



ARIZONA
TELEMEDICINE
PROGRAM



SOUTHWEST
TELEHEALTH
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THE UNIVERSITY OF ARIZONA
JAMES E. ROGERS COLLEGE OF LAW
Health Law

TELEHEALTH PRESCRIBING OF CONTROLLED SUBSTANCES

ARIZONA TELEMEDICINE COUNCIL 4.19.23

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Reminder and disclosure

The information contained and delivered in this presentation are for educational and informational purposes only and should not be considered legal advice.

The views, opinions, and positions expressed are mine alone and do not necessarily reflect the views, opinions, or positions of my employers or affiliated organizations.

I hope the information presented will help you better navigate telehealth policy issues and support adding your voice to these discussions.

Overview

Federal

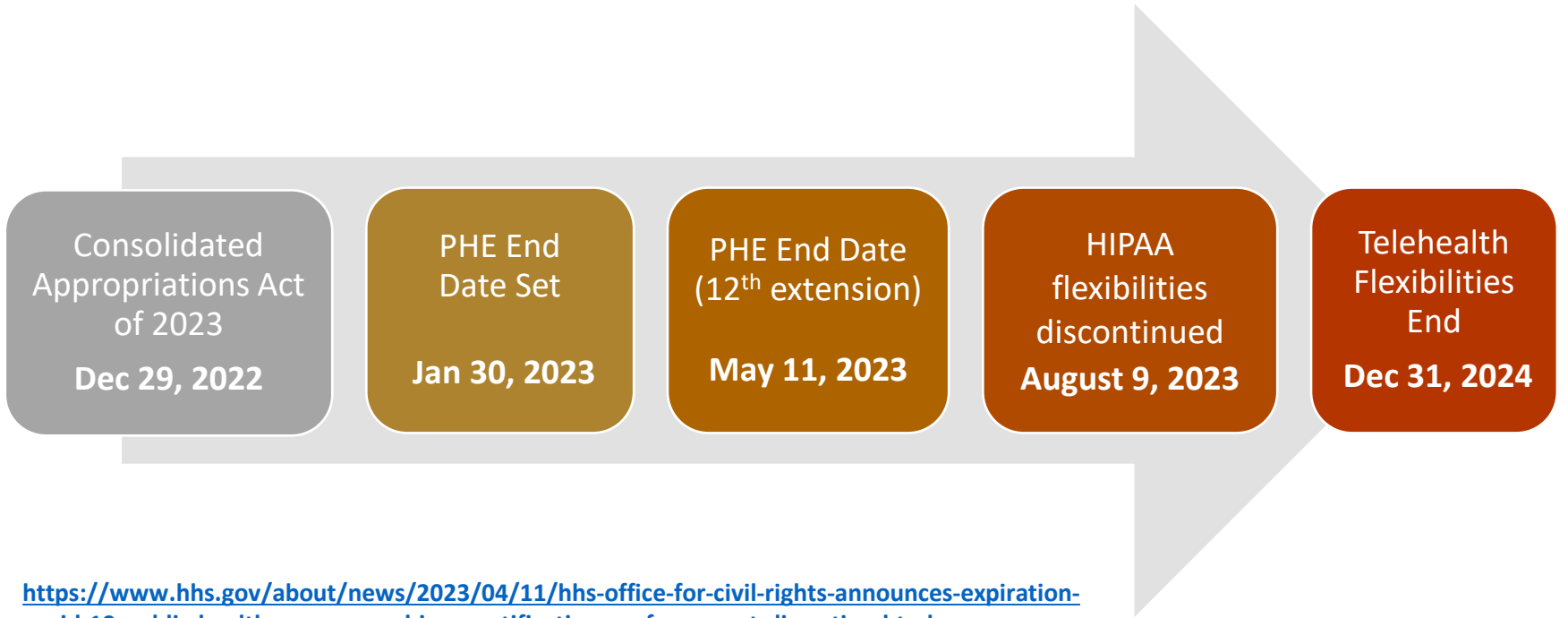
- Public Health Emergency is Ending
- **Virtual Prescribing of Controlled Substances**
- Regulatory Oversight and Drug Advertising

State Level – (Arizona)

- Virtual Prescribing in Arizona
- Looking ahead

PHE is Ending

Key Dates for Telehealth



<https://www.hhs.gov/about/news/2023/04/11/hhs-office-for-civil-rights-announces-expiration-covid-19-public-health-emergency-hipaa-notifications-enforcement-discretion.html>

Medicare Telehealth Policies Post-PHE

MARCH 2, 2023



THE NATIONAL
TELEHEALTH POLICY
RESOURCE CENTER

AT-A-GLANCE:

MEDICARE TELEHEALTH/CONNECTED HEALTH WAIVERS POST-PHE

The chart below shows what the status will be for a temporary telehealth-related policy in a post-public health emergency (PHE) landscape. This resource provides an at-a-glance overview of the federal telehealth waivers that were made in response to COVID-19 and is meant to be a summary. Footnotes have also been provided where more explanation may be needed. More detailed information can be found through the [Centers for Medicare and Medicaid Services \(CMS\) fact sheets](#) for each individual provider type. Please note that this at-a-glance chart is divided by provider type, and the page number for each entry refers to that specific CMS fact sheet, which has been hyperlinked in the heading for each section where you can read the full information. The same policy may appear in multiple fact sheets, but the At-A-Glance may only reference it in one fact sheet as the status of that policy post-PHE does not change from fact sheet to fact sheet. The information for this chart was pulled from the CMS fact sheets dated February 24, 2023. Keep in mind that CMS may provide future updates to these documents.

COVID POLICY	PERMANENT ¹	ENDS WITH PHE	ACTIVE THROUGH 2023 ²	EXPIRES 12/31/24 ³	FACT SHEET PAGE
FACT SHEET: PHYSICIAN & OTHER CLINICIANS					
Allowing all eligible Medicare providers to provide services via telehealth.				X	5
Temporarily continue to allow the use of audio-only to provide certain services.				X	5, 8
Temporarily waive site requirements such as patient needing to be in a rural area or in a specified health care site when receiving services via telehealth.				X	5
Temporarily suspend in-person visit requirement for delivery of mental health services via telehealth when patient is not located in a geographically and/or site eligible location.				X	5

¹ Source of change: Physician Fee Schedule

² Source of change: Physician Fee Schedule

³ Source of Change: Consolidated Appropriations Act of 2023.

Disentangling Telehealth from the Public Health Emergency

By Tara Sklar, JD, MPH on Jan 12, 2023



Five Key Telehealth Takeaways from the Consolidated Appropriations Act of 2023

<https://telemedicine.arizona.edu/blog/disentangling-telehealth-public-health-emergency>

Extended to December 31, 2024

Legislation signed on 12/29/22.

Sec. 4113. Advancing Telehealth Beyond COVID–19.

#1: Home is considered an originating site.

#2: Medicare reimbursement for audio-only telehealth services.

#3: In-person visits for telebehavioral health waived under CAA, but virtual prescribing for controlled substances tied to PHE.

#4: Extend pre-deductible telehealth waiver.

#5: Expand care options with eligible practitioners, safety net providers, and acute hospital care at home programs.

DEA's Proposed Rules for Telehealth Prescribing of Controlled Substances Post-PHE

Join us: March 23, 2023

9am PDT, 10am MDT, 11am CDT, 12pm EDT

Objectives:

1. Understand key provisions of the proposed rules and new process if the rules go into effect.
2. Increase understanding of the current public comment period and how to participate.
3. Learn what to do now in case the proposed rules go into effect post-PHE.

Presenters:

Christa Natoli, CTeL Executive Director

Ben Steinhafel, CTeL Director of Policy & External Affairs

Tara Sklar, JD, MPH, ATP Associate Director Telehealth Law & Policy

Facilitator: **Elizabeth Krupinski, PhD**, SWTRC Director

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CTeL

TELEHEALTH | RESEARCH · POLICY · ACTION



To register visit: www.Telemedicine.Arizona.edu

Webinar recording from March 23, 2023:

<https://swtrc.wistia.com/medias/xrud2yhaq2>



ARIZONA TELEMEDICINE PROGRAM WEBINAR SERIES

The practice and delivery of healthcare is changing with an emphasis on improving quality, safety, efficiency, & access to care. Telemedicine can help you achieve these goals! The Arizona Telemedicine Program and Southwest Telehealth Resource Center invite you to a free one-hour CME webinar on the implementation and practice of telemedicine.

CME provided by The University of Arizona College of Medicine - Tucson

NAVIGATING TELEHEALTH LEGISLATIVE AND POLICY CHANGES BEYOND THE PUBLIC HEALTH EMERGENCY

WEDNESDAY, APRIL 12, 2023

12:00 pm MST = 1:00 pm CST = 2:00 PM EST

Join us to learn about the latest in telehealth legislation and policy changes.

OUTCOME OBJECTIVES

- Incorporate into telehealth practice current legislation, policies, and regulations.
- Implement recommended processes for complying with telehealth legislation and regulations.
- Gain proficiency in current federal and state legislation that impact telehealth and virtual care options.
- Increase understanding in the impact of telehealth legislation across provider specialty areas and patient population groups.

CONTINUING MEDICAL EDUCATION

Accreditation Statement

The University of Arizona College of Medicine - Tucson is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Arizona College of Medicine - Tucson designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credits[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosure Statement

All Faculty, CME Planning Committee Members, and the CME Office Reviewers have disclosed that they do not have any relevant financial relationships with ineligible companies that could constitute a conflict of interest concerning this CME activity.

For more information, contact Melanie Esher, MAdm, at mesher@telemedicine.arizona.edu

This webinar is made possible through funding provided by Health Resources and Services Administration, Office for the Advancement of Telehealth (1U42527).

PRESENTER



Tara Sklar, JD, MPH
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Tara Sklar is the Faculty Director of the Health Law & Policy Program at Arizona Law. She also holds appointments as Senior Advisor for Telehealth Law & Policy with the Arizona Telemedicine Program and for Innovations in Healthy Aging with the University of Arizona Health Sciences. Sklar currently serves as a telehealth policy consultant with the Department of Health and Human Services, Health Resources & Services Administration in the Office for the Advancement of Telehealth.

REGISTRATION

www.telemedicine.arizona.edu

Webinar recording from April 12, 2023:

<https://swtrc.wistia.com/medias/zapr3125bp>

30-day public comment period ended on **March 31, 2023**



FEDERAL REGISTER

The Daily Journal of the United States Government



PR Proposed Rule

Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

35,466
comments
submitted

<https://www.regulations.gov/document/DEA-2023-0029-0001>

 **Federal PHE ends on May 11, 2023
with return of Ryan Haight Act**



Ryan Haight Online Pharmacy Consumer Protection Act (2008) requires in-person medical evaluation for virtual prescribing of controlled substances returns post-PHE **unless DEA proposed rules become final.**

- Controlled Substances Act (1970) places drugs into five schedules based on potential for abuse and dependence.



Is my prescription a controlled medication?

NO, IT'S A NON-CONTROLLED MEDICATION

Many common prescriptions are **non-controlled medications** and will **not** be impacted by these rules, including:

- Acne creams
- Blood pressure medications
- Antibiotics
- Cholesterol medications
- Birth control
- Insulin

YES, IT'S A CONTROLLED MEDICATION

Controlled medications are classified into one of five schedules based on medical use and potential for abuse or dependency. Examples of common controlled medications include:

- SCHEDULE II**
 - Adderall
 - Oxycodone
 - Ritalin
 - Vicodin
- SCHEDULE III**
 - Anabolic Steroids
 - Buprenorphine
- SCHEDULE IV**
 - Ambien
 - Tramadol
 - Valium
 - Xanax
- SCHEDULE V**
 - Lomotil
 - Lyrica

Schedule III-V

UP TO 30-DAY INITIAL
PRESCRIPTION



For a complete list of controlled medications visit:
https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

Exceptions to Ryan Haight Act's in-person requirement



Patient is being treated in a DEA-registered hospital or clinic.

Patient is being treated in the physical presence of a DEA-registered practitioner.

Telehealth visit conducted by a DEA-registered practitioner for Indian Health Service.

Telehealth visit conducted **during a PHE** as declared by Secretary of the U.S. DHHS.

Telehealth visit conducted by a practitioner with a **special telemedicine registration**.

Telehealth visit conducted by a **VHA practitioner during a medical emergency**.

Telehealth visit conducted under other circumstances specified by DEA regulations.



Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

- Establish a **qualified telemedicine referral pathway**.
- Practitioner who issue a “telemedicine prescription,” must have a **DEA registration** in both the state where the patient is located and the state where the practitioner is located. DEA registered practitioners do not need a “physical address” in each state they practice medicine.
- 180-day waiver** for in-person requirement for patients with an established telemedicine relationship.

Qualifying Telemedicine Referral

Referring practitioner has conducted **at least one in-person medical evaluation of the patient.**



A qualifying telemedicine referral must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred.

If the prescribing telemedicine practitioner receives a qualifying telemedicine referral for the patient, a prescription may be issued for any controlled substance.



What happens next?

DEA has **41 days** - April 1 to May 11th

DEA must conclude that proposed rule **accomplishes the goals** of the problems identified.

DEA must also consider whether **alternate solutions** would be more effective or cost less.

Mismatch Between the Problem the DEA is Trying to Solve and the Proposed Rules

Effective oversight already exists via safeguards and data monitoring

Safeguards

- Business practices that confirm patient identity
- Policies that monitor for potential abuses
- Compliance with state law
- Approaches that assure effective oversight without limiting access via in-person visits

Data

- Lack of evidence indicating abuse and diversion (aggregate or anecdotal)

Disproportionate impact on marginalized groups, Medicaid beneficiaries, and counter to other federal efforts.

Gender affirming care
and access to
testosterone.

Patients at end of life on
palliative care and
hospice at home.

Veterans Health
Administration and Biden
Administration efforts to
improve access to
behavioral health
for veterans.

DEA Telehealth Proposal Brings Risks, Not Patient Protections

[Georgia Gaveras, DO](#)

MARCH 23, 2023

“Choosing a psychiatrist should not simply be determined by proximity.

Expertise, ability, and therapeutic alliance — the trust and safety a patient feels with their psychiatrist— are all critical for successful outcomes.”

Alternatives to a blanket in-person requirement

- ❑ Proposal not tenable given **demand** far exceeding supply.

Half of U.S. counties have zero psychiatrists.

- ❑ Recognize **short notice** and lack of infrastructure.

Change care delivery and business models (providers)

Compliance and enforcement (DEA)

- ❑ Propose enforcement discretion by not requiring an in person visit for **established provider-patient relationships** (beyond proposed 180-days) until end of December 31, 2024 (CAA 2023).

Prepare for the impact

- ❑ **DEA registration** required in states where provider is located and where patients reside otherwise in violation of federal law.
- ❑ Strategy to schedule **current patients** for an in-person visit within 180-days of post-PHE. **One in-person visit** establishes a virtual prescribing relationship.
- ❑ **Set up process for new patients to have an in-person visit.**
- ❑ Utilize the ‘**qualifying telemedicine referral**’ or a hybrid visit.
- ❑ **Inform patients** of potential new requirement and schedule in-person visits.

Prepare for the impact

☐ Use communication channels

- Inform clinicians, patients, and colleagues
- Use social media to inform the general public

☐ Connect to congressional representatives

- **Congress can push back** on these proposed rules and some members already have published statements about the potential harm.

<https://rollcall.com/2023/04/10/dea-proposal-sparks-concerns-about-access-to-telehealth/>

☐ Keep going

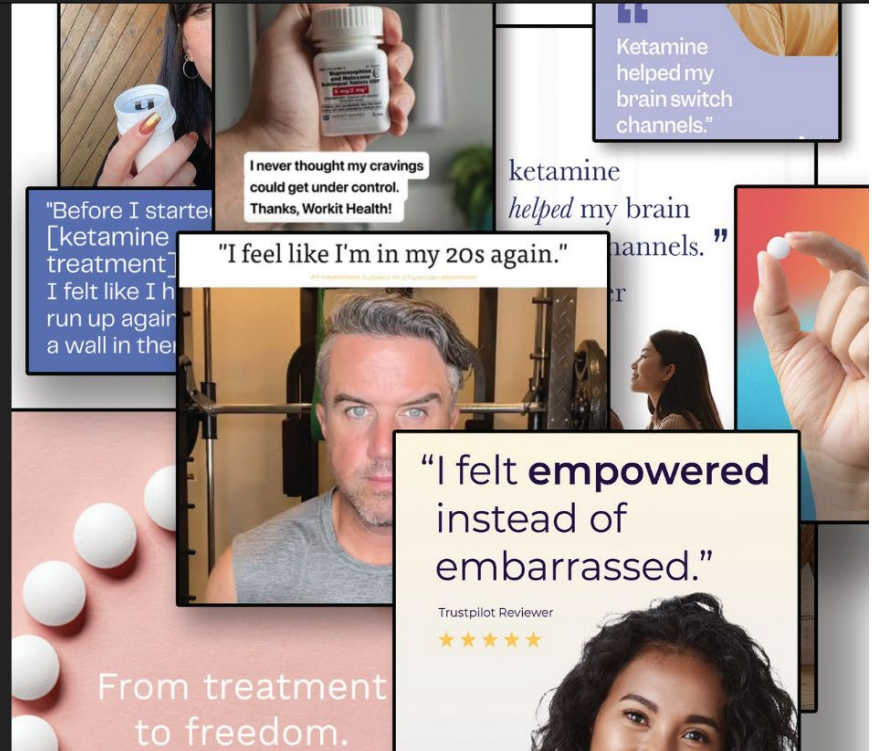
- Document safeguards and publish data

Federal

Regulatory Oversight and Drug Advertising

Misleading Ads Fueled Rapid Growth of Online Mental Health Companies

Some employees and patients say these marketing practices have contributed to the abuse of controlled substances



“Digital ad spending by telehealth companies **swelled to more than \$100 million** in 2021 from around \$10 million in 2020.”



Supports a full ban of direct-to-consumer ads.

*“It turns the healthcare interaction on its head where you’re **starting with the treatment** instead of starting with the problem,”* - Jack Resneck, AMA president.

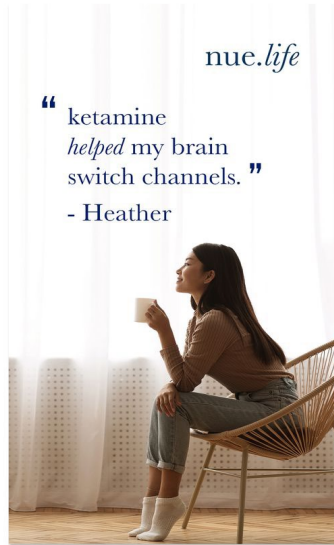


Has oversight over drug manufactures or distributors.

- Present information on each side effect and contraindication and effectiveness – a “true statement of information”
- Not false or misleading
- Approved or permitted for use
- Fair balance (benefits and uses with side effects and risks)



Takes action against **misleading ads**, but it doesn't require prescription-drug ads to include risk information and potential side effects when the ads discuss drug benefits.



Telehealth companies under investigation argue they **facilitate interactions** between patients and providers and do not engage in prescription process.

State - Arizona



At A Glance

MEDICAID REIMBURSEMENT

- Live Video: Yes
- Store-and-Forward: Yes
- Remote Patient Monitoring: Yes
- Audio Only: Yes

PRIVATE PAYER LAW

- Law Exists: Yes
- Payment Parity: Yes

PROFESSIONAL REQUIREMENTS

- Licensure Compacts: IMLC, NLC, OT, PSY, PTC
- Consent Requirements: Yes

<https://www.cchpca.org/>

<https://www.cchpca.org/pending-legislation/>

Virtual Prescribing in Arizona



Arizona State Law § 32-1401(27)(tt) – defines unprofessional conduct as:

“Prescribing, dispensing or furnishing a prescription medication or a prescription-only device... licensee first conducts a **physical or mental health status examination** of that person or has previously established a doctor-patient relationship. **The physical or mental health status examination may be conducted through telehealth as defined in section 36-3601.**”

Arizona State Law § 36-3602(E)

Schedule II drugs may be prescribed only after an in-person or **audio-visual examination** and only to the extent allowed by federal and state law.

Trending in Telehealth: March 13 – March 19, 2023

Friday, March 24, 2023

Trending in the past week:

- Interstate Compacts
- Medicaid Reimbursement
- Prescribing
- Health Practitioner Licensing
- Behavioral Health

In Arizona, proposed bill ([SB 1457](#)) permit licensed psychologists to prescribe psychotropic medications by obtaining a “**prescription certificate**” from the Arizona Board of Psychologist Examiners.

Conditional prescription certificate under the supervision of a licensed physician in-person, by phone or via video conference.

Full prescribing authority under a “**prescription certificate**” by satisfying the proposed requirements, including the following:

- Complete an additional practicum of at least 400 hours treating at least 100 patients with mental disorders under physician supervision.
- Complete a practicum of at least 80 hours in clinical assessment and pathophysiology under physician supervision

Withdrawn on 3.31.23

<https://www.natlawreview.com/article/trending-telehealth-march-13-march-19-2023>

Legislative Telehealth Definition

Interactive use of **audio**, video or other electronic media, including asynchronous store-and-forward technologies and remote patient monitoring technologies, for the practice of health care, assessment, diagnosis, consultation or treatment and the transfer of medical data; and

Audio-only if an audio-visual telehealth encounter is not reasonably available due to the patient's functional status or lack of technology or infrastructure limits, as determined by the healthcare provider.



AZ HB 2454

Enacted May 2021

Title 36, Chapter 36
Public Health & Safety,
Telehealth

[Sec. 3601: Definitions](#)

[Sec: 3601-3608](#)

Legislative Telehealth Definition

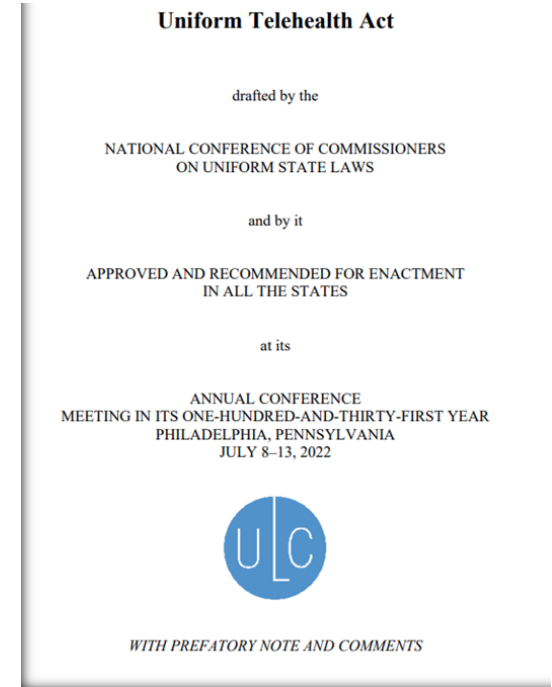
Delivery of medical services through **HIPAA-compliant telecommunications** systems, while the patient is located at an **originating site** and the licensee is located at a distant site.

CO HB 1190
Enacted May 2021



Legislative Telehealth Definition

Use of **synchronous or asynchronous telecommunication technology** by a practitioner to provide health care to a patient at a **different physical location** than the practitioner.



<https://www.uniformlaws.org/committees/community-home?CommunityKey=2348c20a-b645-4302-aa5d-9ebf239055bf>

Recap

Public Health Emergency is Ending

- Be aware of dates and Medicare changes from permanent, temporary, and expiring.

Virtual Prescribing of Controlled Substances

- Follow the DEA for final rule announcement, prepare for impact, and keep going.

Regulatory Oversight and Drug Advertising

- Potential new regulations given bad actors and gap in regulatory oversight.

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Thank you for your time

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