## United States Senate

WASHINGTON, DC 20510-4606

September 13, 2023

The Honorable Anne Milgram Administrator Drug Enforcement Administration U.S. Department of Justice 8701 Morrissette Drive Springfield, VA 22152

Dear Administrator Milgram:

On behalf of our constituent patients, health care providers, and pharmacists, we're writing to share strong concerns with the notice of proposed rulemaking on the future of controlled substances prescribing over telehealth. Although we appreciate the limited flexibilities proposed by the rule, they are insufficient to meet the health care needs of our constituents and the needs of the providers who care for them. We support the Drug Enforcement Administration (DEA) extending the full set of telehealth flexibilities through November 2023 and are encouraged by the upcoming public listening sessions on the proposed regulations. We urge the DEA to consider feedback from health care stakeholders and apply the lessons learned from the COVID-19 pandemic to ensure patients maintain access to care through telehealth, while still minimizing diversion and fraud.

## **Proposed Rule**

As you know, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act") offered seven exceptions to the in-person medical evaluation requirement when providers are engaged in the "practice of telemedicine;" a public health emergency is one such exception, and we're grateful the DEA moved swiftly to utilize that exception during the COVID-19 pandemic.

However, we are concerned that the proposed rule undermines the gains made during the PHE that saw expanded access to critical health care services through telehealth.

**Initial supply:** Prior to an in-person medical evaluation, the proposed rule permits a DEAregistered prescriber to provide an initial 30-day supply of a controlled substance for nonnarcotic schedule III-V medications. We have concerns about our constituents' ability to obtain in-person appointments within 30 days of starting a new medication, and the potential consequences to their health of starting a new medication and abruptly ending it should they not be able to obtain such an appointment. It takes on average 26 days to schedule a new patient appointment with a health care provider.<sup>1</sup>Therefore, a 30-day supply could result in patients going without their medication while they wait for an in-person appointment or will turn to

<sup>&</sup>lt;sup>1</sup> https://www.merritthawkins.com/physician-appointment-wait-times-up-from-2017/

higher-acuity and higher-cost settings of in-person care to meet this deadline, such as emergency departments.

Despite the 180-day grace period after the end of the PHE, new and existing patients will be seeking in-person appointments simultaneously in a health care system that is already burdened by a shortage of health care providers. According to the U.S. Department of Health and Human Services, 163 million Americans live in Mental Health Care Health Professional Shortage Areas.<sup>2</sup> Approximately 8,200 additional psychiatrists would be needed nationwide just to remove this shortage designation.<sup>3</sup> Nationwide averages also obscure the variation among states and territories; for example, Arizona has only 8.5% of its psychiatric health care needs met and would need 227 psychiatrists to meet 100% of these needs.<sup>4</sup> And beyond mental health care, 100 million Americans live in Primary Care Health Professional Shortage Areas, with more than 17,000 primary care providers needed at a minimum to remove the designation.<sup>5</sup>

Medical societies representing health care providers and their patients nationwide have encouraged a window of longer than 30 days for an initial prescription in order to provide enough time to obtain an appointment: the American Medical Association (AMA) and the American Psychiatric Association recommend 180 days, with the Association of American Medical Colleges (AAMC) urging no less a 90-day maximum when the provider believes it is appropriate. In addition, the AMA and the AAMC recommend that existing patients have one year to fulfill the in-person appointment requirement.

**Provider safety:** The proposed rule requires the prescribing provider to report their physical address at the time of the telemedicine appointment. Health care providers have shared they sometimes do telemedicine appointments from their home and have safety and privacy concerns with their home address being on the prescription. We urge you to allow providers to use the business address of their DEA registration.

## **Referrals:**

• *Referring providers:* The proposed rule requires that an in-person medical evaluation be performed by a DEA-registered provider before a referral to another DEA-registered provider who would be permitted to prescribe a controlled substance over telehealth. We are concerned that individuals without adequate in-person access to a DEA-registered provider will see their health care treatment options limited should they be referred to a specialist for a telehealth appointment, or instead a second in-person medical evaluation would be required with a DEA-registered provider prior to seeing a specialist, which would increase costs to the patient and the health care system as a whole. We urge you to work with health care providers to ensure patients do not encounter any truly unnecessary barriers to care.

<sup>&</sup>lt;sup>2</sup> <u>https://data.hrsa.gov/topics/health-workforce/shortage-areas</u>

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> <u>https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?</u> <u>currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D</u>

<sup>&</sup>lt;sup>5</sup> <u>https://data.hrsa.gov/topics/health-workforce/shortage-areas</u>

• *Prescribing practitioner:* The proposed rule requires a referring provider to specifically include the name and National Provider Identifier (NPI) of the prescribing practitioner to which the referring prescriber is referring the patient. In practice, patients are often referred to a group practice where they see whichever specialist has a first available appointment. Or, referrals may not have a provider indicated at all, as the patient often has to explore insurance network coverage and new patient availability. This requirement may prevent patients from receiving the legitimate health care services they need.

**Recordkeeping:** Finally, we have heard widespread concerns about additional recordkeeping and other administrative burdens required from providers and pharmacies. This additional administrative burden will strain an already exhausted workforce could also deter providers from being able to provide this care. Stakeholders have shared that existing recordkeeping requirements should be sufficient for the purpose of DEA being able to combat diversion and fraud, and we encourage you to work with providers on the least burdensome path forward.

## **Special Registration**

In addition to the PHE exception to the Ryan Haight Act discussed above, Congress also created a "special registration" exception, not as an option for DEA to utilize but a requirement to do so most recently in the SUPPORT for Patients and Communities Act ("SUPPORT Act"). We do not believe this NPRM fulfills DEA's obligation to create a special registration.

Congress envisioned this special registration to allow certain health care providers to be cleared and registered to use their clinical judgment when a medical examination can be done over telehealth for the purposes of a controlled substances prescription. DEA envisioned this to be the case, as well: in the preamble to Ryan Haight Act implementation regulations, DEA wrote:

"Special registration for telemedicine—a practitioner who is engaged in the practice of telemedicine within the meaning of the Act is not subject to the mandatory in-person medical evaluation requirement of 21 U.S.C. 829(e) (although such practitioner remains subject to the requirement that all prescriptions for controlled substances be issued for a legitimate medical purpose."

Although we appreciate DEA not requiring a special registration for the initial prescriptions currently proposed, we are concerned that the proposed rule does not include the special registration directed to be created by Congress and even envisioned by the DEA. However, we are pleased to see DEA recently indicate further consideration of a special registration process that would allow clinicians to prescribe a controlled substance via telemedicine without an inperson visit. We appreciate the continuation of the comment process via public listening sessions, and encourage the DEA to review and incorporate stakeholders' feedback in future rulemaking related to telemedicine prescribing.

In addition to allowing qualified health care providers to determine when a medical evaluation over telehealth is appropriate, a special registration would also provide a framework to evaluate the appropriateness of certain prescribers having the ability to prescribe over telehealth medications not covered by the post-COVID-19 proposed rule, namely Schedule II medications and Schedule III-V narcotic medications.

Health care providers across the board continue to ask for a special registration process that would provide a pathway for certain providers to provide more care involving controlled substances over telehealth than the proposed rule allows, and we implore DEA to follow its statutory requirements under the Ryan Haight Act and the SUPPORT Act and do just that.

Thank you for your consideration of these concerns, and we look forward to continuing to work with you on these important issues.

Sincerely,

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Mark R. Warner United States Senator

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