Consumer Technology Association™

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March 31, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted electronically

RE*:* Docket No. DEA-948

Dear Administrator Milgram:

On behalf of the Consumer Technology Association (CTA), we thank you for considering continued access to telehealth services for patients who need essential prescription medications. We appreciate the opportunity to submit comments on two Drug Enforcement Agency (DEA) proposed rule *Expansion of Induction of Buprenorphine via Telemedicine Encounter.*

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA is the trade association representing more than 1500 companies in the U.S. consumer technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division strives to increase the use of technology-enabled value-based health care to reduce health care costs and drive better health outcomes. The Division, which is made up of cutting edge small and large companies in the health care and technology sectors, including telehealth and personal health wearable companies, remote patient monitoring, health care payers, health systems and biopharmaceutical innovators, provides policy advocacy, health care market research and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

The COVID-19 public health emergency (PHE) has vastly accelerated the adoption of telehealth to provide safe, effective, and timely care. During the pandemic, enhanced flexibilities and increased access to telehealth have allowed patients to access critical health care services while keeping vulnerable patients out of clinics and hospitals. Telehealth not only helps most effectively use physician time, it solves other challenges the country faces with health care delivery. Few doctors can make house calls and many of our sickest people are confined to their homes. Their alternative is to go without health care and the medicines they need or to be hospitalized. Restricting telehealth prescribing will result in more hospitalizations. Telehealth will continue to play an important role in our health care

delivery system by expanding access to high-quality health care services and improving health equity. The role of telehealth has been especially acute when it comes to access to behavioral and mental health services. After the pandemic ends, telehealth services should continue to be leveraged to enhance patient experiences, improve health outcomes, and reduce health care costs.

During the PHE, the DEA has waived the requirement for an in-person medical evaluation prior to prescribing controlled substances under the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (Ryan Haight Act). The waiver of the in-person requirement has increased access to critical services for the treatment of mental health and substance use disorders. Despite the waiver, we are unaware of increases in diversion of controlled substances during the PHE. The DEA has not presented any evidence that the waiver has led to increased diversion, nor has the agency substantiated that reinstating the in-person evaluation requirement will help stop diversion of controlled substances. The country is in the midst of addiction and mental health crises and allowing telehealth prescribing is a valuable tool to help address the issue.[1]

We appreciate the DEA's efforts to provide pathways for patients and providers to use telehealth as a way ensure access to essential health care. However, the proposed rules are overly restrictive for patients, could lead to delayed care, and leave some important questions unanswered. For example, under the proposed rules, unless the patient has already been seen in-person, they will need to do so within a short amount of time. This could be a difficult task for patients, especially given the current primary care and mental and behavioral health provider shortages facing much of the country. The reality is that the county is facing an acute shortage of physicians. The Balanced Budget Act of 1997 essentially fixed the number of physicians by limiting the number of residents for whom Medicare will provide support.[2] Since passage of the Act, the U.S. population has grown by almost 25% to about 340 million people.[3] While the U.S. has allowed many physicians to immigrate from abroad, many American-trained clinicians have left the workforce due to the impact of COVID-19 and other challenges. Ironically, the need for physicians has never been greater given the increasingly aging U.S. population with 1 out of every 5 Americans expected to be 65 and over by the end of the decade—up from about 12 percent in 2000.[4] The issue is particularly acute in rural areas of the country.

Nearly half of Americans live in a mental health workforce shortage area.[5] This is only going to worsen—the Health Resources & Services Administration (HRSA) estimates that by 2030, there will be a 20% decrease in supply of adult psychiatrists, which will not keep pace with the 3% increase in demand for adult psychiatrists.[6] We acknowledge the DEA's attempt to address this issue by allowing telehealth providers to continue prescribing Schedule II–V controlled medications through November 7, 2023, for provider-patient relationships formed via telehealth during the COVID-19 PHE. However, even with this short extension, patients will struggle to meet the requirements and providers will be strained in meeting the demands for in-person visits. This arbitrary timeframe will lead to delayed care.

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[1] https://www.cms.gov/newsroom/press-releases/increased-use-telehealth-opioid-use-disorder-services-during-covid-19-pandemic-associated-reduced

[2] https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_1997_dec_balanced_budget_act_of_1997__implications_for_graduate_medical_education_249_reuter_balancedbudgetact1997_implications_pdf.pdf

[3] https://www.census.gov/topics/population.html

[4] https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html

[5] https://www.kff.org/medicaid/issue-brief/a-look-at-strategies-to-address-behavioral-health-workforce-shortages-findings-from-a-survey-of-state-medicaid-programs/

[6] https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand/behavioral-health

Additionally, the DEA did not provide any clinical justification for reinstating the in-person requirement for all patients needing a prescription for buprenorphine, which is a relatively safe medication that addresses a very significant and ongoing threat to public health. Without additional flexibility, the requirement for in-person visits will likely lead to delays in treatment or no treatment altogether. This would only take us backward in our effort to address the opioid epidemic.

Given the foregoing, we do not believe reinstating the requirement for an in-person medical evaluation prior to prescribing controlled substances in the midst of an addiction epidemic and mental health crisis is in the country's best interest. We respectfully ask the DEA, if it is within its authority, to keep the current requirements under the PHE in place for at least one year. While we recognize and respect the agency's obligation to protect Americans and minimize illegal or unauthorized drugs getting into the system, extension of time is not only needed so thousands of Americans are not suddenly cut off from medicine needed for their treatment or even survival—but it is an opportunity to gather relevant data to make a more informed decisions regarding the in-person requirement. We also ask the DEA to work in collaboration with the Department of Health and Human Services (HHS) to collect the relevant data and rely on HHS' expertise regarding telehealth and prescribing issues.

Finally, we ask the DEA to clarify several items in the proposed rule. First, the rules suggest a past in-person visit could satisfy its requirement but don't specify how recently that in-person visit should have taken place. In addition, the agency acknowledges it was tasked with promulgating rules establishing a special registration process but has chosen not to do so. Stakeholders were anticipating this process as a potential means to continue to provide care via telehealth but now do not have any details or timeframe on when such a process will be established by the agency. We urge the DEA to establish the registration process as it is required to do under the Ryan Haight Act and further confirmed by the SUPPORT Act. Such a process will allow providers to continue providing addiction care via telehealth as the nation continues to grapple with the opioid crisis.

As we emerge from a global pandemic, the nation's addiction and mental health crises show no signs of abating and the DEA should allow providers to use all available tools to effectively address the issue particularly in the face of health care workforce challenges including provider shortages and clinician burnout. We encourage the DEA to engage stakeholders and reconsider the requirements detailed in the proposed rules.

Sincerely,

Consumer Technology Association

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