

March 29, 2023

Honorable Merrick Garland
Attorney General
Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Honorable Miriam Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services
Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Attorney General Garland, Secretary Becerra, Administrator Milgram and Assistant Secretary Delphin-Rittmon,

The undersigned 67 organizations and individuals urge the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) to withdraw the proposed rule related to induction of buprenorphine via telemedicine and continue the telehealth flexibilities under the [Opioid Public Health Emergency](#) to ensure on-going access to life-saving medications for individuals with opioid use disorders. We further request that DEA and HHS significantly alter the proposed rule relating to mental health medications, which will restrict access to urgently needed treatment, particularly in areas with a shortage of mental health providers.

The Administration took prompt and effective steps to expand telehealth services for medications for opioid use disorders (MOUD) and mental health conditions that are subject to the Ryan Haight Act during the COVID-19 public health emergency. Those actions resulted in expanded access to MOUD, improved retention in care, and reduced the risk of a medically-treated overdose.ⁱ Imposing an in-person medical evaluation following a 30-day supply of buprenorphine will disrupt care for tens of thousands of individuals who cannot access an in-person appointment and will make it impossible for countless others to initiate and sustain treatment. The outcome will be deadly for far too many individuals and the effects on their families will be devastating.

A. Buprenorphine Induction Via Telemedicine

Our nation's overdose epidemic – now driven primarily by synthetic opioids – claimed the lives of nearly 108,000 Americans for the year ending October 2022,ⁱⁱ and the COVID-19 pandemic will have long-lasting effects on the mental health and substance use of all youth and adults. Black, American Indian and Alaska Native people have experienced the highest rates of overdoseⁱⁱⁱ and the most limited access to lifesaving medications for opioid use disorder (OUD).^{iv} Among the 2.5 million individuals with OUD, only 1 in 5 (533,000 people) received MOUD in 2021.^v No one disputes the unprecedented need for OUD treatment and the urgency to expand buprenorphine and other MOUD access.

The DEA's 30-day in-person requirement ignores important lessons from COVID-19 and does not strike the right balance between controlling diversion and saving lives.^{vi} Research that examines the effect of the COVID-19 telehealth flexibilities demonstrates – as the proposed rule recognizes – that

buprenorphine was involved in a very small portion of overdose deaths (2.2%) and the proportion of buprenorphine-involved overdose deaths did not increase during the pandemic.^{vii} The research also confirms that buprenorphine misuse is motivated primarily by the need to self-treat cravings and withdrawal symptoms, which would be most effectively addressed through expanded – not reduced – access to treatment.^{viii}

COVID-19 flexibilities have allowed practitioners to make more patient-centered decisions, tailoring the use of telemedicine to an individual’s circumstances and determining whether, when, and how often to see a patient in person.^{ix} They have also allowed for a reexamination of the value of in-person examinations, the optimal frequency of toxicology screens, alternatives for monitoring medication use, and ability to counsel patients via telemedicine about buprenorphine and other drug use.^x Practitioners must be allowed to make these care decisions without the imposition of arbitrary in-person evaluation requirements that have proven to be unnecessary for effective and safe care.

Allowing practitioners to make individualized care decisions via expanded use of telemedicine is also essential to meet the sheer need for treatment among current and new patients. The existing healthcare workforce that has provided MOUD to date is far too limited and geographically inaccessible in many parts of the country to allow for an in-person evaluation within 30-days.^{xi} While the removal of the X-waiver, expanded education related to substance use disorder and OUD care, and de-stigmatization of MOUD will, over time, expand provider availability, the proposed rule inaccurately suggests that a nationwide shortage of prescribers of buprenorphine no longer exists.^{xii} For the foreseeable future, existing prescribers and other medical care settings would need to significantly expand their patient census and MOUD services to meet the proposed DEA in-person care requirement.^{xiii}

The Opioid Public Health Emergency gives the DEA and HHS the authority to continue telemedicine services started during the COVID-19 Public Health Emergency that have improved care access and appropriately placed prescribing and care decisions in the hands of practitioners who are best able to determine the need and frequency for in-person care. Pausing the proposed buprenorphine regulation will also allow federal officials to consult with stakeholders, including people who use drugs, patients receiving MOUD, and practitioners delivering in person, telehealth and hybrid services, on proposed standards that will effectively satisfy Ryan Haight requirements and implement advancements in OUD care delivery.

B. Prescribing Mental Health Medications Subject to Ryan Haight Act Via Telemedicine

Our organizations are also concerned about similar telehealth prescribing restrictions the DEA has proposed placing on important mental health medications. At a time of heightened mental health needs – with key national associations and the U.S. Surgeon General having declared a crisis in youth mental health – these restrictions fail to strike the right balance between sustaining and increasing access to medically necessary treatment and preventing inappropriate prescribing of controlled medications.

The rule must take into account the fact that 55% of U.S. counties have no psychiatrists,^{xiv} and 130 million people live in areas with a shortage of mental health providers.^{xv} Access to mental health treatment, including medications, via telehealth has been critical to overcoming these barriers. Among specialties, psychiatry has the highest telehealth utilization for outpatient office visits, with half of all appointments occurring via telehealth in February 2021.^{xvi} Furthermore, other data suggest that the percentage of telehealth claims associated with a mental health diagnosis has remained steady (roughly 60%).^{xvii}

This is not surprising given both the shortage of providers in many areas and, as the proposed rule itself notes, the fact that CMS has recognized the unique ability of mental health services to be provided via telehealth (including audio-only); these services “are different from other services because they principally involve verbal exchanges between patient and practitioner.”^{xviii} Thus, we believe the proposed rule’s restrictions on telehealth prescribing will cut off access to needed treatment at a time when we are finally making progress in increasing access to care.

We are of course concerned about high-profile reports of inappropriate prescribing of certain mental health medications, yet the proposed rule takes a harmful, unnecessary, and blunt approach. Rather than adopting the proposed rule, we urge the Administration to prevent inappropriate prescribing by putting in place safeguards relating to patient assessments and prescriber training.

Common-sense safeguards that align with the standards of care for mental health treatment can help prevent inappropriate prescribing of mental health medications. The proposed rule’s extraordinarily restrictive approach is inconsistent with the standard of care, which does not require an in-person appointment in order to access needed treatment.

Rather than set back access to substance use disorder and mental health care at a time of national crisis, we urge the Administration to withdraw the proposed rule restricting access to the lifesaving medication buprenorphine and modify the proposed rule to allow telehealth prescribing of all other medications, including mental health medications, with safeguards. If finalized, the proposed rules would reinforce our country’s historic discrimination against individuals with mental health and substance use disorders and undermine the Administration’s otherwise robust and system-changing efforts that are needed to address our nation’s mental health and addiction crises. We urge the Administration to reverse course.

Thank you for considering our views. Please contact Ellen Weber (eweber@lac.org) and David Lloyd (David@thekennedyforum.org) with any questions.

Sincerely,

ACTNow for Mental Health

AIDS United

American Academy of Child and Adolescent Psychiatry

American Association of Psychiatric Pharmacists

American Psychological Association Services, Inc.

Anxiety and Depression Association of America

Association for Ambulatory Behavioral Healthcare

Association for Behavior Health and Wellness

Association of Maternal & Child Health Programs

Autistic Self Advocacy Network

C4 Recovery Foundation
California Consortium of Addiction Programs & Professionals
Center for Law and Social Policy (CLASP)
Collaborative Family Healthcare Association
Community Catalyst
Depression and Bipolar Support Alliance
Drug Policy Alliance
Faces & Voices of Recovery
Faith in Harm Reduction
HIPS DC
HOPICS
Humboldt Area Center for Harm Reduction
Inseparable
Integrated Harm Reduction
Jewish Federations of North America
Jewish Human Service Agencies
Legal Action Center
Maternal Mental Health Leadership Alliance
Mental Health America
NAADAC, the Association for Addiction Professionals
National Alliance on Mental Illness (NAMI)
National Alliance on Mental Illness—New York State (NAMI-NYS)
National Association of Addiction Treatment Providers
National Association of State Mental Health Program Directors
National Council on Alcoholism and Drug Dependence—Maryland Chapter
National Disability Rights Network (NDRN)
National Harm Reduction Coalition
National Health Care for the Homeless Council
National Health Law Program
National Pain Advocacy Center

National Viral Hepatitis Roundtable (NVHR)
Nebraska Appleseed
Overdose Crisis Response Fund
Partnership to End Addiction
Peer Voices Network
Public Justice Center
Rights & Democracy
RI International
SHAPE New Mexico
SMART Recovery
Southeastern Ohio Legal Services
St. James Infirmary
Taner Associates
TASC
The Kennedy Forum
The Policy Center for Maternal Mental Health (formerly 2020 Mom)
Treatment Communities of America
University of Missouri, St. Louis—Addiction Science Team
Velnonart Transformative Health
Vital Strategies
WestCare Foundation
Where There's A Will Fund

Individuals

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- ⁱ Christopher J. Jones, *et al.*, “Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic,” *JAMA PSYCHIATRY* (Oct. 5, 2022) <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953>.
- ⁱⁱ Centers for Disease Control and Prevention, Vital Statistics Rapid Release: Provision Drug Overdose Death Counts. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.
- ⁱⁱⁱ Merianne Rose Spencer, *et al.*, Drug Overdose Deaths in the United States, 2001-2021, National Center for Health Statistics Data Brief No. 457 (Dec. 2022), <https://www.cdc.gov/nchs/products/databriefs/db457.htm#print>.
- ^{iv} Mbabazi Kariisa, *et al.*, Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics – 25 States and the District of Columbia, 2019-2020, *MMWR* (July 22, 2022), <https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e2.htm>.
- ^v Substance Abuse and Mental Health Services Administration, Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (2022), at 55. <https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFRRRev010323.pdf>.
- ^{vi} The proposed rule offers limited support for the 30-day in person evaluation requirement, stating that “requiring an in-person visit with the prescribing practitioner within 30 days is consistent with the usual course of MOUD and purpose of the Ryan Haight Act, and necessary to enforce the CSA and its implementing regulations.” Drug Enforcement Administration, Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. 12890, 12900 (March 1, 2023) [hereinafter DEA]. The “usual course of MOUD” should be defined by the COVID-19 experience, not pre-pandemic practices, and the telemedicine exceptions to Ryan Haight demonstrate that the law requires no set timeline for an in-person evaluation.
- ^{vii} See Lauren J. Tanz, *et al.*, “Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic,” *JAMA NETWORK OPEN* (Jan. 20, 2023) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.
- ^{viii} Beth Han, *et al.*, “Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US,” *JAMA NETWORK OPEN* (Oct. 15, 2021) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785011>.
- ^{ix} Lori Usher-Pines, *et al.*, “Treatment of Opioid Use Disorder During COVID-19: Experiences of Clinicians Transitioning to Telemedicine,” *J. OF SUBSTANCE ABUSE TREATMENT* (2020) [https://www.jsatjournal.com/article/S0740-5472\(20\)30380-9/fulltext](https://www.jsatjournal.com/article/S0740-5472(20)30380-9/fulltext).
- ^x Christopher J. Frank and Lewei (Allison) Lina, “Defining and Supporting High-Quality Telehealth for Patients with Opioid Use Disorder: The Promise and Potential Pitfalls of Telehealth Expansion,” *SUBSTANCE ABUSE* (Oct. 12, 2022) <https://pubmed.ncbi.nlm.nih.gov/36222798/>.
- ^{xi} James R. Langabeer, *et al.*, “Geographic Proximity to Buprenorphine Treatment Providers in the U.S.,” *DRUG AND ALCOHOL DEPENDENCE* (2020) <https://www.sciencedirect.com/science/article/pii/S0376871620302969?via%3Dihub>.
- ^{xii} DEA, *supra* note vi, at 12894.
- ^{xiii} Langabeer, *supra* note xi.
- ^{xiv} “Mapping Supply of the U.S. Psychiatric Workforce,” School of Public Behavioral Health Workforce Research Center, University of Michigan. October 2018.
- ^{xv} Chris Larson, “Where the Mental Health Clinician Shortage Is at Its Worst.” *Behavioral Health Business*. June 24, 2022. <https://bhbusiness.com/2022/06/24/where-the-mental-health-clinician-shortage-is-at-its-worst/>.
- ^{xvi} Oleg Bestsenyy, *et al.*, “Telehealth: A quarter-trillion-dollar post COVID-19 reality?” McKinsey & Company. July 9, 2021. <https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality>.
- ^{xvii} See “FAIRHealth telehealth data from December 2022 as compared to November / December 2021”: <https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/dec-2022-national-telehealth.pdf> (December 2022) and <https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/dec-2021-national-telehealth.pdf> (November / December 2021).
- ^{xviii} Drug Enforcement Administration, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875, 12878 (March 1, 2023).