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April 11, 2022

Submitted via regulations.gov

Dr. Rochelle Walensky, Director
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329

Re: CDC-2022-0024; Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Director Walensky,

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide comments and feedback on the Centers for Disease Control and Prevention's (CDC) Proposed 2022 Clinical Practice Guidelines for Prescribing Opioids.

Overall, we support the proposed fixes to the prescribing guidelines and believe that finalizing the proposed guidelines will improve patients' access to medically necessary treatment for pain. However, we remain concerned that the proposed language still does not strike an appropriate balance between addressing harms associated with opioid use disorders and ensuring individuals receive proper pain management. In particular, by recommending that providers prescribe the lowest effective dosage and by failing to address laws and policies implementing strict prescribing limits, without further amendments, the guidelines will unfortunately continue to allow

providers, payers, and states to misinterpret the recommendations. Our position stems from our expertise both as advocates in the health care access space and as advocates working on harm reduction efforts to reduce the impact of the overdose epidemic.

Low-income individuals struggle to find providers willing to prescribe necessary opioid medications for pain without being stigmatized or chastised. By recommending dosage and duration limits on opioid prescriptions, recommending urine testing to test for licit and illicit use of opioids, and recommending a maximum amount of opioids prescribed for treatment of acute pain, the 2016 guidelines only exacerbated this problem, stigmatizing people who need opioids for pain and who present little risk of developing an opioid use disorder (OUD). To the extent the proposed guidelines are limited to unnecessary opioid initiation and apply only to patients at heightened risk of OUD, we commend CDC for seeking to fix the mistakes of the past guidelines.

Our comments below discuss the evidence demonstrating that opioid prescribing restrictions have limited effectiveness in reducing opioid-related overdoses and the overall burden of OUD. We also highlight the negative consequences that pain patients, particularly Medicaid beneficiaries and low-income individuals, have experienced in response to the 2016 guidelines, both through self-imposed prescriber restrictions and through policies implemented by states and health insurers. We also list our support for specific policies contained in the proposal and provide suggestions for improving them.

I. Effectiveness of Opioid Prescribing Guidelines in Reducing OUD Deaths

Data from the CDC indicates that opioid prescribing peaked in 2012 and has been in a decline since and currently opioid prescriptions have decreased to the same rates as in 1993.¹ The 1993 rates are notably before the 1996 introduction of OxyContin, a large contributor to overprescribing.² While the 2016 guidelines have been embraced by the

¹ See CDC, *U.S Opioid Dispensing Rate Maps*, <https://www.cdc.gov/drugoverdose/rxrate-maps/index.html> (last visited April 5, 2022); Duke University, *FDA Public Workshop on Opioid Prescriber Education*, <https://healthpolicy.duke.edu/events/fda-public-workshop-opioid-prescriber-education> (last visited Apr. 5, 2022).

² Theodore Cicero, James Inciardi, & Alvaro Munoz, *Trends in abuse of Oxycontin and other opioid analgesics in the United States: 2002-2004*, 6(10) J OF PAIN 662-672 (2005) <https://pubmed.ncbi.nlm.nih.gov/16202959/>.



medical and public health communities and have had a significant impact on the continued decline of opioid prescribing, overdose rates have not declined.³

The majority of opioid related overdose deaths are not among individuals with opioid prescriptions. CDC data shows that the estimated overdose deaths from opioids increased to 75,673 in the 12-month period ending in April 2021, an increase in 19,609 from the year before.⁴ However, the CDC data notes that from 2018 to 2019 there was approximately a seven percent decrease in prescription opioid related deaths.⁵ This is in contrast to the rates of opioid overdoses caused by synthetic opioids other than methadone which has increased by over fifteen percent from 2018 to 2019 and accounted for nearly seventy three percent of all opioid related overdose deaths in 2019.⁶ One study found that approximately one percent of overdoses had an opioid prescription and an analysis of CDC shows “no evidence of correlation between the number of opioids prescribed and the non-medical use of opioids or of opioid addiction.”⁷

³ Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20(4) PAIN MEDICINE 724-735 (2019), <https://academic.oup.com/painmedicine/article/20/4/724/5301726?login=true>; Deborah Dowel et al., *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENGLAND J OF MED. 2285-2287 (2019), <https://www.nejm.org/doi/10.1056/NEJMp1904190>.

⁴ See CDC, *Drug Overdose Deaths in the U.S. Top 100,000 Annually*, https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm (last visited April 5, 2022).

⁵ See CDC, *Prescription Opioid Overdose Death Maps*, <https://www.cdc.gov/drugoverdose/deaths/prescription/maps.html> (last visited April 5, 2022).

⁶ See CDC, *NCHS Data Brief No. 329 Drug Overdose Deaths in the United States, 1999–2017* (Nov. 2018), <https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf>; See CDC, *Synthetic Opioid Overdose Data* <https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html> (last visited April 5, 2022).

⁷ Alexander Walley et al., *The Contribution of Prescribed and Illicit Opioids to Fatal Overdoses in Massachusetts, 2013-2015*, 134(6) PUBLIC HEALTH REPORTS 667-674 (2019), https://journals.sagepub.com/doi/full/10.1177/0033354919878429?fbclid=IwAR2z8qg_1oyvqgOEkcYtE8zzFaNY1PbqdT_q5pti9DEVjPHe7HNS5Q5EL8&#articleShareContainer; Jeffrey Singer, Jacob Sullum, & Michael Schatman, *Today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder*, 12 J PAIN RES 617-620 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/>.



Overdose deaths continue to be a public health emergency. However, because overprescribing of opioids has been effectively addressed as evidenced by the decline in opioid prescription rates, and because evidence suggests that overdose deaths are not currently being driven by the rate of opioid prescriptions, continuing to limit opioid prescription does more harm than good. Strict limits and decreases in opioid prescriptions harm chronic pain patients and increases the stigma of opioid use for chronic pain, cancer related pain, and other uses while not decreasing the large portion of overdose deaths related to synthetic opioids other than methadone.

II. Negative Consequences of 2016 Guidelines

The intention of the 2016 Guidelines was to provide recommendations to primary care clinicians on prescribing opioid pain medication for chronic pain. The guidelines do take into consideration the risks associated with opioid prescribing and state that chronic pain patients should receive appropriate pain treatment based on the benefits and risks of their treatment options. Thus, the 2016 Guidelines recognized that there is an appropriate role for use of opioids in treating chronic pain. However, in the application of these guidelines, the clinical context in which some patients may need opioids for pain management was often lost.

In 2019, three of the authors of the 2016 Guidelines released a perspective paper in the *New England Journal of Medicine* called *No Shortcuts to Safer Opioid Prescribing* which acknowledges the harm of inconsistent use of the 2016 Guidelines.⁸ The inconsistent use of the 2016 guidelines has led to intended negative health consequences for many Americans experiencing chronic pain.

The authors of the guidelines and the perspective paper note that the guidelines likely accelerated the decrease in opioid prescribing. The authors note that some policies and practices derived from the 2016 guidelines are inconsistent with the guidelines and these inconsistencies led to an “inflexible application of recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering of drug dosages.”⁹ This resulted in the sudden discontinuation or tapering of existing opioid prescriptions and, at times, the dismissal of patients from a physician’s practice. Both of

⁸ Dowel et al., *supra* note 3.

⁹ *Id.*



these have wider reaching consequences for chronic pain patients. Research shows that those who manage their chronic pain with opioids struggle to find primary care clinics that will take them as a patient and eighty one percent of physicians are hesitant to see a patient who uses opioids to manage their pain.¹⁰ The way in which some physicians interpreted the 2016 guidelines created unnecessary burdens to access care and increased the stigma associated with opioid use for chronic pain.

The guideline authors also note the potential for misapplication of the 2016 guidelines for those outside of the scope of the recommendations.¹¹ This includes patients with pain associated with cancer, end-of-life care, and the use for managing pain in surgical procedures, both populations were never intended to be in the scope of the 2016 guidelines.

Further, abrupt discontinuation or tapering of opioid prescriptions presents additional health concerns for chronic pain patients. A study found that a considerable percentage of patients prescribed long-term opioid therapy are ongoing dose reduction and often at a rapid rate.¹² Two studies found that dosage variability was associated with an increased risk of overdose death. One study found that opioid dose variability was associated with a threefold increased risk of overdose death for patients on long-term

¹⁰ Kara Gavin, Univ. of Michigan Health Lab, Pain Patients Who Take Opioids Can't Get in the Door at Half of Primary Care Clinics (Jan. 25, 2021), <https://labblog.uofmhealth.org/industry-dx/pain-patients-who-take-opioids-cant-get-door-at-half-of-primary-care-clinics> (last visited April 5, 2022); See Quest Diagnostics *HealthTrends Drug Misuse in America 2019 Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis*, https://mma.prnewswire.com/media/1011170/Quest_Diagnostics_Health_Trends_Report.pdf?p=original (last visited April 5, 2022).

¹¹ Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20(4) PAIN MEDICINE 724-735 (2019), <https://academic.oup.com/painmedicine/article/20/4/724/5301726?login=true>.

¹² Joshua Fenton et al., *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008-2017*, 2(11) JAMA NETW OPEN 16271 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755492>.



opioid therapy.¹³ Another study found that discontinuation of opioid therapy did not reduce the risk of death and was associated with an increased risk of overdose death.¹⁴

III. Impact of Guidelines on Low-Income Populations and Medicaid Beneficiaries

The negative impact of the 2016 guidelines have had a disproportionate effect on low-income individuals in need of pain treatment, particularly those enrolled in the Medicaid program. Many of the individuals who rely on opioids to function are low-income people and Medicaid beneficiaries; more than one in three adults under 65 who are enrolled in Medicaid have a disability (compared with about 12% of adults under 65).¹⁵ In addition, prevalence of chronic pain and high-impact chronic pain are both higher among individuals living in poverty and adults with public health insurance.¹⁶

Efforts to scale back opioid prescribing have resulted in people on Medicaid losing access to their medications, often with short notice. Discontinuation often happens abruptly, often in 24 hours for Medicaid enrollees on opioids for more than 90 days.¹⁷ This results in an increased risk of adverse health events, with almost half of these cases resulting in hospitalization or an emergency department visit. In the same study, only about one percent of those with a diagnosed substance use disorder prior to dose reduction were transitioned to an opioid use disorder medication.¹⁸ These actions represent concrete examples of misapplication of the 2016 guidelines.

¹³ Jason Glanz et al., *Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy*, 2(4) JAMA NETW OPEN 2613 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730786>.

¹⁴ Jocelyn James et al., *Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: A Retrospective Cohort Study*, 34(12) J GEN INTERN MED. 2749-2755 (2019), <https://pubmed.ncbi.nlm.nih.gov/31468341/>.

¹⁵ Ctr. on Budget and Policy Priorities (CBPP), *Medicaid Works for People With Disabilities* (2017), <https://www.cbpp.org/research/health/medicaid-works-for-people-with-disabilities>.

¹⁶ James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016*, 67(36) MORBIDITY AND MORTALITY WEEKLY REPORT 1001-1006 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm>.

¹⁷ Tami L. Mark & William Parish, *Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events*, 103 J SUBSTANCE ABUSE TREATMENT 58-63 (2019). <https://pubmed.ncbi.nlm.nih.gov/31079950/>.

¹⁸ *Id.*



For low-income patients who need access to opioids for pain treatment and for whom non-opioid alternatives are not medically appropriate, the guidelines have placed a significant financial barrier. For example, when a prescriber reduces the initial dosage and duration of an opioid prescription for chronic pain to a week in some cases, as recommended by the 2016 guidelines, patients need to return for another office visit to receive a new prescription relatively soon thereafter. This involves costs that may seem insignificant for higher income patients, but that may be prohibitive for lower income patients, including transportation costs, time off from work, and out-of-pocket costs for office visits. Similarly, refilling a prescription in that short time span requires additional pharmacy cost-sharing, including copayments and deductibles, which affects individuals with private coverage in the lower end of the income spectrum.

In addition to the financial burden that results from prescribers limiting opioid prescribing on a voluntary basis, in some cases low-income individuals and Medicaid beneficiaries have been disproportionately harmed by system-wide policies and state- and managed care organizations (MCO)-imposed restrictions. First, while the opioid prescribing guidelines heavily rely on the use of alternative therapies for pain, these alternatives are not always covered by Medicaid and coverage levels vary significantly from state to state. For example, despite the fact that the vast majority of Medicaid programs cover physical and occupational therapy, only about half of the states cover chiropractic services and less than 20 percent of Medicaid programs and MCOs offer information about acupuncture services.¹⁹ States may also impose significant barriers to access non-opioid alternatives for pain management, such as prior authorization. Furthermore, few states have taken a proactive approach of encouraging MCOs and patients to utilize these alternative treatment services when available and effective.

Second, several states have imposed strict limits on opioid prescribing. In 38 states and the District of Columbia, the 2016 CDC guidelines were not only made mandatory, but in some cases the limitations adopted are even stricter than the CDC

¹⁹ Hannah Dorr & Charles Townley, Nat'l Acad. for State Health Policy (NASHP), *Chronic Pain Management Therapies in Medicaid: Policy Considerations for Non-Pharmacological Alternatives to Opioids* (2016), <https://www.nashp.org/chronic-pain-management-therapies-medicaid-policy-considerations-non-pharmacological-alternatives-opioids/>.



recommendations.²⁰ For example, many state statutes do not distinguish between chronic and acute pain. Others require prescribers to limit all initial opioid prescriptions to as little as three days duration and 30 MME dosage for all pain patients. These laws formalized the disproportionate effect the guidelines have had on low-income patients. On top of that, some states have implemented limits specific for Medicaid beneficiaries. For example, right after the 2016 guidelines were finalized, Arizona governor Doug Ducey signed an executive order limiting initial opioid prescriptions to seven days regardless of whether the prescription was for chronic or acute pain.²¹ Similarly, in 2018, the Alabama Medicaid agency established a limit of five days on the duration of an initial opioid prescription that the program would cover, again without making important distinctions or emphasizing coverage of non-opioid alternatives.²²

IV. Support for Specific Proposals and Recommendations

NHeLP commends the CDC for recognizing the unintended consequences the 2016 opioid prescribing guidelines have had on pain patients and for taking steps to minimize those consequences and emphasize the voluntary nature of the guidelines. However, we remain deeply worried that the draft guidelines will not go far enough in reducing the burden of misapplication of the 2016 guidelines and are insufficient to strike an appropriate balance between reducing the harms associated with opioid use disorders and proper pain management.

We strongly support the removal of the explicit recommendation that prescribers do not go beyond 90 MME per day regardless of the circumstances. This recommendation lacked evidence to support it and significantly disrupted the patient-doctor relationship and prescribers' ability to use professional judgment to determine medical necessity.

²⁰ Amy Lierberman & Corey Davis, Network for Pub. Health Law, *Laws Limiting the Prescribing or Dispensing of Opioids* (2021), <https://www.networkforphl.org/resources/laws-limiting-the-prescribing-or-dispensing-of-opioids/>.

²¹ AZ Central, Ducey Limits Medicaid, State Insurance Opioid Prescriptions (Oct. 24, 2016), <https://www.azcentral.com/story/news/local/arizona/2016/10/24/ducey-limits-medicaid-state-insurance-opioid-prescriptions/92688280/>.

²² U.S. Dep't of Health and Hum. Serv., Off. of the Inspector Gen., *Fact Sheet: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use* (last visited Apr. 6, 2022), https://oig.hhs.gov/oas/reports/region4/41900125_Factsheet.pdf.



Similarly, we are pleased to see the elimination of the recommendation that initial opioids for acute pain be limited to between three to seven days in duration, which, as explained above, disproportionately harms low-income patients in need of pain treatment.

Nonetheless, we are concerned that the recommendation that prescribers use “the lowest dosage to achieve expected effects” may prolong the unintended consequences of the original guidelines. While we agree that prescribers should prescribe the lowest level of care necessary for effective treatment, we also believe providers should not prescribe a lower dosage than necessary and that the consequences of doing such could be just as harmful, if not more, than exceeding the lowest amount for individuals with no apparent risk of developing an OUD. This broad statement could result in prescribers resorting to the exact limitations that are now being removed without appropriately balancing effectiveness and potential side effects of opioid-based treatment for pain. On top of that, this statement keeps the door open for states and MCOs to continue imposing mandatory limits on opioid prescribing. We suggest that the guidelines focus on asking prescribers to evaluate whether a non-opioid alternative would achieve the same result, while still explicitly allowing providers to make dosage determinations that consider the totality of all circumstances.

In addition, we believe decisions about whether to taper down patients who are already using opioids for pain should be left to providers to decide on a case-by-case basis avoiding one-size-fits-all solutions. We are concerned that the language around patients already receiving higher opioid dosages remains virtually unchanged, although we appreciate the new language that seeks to discourage abrupt discontinuation. Our experience working with local legal aid programs demonstrates that a troubling number of Medicaid beneficiaries has been subject to abrupt tapering and unnecessary discontinuation of their medically necessary medications. The new guidelines should instead encourage providers to consider non-opioid alternative treatments throughout the course of treatment with opioid medications, without suggesting that patients be tapered down if the risks outweigh the benefits. While in the abstract this is a reasonable suggestion, it inevitably leads prescribers to refrain from prescribing higher doses of opioids even for patients who would benefit from them.



Finally, we encourage the CDC to explicitly address the fact that the 2016 guidelines have led to inappropriate strict limits imposed by law or through insurers' policies. The new guidelines should acknowledge that those actions are in conflict with the spirit of the guidelines, which rely on their voluntary nature and flexibility for their effectiveness, and should call on states and insurers to eliminate these types of limitations. Prescribers should be able to rely on their professional judgment when determining the best course of action for their patients experiencing pain without fear of being subject to penalties from state government or payers.

V. Conclusion

We appreciate the opportunity to provide comments and input on the CDC's proposed new guidelines on opioid prescribing. These new guidelines represent a step in the right direction, but the risk of misapplication, which disproportionately affects low-income individuals and Medicaid beneficiaries, will unfortunately remain. We call on the CDC to take into consideration the many laws and other strict prescribing limits that have been put into place as a result of the 2016 guidelines, and accordingly modify the guidelines to ensure prescribers have the ability to recommend a course of treatment without fear of retaliation so that patients have access to medically necessary opioid medications.

If you have any questions about our comments, please contact Héctor Hernández-Delgado at hernandez-delgado@healthlaw.org or Alexis Robles-Fradet at robles-fradet@healthlaw.org.

Sincerely,



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