DEA’S PROPOSED RULES FOR TELEHEALTH PRESCRIBING OF CONTROLLED SUBSTANCES:

Learn what to do now in case the proposed rules go into effect post-PHE.

Tara Sklar, JD, MPH
Associate Director, Telehealth Law & Policy, Arizona Telemedicine Program
Faculty Director, Health Law & Policy Program, Arizona Law
Overview for next 10 minutes

30-day public comment period

Effective oversight: Provider safeguards & DEA role

What can I do now?

DEA registration and increase in-person visits

Prepare for impact

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

Over 5,550 comments submitted as of 3.22.23

Can load up to 20 files
MISMATCH BETWEEN THE PROBLEM THE DEA IS TRYING TO SOLVE AND THE PROPOSED RULES

Effective oversight already exists: Provider safeguards and data monitoring

Provide evidence for why the DEA should reconsider an in person visit requirement given provider safeguards are already in place:

- 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)
Offer an alternative to a blanket in-person requirement.

- Proposal not tenable given demand far exceeding supply and could lead to unintended consequences.

- Recognize short notice and lack of infrastructure.

Changing care delivery and business models (providers)
Compliance and enforcement (DEA)
Propose approaches that fit with compliance efficiencies via enforcement discretion:

- Not require in person visit for established provider-patient relationships that developed during the PHE (beyond proposed 180-days).

- Explain how a special telemedicine registration would not be too burdensome; whereas, obtaining DEA registration in multiple states is administratively burdensome and costly without proven oversight benefits.

- **Extend** this in person requirement flexibility until December 2024, akin to CAA 2023.

- Approaches to make rules more workable for providers and patients.
Tips for public comment

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

- Cite specific, measurable impacts.
- Avoid hearsay or prophetic ("chicken little") statements.
- Gender affirming care and access to testosterone (Schedule III).
- 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.

President Biden’s Budget Honors Our Nation’s Sacred Commitment to Veterans and Military Families.
What happens **at the end of the comment period**?

- All comments are reviewed and recommendations from committee to the head of the DEA, Anne Milgram, on whether to **modify**, **reject**, or publish the proposal as a final rule.

DEA may already be categorizing comments and determining how to respond.

- By law - Administrative Procedures Act – the DEA, as a federal agency, is **required to respond** to every unique, fact-based comment.
- Replies can be bundled by topic or category in bulk responses.

- Responses are **published**, along with final regulation, in Federal Register.
When will the Final Rule come out?

DEA has **41 days** - April 1 to May 11\textsuperscript{th} - to determine what goes into the final rule and prepare infrastructure to properly enforce.

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.
Consolidated Appropriations Act, 2023

#1: Patients can continue to access telehealth from their home.

#2: Audio-only telehealth services is allowed.

#3: In-person visits for telebehavioral health not required under the CAA, but virtual prescribing for controlled substances still 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.

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

Full text of the legislation signed on 12/29/22.

Sec. 4113. Advancing telehealth Beyond COVID–19.
Almost 1 in 5 beneficiaries used certain audio-only telehealth services, with the vast majority of these beneficiaries using them exclusively.

- Older beneficiaries were more likely to use these audio-only services than younger beneficiaries.

- Notable because older beneficiaries were less likely to use all telehealth services than younger beneficiaries.


Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks
https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf
Figure 2. Telehealth Modality (Video vs. Audio) Among Telehealth Users, By Race/Ethnicity

- **Highest video telehealth use** occurred among:
  - young adults ages 18 to 24 (72.5%)
  - those earning at least $100,000 (68.8%)
  - those with private insurance (65.9%)
  - White individuals (61.9%)

- **Lowest video telehealth use** occurred among:
  - those without a high school diploma (38.1%)
  - adults ages 65 and older (43.5%)
  - Latino (50.7%), Asian (51.3%) and Black individuals (53.6%)

States Providing Medicaid Coverage of Behavioral Health Services Delivered via Audio-Only Telehealth, as of 7/1/2022

- Blue: Audio-only coverage of mental health and SUD service (44 states incl DC)
- Green: Audio-only coverage of mental health services (not SUD) (3 states)
- Orange: No audio-only coverage of mental health or SUD services (2 states)
- Gray: NR (2 states)

NOTE: Findings are from KFF’s 22nd annual budget survey of Medicaid officials conducted by KFF and Health Management Associates (HMA). SOURCE: Telehealth Delivery of Behavioral Health Care in Medicaid: Findings from a Survey of State Medicaid Programs • PNG

KFF

Jan 10, 2023
What can I do now?
*DEA registration and strategies to increase in-person visits*

**After submit comments**

**Prepare for the proposed rule to become final...**

- **DEA registration** required in states where provider is physically located and where patients reside otherwise in violation of federal law.

- Start a strategy to schedule *current patients* for an in-person visit.
  - One in-person visit establishes a virtual prescribing relationship.

- Set up process for *new patients* to have an in-person visit.
Strategies to see current patients within 180-day window post-PHE.

- Rent an office space for one day a week.
- Utilize the ‘qualifying telemedicine referral.’
- Hybrid visit: In-person exam with a provider, patient, and telehealth prescriber joining virtually.
- Inform current patients of potential new requirement and start scheduling in-person visits.
How can we better prepare for this impact?

- **Use your communication channels**
  - Inform clinicians, patients, and colleagues
  - Use social media to inform the general public
  - Connect to contacts in the local press and write letters to the editor
  - Encourage everyone to submit comments now!

- **Connect to your congressional representatives**
  - Congress can push back on these proposed rules and some members already have published statements against about the potential harm.
Prepare for impact

Help inform the public and key takeaways

Comment
✓ Comment before 3.31.23
✓ Inform others and support them submitting comments before 3.31.23
  (including colleagues, patients, caregivers, and general public)

Prepare
✓ DEA Registration
✓ Strategy to see current patients in-person and new patients for initial visit going forward

Keep going
✓ Congress
✓ Document safeguards and publish data
Upcoming webinars

March 29, 2023  
(12 pm MST)  
Continuing Legal Education  
Arizona’s Telehealth Policy Landscape and Navigating the End of the Public Health Emergency  
Click here to register or learn more!

April 12, 2023  
(12 pm MST)  
Continuing Medical Education  
Telehealth Legislative and Policy Changes Beyond The Public Health Emergency  
https://aztelemedicine.zoom.us/webinar/register/WN_ZRwiVJiaTTWJmp-Q0JAdRg