions

Emily Diehl, Manager, Federal Policy and Advocacy

emilyd@thenationalcouncil.org

