



Accurate Clinic

2401 Veterans Memorial Blvd. Suite 16
Kenner, LA 70062 - 4799
Phone: 504.472.6130 Fax: 504.472.6128

www.AccurateClinic.com

Eric Ehlenberger MD

Recent DEA actions appear to stem from "corresponding responsibility" enforcement policies and settlement-driven "red flag" systems, rather than formal regulations. These pharmacy-level restrictions are not based on individualized patient assessment and directly contradict CDC guidance emphasizing flexible, patient-centered care.

Why the DEA is Doing This

The DEA enforces "corresponding responsibility" under the Controlled Substances Act, which holds pharmacists legally accountable for ensuring prescriptions are issued for legitimate medical purposes. [1][2] Pharmacies face potential DEA registration revocation if they fail to resolve "red flags" suggestive of diversion, including **patients traveling far distances** and pattern prescribing. [1]

Additionally, settlement agreements with major pharmacy chains (CVS, Walgreens, Walmart) and drug distributors require implementation of specific metrics to identify "red flags," including **the extent to which a pharmacy serves out-of-area patients** and monitoring of "highly diverted" controlled substances. [1] These settlements have created self-imposed thresholds and algorithms that pharmacies use to avoid legal liability, even though **the DEA clarified in 2023 that neither the DEA nor federal law imposes quantitative limits on controlled substance ordering or dispensing.** [1]

The 120-tablet monthly limit and 50-mile geographic restriction appear to be **pharmacy-level compliance strategies** to avoid triggering these red flag systems, rather than evidence-based patient safety measures.

Arguments Supporting Such Actions

Proponents might argue that these restrictions:

- Help prevent diversion of prescription opioids to illicit markets
- Reduce pharmacy liability for "knowingly filling" illegitimate prescriptions
- Align with suspicious order reporting requirements under federal law [1][2]

However, **evidence supporting the effectiveness of such blanket restrictions is weak.** Studies show that state opioid prescribing cap laws were **not associated with changes in opioid prescribing, overdose rates, or substitution with non-opioid treatments** among chronic pain patients. [3][4]

Arguments Refuting These Actions

1. Contradiction of CDC Guidelines

The 2022 CDC Clinical Practice Guideline explicitly states that recommendations are **"not intended to be implemented as absolute limits of policy or practice"** and emphasizes that they are **"voluntary and intended to be flexible to support, not supplant, individualized, patient-centered care."**

The CDC specifically criticized policies that have gone "well beyond its clinical recommendations," including:[\[5\]](#)

- **Rigid application of dosage thresholds**
- Duration limits by insurers and pharmacies
- Patient dismissal and abandonment[\[5\]](#)

2. Documented Patient Harms

Research demonstrates significant unintended consequences of restrictive opioid policies:

- **Increased pain, reduced quality of life, and greater risks of harm** among chronic pain patients[\[6\]](#)
- **Erosion of the physician-patient relationship**[\[6\]](#)
- **Forced tapering associated with a 69% increase in overdoses and 130% increase in mental health crises**[\[7\]](#)
- **Increased health plan disenrollment** after dose reductions, suggesting patients leave the healthcare system[\[8\]](#)
- **Barriers to legitimate access** without evidence of improved safety outcomes[\[9\]\[10\]](#)

3. Geographic Restrictions Lack Evidence

The American Society of Addiction Medicine (ASAM) 2024 guideline explicitly recommends that red flag policies should **"remove policies that inappropriately or unreasonably limit geographic distance between patient and prescriber or patient and pharmacy, especially considering increased utilization of telemedicine."** Geographic restrictions disproportionately harm rural patients who may have no choice but to travel significant distances for care.[\[1\]](#)

4. Arbitrary Quantity Limits Ignore Clinical Needs

A 120-tablet monthly limit (approximately 4 tablets daily) may be inadequate for patients legitimately prescribed immediate-release opioids every 4-6 hours for chronic pain conditions. The ASCO guideline notes that immediate-release opioids require administration every 4 hours to maintain stable blood levels and analgesia, which would require 180 tablets monthly for around-the-clock dosing.[\[9\]](#)

5. No Evidence of Effectiveness

Multiple studies found that state prescribing cap laws showed **no association with changes in opioid prescribing patterns or overdose outcomes.**[\[4\]\[3\]](#) One study noted that these laws often don't restrict prescriptions to shorter durations than clinicians would normally prescribe, with mean initial prescription duration already at 5.1 days before 7-day limits were imposed.[\[11\]](#)

How to Combat This Activity

Legal and Advocacy Strategies:

1. **Document patient harm:** Collect detailed records of patients unable to access prescribed medications, including documentation of increased pain, emergency department visits, or transitions to illicit substances.
2. **File complaints with appropriate agencies:**
HHS Office for Civil Rights: Denials of prescribed medications may violate the Americans with Disabilities Act (ADA) and federal civil rights laws^[1]
State Board of Pharmacy: Challenge policies that prevent pharmacists from fulfilling legitimate prescriptions
State Medical Board: Document how pharmacy restrictions interfere with the practice of medicine
3. **Engage state legislators:** The ASAM guideline recommends that states **enact laws establishing pharmacies' duty to dispense lawful prescriptions without undue delay.** Louisiana could pass legislation requiring pharmacies to fill legitimate prescriptions regardless of patient location.^[1]
4. **Contact state attorney general:** Request review of opioid settlement agreements to **ensure adequate access to medications** and remove provisions hindering access.^[1]
5. **Invoke CDC guidance:** Provide pharmacies and DEA officials with the 2022 CDC guideline language explicitly stating that recommendations should not be implemented as inflexible policies and that misapplication has caused patient harm.^[5]
6. **Professional society support:** Engage medical societies to issue statements supporting individualized prescribing and opposing blanket restrictions. The ASCO guideline specifically addresses barriers to opioid access and notes that regulations "greatly hinder availability."^[9]
7. **Media and public awareness:** Document the "opioid paradox" where **prescription restrictions have not reduced overdose deaths (which continue to rise from illicit synthetic opioids) while harming legitimate pain patients.**^{[12][10]}

Clinical Documentation:

Ensure prescriptions include:

- Clear documentation of medical necessity
- Diagnosis codes
- Treatment plans showing individualized assessment
- Documentation of non-opioid therapies tried
- Evidence of ongoing monitoring and reassessment

This creates a stronger record that prescriptions are for "legitimate medical purposes" under DEA regulations.

Collaborative Approach:

Consider working with patient advocacy organizations, pain medicine societies, and civil rights groups to mount a coordinated challenge to these policies. The evidence strongly suggests these blanket restrictions harm patients without improving safety outcomes and represent a misapplication of guidelines that were never intended to be rigid rules.^{[5][6][10]}

References

1. [The Role of Pharmacists in Medications for Addiction Treatment](#). American Society of Addiction Medicine (2024).
2. [Federal and State Pharmacy Regulations and Dispensing Barriers to Buprenorphine Access at Retail Pharmacies in the US](#). Qato DM, Watanabe JH, Clark KJ. JAMA Health Forum. 2022;3(8):e222839. doi:10.1001/jamahealthforum.2022.2839.
3. [Effects of Opioid Prescribing Cap Laws on Opioid and Other Pain Treatments Among Persons With Chronic Pain](#). McCourt AD, Tormohlen KN, Schmid I, et al. Journal of General Internal Medicine. 2023;38(4):929-937. doi:10.1007/s11606-022-07796-8.
4. [State Prescribing Cap Laws' Association With Opioid Analgesic Prescribing and Opioid Overdose](#). Tormohlen KN, McCourt AD, Schmid I, et al. Drug and Alcohol Dependence. 2022;240:109626. doi:10.1016/j.drugalcdep.2022.109626.
5. [CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022](#). Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. MMWR. Recommendations and Reports : Morbidity and Mortality Weekly Report. Recommendations and Reports. 2022;71(3):1-95. doi:10.15585/mmwr.rr7103a1.
6. [The Social Organization of Opioid Policies and Their Implications for People With Chronic Pain and Clinicians: An Institutional Ethnography](#). Comer L. The International Journal on Drug Policy. 2023;120:104173. doi:10.1016/j.drugpo.2023.104173.
7. [Fourth Wave of Opioid \(Illicit Drug\) Overdose Deaths and Diminishing Access to Prescription Opioids and Interventional Techniques: Cause and Effect](#). Manchikanti L, Singh VM, Staats PS, et al. Pain Physician. 2022;25(2):97-124.
8. [Opioid Dose Trajectories and Associations With Mortality, Opioid Use Disorder, Continued Opioid Therapy, and Health Plan Disenrollment](#). Binswanger IA, Shetterly SM, Xu S, et al. JAMA Network Open. 2022;5(10):e2234671. doi:10.1001/jamanetworkopen.2022.34671.
9. [Use of Opioids for Adults With Pain From Cancer or Cancer Treatment: ASCO Guideline](#). Paice JA, Bohlke K, Barton D, et al. Journal of Clinical Oncology : Official Journal of the American Society of Clinical Oncology. 2023;41(4):914-930. doi:10.1200/JCO.22.02198.
10. [A Crisis of Opioids and the Limits of Prescription Control: United States](#). Kertesz SG, Gordon AJ. Addiction (Abingdon, England). 2019;114(1):169-180. doi:10.1111/add.14394.
11. [Opioid Prescribing Patterns After Imposition of Setting-Specific Limits on Prescription Duration](#). Allen LD, Pollini RA, Vaglianti R, Powell D. JAMA Health Forum. 2024;5(1):e234731. doi:10.1001/jamahealthforum.2023.4731.
12. [Systematic Evaluation of State Policy Interventions Targeting the US Opioid Epidemic, 2007-2018](#). Lee B, Zhao W, Yang KC, Ahn YY, Perry BL. JAMA Network Open. 2021;4(2):e2036687. doi:10.1001/jamanetworkopen.2020.36687.