September 30, 2020

**Re: Docket # DEA-2020-0026-0001**

The National Pain Advocacy Center (NPAC), a new 501c3 organization that advocates for the health and human rights of people in pain, would like to thank you for the opportunity to provide input on the Drug Enforcement Administration's Docket No. DEA-2020-0026-0001, the Notice on Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances. NPAC is an alliance of clinicians, scientists, public health experts, civil rights attorneys, and people with the lived experience of pain, which promotes equitable and effective pain management.

Prescription opioids are not merely substances that are misused, they are also essential medications. NPAC is concerned that the proposed limits will have a disparate impact on people in serious pain and people with opioid use disorders who appropriately rely on such medication. People with severe acute pain, people with pain related to cancer or sickle cell disease, and people with severe chronic pain from illnesses like MS or serious injuries like those to the spinal cord, often require the medical use of opioids. Expanded use of medications like buprenorphine or methadone to treat opioid use disorder, typically referred to as MOUD (medication for opioids use disorder) or MAT (medication assisted treatment), is a critical aspect of addressing the crisis surrounding opioids.

Thus far, cuts to the medical supply of opioids have not resulted in a reduction of drug overdose deaths. As the supply of prescribed opioids has fallen since 2011, drug overdose deaths have only climbed.[1] Efforts to reduce inappropriate opioid prescribing are important and laudable, but they must also be targeted, nuanced and evidence-based to have the intended effect, which is to help and not to endanger patient safety.

Injectable opioids used in hospital systems are similarly critical medications. Past DEA cuts to the supply, when coupled with unexpected but foreseeable events like manufacturing issues or a global pandemic, have created challenges in

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[1] Casey, Michael, Drug Overdose Deaths Rise Significantly in Past 5 Years, December 16, 2016, Associated Press, https://apnews.com/9aa2eef4c88d4949888a987fdd342d0e; see generally, Drug Overdose Death Data, Centers for Disease Control and Prevention, 2016, https://www.cdc.gov/drugoverdose/data/statedeaths.html; Rose A. Rudd, MSPH; Noah Aleshire, JD; Jon E. Zibbell, PhD; R. Matthew Gladden, PhD, Increases in Drug and Opioid Overdose Deaths-United States, 2000-2014, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

hospital systems. In 2018, when hospitals experienced shortages of medication,[2] physicians reported that restriction-based medication shortages resulted in harm to patient outcomes and an increased likelihood of medical errors.[3] Once again, with COVID19, news articles have raised the specter of an insufficient supply for patients needing opioids who require ventilation.[4]

The DEA's published Notice rightly expresses an intention to mitigate the danger of hospital shortages in 2021, by considering "both the potential for diversion as well as the anticipated increase in demand for opioids used to treat patients with COVID-19." While this intention is important, there are difficult line-drawing problems in effectuating it.

For instance, according to the Notice, the DEA has asked the Centers for Medicare and Medicaid Services (CMS) for estimated rates of overprescribing, defined as "significantly more medicine than is medically necessary." The problem arises in the DEA's proposed method of distinguishing between appropriate and inappropriate prescribing.

We concur with the National Council on Independent Living in its concern regarding the potential disparate impact on people with disabilities of the proposed cuts and in articulating the following concerns:

- As the Notice indicates, "CMS…does not have the ability systematically to distinguish between appropriate and inappropriate prescriptions without investigations." Indeed, it is not possible to determine how many patients were prescribed "significantly more medicine than is medically necessary" without studying individual medical records.

- We are concerned to see that, where CMS cannot readily identify overprescribing from a large data set, the DEA intends to "solicit the raw data from CMS to determine overprescribing rates based on CDC prescription guidance for schedule II substances."

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[2] Pauline Bartolony, The Other Opioid Crisis: Hospital Shortages Lead To Patient Pain, Medical Errors, Kaiser Health News, March 16, 2018, https://khn.org/news/the-other-opioid-crisis-hospital-shortages-lead-to-patient-pain-medical-errors/; also covered by CNN, March 19, https://www.cnn.com/2018/03/19/health/hospital-opioid-shortage-partner/index.html, and in the LA Times, March 21st, http://www.latimes.com/business/la-fi-opioid-painkiller-hospitals-20180316-story.html. See also, Ross, Casey, Hospitals Are Confronting A New Opioid Crisis An Alarming Shortage of Pain Meds, March 15, 2018, https://www.statnews.com/2018/03/15/hospitals-opioid-shortage/.

**3** Id.

[4] Silverman, Ed, A New Covid-19 Problem: Shortages of medicines needed for placing patients on ventilators, March 31, 2020, https://www.statnews.com/pharmalot/2020/03/31/a-new-covid-19-problem-shortages-of-medicines-needed-for-placing-patients-on-ventilators/

- Here, the DEA's stated intention may well rely upon a misapplication of the *Center for Disease Control and Prevention (CDC)'s Guideline for Prescribing Opioids for Chronic Pain.* If the DEA in fact uses dosage thresholds from the CDC guidance, it will have misapplied the guideline in precisely the way the CDC has publicly warned against.[5] The CDC has stated that its cautionary dosage thresholds are intended to guide primary care clinicians when starting a new patient on opioids.[6] They are not even intended to apply to those who are stable on opioids, and certainly not to flag outliers as inappropriate prescribers absent additional valid evidence.

- The Health and Human Services (HHS) Inter-Agency Task Force Report, compiled as part of effectuating the Comprehensive Addiction and Recovery Act (CARA), found that the therapeutic window for opioid dosage is highly variable.[7] New research shows that, while risk of overdose correlates with higher dosage, there is no particular dosage that signifies a threshold for increased risk,[8] and CMS "outlier prescriber" measures do not accurately predict adverse events.[9]

- Deriving conclusions about "doctor shopping" from CMS data poses additional problems. Recent studies suggest that up to 40% of primary care physicians will not accept patients who take opioids long-term for

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[5] CDC Advises Against Misapplication of the *CDC Guideline for Prescribing Opioids for Chronic Pain,* April 24, 2019. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html See also Dowell, D., Haegerich, T., Chou, R., *No Shortcuts to Safer Opioid Prescribing*, 380 New Eng. Jol of Med., 2285-2287 (2019) DOI: 10.1056/NEJMp1904190 noting the danger to patient safety in misapplying the guideline, especially given the low evidentiary basis for the dosage and supply provisions. *See also* HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, October 2019. https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

[6] Letter from CDC Director Robert Redfield, April 10, 2019. https://img1.wsimg.com/blobby/go/3d70257f-a143-4a5b-b9df-f7d265df0d3d/downloads/Alford Final .pdf?ver=1554957603807

[7] Final Report, Pain Management Best Practices Inter-Agency Task Force: Updates, Gaps, Inconsistencies, and Recommendations, May 23, 2019, https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

[8] Nabarun Dasgupta, Michele Jonsson Funk, Scott Proescholdbell, Annie Hirsch, Kurt M. Ribisl, Steve Marshall, Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality, *Pain Medicine*, Volume 17, Issue 1, January 2016, Pages 85–98, https://doi.org/10.1111/pme.12907

[9] Yu-Jung JennyWei, PhD, Cheng Chen, BSPharm, Amir Sarayani, PharmD, Almut G.Winterstein, PhD , "Performance of the Centers for Medicare & Medicaid Services' Opioid Overutilization Criteria for Classifying Opioid Use Disorder or Overdose" JAMA February 12, 2019 Volume 321, Number 6. https://jamanetwork.com/journals/jama/fullarticle/2724180

pain, and 81% of physicians are reluctant to accept such patients.[10] [11] In this environment, patients may be forced to search for new doctors simply to receive care, thereby adding to their list of providers for a reason that is not a proxy for drug-seeking behavior. Focusing on the doctors' geographic proximity to the patient is similarly imprecise: Geographically distant specialists may be the best (or only) providers available for people with certain conditions in some areas.

In sum, we are concerned that further blanket reductions in the overall medical supply of opioids may result in harm to patients who have genuine medical need for them. Opioid prescribing has fallen to a ten-year low, and high dose prescribing has dropped 47 percent.[12] The disparate effects on pain patients from this nationwide reduction have been documented in medical literature,[13] [14] [15] [16] [17]

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[10] Lagisetty PA, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert ASB. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928. https://doi.org/10.1001/jamanetworkopen.2019.6928

[11] Quest Diagnostics and Center for Addiction, HealthTrends, *Drug Misuse in America: Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis* (2019) https://questdiagnostics.com/home/physicians/health-trends/trends/pdm-health-trends.html

[12] Annual Surveillance Report of Drug-Related Risks and Outcomes, 2017, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

[13] Mark, T.L., Parish, W., Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events, 103 J. Subst. Abuse Treat. 58-63 (2019). doi: 10.1016/j.jsat.2019.05.001 Anyone who has taken opioids long-term is likely to develop physical dependence, requiring that opioids be tapered slowly to avoid side effects. Dependence is distinct from addiction, because it lacks the behavioral component that characterizes a use disorder. *See e.g.,* National Institute on Drug Abuse, Media Guide: The Science of Drug Use and Addiction: The Basics, https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics

[14] Glanz JM, Binswanger IA, Shetterly SM, Narwaney KJ, Xu S. Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy. *JAMA Netw Open.* 2019;2(4):e192613. doi:10.1001/jamanetworkopen.2019.2613

[15] James, J.R., Scott, J.M., Klein, J.W. et al. Mortality after discontinuation of primary care-based chronic opioid therapy for pain: a retrospective cohort study. J GEN INTERN MED (2019) 34: 2749. https://doi.org/10.1007/s11606-019-05301-2

[16] Fenton, J., Agnoli, A., Xing, G., et al., Trends and Rapidity of Dose Tapering among Patients Prescribed Long-Term Opioid Therapy, 2008-2017. *JAMA Netw Open.* 2019;2(11):e1916271. https://doi.org/10.1001/jamanetworkopen.2019.16271

[17] Perez, H., M. Buonora, C., Cunningham, M. et al., Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study, J Gen Intern Med (Aug 19 2019). doi: 10.1007/s11606-019-05227-9

in a warning from the Food and Drug Administration (FDA),[18] and in national news media.[19] Without nuanced and evidence-based means to draw the sorts of distinctions DEA intends to between appropriate and inappropriate use, we believe that an additional supply limit, especially in the midst of a global pandemic, may well do more harm than good.

Sincerely,

Kate M. Nicholson

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Confirmed receipt tracking number, submitted September 30. Your Comment Tracking Number: **1k4-9j98-6oul**

[18] FDA identifies harm reported from sudden discontinuation of opioid pain medicines, April 9, 2019. https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes

[19] NBC Nightly News, April 2, 2019. https://www.youtube.com/watch?v=Egfjxhmot1s