

TELEPSYCHIATRY: KEEPING UP WITH YOUR REGULATORS' WAIVERS

FEDERAL REGULATORS

- HHS – OCR enforces HIPAA's Privacy and Security Rules
 - **Waiver:** Discretionary enforcement when non-HIPAA compliant telemedicine platforms are used.
 - **Impact:** Allows use of “non-public” facing applications that do not provide Business Associate Agreements to temporarily be used. Note that public-facing apps such as Facebook Live or TikTok cannot be used.
 - **For more information:** www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
 - **When waiver will end:** Once the federal COVID Public Health Emergency (PHE) ends.
 - **How to know when the waiver ends:** HHS should announce the expiration of the PHE and it will be posted on www.prms.com/faq.
 - **Significance of the waiver ending:** You will likely have to go back to using a HIPAA-compliant telemedicine platform that will provide a Business Associate Agreement.
 - **Risk management thoughts:** Given the confidentiality of psychiatric treatment, the advice is to at least consider, if possible, utilizing a HIPAA-compliant platform, rather than relying on the waiver.
 - **Prediction:** This waiver will not last post-PHE, given the importance of protecting the confidentiality and security of patient information.
- DEA – Regulates the prescription of controlled substances nationwide
 - **Waiver #1:** PHE exception to Ryan Haight Act (RHA) requirement of a one in-person visit prior to prescribing controlled substances.
 - **Impact:** Temporarily allows for the prescribing of controlled substances without first having one in-person visit.
 - **For more information:** www.deadiversion.usdoj.gov/coronavirus.html
 - **When waiver will end:** Once the federal COVID PHE ends.
 - **How to know when the waiver ends:** HHS should announce the expiration of the PHE and it will be posted on www.prms.com/faq.
 - **Significance of the waiver ending:** You will need to see the patient in-person prior to prescribing controlled substances, unless one of the very limited exceptions under the RHA or under another federal law applies. Also, for those patients you started on controlled substances during the pandemic without an in-person visit under the waiver, you may need to see them once in-person post-PHE.
 - **Risk management thoughts:** Remember that state law could also, separate and apart from federal law, require in-person visits – see discussion below.
 - **Prediction:** While many are advocating for this waiver to become permanent after the PHE ends, this is unlikely to occur. In a recent DEA regulation under the RHA, dealing exclusively with online pharmacies (the formal name of the Act is the Ryan Haight Online Pharmacy Consumer Protection Act), the DEA noted in the comments that the in-person requirement is the DEA's way to protect the public from prescriptions based solely on an online questionnaire. The comments also noted the DEA's obligation to have issued a regulation for the telemedicine registration (under which no in-person visit is required) by October 2019, and indicated that more on that would be forthcoming in the future.
 - **Waiver #2:** DEA registration in patient's state (in addition to the prescriber's state) temporarily not required
 - **Impact:** No federal DEA registration in the state where the patient is located is required during the pandemic.

- **For more information:** [www.deadiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](http://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf)
- **When waiver will end:** Once the federal COVID PHE ends.
- **How to know when the waiver ends:** HHS should announce the expiration of the PHE and it will be posted on www.prms.com/fag.
- **Significance of the waiver ending:** If the requirement goes back into effect, you will need a DEA registration in the patient's state. However, these historically are issued only to those with a license in the state. You may also need an address in that state to get the state DEA registration.
- **Risk management thoughts:** Those patients for whom you are currently prescribing controlled substances under this waiver should be made aware of the potential that you will not be able to continue prescribing
- **Prediction:** This requirement, which came into existence in 2007, is likely to go back into effect post-PHE.

STATE REGULATORS – STATE LICENSING BOARDS

- **Waiver #1:** State licensure
 - **Impact:** Many, but not all, states have waived licensure to some degree to allow out-of-state physicians to treat patients in their states without a state license. The impact varies by state – some states require physicians to apply for a temporary license, some only allow if treating COVID directly, some allow this only for established patients, etc. Remember that the federal waiver of state licensure for Medicare reimbursement is relevant only to being paid for services to Medicare patients - state licensure requirements must still be followed.
 - **For more information:** www.prms.com/fag (first Quick Link is to state licensure waiver information)
 - **When waiver will end:** Varies by state, and is not necessarily tied to the federal COVID PHE end date.
 - **How to know when the waiver ends:** You can check with the individual licensing board (it should be on the board's website); we are also monitoring this and updating our state waiver information on www.prms.com/fag.
 - **Significance of the waiver ending:** You need to avoid the unauthorized practice of medicine. Your professional liability insurance will not cover this, and the jurisdiction(s) where you are licensed could impose discipline.
 - **Risk management thoughts:** Psychiatrists treating out-of-state patients under a state's waiver of licensure should ensure patients are aware of the temporary nature of the ability to do this, and patients' expectations should be managed accordingly. Once the waiver expires, you can email the state licensing board, and explain the facts (e.g., only one patient, border state, your sub-specialty expertise, etc.) to see if you actually need a license in that state to continue to treat that patient. You may be offered options such as a "registration" (as is available in Florida), or be told that no license is needed (as is true with some states with shared borders), or even possibly be given permission to continue to treat without a license based on your sub-specialty (as was the case for at least one child and adolescent psychiatrist). If you do not receive permission to continue to treat without a full license after the waiver ends, you will need to terminate (give 30 days' notice) your treatment relationship, or have the patient come into your state (or a state where you are licensed) for the telepsychiatry or in-person appointment.
 - **Prediction:** Historically states have been slow to facilitate telemedicine, but perhaps the pandemic will result in more consideration of telemedicine by the state licensing boards. We hope more states will offer a registration instead of full licensure, as well as expanding other licensure exceptions.
- **Waiver #2:** State requirements for prescribing controlled substances
 - **Impact:** In addition to federal law, states can also regulate the prescribing of controlled substances, with different requirements. There is no consistency among the states – a few have a regulatory framework very similar to / exactly the same as the federal framework. But others may require an in-person visit for periodic monitoring, in addition to prior to prescribing. During the pandemic, most states have waived their requirements, some explicitly as New Jersey did in this document - www.njconsumeraffairs.gov/COVID19/Documents/FAQ-Telehealth.pdf. Once the state requirements go back into effect, they will need to be followed. This may result in the need to

terminate treatment with those patients that cannot meet the requirements, such as those related to in-person visits.

- **For more information:** Check the state's licensing board's website for prescribing requirements and COVID waivers.
- **When waiver will end:** Varies by state.
- **How to know when the waiver ends:** Check the state licensing board's website.
- **Significance of the waiver ending:** You will need to comply with state requirements, in addition to federal requirements, to continue to prescribe controlled substances. This may mean that patients will need to be seen in-person, depending on the state.
- **Risk management thoughts:** It may be difficult to determine state law on prescribing controlled substances. Your Risk Managers may be able to provide some assistance. In the meantime, be sure to check the Prescription Monitoring Program (PMP) in the patient's state prior to prescribing controlled substances, even if not technically required to do so. The PMP is one of the best patient safety tools. If you do not have access to the PMP in the patient's state, consider asking the pharmacist to review the PMP prior to dispensing your prescription.
- **Prediction:** Psychiatrists may have to devote considerable time to learning the rules of prescribing controlled substances out-of-state via telemedicine. While some boards have made such information readily available, the majority of boards have not.

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