

Navigating Telehealth Legislative and Policy Changes Beyond the Public Health Emergency Tara Sklar, JD, MPH Faculty Director Arizona Law and Associate Director Policy for Telehealth Law & Policy 4/12/2023 Webinar - Questions and Answers

Disclosure statement:

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.

Questions

Will home visits two way audio/video using HIPAA compliant platform RVUs be affected after end of PHE?

Answer: If the platform is HIPAA compliant, then there is not an issue with the PHE ending. Source: The Department of Health and Human Services Office for Civil Rights issued an announcement (<u>https://www.hhs.gov/about/news/2023/04/11/hhs-office-for-civil-rights-announces-expiration-covid-19-public-health-emergency-hipaa-notifications-enforcementdiscretion.html</u>) on April 11th with more specific information regarding the end of HIPAA flexibilities that occurred during the PHE and the 90-day transition period to August 9, 2023 where penalties will not be enforced for covered providers acting in good faith.

Ryan Haight exemption 6 covers VA emergency teleprescribing? How broad is that?

Not broad, limited to medical emergencies, which is defined as:

Prevents the patient from being in the physical presence of a practitioner who is an employee or contractor of the Veterans Health Administration or from being physically present at a hospital or clinic operated by the Department of Veterans Affairs;

Requires immediate intervention by a practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

Practitioner limited to a maximum of a five-day supply of the controlled substance.

Source: https://www.ecfr.gov/current/title-21/chapter-II/part-1300/section-1300.04

If DEA did not respond to 2019 mandate to implement special registration, is there any actual potential for intervention before May 11?

It seems unlikely that the DEA will modify the proposed rule to include a special telemedicine registration given they did not implement a registration in the fifteen years following passage of the Ryan Haight Act and after directed to by Congress in the Special Registration for Telemedicine Clarification Act of 2018.

Source: https://www.congress.gov/bill/115th-congress/house-bill/6

Is there much similarity or shared "best practice" for state registration systems or the 7 states? I understand the ULC Model was loosely derived from FL, but the ULC model does not detail considerations of setting up the registration system or what LOE is needed by the state.

There are some similarities for states that have already enacted telehealth registration pathways. The following seven states have enacted a telehealth registration option for providers.

Similarities:

- Current, valid, and unrestricted license in another state;
- Not subject to past disciplinary proceedings in any state where the provider holds a professional license;
- Must maintain and provide evidence of professional liability insurance;
- Must not open an office or offer in-person treatment in that state; and
- Must annually register and pay a fee with the appropriate state licensing board.

Source with links explaining the registration process in each state: <u>Arizona</u>, <u>Florida</u>, <u>Indiana</u>, <u>Kansas</u>, <u>Minnesota</u>, <u>Vermont</u>, and <u>West Virginia</u>.

Is the in person visit need to occur yearly? Or just once? So a pcp could just do a referral? Just to clarify, is it currently legal to prescribe controlled substances via telemed?

Only one in person medical evaluation is required.

Yes, a PCP could provide a 'qualifying telemedicine referral' to the prescribing telemedicine provider.

Yes, it is legal to virtually prescribe controlled substances; however, laws vary by state with additional requirements or restrictions. Federally, the Ryan Haight Act requires an in-person visit to virtually prescribe controlled substances, but that was waived during the PHE.

If a physician sees a patient in person, can they write a RX for a controlled substance with multiple 30 day refills in one RX? If a physician is licensed in multiple states, can they get a referral for a patient the is physically in another state and still treats them via telemedicine?

If a physician sees a patient in person that can write a prescription for a controlled substances via telehealth at a future visit. Schedule III and IV controlled substances cannot be filled or refilled more than 5 times or more than 6 months after the date the prescription was issued, whichever occurs first.

Schedule II prescriptions cannot be refilled.

Source: Title 21 Code of Federal Regulations 1306.22 refilling of prescriptions. https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_22.htm.

Under the proposed DEA rules, a provider must have a DEA registration in both the state where the patient is located and the state where the provider is located to virtually prescribe controlled substances irrespective of the qualified telemedicine referral.

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

Would you please speak more about the adverse impact in-person treatment has on transgender people seeking gender affirming care?

Gender affirming is impacted by the DEA proposed rules for those seeking access to testosterone as it is a Schedule III Controlled Substance. Under the DEA proposed rules, a virtual prescription does require one in person medical evaluation for a telehealth provider to prescribe this medication for anyone seeking this medication.

Are you seeing any movement at the federal level to make the telehealth flexibilities extended to the end of 2024 permanent for Medicare (outside of behavioral health, which was made permanent)?

The DEA received 35,466 comments and I suspect the request to extend a waiver with the Ryan Haight Act to December 31, 2024, along with the other telehealth flexibilities listed in the Consolidated Appropriations Act of 2023 was proposed, as well as comments to make the waiver permanent. The DEA is required to respond to every unique, fact-based comment in the final rule that will be published in the federal register.

Source: <u>https://www.federalregister.gov/reader-aids/office-of-the-federal-register-blog/2015/03/when-does-this-rule-go-into-effect</u>

Will there be public comment opportunities or ways to provide feedback to Congress? To make telehealth flexibilities permanent?

There is strong bipartisan support for access to telehealth and some Congress members have spoken out about the harm that can occur with requiring an in-person visit for virtual prescribing of controlled substances.

Examples from congressional leaders:

" I am concerned that a 30-day deadline to see a provider in-person would cause a lapse in treatment for individuals who have received initial prescriptions and encounter a situation in which they cannot see a doctor within the one-month deadline," Rep. <u>Frank Pallone Jr.</u>, Representative from New Jersey wrote in a March letter to Anne Milgram, DEA Administrator.

Fourteen other congressional members, led by Rep. <u>Ann McLane Kuster</u>, from New Hampshire., wrote in a letter to Milgram that "a patient who starts their 30-day treatment via telemedicine has no guarantee they will be able to access an in-person visit within one month – especially in rural and medically underserved areas."

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

Another avenue to voice your concerns is to connect with your Congressional Representative about this issue and, if possible, share anonymized data to back-up your points.

For group practices, FQHC, can an out of state provider who hasn't themselves seen the patient Rx controlled substances on patients who have been seen in the FQHC?

A FQHC provider who sees the patients in person can provide a 'qualifying telemedicine referral' to the prescribing telemedicine provider.

So even if our clinic does not prescribe scheduled drugs, we would have to have a DEA number to prescribe legend medications (birth control pills, depo subcutaneous, etc)?

The DEA proposed rules only apply to an in-person visit for virtual prescribing of controlled substances.

Does virtual clinic to clinic visit suffice for in-person visit. The patient physically presents to a satellite clinic while psychiatrist is at remote location? thank you

The DEA proposed rules would require the patient to be seen in person by a provider who can then issue a 'qualifying telemedicine referral' to the prescribing telemedicine provider (e.g., a psychiatrist).

Do we have any idea about the timeframe around the DEA Rx proposed rule in-person requirement, i.e. in-person ever or during a specific period relative the rx?

One in-person visit is required to virtually prescribe controlled substances. This visit has to occur within six months of the final rule becoming effective for current patients and at an initial visit for new patients.

Can you comment on virtual supervision of trainees which is scheduled to end on 5/11/23? Is this date going to potentially be pushed out?

During the PHE, teaching physicians may direct care and review services each resident provides during or at once after each visit virtually, and that is set to expire with the PHE. The exception is after the PHE, teaching physicians in residency training sites located outside of a metropolitan statistical area (MSA) may continue to direct, manage, and review care furnished by residents through audio/video real-time communications technology.

Source: Teaching Hospitals: CMS Flexibilities to Fight COVID-19

Do you have any guesses as to when we will hear from the DEA? Do you think they will address the comments before May 11th? The days continue to fly.

Yes, the days are flying by. I am sure things are busy at the DEA right now in sorting through these 35,466 comments and potentially modifying their proposed rule. One answer I can give is that there is typically 30-days from the effective date of the final rule so there is still some time even after the PHE ends on May 11th to adjust.

Are there any proposed changes with the Originating Site fee?

During the PHE, when a practitioner furnishes professional services in the hospital outpatient department, furnishes telehealth services to the patient's home during the COVID-19 PHE as a "distant site" practitioner, they bill with a hospital outpatient place of service, since that is

likely where the services would have been furnished if not for the PHE. The hospital may bill under the Outpatient Prospective Payment System (OPPS) for the originating site facility fee associated with the telehealth service.

This site fee is expected to expire with the PHE.

Sources: <u>Hospitals and CAHs, ASCs and CMHCs: CMS Flexibilities to Fight COVID-19</u> and <u>https://www.cchpca.org/topic/originating-site/</u>

What was the website where we can search law specific to our state?

National Policy Telehealth Resource Center <u>https://www.cchpca.org/</u>

Can you please send hhs link on 90day transition without penalties for hipaa non-compliant platforms? https://public-inspection.federalregister.gov/2023-07824.pdf

Providing access for people who are hard of hearing or use sign language has definitely been an issue for us -The lack of closed captions :/

You may be interested in this resource from the HHS Office for Civil Rights (OCR) and DOJ's Civil Rights Division (CRT) on Non-Discrimination in Telehealth

Source: <u>https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-</u>nondiscrimination-in-telehealth/index.html

Relevant text from Guidance:

Although telehealth has many advantages, accessing care via telehealth may present challenges for certain populations. Sometimes these challenges, if not addressed, may result in these populations facing barriers and issues accessing this care. Some examples may include:

- A person who is blind or has limited vision may find that the web-based platform their doctor uses for telehealth appointments does not support screen reader software.
- A person who is deaf and communicates with a sign language interpreter may find that the video conferencing program their provider uses does not allow an interpreter to join the appointment from a separate location.
- A limited English proficient (LEP) person may need instructions in a language other than English about how to set up a telehealth appointment.

A health care provider's failure to take appropriate action to ensure that care provided through telehealth is accessible can result in unlawful discrimination.