CATHY McMORRIS RODGERS, WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-3641
Minority (202) 225-2927

March 31, 2023

Administrator Anne Milgram
Drug Enforcement Agency
8701 Morrisette Drive
Springfield, VA 22152

Dear Administrator Milgram,

I am writing to provide my views on the recent Drug Enforcement Administration's (DEA) Notices of Proposed Rulemaking (NPRM) related to the telemedicine prescribing of controlled substances, including non-narcotic substances in schedules III–V and buprenorphine.[1,2] I was pleased to see DEA act on the issue of telemedicine prescribing ahead of the proposed end of the public health emergency (PHE) declared in response to COVID-19, which is set to expire on May 11, 2023.[3] However, I am concerned that the proposed rules, which will require an in-person evaluation by a provider within 30 days of an initial telemedicine prescription and potentially burdensome recordkeeping requirements will negatively impact access to care.

The COVID-19 Pandemic forced our country's health system to adapt to the physical restrictions necessary to stop the spread of communicable disease. Simultaneously, we were forced to reexamine the pre-existing faults of a health system that was often inaccessible to many, including historically underserved urban and rural communities.[4] Inequities during the pandemic were further exacerbated by the third wave of the opioid epidemic and a worsening

[1] DEA Proposed Rule, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*, 88 FR 12875 (https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had).

[2] DEA Proposed Rule, *Expansion of Induction of Buprenorphine via Telemedicine Encounter*, 88 FR 12875 (https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had).

[3] Department of Health and Human Services, *Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap* (https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html).

[4] American Medical Association, *America's health care crisis is much deeper than COVID-19*, July 22, 2020 (https://www.ama-assn.org/about/leadership/america-s-health-care-crisis-much-deeper-covid-19).

mental health crisis.[5,6] The tragic consequences of inaccessible care are reflected in the devastating number of overdose deaths, over 106,000 in 2021, with synthetic opioids like fentanyl being the main driver of these deaths.[7] The telemedicine flexibilities provided during the COVID-19 PHE pursuant to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 have proven effective at increasing access to treatment and medication for many conditions, including, but not limited to, mental health and opioid use disorders.[8]

I was encouraged to see that DEA considered the efficacy of buprenorphine for opioid use disorder and its lower risks and consequences of diversion, especially in combination with naloxone, when drafting their proposed rule.[9] Data show that the main drivers of diverted buprenorphine are consistent with therapeutic use, such as preventing withdrawal and maintaining abstinence, and that lack of access to health care and legitimate prescriptions by a doctor contribute to diverted use.[10] However, I urge you to go further and consider a permanent extension of pandemic era telemedicine flexibilities for buprenorphine and buprenorphine/naloxone combinations. This step would be consistent with the actions Congress and the Biden Administration have taken to increase access to treatment and promote recovery for opioid use disorder.

I also have serious concerns regarding the NPRM's proposed documentation requirements for practitioners prescribing buprenorphine via telehealth. The documentation requirements proposed for each patient telehealth encounter are significant and unnecessary. They could also pose a continuing obstacle and disincentive to practitioners prescribing medication assisted treatment for opioid use disorder (OUD).[11] I believe that these

---

[5] American Psychological Association, *Phycologists Report Large Increase in Demand for Anxiety, Depression Treatment*, November 17, 2020 (https://www.apa.org/news/press/releases/2020/11/anxiety-depression-treatment).

[6] American Psychological Association, *Substance use during the pandemic*, March 1, 2021 (https://www.apa.org/monitor/2021/03/substance-use-pandemic).

[7] National Institute on Drug Abuse, Drug Overdose Death Rates, February 9, 2023 (https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates).

[8] Frost MC, Zhang L, Kim HM, Lin L, *Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic*, JAMA, 2022 (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797201).

[9] *See Note 2*

[10] Cicero, Theodore J., Ellis, Mathew S., Chilcoat, Howard D., *Understanding the use of diverted buprenorphine*, Drug and Alcohol Dependence, Volume 193, 2018 (https://www.sciencedirect.com/science/article/pii/S0376871618307245).

[11] The NPRM proposes to require the following documentation and recordkeeping requirements, rather than a special registration pursuant to Section 3232 of the SUPPORT for Patients and Communities Act (P.L. 115-271), for each patient encounter involving a controlled substance prescribed via telehealth: records indicating whether the telemedicine encounter was conducted using audio-video or audio-only technology; patient's reason for requesting an audio-only encounter, if the encounter was audio-only; record all attempts to comply with the requirement to review PDMP data; require practitioners who were unable to access their state PDMP system to record the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system; , if the patient seeks a medical evaluation pursuant to an in-person evaluation and telemedicine referral; the prescribing practitioner to record the full name, DEA registration

documentation requirements are contrary to both the Biden Administration's stated goal of expanding access to buprenorphine and Congress's intent in eliminating barriers to buprenorphine prescribing through the elimination of the X-waiver in the Continuing Appropriations Act, 2023.[12] I strongly urge you to reconsider these barriers proposed in the NPRM that I believe will restrict timely access to buprenorphine treatment via telemedicine, and which will have disproportionate impact on rural, low-income, and at risk individuals. [13] Nearly 40 percent of counties lack in-person availability of buprenorphine prescribers.[14] I urge the agency to streamline administrative processes in which practitioners must complete documentation once they have been validated as eligible to provide opioid use disorder care via telehealth.

I fully understand that DEA had to weigh a myriad of factors when composing the proposed rules. Among them, DEA had to consider the proliferation of many controlled schedule II and both narcotic and nonnarcotic III-V substances via telemedicine during the pandemic. I have closely monitored DEA enforcement actions against bad actors in the digital health space, including investigations into companies that may have engaged in prescribing practices and dispensing in violation of the Controlled Substances Act. [15] I also share concerns about companies that engage in misleading marketing, including those that promote the distribution of substances to treat mental health disorders for which a robust scientific body of evidence, regulatory approval, or safety profiles are lacking.[16] I appreciate DEA's commitment and mission to keep the American public safe and take actions to prevent the diversion and misuse of controlled substances.

It is clear that the NPRM related to controlled substances attempts to strike a careful balance of appropriate clinical care, regulatory clarity, record keeping, and continuity of treatment for individuals that traditionally do not have access to care. In determining the final

---

number, National Provider Identifier (NPI) number of the DEA-registered practitioner in the physical presence of the patient, and if issued a qualifying telemedicine referral, the name and NPI of the referring practitioner, a copy of the referral and any communications; maintain a record for each prescription issued pursuant to a telemedicine encounter indicating date; full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; address at which the practitioner, and the city and State in which the patient, is located.

[12] Consolidated Appropriations Act, 2023. P.L. 117-328

[13] *See Note 8*

[14] Department of Health and Human Services Office of Inspector General, Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder, January 2020 (https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf)

[15] DEA, *DEA Serves Order to Show Cause on Truepill Pharmacy for its Involvement in the Unlawful Dispensing of Prescription Stimulants*, December 15, 2022 (https://www.dea.gov/press-releases/2022/12/15/dea-serves-order-show-cause-truepill-pharmacy-its-involvement-unlawful#:~:text=An%20Order%20to%20Show%20Cause%20is%20an%20administrative%20action%20to,or%20distribute%20a%20controlled%20substance).

[16] Hamby, Chris, *A Fraught New Frontier in Telehealth: Ketamine*, New York Times, February 20, 2023 (https://www.nytimes.com/2023/02/20/us/ketamine-telemedicine.html).

rule, I would urge you to consider the average wait time for patient appointments with a provider. In 2022, the average patient appointment wait-time was 26 days and wait-times for patients in rural communities are likely longer.[17] 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. Abrupt discontinuation of important therapeutics can be harmful or even deadly. In determining a more appropriate timeframe for an in-person medical evaluation, I also urge you to work closely with the Department of Health and Human Services and its subagencies.

Recognizing three years of safe telehealth prescribing, it is imperative that DEA strike a patient-centered balance to ensure the most vulnerable members of our communities have safe and secure access to the care they need. I appreciate you acting on this important issue and your dedication to keeping our communities healthy and safe. I look forward to your final rules related to telemedicine prescribing of controlled substances.

Sincerely,

Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce

[17] Heath, Sara, Average Patient Appointment Wait Time Is 26 Days in 2022, Patient Engagement HIT, September 15, 2022 (https://patientengagementhit.com/news/average-patient-appointment-wait-time-is-26-days-in-2022).