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ATA's Recommendations on Ensuring Appropriate Treatment and Protecting Patients Through Online Prescribing of Controlled Substances

Background: The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) amended the federal Controlled Substances Act by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called "rogue Internet sites" that unlawfully dispensed controlled substances by means of the Internet The Act requires a Drug Enforcement Administration (DEA)-registered practitioner to conduct at least one in-person exam of a patient before prescribing a controlled substance by means of the internet, including through telemedicine.

The law contains seven "telemedicine exceptions" to the in-person exam requirement, but most of these exceptions have limited utility in contemporary telemedicine arrangements when the patient is located at home. One exception, referred to in the law as the special telemedicine registration, would provide more opportunity for safe telemedicine practice, but has yet to be implemented. In 2009, the DEA acknowledged the Ryan Haight Act includes developing "a special registration relating to the practice of telemedicine," and the DEA promised it "will issue a separate rule promulgating regulations consistent with this directive."[1]

And yet, despite years of congressional reports and requests since the passage of the Ryan Haight Act, the Attorney General has never issued a proposed rule to create the special telemedicine registration. Following a 2016 meeting with the American Telemedicine Association (ATA) and other key stakeholders, the DEA issued a revised notice of rulemaking stating an intent to publish the new rules in 2017. No rules were published. In 2018, Congress passed and the President signed into law the SUPPORT for Patients and Communities Act, which included language from the Special Registration for Telemedicine Act of 2018 specifically and unequivocallcy directing the Attorney General to promulgate the special registration rules to allow physicians to prescribe controlled substances via telemedicine without an in-person exam within oneyear of passage (deadline of October 24, 2019).[1] The Attorney General once again missed the deadline and has yet to publish the regulations.

State of Play: During the COVID-19 Public Health Emergency (PHE), the DEA, in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), used the Ryan Haight Act's "public health emergency" exception to temporarily remove the in-person exam requirement.The flexibility allowed during the PHE has not resulted in an increase in illegal drug diversion, inappropriate prescribing, or the prevalence of opioid dependency. On the contrary, having easier access to critical care is helping to combat the spikes in mental health and substance use.

Problem: The day the PHE expires, the Ryan Haight Act's in-person exam requirement will return – and patients' current access to care will be significantly restricted – unless Congress acts and/or the Attorney General finally complies with federal law and creates the special registration process.

Rescinding the ability to prescribe without an initial in-person visit after the pandemic ends will lead to disruption of care for many patients currently prescribed legitimate, clinically-indicated controlled substances via telemedicine. This will create a major roadblock and delay treatment for patients seeking care, particularly vulnerable patients who rely on these medications for long-term medical needs. The Ryan Haight Act's pre-pandemic restrictions on telemedicine (now 13 years old) are needless barriers to critical health services by legitimate providers seeking to provide clinically appropriate services including medication-assisted treatment (MAT) and substance use disorder services, child and adolescent psychiatry and mental health services, and endocrinology and hormone treatment care. Further, such statutory-based processes for legitimate providers to meet care needs has no impact on the other options available to DEA and other enforcement bodies for continuing the important task of limiting and prosecuting those who misuse digital tools for distributing controlled substances.

[1] 74 FR 15596, 15603

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ATA Recommendations

The ATA believes the ultimate choice about a patient's care plan, including the modality of care and clinically valid services, should be the decision of an empowered patient and their provider in accordance with the standard of care. **As such, the ATA recommends policymakers ensure patients continue to have access to certain controlled substances prescribed via telemedicine once the PHE ends.**

Within its current authority, the DEA should:

1. **Publish the special registration for telemedicine rules.** The ATA has long supported the creation of special registration rules and even published concrete recommendations on how a special registration could be structured. The Attorney General should uphold the law and finalize the telemedicine special registration rule, thereby allowing DEA-registered practitioners to prescribe controlled substances via telemedicine without an initial in-person medical evaluation.

However, it is highly probably that the COVID-19 PHE could end before those rules are finalized. In the interim, DEA should, within its current authority:

2. **Update its guidance about telemedicine to waive the prior in-person requirement for treatment using medication-assisted treatement (MAT) for the duration of the ongoing opioid epidemic public health emergency**[2]. With this flexibility, providers offering treatment of substance use disorder with buprenorphine can continue doing so via telemedicine without their patients fearing that care will be terminated when the COVID-19 PHE waiver ends.

3. **Propose a solution for those patients who have established a valid provider-patient relationship via telemedicine during the COVID-19 PHE** that allows them to continue receiving legitimate medical treatment including controlled substances (e.g., exercise enforcement discretion to "grandfather in" an exemption for those patients from the in-person exam requirement when the COVID-19 PHE ends).

4. **Propose a solution for those patients who will establish a valid provider-patient relationship via telemedicine before the Special Registration for Telemedicine is finalized** and in effect, allow them to receive legitimate medical treatment including controlled substances (e.g., exercise the same enforcement discretion from an in-person exam until such time as the Special Registration is active).

For each of those solutions, the DEA should also continue to allow providers who have at least one valid, active DEA license to qualify, consistent with DEA's March 23, 2020 guidance.

The COVID-19 pandemic has changed the policy environment and taught us that while a special registration may have been appropriate policy to consider in 2008 and even in 2019, it is time for a more permanent exemption for certain controlled substances. **As such, the ATA urges Congress to allow providers to continue to prescribe controlled substances via telemedicine regardless of where the patient is located.**

The ATA recognizes that some controlled substances, including schedules I and II, pose a risk of dependency and illegal diversion. As such, permanent policy should focus on ensuring patients have access to schedule II (stimulants only), controlled substances under schedules III and IV, and certain medications for treatments for substance use and opioid use disorders (suboxone, nalozone, buprenorphine). For certain schedule II stimulants, the ATA believes the policy should ensure that patients treated via clinically valid telepsychiatry have access to medications, including stimulants, necessary to treat their medical and mental health needs.

[1] *See* 21 U.S.C. § 831(h)(2).
[2] issued by the Department of Health and Human Services on October 26, 2017