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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 prohibits the distributing, dispensing or delivery of controlled substances by means of the "Internet" (a broadly defined term) without a valid prescription. The Act requires a Drug Enforcement Agency-registered practitioner to conduct at least one in-person exam of the 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 activate 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 unequivallcy directing the Attorney General to activate the special registration allowing physicians to prescribe controlled substances via telemedicine without an in-person exam.[2] The law gave the Attorney General one-year (deadline of October 24, 2019) to promulgate final regulations specifying the circumstances in which a special telemedicine registration may be issued and the procedure for obtaining such registration.[3] The Attorney General never published 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 emergency" exception to temporarily remove the in-person exam requirement. Thus far, there has been no evidence that the flexibility allowed during the PHE has 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 or the Attorney General finally complies with federal law and activates the special registration. That said, 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 many other options available to DEA and other enforcement bodies for continuing the important task of limiting and prosecuting those who mis-use digital tools for distributing controlled substances.

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.

The ATA has historically 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. Unfortunately, the Attorney General has continually ignored the pleas of not only patients and stakeholders but also Congress and the Executive Branch itself by refusing to issue regulations when it was statutorily instructed to do so.

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 and the Attorney General to allow providers to continue to prescribe controlled substances via telemedicine regardless if the patient is located in a hospital or their home.**

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, naloxone, 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.

The ATA will advocate with Congress as well as individual states to ensure clinically appropriate care is available to patients when and where they need it.

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[1] 74 FR 15596, 15603.

[2] The law was added to Title III, Subtitle B, Chapter 4 of a larger legislation titled the "SUPPORT for Patients and Communities Act" and provides:

> Section 311(h)(2) of the Controlled Substances Act (21 U.S.C. 831(h)(2)) is amended to read as follows:
> (2) REGULATIONS.— Not later than 1 year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying—
> (A) the limited circumstances in which a special registration under this subsection may be issued; and
> (B) the procedure for obtaining a special registration under this subsection.

[3] *See* 21 U.S.C. § 831(h)(2).