The Honorable Anne Milgram, Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW 8701 Morrissette Drive
Springfield, Virginia 22152

March 31, 2023

Re: "**Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket DEA-407)**"

My colleagues and I have a longstanding commitment to serve patients with pain, medication dependence, substance misuse, substance use disorder and – often – disadvantaged social situations. My colleagues are internal medicine and addiction medicine physicians, academic scholars, and patient advocates. As primary drafter, I have board certifications in both internal medicine (American Board of Internal Medicine) and in addiction medicine (American Board of Preventive Medicine). I have a 27 year history of frontline care for vulnerable populations, most notably homeless and formerly homeless individuals who live in urban and rural settings, including Veterans. My research publications include consideration of prescription opioid misuse, addiction treatment, challenges of care delivery for poverty populations, and challenges in the care of patients with long-term pain. None of us have ties to the pharmaceutical industry or opioid litigation.

We affirm that it would be uncommon for any of us to consider prescription of a controlled substance without an initial in-person visit. However, we believe that the proposed rule offers an unnecessarily tight restriction, coupled to requirements that – as currently worded – are either confusing or would put both the integrity and privacy of medical records at risk, as reviewed below:

I. The prohibition on initiation of any Schedule II or 'narcotic' Schedule III should be reconsidered

First, the rule lays out a too-broad prohibition on initiation of any Schedule II, or "narcotic" Schedule III drug, a posture that no longer fits the circumstances of the US overdose crisis, and which incurs a risk to many patient groups. The DEA justifies with the following reason "*Given the ongoing opioid epidemic at the time of publishing, DEA believes that allowing for the prescription of any schedule II substances or the general prescription of narcotic controlled substances as a result of telemedicine encounters would pose too great a risk to the public health and safety*." The rule proposes some exceptions, including a "qualifying telemedicine referral".

We note that the Ryan Haight Act itself does not **require** the DEA to propose such a broad prohibition. Further, as noted by ASAM in its letter, the Controlled Substance Act would seem to grant authority to the Attorney General and the Secretary to permit "telemedicine" if it is in a

manner "*consistent with effective controls against diversion and otherwise consistent with the public health and safety" (21 U.S.C. 802(54)(G))*

Moreover, while the DEA cites "*the ongoing opioid epidemic*" as prohibitive, analysis of US overdose data reflects a torrent of illicit fentanyl deaths. Deaths involving prescribed opioids have remained stable. Also, opioid prescriptions fell 44% from 2011 to 2020, and morphine milligram equivalents dropped 55% in the same period. Data presented by the FDA show that prescriptions per capita in 2020 matched levels last seen in 1993.[1]

These circumstances do not justify imprudent forms of telemedicine-based prescribing. However, these circumstances should allow DEA to take careful measure of other, real evidence that shows why there now is a pressing need, where appropriate, for **initiation** of a Schedule II or "narcotic" Schedule III without prior in-person visit.

Specifically, a series of peer-reviewed studies and media reports have documented that among the 8-10 million Americans who receive opioids on a chronic basis,[2] termination of opioids is typically abrupt, not patient-centered, and coupled with termination of the care relationship altogether.[3-5]

People in this "recently cut-off" group are – with increasing frequency- losing access to a clinical prescriber who they cannot replace at all, or at least not in a timely fashion. And it's **their safety** that DEA should take into account prior to rejecting telehealth for initiation of Schedule II or "narcotic" Schedule III in the absence of a "qualifying telehealth referral."

The patients in this group may require telehealth because they are stranded and clinicians who will receive them are hard to find. Scholarly work shows that up to 50% of potential clinicians are unwilling to receive or serve patients on prescribed opioids, which has been published in peer-reviewed literature.[6,7]

In the wake of a legal investigation of one prescriber covered in the media (whose certificate was pulled), one of us witnessed a patient with pain who was left stranded. This patient could find no prescriber initially. This patient had to enter an opioid treatment program in order to avert what could have been the patient's death, either from Takotsubo cardiomyopathy or mental health deterioration. After several weeks of work by a dozen people reaching out on the patient's behalf, a prescriber in a different state was found. However, several weeks were required to arrange transportation.

Others similarly stranded found no one to assume their care. Some died. **These deaths were expected and preventable**. Indeed, the Food and Drug Administration has cautioned against sudden opioid stoppage for this reason.[8] A series of peer-reviewed studies indicate that the risks of dose reduction or stoppage include suicidal events, overdose events with other substances, mental health destabilization, and medical destabilization for other conditions such as diabetes.[9-14] Takotsubo cardiomyopathy and heart failure are also reported.[15] We have contributed to this literature.[16] One signatory (Gordon) and I (Kertesz) are investigators funded

by the US federal government to closely examine the suicides that have occurred after disruption of prescribed opioids in patients who were taking this medication longterm to manage pain.

The core concern is summarized as follows: where patients with long-term opioid receipt are both opioid-dependent and clinically stranded, there needs to be flexibility to allow these patients a chance to avert risks to their health and safety. These risks have been affirmed by both the CDC and FDA. To overlook these safety considerations risks the health and lives of a large cohort of vulnerable patients.

II. There are two options that DEA could consider to protect stranded patients.

The first option in any revision would be to allow that **continuing a prior dose**, from a prior prescriber, simply does not count as **initiation**. Rather, it is a **continuation**, provided that the continuing prescriber has met standards of care as required by their state medical board and other applicable entities; careful evaluation via telehealth coupled with review of PDMP, likely would meet this standard in most states. This approach would be analogous to flexibilities that the Substance Abuse and Mental Health Services Administration allows for "guest dosing" at an Opioid Treatment Program. The guests are not mandated to re-initiate at 30 mg of methadone. Their situation counts as "continuation."

A second option **would be to allow a 60-day initiation of opioid pain medicines via telehealth,** provided the clinician has documented the situation with care, doing so in a way that adheres to rules of their medical board, and documented review of prescription drug monitoring program records. This approach would then reflect the Federation of State Medical Boards, as cited by the American Society of Addiction Medicine in its response to DEA-948: namely, "a *physician patient relationship may be established via either synchronous or asynchronous telemedicine technologies without any requirement of a prior in-person meeting, so long as the standard of care is met*." We recognize some could suggest the proposed "*qualifying telehealth referral*" provision affords a kind of flexibility. However, we don't believe that the "qualifying telehealth referral" will protect patients with pain under exigent circumstances, as we'll explain

Specifically, when patients' opioid pain medicines are stopped abruptly, their prescribers are often responding to pressure, or a policy mandate, or- alternatively- they have lost their DEA certificate. These situations entail conflict with the patient and/or termination of the care relationship. A "qualifying telehealth referral" is not likely to be forthcoming.

We therefore urge the DEA to adopt either one of the two options laid out above. If a potential prescriber can assist a newly stranded patient with pain and dependence on prescribed medication, but that patient lacks control of time and transportation, then telehealth will avert a risk to safety denounced by both the CDC and the FDA.[17,18]

III. The rule's language on record-keeping is unclear, and seems to require forms of record-keeping that jeopardize data security and privacy

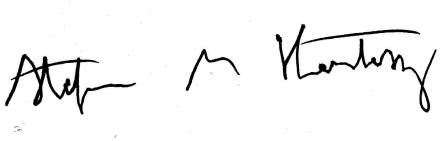
The draft rule itself proposes that registrants must create a “log” for each prescription issued pursuant to a telehealth encounter prepared in the absence of prior in-person visits. The DEA “*does not anticipate it imposes a major burden on registrants*". We underscore that this rule, and its use of the word “log,” does – on face– **seem to require a parallel system of medical records, in addition to the regular medical record**.

There is likely to be great cost and logistical work to set up a parallel system of records. That will disincentivize provision of the care itself. Additionally, any time medical care is recorded in a dual and parallel system of records, this introduces risks to patient privacy and to their safety if information is not scrupulously duplicated across systems. If the DEA intended the word “log” to be understood in a different way, the final regulation should clarify. However, we recommend that the DEA not require creation of a parallel system of records for care of a particular patient group, or via a particular modality.

Finally, in conjunction with the log, the DEA draft rule creates additional uncertainty by requiring storage of records “*at the registered location on the certificate of registration issued pursuant to section 303(f) of the Act (21 U.S.C. 823(g)).”* The problem is that while DEA **solicits** both a practice address and a mailing address, the sole address on the certificate mailed to a DEA registrant is often the preferred mailing address, not the business address. Thus, the rule (as drafted) implies a requirement to save medical records **not** at the place of clinical practice but, potentially, **in the registrant’s home**. Doing so may be a security risk. Usually, such storage violates the rules set by most health care employers. Therefore, we recommend clarifying the language and intent of this provision.

Please note that in submitting these comments, the signatories represent their own views and do not purport to present views of any agency where we are employed. Detailed bios for each signatory are offered below the signatures and references.

Signatures



Stefan G. Kertesz, MD, MSc
Professor of Medicine, Heersink UAB School of Medicine
Chair, Pain and Addiction Special Interest Group, UAB
Program Director, Homeless Patient-Aligned Care Team & Member Pain Committee
Birmingham Veterans Affairs Health Care System

Adam J. Gordon, MD MPH FACP DFASAM
Elbert F. and Marie Christensen Endowed Research Professorship
Professor of Medicine and Psychiatry
Director, Program for Addiction Research, Clinical Care, Knowledge, and Advocacy (PARCKA)
Co-Director, Greater Intermountain Node (GIN) of the NIDA CTN
University of Utah School of Medicine
Chief, Addiction Medicine
National Director, Medication Addiction Treatment in the VA (MAT-VA) Initiative
National Director, Coordinating Center of the Advanced Interdisciplinary Fellowship in Addiction Treatment
Director (emeritus), Vulnerable Veteran Innovative Patient Aligned Care Team (VIP) Initiative
Salt Lake City VA Health Care System

(signed electronically)

Ajay Manhapra, MD
Section Chief, Pain Medicine at Hampton VAMC
Lecturer, Department of Psychiatry, **Yale School of** Medicine

(signed electronically)

Leah J. Leisch, MD
Assistant Professor at Heersink UAB School of Medicine.
Director, addiction medicine fellowship at University of Alabama at Birmingham.
Director of the Opioid Reassessment Clinic at the Birmingham VA Medical Center
Director of Substance Use Services at the Beacon Integrated Health Clinic

(signed electronically)

Sally Satel, MD
Sally Satel, M.D.
American Enterprise Institute
Lecturer, Yale University

References

1. Woods C. “Prescription Opioid Utilization Patterns in the U.S.” FDA Public Workshop on Opioid Prescriber Education. October 13, 2021. Accessed at https://healthpolicy.duke.edu/sites/default/files/2021-10/Opioid%20Prescriber%20Education%20Workshop%20Slide%20Deck.pdf on January 29, 2022..

2. Mojtabai R. National trends in long-term use of prescription opioids. *Pharmacoepidemiol Drug Saf.* 2018;27(5):526-534.

3. Perez HR, et al. Opioid Taper Is Associated with Subsequent Termination of Care: a Retrospective Cohort Study. *J Gen Intern Med.* 2020;35(1):36-42.

4. Neprash HT, et al. Abrupt Discontinuation of Long-term Opioid Therapy Among Medicare Beneficiaries, 2012-2017. *J Gen Intern Med.* 2021.
5. Stein BD, et al. Rapid Discontinuation of Chronic, High-Dose Opioid Treatment for Pain: Prevalence and Associated Factors. *J Gen Intern Med.* 2021.
6. Lagisetty P, et al. Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study. *Pain.* 2020;162(5):1379-1386.
7. Lagisetty PA, et al. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928.
8. United States Food and Drug Administration. FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. FDA Drug Safety Communication. 4/19/19. Accessed at https://www.fda.gov/Drugs/DrugSafety/ucm635038.htm on December 2, 2020. 2019.
9. Magnan EM, et al. Association Between Opioid Tapering and Subsequent Health Care Use, Medication Adherence, and Chronic Condition Control. *JAMA Netw Open.* 2023;6(2):e2255101.
10. Fenton JJ, et al. Long-term Risk of Overdose or Mental Health Crisis After Opioid Dose Tapering. *JAMA Netw Open.* 2022;5(6):e2216726.
11. Agnoli A, et al. Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids. *JAMA.* 2021;326(5):411-419.
12. Hallvik SE, et al. Patient outcomes after opioid dose reduction among patients with chronic opioid therapy. *Pain.* 2022;163(1):83-90.
13. DiPrete BL, et al. Association of Opioid Dose Reduction With Opioid Overdose and Opioid Use Disorder Among Patients Receiving High-Dose, Long-term Opioid Therapy in North Carolina. *JAMA Network Open.* 2022;5(4):e229191-e229191.
14. James JR, et al. Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: a Retrospective Cohort Study. *J Gen Intern Med.* 2019;34(12):2749-2755.
15. Back DK, et al. Substance Withdrawal-Associated Takotsubo Cardiomyopathy: A Review of the Literature. *Prim Care Companion CNS Disord.* 2023;25(1).
16. Oliva EM, et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation. *BMJ.* 2020;368:m283.
17. Dowell D, et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. *MMWR Recomm Rep.* 2022;71(3):1-95.
18. Dowell D, et al. No Shortcuts to Safer Opioid Prescribing. *N Engl J Med.* 2019;380(24):2285-2287.

Bios:

Stefan G. Kertesz, MD, MSc has a professional mission to assure effective delivery of health care to patient populations who are disadvantaged or poorly served by mainstream systems of care. He is a Professor of Medicine at the Heersink UAB School of Medicine and Professor at the UAB School of Public Health. He is an attending physician at the Birmingham, Alabama VA Health Care System, board-certified in addiction medicine and internal medicine. He has a 26-year history of delivering primary care to persons who have experienced homelessness and addiction, and has led VA- and NIH-funded research on care for vulnerable populations,

focusing on pain, care delivery, and addiction, since 2002. In 2019 he co-led a successful public petition that resulted in public declaration by the US Centers for Disease Control and Prevention to caution against misapplication of its 2016 Guideline. Dr. Kertesz received the 2021 David Calkins Award in Health Policy Advocacy, Society of General Internal Medicine. At present, Dr. Kertesz leads the CSI:OPIOIDs study, focused on close examination of suicide deaths occuring after prescription opioid stoppage or reduction. He assisted in the development of ALAHOPE, a statewide curriculum on opioids, pain and substance use disorder for health professions students.

Adam J. Gordon, MD MPH FACP DFASAM has a professional mission to improve the access and quality of care of patients who have vulnerabilities, including those with addiction and substance use disorders. He is the Elbert F. and Marie Christensen Endowed Research Professor, tenured Professor of Medicine and Psychiatry and Associate Chief of Epidemiology, at the University of Utah School of Medicine and the Section Chief of Addiction Medicine at the VA Salt Lake City Health Care System. He is a board-certified internal medicine and addiction medicine physician and is a Fellow in the American College of Physicians (FACP) and a Distinguished Fellow in the American Society of Addiction Medicine (DFASAM). He is the PI of the Greater Intermountain Node (GIN), a Center site of the NIH NIDA Clinical Trials Network; he founded and is the Director of the Program for Addiction Research, Clinical Care, Knowledge, and Advocacy (PARCKA); and he founded and is the Emeritus Director the Vulnerable Veteran Innovative Patient-Aligned-Care-Team (VIP) Initiative, a clinical-evaluation initiative at the VA Salt Lake City Health Care System. He is a Core Faculty member of the VA Salt Lake City Informatics, Decision-Enhancement and Analytic Sciences (IDEAS) Center, a Department of Veterans Affairs Health Services Research and Development (HSR&D) Center of Innovation (COIN).

Dr. Gordon has has authored over 315 peer reviewed articles in high impact journals, and was awarded the 2021 VA Health Services Research and Development (HSR&D) “Health System Impact Award” and the 2022 David C. Lewis, MD Service to Association for Multidisciplinary Education and Research in Substance Use and Addiction (AMERSA) Award.

Ajay Manhapra, MD is Section Chief for Pain Medicine at Hampton VAMC, and Lecturer with the Yale School of Medicine. He is board certified in addiction medicine and internal medicine. He has specific expertise in pain/addiction overlap care, in treatment-refractory chronic pain with opioid dependence, opioid addiction, and complex mental and medical Illness. Dr. Manhapra established the High Risk Pain Pact.

Leah J. Leisch, MD is Assistant Professor at Heersink UAB School of Medicine. She is board-certified in internal medicine and addiction medicine. She directs the addiction medicine fellowship at University of Alabama at Birmingham. She is Director of the Opioid Reassessment Clinic at the Birmingham VA Medical Center, and Director of Substance Use Services at the Beacon Integrated Health Clinic with University of Alabama at Birmingham. Dr. Leisch leads in several unique clinical initiatives that focus on enhancements to and stabilization of care in patients with pain and opioid receipt where the care has either not optimized function or where

safety of opioid management presents a serious clinical concern. She assisted in the development of ALAHOPE, a statewide curriculum on opioids, pain and substance use disorder for health professions students.

Sally Satel, MD
Sally Satel, M.D. is a practicing psychiatrist and lecturer at the Yale University School of Medicine. She is a Fellow at the American Enterprise Institute. She has written five books that cover health ethics, health policy, discourse on neuroscience and the interface of political discourse with health care. In 2019, she co-led a successful public petition that resulted in public declaration by the US Centers for Disease Control and Prevention to caution against misapplication of its 2016 Guideline. She also serves as Staff Psychiatrist at Partners in Drug Use Rehabilitation and Counseling (PIDARC).