NPAC
NATIONAL PAIN ADVOCACY CENTER

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March 31, 2023

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

Dear Administrator Milgram:

Re: DEA Proposed Rule, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, DEA-2023-04248, DEA-407/DEA-2023-0029-0001.

On behalf of the National Pain Advocacy Center (NPAC), we write in response to the DEA's Proposed Rule, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*, to express grave concern that its roll-back of telemedicine prescribing will create impediments to essential medication and exacerbate care access problems for several patient populations.

NPAC is a 501(c)(3) nonprofit alliance of clinicians, scientists, public health experts, and people with lived experience, working to advance the health and human rights of people living with pain. We envision a world in which pain is treated equitably and effectively. NPAC includes experts in pain and addiction, people with lived experience of pain, and people in recovery from addiction. Many members have concurrent disabilities, such as ADHD and mental health conditions, implicated by this rule.

NPAC was also one of 70 organizations, including the American Medical Association, the American Psychiatric Association, the American Association of Nurse Practitioners, and the American Mental Health Counselors Association, that has urged the DEA to extend telemedicine prescribing of controlled medication within the bounds permitted by the Ryan Haight Act after the COVID-19 public health emergency [PHE] ends.

We believe that the DEA's proposed rule is overly narrow, burdensome, and unworkable. Because it is not based on an empirical foundation, this framework will predictably result in patients losing access to necessary medication and care if implemented.

We strongly urge the DEA to substantially amend the rule to permit telemedicine prescribing of controlled medications with safeguards that do not impede access to care. Given the heightened risk of overdose in patients currently taking opioids when pain medication is disrupted, we further urge the DEA to extend telehealth flexibilities that ensure the continuity of their care

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under the Public Health Emergency related to illicitly-manufactured opioids and drug overdose mortality.

Background:

During the COVID-19 PHE, telemedicine became a mainstay of healthcare in the U.S. Use of telemedicine persisted even after in-person care resumed, according to Medicare fee-for-service Part B claims data and Medicare enrollment information from 2022. Importantly, individuals with disabilities such as those in NPAC were the most likely to use telehealth services.

Individuals with disabilities experience poorer health outcomes and face heightened barriers to care with transportation barriers being a significant issue. Some disabled persons are more susceptible to COVID-19 because they are immune-compromised; once the PHE ends, many disabled people will face even greater impediments to care because the protections that were in place are being eliminated. Both considerations make extending access to telemedicine services imperative.

Critically, many individuals with disabilities rely on controlled medications to treat conditions such as pain, use disorders, ADHD, mental health issues, epilepsy, and others. The DEA's proposed regulation will disparately impact these disabled patients whose access to care is already imperiled.

The DEA's proposed rollback on telehealth prescribing comes amid colliding public health crises. The overdose crisis continues to take an unconscionable toll on human life with drug-related mortality surpassing 107,000 persons in 2021. Chronic pain remains our most pervasive public health issue, affecting 1 in 6 Americans, with nearly 20 million suffering pain so severe that it regularly limits life activities or work. More than 90% of the country considers mental health issues to have reached crisis proportions. These crises overlap and intersect.

At the same time, and as the Centers for Disease Control and Prevention has acknowledged, policies aimed at curtailing opioid prescribing have imposed barriers to medication and care for people with pain, including those with cancer. Opioid settlement agreements are further impeding access to controlled medications, according to a recent expose in the *New York Times*. People who need Adderall or its generic forms to treat ADHD have lost access to those medications due to a nationwide shortage, as the Food and Drug Administration has recognized. And the uneven distribution of health providers, especially clinicians offering behavioral care, creates persistent gaps in care. The burden of these gaps falls disproportionately on rural communities, racial and ethnic minority groups, people with disabilities, people who are socioeconomically constrained, trans and nonbinary persons, and other marginalized individuals.

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Amid colliding crises and these well-recognized barriers, those most in need—the patients at the center of these crises—are likely to suffer significant harm if the DEA proceeds with this rule.

DEA proposal:

We understand the DEA's proposal to include the following:

- Requiring an in-person visit for all schedule II medications;
- Permitting a 30-day supply via telehealth for schedules III-V medications, including buprenorphine (which is addressed in a concurrent rule), but requiring in-person evaluation thereafter;
- Maintaining location requirements, such that a provider must have registration in the state where both they and the patient are located;
- Imposing significant reporting requirements for telehealth prescribing;
- Maintenance of a record system for telehealth at the location shown on the prescriber's DEA certificate
- Allowing an in-person visit to include one in which a provider sees a patient in a physical location while another provider participates virtually and allowing referrals from an in-person evaluator to a telehealth prescriber provided significant additional reporting requirements are met;
- Flagging all prescriptions as having been issued using telemedicine; and
- Allowing a limited six-month extension for those who have already received medication via telehealth during part of the public health emergency to make further arrangements for care.

Analysis:

Schedule II Controlled Medications

People who use opioids to manage pain currently face access barriers to medication and care. Half of the primary care clinics in the U.S. will refuse to take on a new patient who uses opioids to manage pain, according to national studies. A recent NBC news piece highlighted the plight of a patient who called 150 different providers desperately trying to arrange care.

Interruptions in care continuity may occur because a provider stops prescribing opioids to all patients, retires, falls under investigation, or a patient moves. When the DEA recently suspended a doctor's license in California, for example, his patients were abandoned. Three died. Another was able to stave off withdrawal by using a methadone clinic but the medication did not manage her pain. She, therefore, suffered persistent spasticity that often knocked her out of her wheelchair for several months until she was able to arrange alternative care which required her to travel in that condition to another state.

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Such lapses in care are life-threatening. Studies show that disrupting opioid medication ***increases patients' risk of overdose and suicide*** by three to five times. *See* Appendix A. Disruptions in medication are also linked to increased emergency room visits and hospitalizations, the breakdown of healthcare relationships, poor medication adherence for conditions such as diabetes and hypertension, mental health crises, and the unnecessary destabilization of patients' health and lives. *See id.*

These impediments to continuity of care are likely to be borne disproportionately by people with disabilities, racialized populations, and people living in rural areas or other healthcare deserts. Disparities in pain experience, biases in pain assessment, and inequities in prescribing for pain based on race, gender, gender identity, and disability are well documented. *See* Appendix B.

On the positive side, telehealth prescribing can provide a literal lifeline to patients who experience lapses in and barriers to care.

While we appreciate the DEA's extension of the protections under the PHE for six months to avoid a telehealth cliff for those who have been prescribed medication through a telehealth provider, continuity of care is an ongoing problem. Under the DEA's current proposal, persons using schedule II controlled medications who experience lapses in care will have no time whatsoever to make alternative care arrangements at the risk of their medical deterioration and death. Referrals, while helpful, do not ensure timely access to care.

Nor have blunt cuts in the medical supply of opioids had the intended impact of making America safer: as prescribing has dropped by nearly 50% since 2011, drug overdose mortality more than doubled. The promulgation of more one-size-fits-all policies risks further endangering patient health and safety.

As many as 8 million Americans rely on opioids to manage pain—more than three times the number of persons with a diagnosed opioid use disorder. Throwing their care into jeopardy at the risk of overdose and suicide is reckless. The initiation of illicit street market drugs after prescription-opioid stoppage is evidenced in peer-reviewed literature. This is no time to incentivize people to turn to the illicit market, which is dangerous.

Importantly, the flexibilities that allowed for telehealth prescribing during the PHE do not appear to have resulted in documented harm: a rise in prescription-related drug overdose deaths is not evident in provisional death data from the National Center for Health Statistics. On the contrary, studies that have examined the impact of telehealth prescribing found, not surprisingly, that telemedicine prescribing reduced overdose mortality.

Given the heightened risk of overdose when pain medication is disrupted, we urge the DEA to extend telehealth flexibilities to ensure continuity of care for people currently taking prescribed opioids under the Public Health Emergency

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related to illicitly-manufactured opioids and drug overdose mortality or to substantially amend the proposed rule to provide more discretion to providers to determine, on an individualized basis when an in-person visit is warranted.

Schedule III-V Controlled Medications

Even the provision of a 30-day supply for schedule III-V medications is problematic given the fractured nature of the U.S. healthcare system. In 2022 in urban areas, the average wait time for an appointment with a new primary care provider was 26 days though in some cities it was 45.6 days. not rural areas.

Wait times may be considerably longer for specialist care and care in rural areas.

According to data from the Health Resources and Services Administration, 99 million Americans, live in health professional shortage areas.

Rural regions are especially hard hit, where hospital closures, including the 33 that shuttered between 2020 and 2023 alone, have further limited access to healthcare. A systemic review of barriers to access to pain care for older adults in rural areas identified transportation-related issues as a major access barrier to pain and palliative care – precisely the type of barrier mitigated by telemedicine.

While there remains a digital divide in this country with persistent disparities in broadband access in infrastructure, and we will continue to advocate for mitigating such inequities in telehealth, telemedicine is a critical lifeline for many.

Specific concerns with the proposal:

Real-time 3-person, 2-location visits are impractical for outpatient care and referrals will not ensure timely access to care

We recognize that by defining an in-person visit to include one in which one provider performs an in-person examination while another participates virtually, and by allowing referrals, the proposed rule endeavors to create additional but narrow routes for access to telehealth care. We are concerned, however, that the proposed carve-outs are mostly unworkable for outpatient care and so few providers will take advantage of these exceptions.

The limited telemedicine referral process will not ensure timely access to care. At a minimum, to reflect the current realities of medical practice, the referring clinician should be allowed to refer to a hospital, facility, or specialty group rather than being required to name a specific telemedicine provider.

Record-keeping requirements are burdensome and require clarification

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The DEA requires a "log" of medications prescribed through a telemedicine encounter without defining whether recording prescriptions in a HIPAA-compliant standard system of medical records is sufficient to constitute a "log." Does the DEA intend for prescribers to create a separate system of records solely for tracking telehealth prescriptions? Creating a segregated system of records poses risks related to privacy and security and requires clinicians to bear the additional costs of creating such systems. We urge the DEA to permit the notation of telemedicine prescriptions in existing medical record systems.

The current proposal also invites confusion when it states that records must be maintained at the location "on the certificate" issued by DEA to the registrant. Although registrants report both a practice address and a preferred mailing address to the DEA, the certificate they receive shows the preferred mailing address. Therefore, the phrase 'on the certificate' may be read by many practitioners to require the maintenance of telehealth prescription records in locations other than the practice address.

Flagging of telemedicine prescriptions invites rejection of prescription fills

The DEA's proposal to flag all prescriptions issued during a telemedicine encounter is especially alarming, given widespread reports that major pharmacy chains like Walmart have refused to fill telemedicine prescriptions. Flagging suggests that these prescriptions are somehow suspect or less *bona fide* than those issued during in-person visits, and gives permission to pharmacies to decline medication fills.

Licensing location requirements will burden care

Finally, restoring location requirements under which providers must be licensed in both their state and the location of the patient unnecessarily burdens access to patients in need of care. People with limited mobility, those with various stigmatized conditions, and those living in rural areas often rely on telemedicine relationships with geographically distant practitioners simply because they either lack access to nearby practitioners or there are no qualified nearby practitioners that will provide them with care. This is a significant issue for trans individuals because of the scheduling of hormones.

Permitting a licensed provider to prescribe to a patient in a remote location without requiring registration in the patient's location would protect this care while maintaining the safeguard that the clinician and dispenser have prescribing authority under existing DEA mandates.

Response DEA questions:

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The DEA specifically asked for comments on practitioner reporting requirements, the 30-day supply for schedule III-V medications, whether the DEA should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications, and whether this rule should be combined with the DEA's rulemaking, *Expansion of Induction of Buprenorphine via Telemedicine Encounters.*

We addressed specific concerns regarding reporting requirements, above, and worry that they are sufficiently burdensome to lead clinicians to avoid telemedicine prescribing.

The 30-day supply is insufficient given the well-known gaps in the U.S. healthcare system. If the average length of time to arrange for care in U.S. cities is 26 days, with some cities reporting 45 days and longer periods required for specialists or those living in care deserts, a 30-day supply is too restrictive.

The DEA's proposal to limit prescriptions to indications in the FDA-approved labeling interferes with the practice of medicine in likely contravention of federal law. *See* Buckman Co. v. Plaintiffs' Legal Comm, 531 U.S. 341 (2001) (explaining that not even the FDA can constrain off-label use as that would amount to direct interference in the practice of medicine). Off-label use of FDA-approved medications may be the only effective tool for managing rare diseases or conditions unresponsive to other treatments and is relatively commonplace. For the DEA to suggest such a dramatic change in a single sentence without carefully vetting the implications of that change is ill-advised.

In principle, we have no opposition to the DEA combining this rule with the rule on induction of buprenorphine for opioid use disorder, although we have urged the DEA to withdraw the buprenorphine rule. Combining the rules raises the issue of opioid exceptionalism by creating different requirements for prescribing buprenorphine for opioid use disorder and pain at a time when entities like the Veteran's Administration are embracing buprenorphine for pain.

DEA's stated commitment to prevent lapses in care:

The DEA says that it is committed to ensuring that people who need controlled medications receive them and states, "This rule is designed to ensure that patients do not experience lapses in care." But how? The proposal is out of sync with the realities of the U.S. healthcare system. The rule contains no mechanisms to ensure nor metrics to evaluate patient safety or continuity of care whatsoever.

Moreover, at a time when both CDC and the Food and Drug Administration have declared that patients with long-term pain are at risk when opioids are

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stopped abruptly, the DEA's proposed rule will increase highly risky and life-threatening disruptions in medication and care.

Conclusion:

In conclusion, we understand that physical exams facilitated by in-person visits are ideal and even essential in some healthcare situations. We appreciate that the government has a legitimate interest in preventing diversion and reining in the potentially questionable actors such as those who came on the scene amid the ramping up of a telehealth response to COVID-19 (although Cerebral is no longer prescribing Adderall via telemedicine).

Still, in-person visits are not a good proxy for *bona fide* healthcare relationships. After all, the pill mills that the DEA has spent considerable effort containing occurred in the context of in-person care. Patient outcomes can be superior with telemedicine even in primary care settings. The DEA's rule needs to provide greater discretion to providers to determine when in-person care is needed.

Healthcare delivery changed with the COVID-19 PHE. Systems were erected and refined to extend safe, effective, and necessary care to millions of Americans. The DEA's proposal to turn back the clock risks the health and lives of vulnerable patients. Amid colliding public health crises, the DEA should thoughtfully support expanded access, not cut lifelines.

Sincerely,

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Appendix A: Studies on barriers to continuity of care and disruption of opioid medication for pain

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On barriers to care:

- Two surveys found that half of all primary care clinics are unwilling to take on a new patient who uses opioids to manage pain.
- The original study is of clinics in Michigan (Lagisetty, JAMA Netw Open 2019).
- A follow-up study looked at primary care clinics in 9 states (Lagisetty, PAIN 2021).

On risks associated with disruption, discontinuation, and tapering of opioid medication:

- Disruption/discontinuation of opioids in patients stable on opioids is on the rise. (Neprash, J Gen Intern Med 2021).
- Just destabilizing a patient's dose resulted in a three-fold increased risk of overdose death. (Glanz, JAMA Netw. Open 2019).
- Higher incidence of overdose and mental health crises continued two years after the dose is destabilized. (Fenton, JAMA Open Netw. 2022).
- Heightened risk of overdose and suicide in patients without OUD/misuse risk w/ no difference in outcome btw. abrupt discontinuation or slow taper. (Larochelle, JAMA Netw. Open 2022).
- Tapering resulted in an increased risk of death in primary care settings (James, J Gen Intern Med 2019).
- Veterans who were tapered experienced a higher risk of death from overdose or suicide (Oliva, BMJ 2020).
- Tapering is associated with mental health crises and overdose events. (Agnoli, JAMA 2021).
- In Medicaid patients on opioids for more than 90 days found discontinuation often happened abruptly, within 24 hours, with almost half of such cases resulting in hospitalization or an ER visit (Mark, J Subs.t Abuse Treat. 2019).
- Increase in emergency department visits and hospitalizations, fewer primary care visits, and lower medication adherence for chronic conditions like diabetes and hypertension occurred with dose destabilization. (Magnan, JAMA Netw. Open 2023).
- Opioid disruption is associated with later termination of care relationships (Perez, J Gen Intern Med 2020).

Appendix B: Studies on disparities, inequities, and biases in pain care

Race:

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- Clinicians incorrectly believe that Black people feel less pain than White people, resulting in systematic undertreatment. These biases persist in medical students and trainees. (Hoffman et al, 2016)
- Brain imaging studies find that Black patients may experience more pain (Losin et al, 2020)
- Inequities in healthcare in general disproportionately affect people of color (Century Foundation, 2019)
- Disparities in pain go well beyond Black vs. white, reaching indigenous, multiracial, Hispanic, etc. (Zajacova et al, 2022)
- 20 years of studies show that Black and Hispanic patients are less likely to receive pain medication for acute pain in the ER (Lee et al, 2019)
- This persists: Black patients report higher average levels of pain but, in 90% of US healthcare systems, receive significantly lower doses of pain medication (Morden et al, 2021)
- Black and Hispanic patients with cancer who are nearing the end of life are less likely than White patients to get needed opioid medications to control their pain (Enzinger et al, 2023)

Sex & Gender:

- Women experience greater pain**,** have more diseases causing pain, and have their pain dismissed by clinicians (various articles)
- Different biological pathways may be responsible for pain in males (glial cells) and females (t cells) (2020) & Nature (2019)
- A meta-analysis reveals gender bias in pain treatment and heightened barriers to care (2018)

- Gender identity also plays a role in the severity of pain (2020)
- Significant health disparities affect people who are transgender (2018)

Disability:

- Pain is the chief cause of disability worldwide, according to the global burden of disease studies (2016), and in the US according to the Institute for Health Metrics and Evaluation (IHME) (2016)
- People with disabilities face physical and communication barriers that limit their access to pain treatment (various, CDC)
- People with disabilities face barriers related to misperceptions and biases of providers (NAESM, various)

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