Center for U.S. Policy

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CDC Desk Officer
Office of Management and Budget
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Submitted through www.reginfo.gov/public/do/PRAMain

Subject: CDC Guideline for Prescribing Opioids for Pain [89 FR 104159]

The Center for U.S. Policy (CUSP) is a nonpartisan, not-for-profit research and education organization dedicated to enhancing the health, safety, and economic opportunity of all Americans. CUSP prioritizes ensuring access to individually appropriate treatment for individuals experiencing pain and other conditions that may require controlled medications.

We are writing to provide input on the Centers for Disease Control and Prevention's information request, "Comprehensive Evaluation of the Implementation and Uptake of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain." We appreciate the CDC's extension of the public comment period by an additional 30 days.

I. The Guideline Continues to Be Misinterpreted Despite Clarifications

In the request for information, the CDC correctly acknowledges that the 2016 Clinical Practice Guideline for Prescribing Opioids for Pain (2016 Guideline) led to the creation of laws and policies that "potentially contribut[ed] to patient harm."[1] The drafters of the updated 2022 Clinical Practice Guideline for Prescribing Opioids for Pain Guideline (2022 Guideline) attempted to rectify such misuse by clarifying, "[t]his clinical practice guideline *should not be applied as inflexible standards of care* across patient populations by health care professionals; health systems; pharmacies; third-party payers; or state, local, or federal organizations or entities" [emphasis added]. Specifically, to address the widespread policy misapplications that stemmed from the 2016 Guideline, the CDC's 2022 update explicitly disavows the following practices:

- Specific prescription dosages and durations
- Rigid application of opioid dosage thresholds
- Rapid opioid tapers and abrupt discontinuation without collaboration with patients
- Application of the Guideline's recommendations for opioid use for pain to medications for opioid use disorder treatment
- Duration limits by insurers and pharmacies
- Patient dismissal and abandonment

[1] Ctrs. for Disease Control and Prevention, *Comprehensive Evaluation of the Implementation and Uptake of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain,* 89 Federal Register 104159, https://www.federalregister.gov/documents/2024/10/01/2024-22474/proposed-data-collection-submitted-for-public-comment-and-recommendations.

Despite these clarifications, CDC recommendations continue to be misapplied in governmental laws, regulations, and administrative rules; law enforcement actions, prosecutions, and convictions; licensing board disciplinary actions; and health insurers' coverage policies.

A. Governmental laws, regulations, and administrative rules

The 2016 Guideline was intended as a set of voluntary, flexible recommendations to guide physicians in delivering individualized, patient-centered care for pain management. [2] However, many governmental laws, regulations, and administrative rules misapplied the Guideline by interpreting its recommendations as mandatory, inflexible standards of care.[3] Certain state laws, regulations and administrative rules turned voluntary thresholds into prescriptive caps, such as limiting opioid prescriptions to three to seven days or imposing dose ceilings.[4]

For example, the National Committee for Quality Assurance and the Centers for Medicare and Medicaid Services adopted morphine milligram equivalent (MME) thresholds from the 2016 Guideline to inform payment quality metrics. Additionally, a 2020 report from the Office of Inspector General compares CDC's recommended dose and duration limits with state Medicaid policies. Some of these restrictive interpretations not only exceeded the Guideline's recommendations but also undermined its primary intent – "to support, not supplant, individualized, patient-centered care." [5] The 2022 Guideline underscored the voluntary nature of its recommendations, explicitly clarifying that it is not a regulation or law and should not be applied as a one-size-fits-all standard; however, the influence of the 2016 Guideline persists, as many of these laws and regulations remain in effect.

B. Law enforcement actions, prosecutions, and convictions

The 2016 Guideline and related policies were improperly used by the Drug Enforcement Administration (DEA) and other law enforcement authorities to investigate, sanction, and in some cases, imprison clinicians for providing care that deviated from the Guideline's

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[2] Ctrs. for Disease Control and Prevention, *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*, https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#:~:text=Of%20particular%20concern%2C%20some%20policies,behavior%20(66%E2%80%9371).

[3] *Id*.; Will Stone, *CDC issues a revamp of opioid guidelines, giving clinicians more leeway*, NPR (Nov. 3, 2022) https://www.npr.org/2022/11/03/1134079070/cdc-issues-a-revamp-of-opiod-guidelines-giving-clinicians-more-leeway; Network for Good, *Laws Limiting the Prescribing or Dispensing of Opioids*, https://www.networkforphl.org/wp-content/uploads/2021/05/50-State-Survey-Laws-Limiting-the-Prescribing-or-Dispensing-of-Opioidspf-CSD_FINAL.pdf.

[4] Christine Vestal, *States Likely to Resist CDC Proposal Easing Opioid Access*, STATELINE (Mar. 1, 2022), https://stateline.org/2022/03/01/states-likely-to-resist-cdc-proposal-easing-opioid-access/

[5] Amy Frontz, *Update on Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic*, Office of the Inspector General (Oct. 2020), https://oig.hhs.gov/reports/all/2020/update-on-oversight-of-opioid-prescribing-and-monitoring-of-opioid-use-states-have-taken-action-to-address-the-opioid-epidemic/; Christine Vestal, *States Likely to Resist CDC Proposal Easing Opioid Access*, *supra* note 4; Centers for Disease Control and Prevention, *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*, *supra* note 1.

recommendation.[6] Similarly, the 2022 Guideline continues to be misused to define what constitutes "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" – a standard established, but not explicitly defined by the Controlled Substances Act (CSA).[7] Originally intended to carve out medical practice from federal drug trafficking law, the CSA's language has been interpreted by courts in ways that allow prosecutors and their expert witnesses to unduly influence medical practice. Prosecutors and expert witnesses often rigidly and inappropriately compare healthcare provider actions' against CDC recommendations, as well as against state and local policies, laws, and regulations derived from those recommendations. Tailoring prescription treatment decisions to each patient is an inherent part of a prescriber's daily medical practice, yet prosecutors seek to persuade juries that deviations from the Guidance are evidence of criminal violations of the CSA.

Despite the clarifications introduced in the 2022 Guideline, government expert witnesses continue to testify that failure to adhere strictly to rigid dose thresholds or to abruptly discontinue opioids constitutes evidence of illegitimate medical practice outside the usual course of professional practice. We have personally witnessed numerous instances where the Guideline recommendations have been improperly cited in prosecutions, including cases brought under the CSA. These instances include:

- A written report from the government's expert witness stating, " … guidelines … are the framework to determine if a physician with a DEA registration is prescribing scheduled medications in the usual course of professional practice for legitimate medical purpose."
- A statement in a court hearing from the government's expert witness that his understanding of the standard for evaluating the controlled-substance prescriptions of the doctor on trial – "a legitimate medical purpose in the usual course of professional practice" – was informed, in part, by "the CDC guidelines."
- A report of U.S. investigative findings dated June 2024 that lists "High daily doses of opioids" among "red flags" and cites the following as support: "CDC guidelines: Avoid daily dosages above 90 MMEs."
- A statement in a patient interview by a Medicaid fraud investigator that a doctor under investigation was "kind of maxing out … what he might be able to articulate as a legitimate purpose, even though the CDC" and the [relevant state] board "say 120 MMEs, he's above that."
- A written opinion from the government's expert witness that a doctor "acted outside the usual course of professional practice" that repeatedly cites as evidence that the doctor exceeded a rigid MME daily dose threshold.
- A training video titled, "Opioid/Drug Diversion investigations" released March 24, 2021, and in which an Assistant Attorney General from the Medicaid Fraud Control Unit of New York describes how to bring a criminal or civil fraud action (including through the False Claims Act) against a "high opioid prescriber" by developing a "target list" that ranks prescribers by the number of MMEs. He tells his audience to look for anything over 90 MMEs per day for longer than 90 days and cites as his source the 2016 CDC

[6] Lynn Webster, *CDC Revised Opioid Prescribing Guideline Falls Short of What People in Pain Need*, May 16, 2022, https://lynnwebstermd.com/2022/05/16/cdc-revised-opioid-prescribing-guideline-falls-short-of-what-people-in-pain-need/.
[7] 21 C.F.R. § 1306.04(a).

Guideline for Prescribing Opioids for Chronic Pain. He states of this dosing regimen, "there is almost no excuse for that."[8]

In acknowledgement of the ongoing misuse of the CSA, CUSP filed an amicus brief asking the U.S. Supreme Court to overturn the drug trafficking conviction of a physician who did not demonstrate proven intent to prescribe unlawfully. [9] The brief reasoned that role of medical boards in guarding patient safety has been undermined through the improper utilization of the CSA. Likewise, the Guideline has been misused to unjustly characterize deviations from its recommendations as prescribing without "a legitimate medical purpose in the usual course of professional practice."

C. Licensing board disciplinary actions

Following the 2016 Guidance, many state licensing boards updated their policies to impose standards that aligned with its recommendations, including incorporating the principles into their regulatory frameworks.[10] Despite the release of updated Guidance in 2022, which stated, "state medical boards should not use this clinical practice guideline to set rigid standards or performance incentives related to dose or duration of opioid therapy," the 2016 version continues to exert significant influence over the practice of medicine, particularly as some states have rejected the updated policy.[11] As a result, the Guidance has become a basis for disciplinary actions against physicians whose practices deviate from its provisions, despite its original intention as an advisory document. Consequently, some pain management specialists are closing their practices, while others are reducing or discontinuing their patients' opioid treatments solely due to concerns about losing their medical licenses.[12]

[8] David Abrams and Brandon Phillips, Opioid/Drug Diversion investigations, ATTORNEY GENERAL OF THE STATE OF NEW YORK, MEDICAID FRAUD UNIT (Mar. 24, 2021), https://videopress.com/v/ab0jLpf0.
[9] Center for U.S. Policy, *CUSP Files Amicus Brief in Ruan Supreme Court Case* (Jan. 7, 2022), https://centerforuspolicy.org/cusp-files-amicus-brief-in-ruan-supreme-court-case/.
[10] North Carolina Medical Board, *Board makes preliminary move to adopt CDC opioid policy* (Nov. 18, 2016), https://www.ncmedboard.org/resources-information/professional-resources/publications/forum-newsletter/article/board-makes-preliminary-move-to-adopt-cdc-opioid-policy; Corey Davis, *State-by-State Summary of Opioid Prescribing Regulations and Guidelines,* The Network for Public Health, https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/appendix-b-state-by-state-summary.pdf.
[11] Centers for Disease Control and Prevention, *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*, *supra* note 1; Florida Health, *Now is Not the Time for the CDC to Relax Opioid Prescription Guidelines* (Nov. 22, 2022), https://www.floridahealth.gov/newsroom/2022/11/20221122-cdc-relax-opioid-guidelines.pr.html.
[12] Kate Nicholson et al., *Now is Not the Time for the CDC to Relax Opioid Prescription Guidelines*, STAT NEWS (Dec. 6, 2018), https://www.statnews.com/2018/12/06/overzealous-use-cdc-opioid-prescribing-guideline/

D. Health insurers' coverage policies

Health insurers used the 2016 Guideline as the basis to restrict access to medication for long-term pain patients — a serious concern acknowledged by the CDC.[13] The Guideline, which recommends limiting doses to 50 to 90 MME per day, was used to justify supply limits and delays or outright denials of refill requests.[14] At the same time, health insurers have maintained limited access to alternative pain therapies.[15] These restrictive policies overlook the importance of individualized patient care and have resulted in reduced access to treatment.

Consequently, due to the widespread misapplication of the Guideline, many physicians are hesitant to prescribe opioid therapy, fearing legal consequences. This has left a substantial portion of the 50 million Americans living with chronic pain unable to access adequate relief from medical professionals.[16] The downstream public policy consequences of this issue extend beyond pain treatment, affecting medications used for treating opioid use disorder (OUD).The American Society of Addiction Medicine (ASAM) has highlighted that "[f]ear of intrusion into clinical practice by the Department of Justice (DOJ), including the Drug Enforcement Administration (DEA), is a key buprenorphine prescribing barrier."[17] Despite this significant concern, the ASAM notes, "advocates and policymakers have paid little attention to fear of DOJ or DEA intrusion …" The consequences of these misapplications of the Guideline are alarming, as medications for OUD have been proven to save lives, reducing mortality risks by 50 percent among individuals with OUD.

Therefore, we respectfully request that the CDC publicly report examples of how its 2016 and 2022 Guidelines have been misinterpreted by these various entities. Furthermore, we urge the CDC to publicly call for changes to laws and policies that exceed CDC's present-day purposes for the Guideline and publish a statement on the differences between controlled substance laws and clinical guidelines and disavow strict application of the Guideline in legal and regulatory contexts.

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[13] Regulations.gov, *Updated Draft CDC Guideline for Prescribing Opioids Overview of Public Engagement Work, Docket (CDC-2022-0024)* (Feb. 10, 2022), https://www.regulations.gov/document/CDC-2022-0024-0005; Jayne O'Donnell and Ken Alltucker*, Feds issue new warning to doctors: Don't skimp too much on opioid pain pills*, USA TODAY (Apr. 25, 2019), https://www.usatoday.com/story/news/health/2019/04/24/opioid-pain-pills-crackdown-doctors-prescriptions-cdc-fda/3562373002/.

[14] Kate Nicholson et al., *Now is Not the Time for the CDC to Relax Opioid Prescription Guidelines*, *supra* note 12.

[15] Pat Anson, AMA: 'CDC Guideline Has Harmed Many Patients', PAIN NEWS NETWORK (Jun. 19, 2020), https://www.painnewsnetwork.org/stories/2020/6/19/ama-cdc-guideline-has-harmed-many-patients.

[16] Ctrs. for Disease Control and Prevention, *Chronic Pain and High-impact Chronic Pain Among U.S. Adults* (Nov. 2020), https://www.cdc.gov/nchs/products/databriefs/db390.htm.

[17] American Society of Addiction Medicine, P*ublic Policy Statement on Reducing Risk of Federal Investigation or Prosecution for Prescribing Controlled Addiction Medications for Legitimate Medical Purposes* (Adopted Dec. 12, 2024), https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2025/01/03/reducing-risk-of-federal-investigation-or-prosecution-for-prescribing-controlled-addiction-medications-for-legitimate-medical-purposes.

II. Misuse of the Guideline in Conjunction with PDMPs and Algorithmic Software Influences Medical Practice

In an effort to address controlled prescription drug misuse, policymakers established state Prescription Drug Monitoring Programs (PDMPs) to track, report, and monitor the dispensing of controlled substances, with the goal of reducing misuse and diversion. However, modern PDMPs have evolved far beyond passive data collection systems. They now employ complex algorithms to assess patient risk for controlled substance misuse and influence clinical treatment decisions. Companies that use proprietary algorithms to generate risk scores from PDMPs operate with minimal oversight, and these scores are not validated against clinical outcomes.[18]

The CDC's 2022 Guideline expressed concerns about these algorithmic scores, particularly regarding their potential to disproportionately affect certain patient populations. These risk scores compel providers to adjust their prescribing practices to align with patients' calculated risk scores, potentially forcing patients to seek illicit sources for symptom relief. In fact, studies show that PDMP risk scoring pressures clinicians to reduce medication doses, stop prescriptions, and even abandon patients, often ignoring the severe negative consequences that follow these treatment choices.[19] This fear has led many prescribers to refuse or drop patients who require opioid pain management or other medically necessary controlled substances. Following the release of the 2016 Guideline, the national monthly dispensing rate declined at more than twice the previous rate.[20] Moreover, between 2019 and the present, the national opioid dispensing rate steadily decreased from 46.8 to 37.5 prescriptions per 100 people.[21] As a result, many patients have been left without access to vital treatments.

Therefore, we urge the CDC to examine and report how proprietary algorithms used by state public health and safety officials have impacted prescriber behavior and patient outcomes, including denials of medically necessary controlled medications, associated health crises, and deaths by suicide.

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[18] Jennifer Oliva, *Dosing discrimination: regulating PDMP risk scores*, 110 CALIF LAW REV 1-47 (2022), https://lawcat.berkeley.edu/record/1228027; Cochran G, et al. *Validation and threshold identification of a prescription drug monitoring program clinical opioid risk metric with the WHO alcohol, smoking, and substance involvement screening test*, 228 DRUG ALCOHOL DEPEND. (2021); *see* The Center for U.S. Policy, *CUSP FDA Citizen Petition to Protect Patients* (Apr. 28, 2023), https://centerforuspolicy.org/fdacp2023-2/ (filing a Citizen Petition that requests that the FDA (1) deem Bamboo's NarxCare software a misbranded device; (2) issue a Warning Letter to Bamboo; (3) commence mandatory recall procedures with respect to the NarxCare software; and (4) take any other prompt action the agency deems appropriate to prevent serious, adverse health consequences or death) .

[19] Jennifer Oliva, supra note 12 at 75.

[20] Xiru Lyu, et al., State-to-State Variation in Opioid Dispensing Changes Following the Release of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, 6 JAMA Netw. Open (Sep. 11, 2023)

[21] Ctrs. for Disease Control & Prevention, *U.S. Opioid Dispensing Rate Maps* (Nov. 7, 2024), https://www.cdc.gov/overdose-prevention/data-research/facts-stats/opioid-dispensing-rate-maps.html

III. Conclusion

In conclusion, the CDC has acknowledged unintended consequences resulting from the dissemination and misapplications of the 2016 Guideline. Dire problems persist due to the investigative, legal, and judicial misuse of the 2022 Guideline. We respectfully urge that the CDC take steps to track and address this misuse of the Guideline. Specifically, the CDC should:

(1) Publicly report examples of how its 2016 and 2022 Practice Guideline has been misinterpreted in:
    a. Governmental laws, regulations, and administrative rules;
    b. Law enforcement actions, prosecutions, and convictions;
    c. Licensing board disciplinary actions; and
    d. Health insurers' coverage policies.

    CUSP is also aware of the misapplication of the Guideline in civil litigation against prescribers and in health care programs' clinical policies. We would be pleased to assist the CDC in identifying, interpreting, and reporting such examples.
(2) Publicly call for changes to laws and policies that exceed CDC's present-day purposes for the Guideline;
(3) Publish a statement on the differences between controlled substance laws and clinical guidelines and disavow strict application of the Guideline in legal and regulatory contexts; and
(4) Examine and report how proprietary algorithms used by state public health and safety officials have impacted prescriber behavior and patient outcomes, including denials of medically necessary controlled medications, associated health crises, and deaths by suicide.

Sincerely,

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