Prescribing in Telemedicine: Charting the Course Beyond the PHE Era

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Disclosure

Any information provided in today's talk is solely for informational purposes and not to be regarded as legal advice.

Today's objectives

1. **Understand the current landscape** of prescribing medications in telemedicine, including relevant regulations and guidelines.

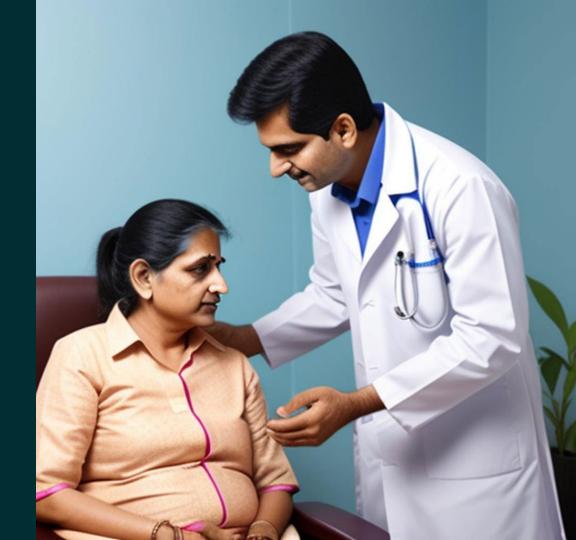
2. **Identify emerging trends and barriers** in telemedicine that are influencing the prescription and management of medications.

3. Discuss potential technologies in prescribing medications via telemedicine.

House call

Question:

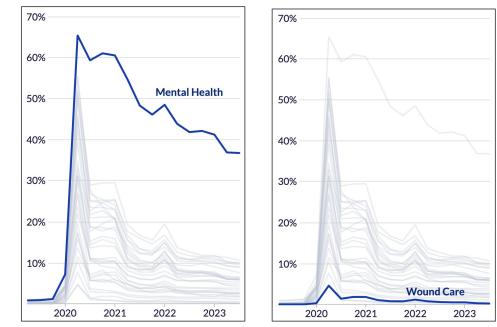
When you hear this term, what comes to mind?



Adoption of telemedicine

- Telemedicine as a "house call"
 - Synchronous
 - Asynchronous
 - Store and forward
- Hockey stick growth curve
 - Mental health (65.5%)
 - Endocrinology (55.5%)
 - Geriatrics (55.2%)
 - Transplant (52.2%)
 - GI (51.5%)

Percentage of Encounters Conducted Using Telehealth



Bartelt K, Piff A, Allen S, Barkley E. Telehealth Utilization Higher Than Pre-Pandemic Levels, but Down from Pandemic Highs. Epic Research.

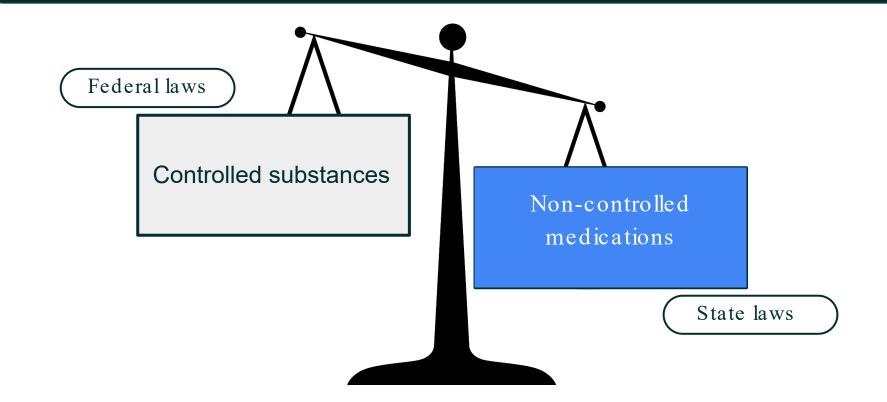
Prescribing in telemedicine

- Slow integration of services
- Hospitals as early entrants
- Provider/patient perceptions
- Other barriers
 - Reimbursement
 - Regulatory and policy

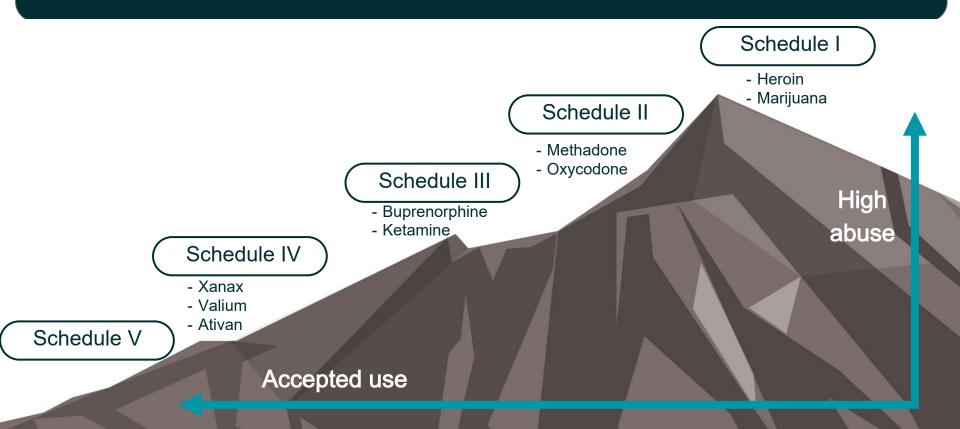


Review of rules and regulations

Prescribing rules and regulations



The Controlled Substance Act



The Ryan Haight Act

In 2008, The Ryan Haight Online Pharmacy Consumer Protection Act was enacted to curb "pill mills".

Exceptions:

- 1. DEA-registered hospital or clinic
- 2. DEA-registered practitioner
- 3. Indian Health Services
- 4. VA practitioner during medical emergency
- 5. Special DEA registration
- 6. During a Public Health Emergency
- 7. Other regulations (DEA/HHS)

An Act

To amend the Controlled Substances Act to address online pharmacies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008".

SEC. 2. REQUIREMENT OF A VALID PRESCRIPTION FOR CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.

Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

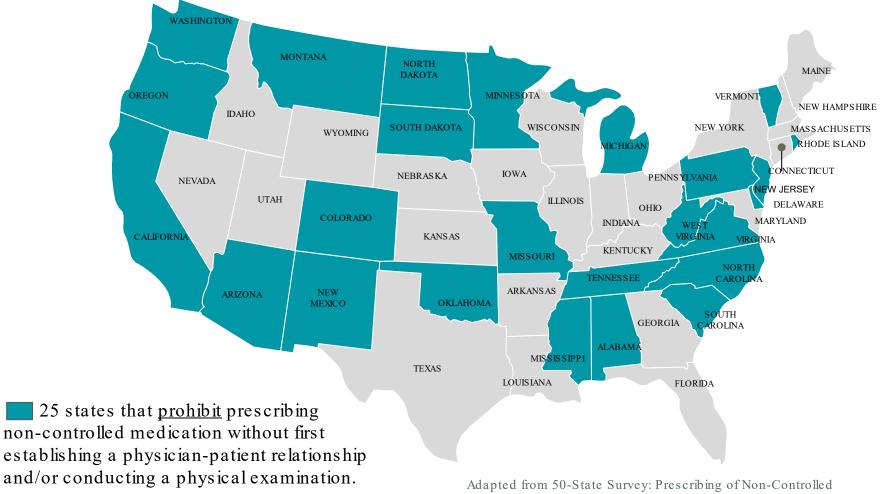
"(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

"(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

Federal and state laws

- Federal laws set the baseline
- State medical boards govern and enforce federal laws and can also extend laws using the following criteria:
 - 1. Is a pre-existing provider-patient relationship required?
 - 2. How is a provider-patient relationship established?
 - 3. Is a physical examination required?
 - 4. Can a physical examination be conducted via telehealth?
 - 5. What are the requirements for a physical examination?

* State law exceptions to the above requirements/prohibitions



Accessed on 9/15/2023

Substances via Telemedicine, CTeL. 2023.

Examination requirements

In states require that an exam, most say the evaluation should include some combination of:

- a medical history,
- a diagnosis,
- a therapeutic plan, and/or
- the availability of follow-up care

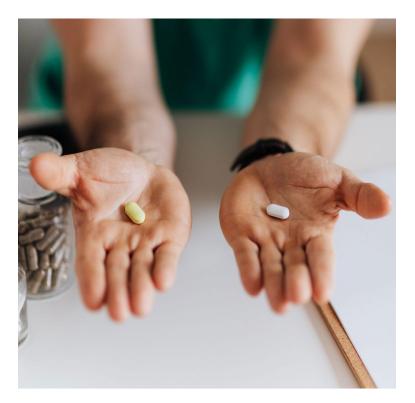


Other state law exceptions: medications

States with specific limitations on what can be prescribed:

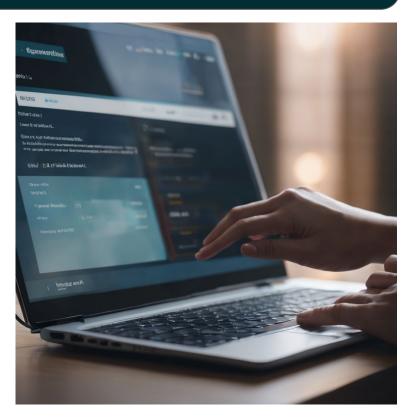
- Schedule II
- Abortion-inducing drugs
- Medical marijuana

Exceptions found in standalone sections



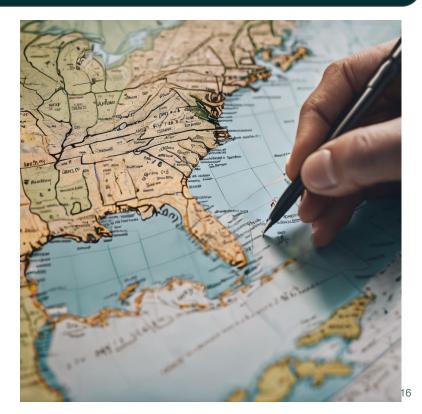
Other state law exceptions: questionnaires

There are 36 states that specifically prohibit prescribing non-controlled medication based solely on a medical questionnaire or a patient-supplied history.



Provider licensure and registration

- State-based licensing regimes
- Licensing compacts and registrations
- Challenges of interstate prescribing
- Prescribing increases complexity



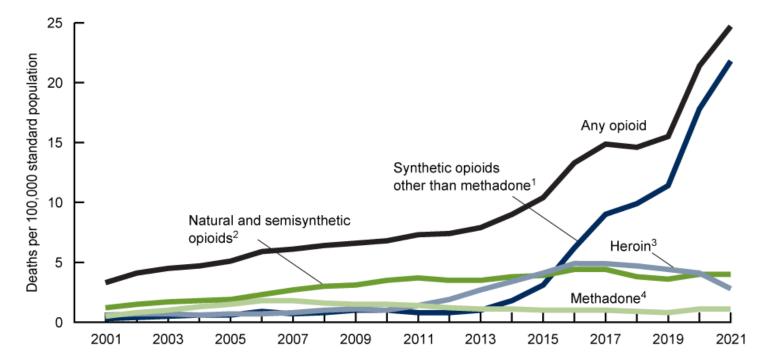
Emerging trends and barriers

Pandemic shifts telemedicine

- Flexibilities were enacted in March 2020
- Waived in-person requirements
- COVID-19 prompted temporary flexibilities
- Rise of telehealth startups



Addiction and the public health crisis



Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001 –2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://dx.doi.org/10.15620/cdc:122556



Alabama airdrop

Bicycle Health Doctors Fly to Alabama for a Second Year to Ensure Opioid Treatment Continuity for Patients

A lack of in-state treatment options, combined with the state's in-person requirement, forces extreme measures from virtual OUD treatment providers to protect patient access to care

July 25, 2023 09:00 ET| Source: Bicycle Health

Drug Addiction Treatment Act (DATA)

- Initially conceived in 2000
- X-waiver requirements
- In 2022, 6% of medical providers licensed to prescribe buprenorphine
- Consolidated Appropriations Act, 2023 eliminated the X-waiver
- Major challenges still exist

Original Investigation

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July 21, 2023

Characteristics and Prescribing Patterns of Clinicians Waivered to Prescribe Buprenorphine for Opioid Use Disorder Before and After Release of New Practice Guidelines

Christopher M. Jones, PharmD, DrPH, MPH¹; Yngvild Olsen, MD, MPH²; Mir M. Ali, PhD³; <u>et al</u>

 \gg Author Affiliations ~~|~~ Article Information

JAMA Health Forum. 2023;4(7):e231982. doi:10.1001/jamahealthforum.2023.1982

Post-PHE: state of prescribing

- Proposed rules announced on March 1, 2023
- DEA, jointly with SAMHSA, issued temporary rules
- Providers may use telehealth visits to prescribe controlled substances through December 31, 2024
- Expecting a final rule this year

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Post-PHE: state of prescribing

Telehealth visit <u>without</u> :	Non-controlled medication	Buprenorphine for opioid use disorder	Schedule III-V controlled substance	Schedule II controlled substance
Virtual first process: Prior in-person medical Evaluation	Permitted	Initial 30-day prescription	Initial 30-day prescription	Not permitted
Qualified telemedicine referral process: Referral from medical practitioner who conducted prior in - person evaluation	Permitted	Initial 30-day prescription	Initial 30-day prescription	Not permitted

Post-PHE: state of prescribing

- SAMHSA finalized rules for opioid treatment programs (OTPs)
- Initiate buprenorphine treatment via telehealth
 - \circ Audio-visual
 - \circ Audio-only
- Limited methadone treatment for new patients via telehealth
 - Audio-visual



Substance Abuse and Mental Health Services Administration

The TREATS Act

The Telehealth Response for Eprescribing Addiction Therapy Services (TREATS) Act was reintroduced at the end of 2023 to remove barriers to substance use disorder.

A BILL

To amend title XVIII of the Social Security Act to increase the use of telehealth for substance use disorder treatment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

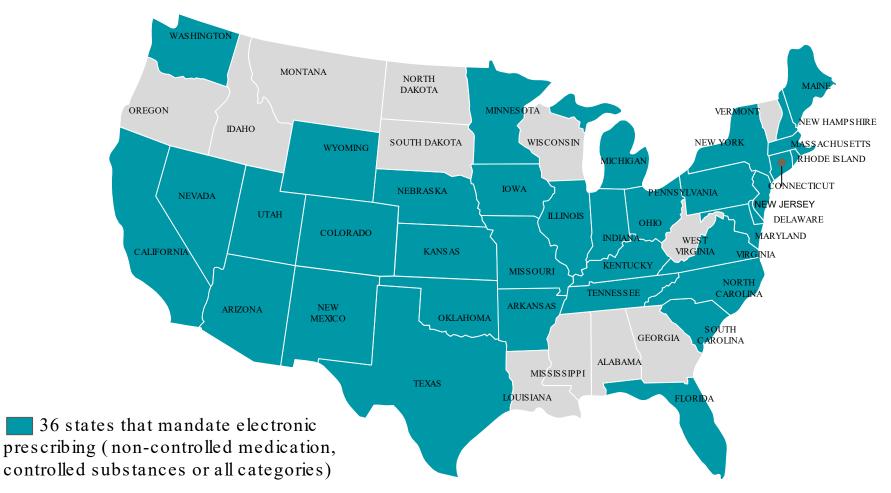
SECTION 1. SHORT TITLE.

This Act may be cited as the "Telehealth Response for E-prescribing Addiction Therapy Services Act" or "TREATS Act".

SEC. 2. TELEHEALTH FOR SUBSTANCE USE DISORDER TREATMENT.

(a) SUBSTANCE USE DISORDER SERVICES FURNISHED THROUGH TELEHEALTH UNDER MEDICARE.—Section 1834(m)(7) of the Social Security Act (42 U.S.C. 1395m(m)(7)) is amended by adding at the end the following: "With respect to telehealth services described in the preceding sentence that are furnished on or after January 1, 2020, nothing shall preclude the furnishing of such services through audio or telephone only technologies in the case where a physician or practitioner has already conducted an in-person medical evaluation or a telehealth evaluation that utilizes both audio and visual capabilities with the eligible telehealth individual "

Potential technologies and opportunities



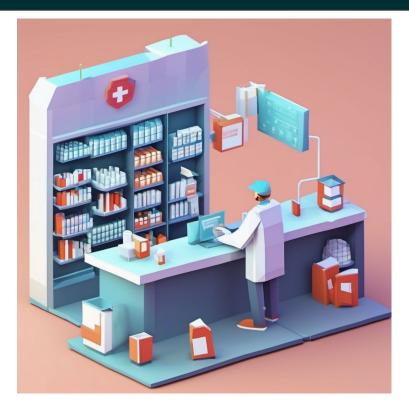
Accessed on 9/15/2023

Adapted from Change Healthcare (Optum). Electronic Prescribing for Controlled Substances (EPCS) Mandates and Interactive Map.

Electronic prescribing policy updates

DEA Final Rule (2023): Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling

- Prescription can be transferred one-time
- Patient must initiate request
- Patient must confirm the availability to fill script from pharmacy
- Pharmacy responsible for interoperability



Prescription drug monitoring programs (PDMP)

- Support access to legitimate medical use of controlled substances
- Identify, deter, or prevent drug abuse and diversion
- Facilitate the identification of persons addicted to prescription drugs,
- Limitations do exist
 - Proactive vs reactive auditing
 - Inter-state review by providers
 - Integration into EHR and pharmacy systems

What is the future outlook?



Thank you for attending today

Share any insights or have further questions?

Connect with me on Linkedin

