Policybi

ENDING THE OPIOID AND OVERDOSE CRISIS

Four Federal Policy Recommendations

The pandemic has worsened an existing drug overdose crisis that claimed the lives of more than 81,000 people in the U.S. from May 2019-June 2020. As the Biden-Harris administration firms up and implements its <u>proposed response</u>¹ to the opioid epidemic, this brief provides evidence-based recommendations to consider.

We focus our recommendations on the evidence and our experience in three areas: reducing the demand for opioids through policies that increase access to prevention, treatment, and recovery services; reducing the harms from opioid use through strategies that reduce morbidity and mortality; and reducing the supply of opioids through opioid stewardship that limits prescribing by the medical community and promotes adequate pain management. We also address the accountability of the pharmaceutical industry in contributing to the crisis and recommend ways to target settlement funds for maximal impact on the communities most affected.

RECOMMENDATIONS



Increase the Availability of Prevention, Treatment, and Recovery Services.

The Biden administration should expand access to medications for opioid use disorder, which reduce overdose risk and promote higher rates of recovery when compared to abstinence-based treatment. Despite strong evidence of the effectiveness of these medications, most patients continue to receive treatment without medications in all outpatient and residential settings. There are also longstanding gaps in access to medication treatment in correctional settings, and little connection to treatment upon release. The following strategies can increase access to prevention, treatment, and recovery services across all settings.

Eliminate the X-waiver. For 20 years, federal policy has required that health care providers receive a waiver and additional training (the X-waiver) to prescribe buprenorphine, which limits the number of patients that these providers can treat. The bipartisan Mainstreaming Addiction Treatment Act³ would eliminate the X-waiver and integrate opioid use disorder treatment into mainstream practice.

Make expansions to telehealth prescribing permanent. During the pandemic, the federal government expanded access to buprenorphine by allowing telehealth prescribing, which increased ease of access to treatment for many people living in rural areas or areas with a shortage of providers. Making this permanent would improve access to remote drug screening and prescribing and address access challenges⁴ in rural and underserved areas.

Relax federal regulations on methadone. Methadone can be dispensed only at highly regulated and monitored opioid treatment programs, where people must present daily for treatment until they are eligible for take-home doses. Onerous federal and state regulations result in crowded methadone clinics that may be too distant from some patients who might benefit (for example, in rural areas). Relaxing these regulations would allow methadone to be prescribed in primary care settings, putting it more on par with buprenorphine and addressing racial disparities in the use of these medications. Canada, for example, has authorized approved pharmacies to dispense methadone to patients without resulting problems with diversion.

Use payment and policy levers to increase the provision of effective medications in treatment programs. Nationally, the share of opioid treatment centers offering any medications for opioid use disorder increased from just 20% to 37% from 2007-2016.6 Payment and policy levers⁷ could accelerate the provision of evidence-based treatments. For example, Medicare and Medicaid reimbursement

for inpatient or residential treatment of substance use disorders could be made contingent on the availability of these medications. In conjunction with the states, the federal government could make the availability of medication treatment a requirement a condition for licensure of treatment programs and facilities.

Strengthen access, reimbursement, and best practices for peer recovery specialists. This has become an increasingly vital <u>strategy</u>⁸ in caring for patients with opioid use disorder. Peers are essential in helping patients stay safe, obtain social services, and navigate treatment. However, peer services are not available in many areas, and effective approaches to incorporating peers in health care settings remain in development. Given variation in approaches to reimbursement for peer services across states, federal guidance is needed to standardize coverage as well as requirements for optimal use of peer services.

Increase support for treating opioid use disorder in primary care through collaborative care models. Primary care providers are more likely than many mental health providers to accept insurance, and may be more accessible to the nearly 120 million Americans who live in mental health care Professional Shortage Areas. Importantly, primary care providers can also offer a more coordinated approach to treatment, as OUD is often correlated with health conditions like chronic pain. Medicare payment policy and programs can bolster primary care capacity to treat these patients. For example, in 2017, Medicare introduced four new payment codes that made behavioral health directly and separately reimbursable to primary care providers for the first time, an approach that is now being used by health systems nationwide, including Penn Medicine. In addition to new payment codes, the administration should support and evaluate innovative programs like the Value in Opioid Use Disorder Treatment Demonstration Program from the Centers for Medicare & Medicaid Services' Innovation Center, which offers providers a monthly management fee and performance incentives to improve access, engagement, and retention in evidence-based treatments.



Promote and Support Harm Reduction Strategies.

The Biden administration should increase support for harm reduction strategies, such as naloxone access, syringe services programs, fentanyl testing strip distribution, safe consumption spaces, and decriminalization. These strategies are evidence-based and reduce the risk of morbidity and mortality associated with substance use, including opioids and stimulants. In many cases, harm reduction organizations can connect people with vital medical and social services, and expand the reach of "low-barrier" treatment programs and providers that prioritize reduction of drug-related harms over abstinence.¹⁵

Increase funding to states for naloxone distribution. Universal naloxone access is vital to increase rates of overdose reversal in the community. It has been well-demonstrated that laypeople can safely and effectively <u>reverse overdoses</u> with naloxone and that greater community-level naloxone distribution is associated with fewer overdose deaths.¹⁴

Allow pharmacy dispensing and community distribution of naloxone without a prescription. Access laws currently in place in many states¹⁵ – for example, those allowing for third-party prescribing or for pharmacies to dispense naloxone to individuals without a prescription – can increase naloxone dispensing at community pharmacies.¹⁶ Access laws should be expanded to include options for mailing naloxone, which would address stigma and geographic barriers to pharmacies. Mail and community programs ensure naloxone gets in the hands of those most likely to witness and reverse overdoses.

Legalize fentanyl test strips and increase availability, including via mail-based services. Fentanyl test strips can reduce fatal overdoses14 by alerting individuals to substances that are contaminated with fentanyl. ^{12,13} In many parts of the country, opioids and non-opioids alike can be <u>mixed with fentanyl.</u> ¹⁷ including <u>pressed pills</u> ¹⁸ that are sold on the street as amphetamines or benzodiazepines. Despite their effectiveness, testing strips are illegal in many states, which <u>interferes</u> with distribution efforts even when the laws aren't enforced. ¹⁹ The Biden administration should endorse a nationwide effort to overturn state laws that consider fentanyl strips to be illegal drug paraphernalia, and support increasing the availability of fentanyl strips through community- and mail-based services.

Legalize and fund syringe exchange programs. The legality of syringe exchange programs varies across states and municipalities. Meanwhile, its criminalization hampers effective public health responses to the current opioid overdose crisis and other substance use disorders including limiting the transmission of \underline{HIV}^{20} hepatitis \underline{C}^{21} and other infectious complications of injection. The Biden administration should support legalizing syringe exchange programs in all jurisdictions and direct funding for these programs, including services by mail to overcome geographic and stigma-related barriers to use.

Permit the operation of safe consumption spaces. Also known as overdose prevention sites or supervised injection facilities, <u>safe</u> <u>consumption spaces</u> are legal and operating in 11 countries²³ and promote health through <u>HIV testing</u>²⁴ and referral to <u>other health</u> <u>services</u>, ²⁵ including opioid use disorder treatment. There are currently no sanctioned safe consumption spaces in the U.S., although <u>research</u> of one unsanctioned consumption space has found no instances of fatal overdoses since the site opened in 2014. ²⁶ The U.S. Department of Justice and the U.S. Attorney General should clarify that these spaces do not fall under federal 'crack house' statutes, and halt all enforcement actions against safe injection sites.



Reduce Overprescribing of Opioids While Improving Access to Effective Pain Management.

In response to escalating deaths, opioid prescribing stewardship has evolved and improved, spearheaded by clinical guidelines issued by the <u>CDC</u> in 2016,²⁷ and a myriad of state and professional society guidelines. While education and awareness has decreased overprescribing, additional strategies can further reduce opioid prescribing. The Biden administration should support and widely disseminate, through all Department of Health and Human Services agencies, the following strategies to reduce overprescribing:

Limit and standardize new opioid initiation. Patients who are opioid-naïve should be kept naïve, with new opioid prescriptions limited to patients with acute severe pain. Multiple studies²⁸ have demonstrated the risk of long-term opioid use once opioids are initiated (even following minor procedures²⁹), a risk that increases when greater quantities of opioid are prescribed. Opioid prescriptions should be standardized using prescribing guidelines³⁰ and diagnosis-based order sets. Electronic health record defaults³¹ and policies limiting the number of pills³² dispensed should be used to decrease opioid exposure to the patient and also benefit communities by decreasing leftover pills that could be misused or diverted. These kinds of interventions, based on behavioral economic principles, should be integrated into health systems to optimize patient-centered choices of judicious and safe analgesic options.

Target providers and patients with tools to decrease opioid prescribing and promote shared decision-making. Giving providers feedback³³ about their prescribing compared to peers and to norms using dashboards and one-on-one education decreases the amounts of opioids prescribed and increases guideline-concordant prescribing. For patients, providing narratives about experiences with opioids can help inform shared decision-making.³⁴ These strategies must be applied uniformly and monitored so they do not widen racial and ethnic disparities in existing pain treatments. Further, they should ensure that opioids are not abruptly discontinued for chronic pain patients.

Improve access to and coverage of effective pain management. Adequate treatment for chronic pain is essential to reducing the use of street-bought substances and their associated risks. Further, it is critical to address existing racial disparities in pain management. However, insurers are often unwilling to pay for non-pharmacologic but effective pain-management approaches, such as acupuncture, physical therapy, and cognitive behavioral therapy, or make coverage approval an <u>onerous and expensive process</u> for providers. We recommend that insurance coverage be improved for effective alternatives to chronic pain management, to make integrated and non-opioid approaches more widely and easily accessible, including increasing Medicare and Medicaid coverage for services provided by multidisciplinary pain clinics. 36



Ensure Effective Distribution of Funds from Pharmaceutical Settlements.

A priority for the Biden administration will be to hold the pharmaceutical industry accountable for deceptive practices that exacerbated the opioid crisis. In addition to litigation against manufacturers, distributors, and pharmacies, the Biden administration intends to seek civil, and potentially criminal, action against responsible individuals. This plan may be a response to <u>criticism</u> of the recent \$8.3 billion settlement between the Department of Justice and Purdue Pharmaceutical for illegal marketing practices, in which the owners of the company avoided criminal penalties.³⁷ The Purdue settlement represents just one of many completed or impending large and complex financial settlements related to opioid prescribing and distribution, including a \$26 billion lawsuit against Johnson & Johnson and three distribution companies.³⁸

Distribute settlement funds to effective programs that target affected individuals and communities. Federal guidance for distribution of opioid settlements should ensure that funds are distributed to directly fund substance use disorder prevention and treatment efforts, and target evidence-based public health and clinical approaches. Despite the deepening fiscal strain on all state and local governments, it is essential that these funds should be targeted toward the people and communities most affected by the overdose crisis – and to strategies for treatment and prevention that are known to work. When possible, provisions ensuring responsible spending should be written into the agreements directly, with mechanisms for enforcement. In addition, the federal government could make additional payments to local government conditional on appropriate use – and public reporting – of settlement funds.

Distribute settlement funds transparently. The federal government should create an easily accessible online database that tracks the distribution of funds along with the spending of these funds. We support the Biden administration's plan to designate an Opioid Crisis Accountability Coordinator, who can coordinate spending between federal agencies as well as federal, state, and local government.

Distribute settlement funds to prioritize racial equity. A recent multi-stakeholder group led by Johns Hopkins recommended that states distribute funds with a focus on <u>racial equity.</u> We support this recommendation that states and localities should direct significant funds to communities affected by years of discriminatory policies and now experiencing substantial increases in overdoses.

REFERENCES

- Biden for President. (2021). The Biden Plan to End the Opioid Crisis. Retrieved from https://joebiden.com/opioidcrisis/.
- National Academies of Sciences, Engineering, and Medicine. (2019). Medications for Opioid Use Disorder Save Lives. Washington, DC: The National Academies Press. https://doi.org/10.17226/25310.
- Senator Lisa Murkowski. (2021). Press Release: Murkowski, Hassan, Tonko, Turner Introduce Bipartisan Bill to Broaden Access to Addiction Treatment. Retrieved from https://www.murkowski.senate.gov/press/release/murkowski-hassan-tonko-turner-introduce-bipartisan-bill-to-broaden-access-to-addiction-treatment
- 4. Kahtri, U. et al. (2020) These Key Telehealth Policy Changes Would Improve Buprenorphine Access While Advancing Health Equity. *Health Affairs Blog*, September 11, 2020. DOI: 10.1377/hblog20200910.49871
- Samet, J.H., Botticelli, M. & Bharel, M. (2018). Methadone in primary care one small step for Congress, one giant leap for addiction treatment. N Engl J Med 2018; 379:7-8 DOI: 10.1056/NEJMp1803982
- Mojtabai, R., Mauro, C., Wall, M.M., Barry, C.L., & Olfson, M. (2019). The Affordable Care Act and opioid agonist therapy for opioid use disorder. *Psychiatr Serv*, 70(7), 617-620. doi:10.1176/appi.ps.201900025
- Sharfstein J., Meisel Z.F. (2019). Low-value treatment for opioid addiction: what is to be done? JAMA Health Forum. doi:10.1001/jamahealthforum.2019.0028
- Kaur, M., & Melville, R.H. (2021). Emergency department peer support specialist program. Psychiatr Serv, 72(2), 230–230.
- Katz, C., El-Gabalawy, R., Keyes, K.M., Martins, S.S., & Sareen, J. (2013). Risk factors for incident nonmedical prescription opioid use and abuse and dependence: Results from a longitudinal nationally representative sample. *Drug Alcohol Depend.*, 132(1-2), 107-113. doi. org/10.1016/j.drugalcdep.2013.01.010.
- Centers for Medicare and Medicaid Services. (2019). Behavioral Health Integration Services. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf
- 11. Messinger, H. (2018). Is Collaborative Care the Answer to the Mental Health Epidemic? Retrieved from https://www.pennmedicine.org/news/news-blog/2018/july/is-collaborative-care-the-answer-to-the-mental-health-epidemic
- 12. Centers for Medicare and Medicaid Services. (2021). Value in Opioid Use Disorder Treatment Demonstration. Retrieved from https://innovation.cms.gov/innovation-models/value-in-treatment-demonstration
- Jakubowski, A. & Fox, A. (2020). Defining Low-threshold Buprenorphine Treatment. J Addict Med., 14, 95-98. doi:10.1097/ADM.000000000000555
- Walley, A.Y., Xuan, Z., Hackman, H.H., et al. (2013). Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ, 346. doi:https://doi.org/10.1136/bmj.f174
- 15. Prescription Drug Abuse Policy System. (2018). Retrieved from http://pdaps.org
- Xu, J., Davis, C.S., Cruz, M., & Lurie, P. (2018). State naloxone access laws are associated with an increase in the number of naloxone prescriptions dispensed in retail pharmacies. Drug Alcohol Depend., 189, 37-41.
- Armenian, P., Vo, K., Barr-Walker, J., & Lynch, K. (2018). Fentanyl, fentanyl analogs and novel synthetic opioids: A comprehensive review. *Neuropharmacology*, 134, 121-132. doi:10.1016/j.neuropharm.2017.10.016
- 18. Whelan, A. (2021). As overdoses rise, Philly health officials warn about "pressed pills" fake painkillers laced with fentanyl. Philadelphia Inquirer. Retrieved from https://www.inquirer.com/health/opioid-addiction/pressed-pills-philadelphia-fentanyl-overdose-crisis-20210123.html
- Lieberman, A. (2020). Removing Legal Barriers to Drug Checking Can Help Reduce Drug-Related Harm. The Network for Public Health Law. Retrieved from https://www.networkforphl.org/news-insights/removing-legal-barriers-to-drug-testing-can-help-reduce-drug-related-harm/
- 20. Gibson, D.R., Flynn, N.M., & Perales, D. (2001). Effectiveness of syringe exchange programs in reducing HIV risk behavior and HIV seroconversion among injecting drug users. AIDS, 15(11), 1329-1341. doi:10.1097/00002030-200107270-00002
- 21. Platt, L., Minozzi, S., Reed, J., et al. (2017). Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. Cochrane Database Syst Rev., 9(9). doi:10.1002/14651858.CD012021.pub2

- 22. Huyck, M., Mayer, S., Messmer, S., & Yingling, C. (2020). Community wound care program within a syringe exchange program: Chicago, 2018-2019. *Am J Public Health*, 110(8), 1211-1213. doi:10.2105/AJPH.2020.305681
- Kral, A.H., Lambdin, B.H., Wenger, L.D., & Davidson, P.K. (2020). Evaluation of an unsanctioned safe consumption site in the United States. N Engl J Med., 383, 589-590. doi:10.1056/NEJMc2015435
- 24. Salmon, A.M., van Beek, I., Amin, J., Grulich, A., & Maher, L. (2009). High HIV testing and low HIV prevalence among injecting drug users attending the Sydney Medically Supervised Injecting Centre. Aust N Z J Public Health, 33(3), 280-283. doi: 10.1111/j.1753-6405.2009.00389.x
- 25. Wood, E., Tyndall, M.W., Zhang, R., Montaner, J.S.G, & Kerr T. (2007) Rate of detoxification service use and its impact among a cohort of supervised injecting facility users. Addiction, 102, 916-919. doi:10.1111/j.1360-0443.2007.01818.x
- 26. Kral, A.H. & Davidson, P.J. (2017). Addressing the nation's opioid epidemic: lessons from an unsanctioned supervised consumption site. Am J Prev Med., 53(6), 919-922. doi:https:// doi.org/10.1016/j.amepre.2017.06.010
- 27. Dowell, D., Haegerich, T.M., & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain— United States, 2016. MMWR Recomm Rep, 65(No. RR-1), 1–49. doi: 10.15585/mmwr.rr6501e1
- 28. Shah, A., Hayes, C.J., Martin, & B.C. (2017). Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use United States, 2006-2015. MMWR Morb Mortal Wkly Rep., 66(10), 265-269. doi: 10.15585/mmwr.mm6610a1
- 29. Berger, I., Strother, M., Talwar, R., Ziemba, J., Wirtalla, C., Xia, L., Guzzo, T., Delgado, M.K., & Kelz, R. (2019). National Variation in Opioid Prescription Fills and Long-Term Use in Opioid Naïve Patients after Urological Surgery. J Urol., 202(5), 1036-1043.
- Howard, R., Waljee, J., Brummett, C., Englesbe, M., & Lee, J. (2018). Reduction in Opioid Prescribing Through Evidence-Based Prescribing Guidelines. JAMA Surg., 153(3), 285-287. doi:10.1001/jamasurg.2017.4436.
- 31. Delgado, M.K., Shofer, F.S., Patel, M.S., Halpern, S., Edwards, C., Meisel, Z.F., & Perrone, J. (2018). Association between Electronic Medical Record Implementation of Default Opioid Prescription Quantities and Prescribing Behavior in Two Emergency Departments. J Gen Intern Med., 10.1007/s11606-017-4286-5.
- 32. Lowenstein, M., Hossain, E., Yang, W., Grande, D., Perrone, J., Neuman, M.D., Ashburn, M., & Delgado, M.K. (2020). Impact of a State Opioid Prescribing Limit and Electronic Medical Record Alert on Opioid Prescriptions: a Difference-in-Differences Analysis. J Gen Intern Med, 35(3), 662-671. doi: 10.1007/s11606-019-05302-1
- Wang, T.T., Delgado, M.K., Hersh, E.V., & Panchal N. (2020). Peer Comparisons to Increase Responsible Opioid Prescribing Among Oral and Maxillofacial Surgeons. J Oral Maxillofac Surg., 16:S0278-2391(20)31510-X. doi: 10.1016/j.joms.2020.12.013.
- 34. Meisel, Z.F., Goldberg, E.B., Dolan, A.R., Bansal, E., Rhodes, K.V., Hess, E.P., Cannuscio, C.C., Schapira, M.M., Perrone, J., Rodgers, M.A., Zyla, M.M., Bell, J.J., McCollum, S., & Shofer, F.S. (2020). Stories to Communicate Individual Risk for Opioid Prescriptions for Back and Kidney Stone Pair: Protocol for the Life STORRIED Multicenter Randomized Clinical Trial. JMIR Res Protoc; 9(9):e19496 doi: 10.2196/19496
- 35. American Board of Pain Medicine. (2019). Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, and Barriers to Providing Multidisciplinary, Non-Opioid Care. Retrieved from http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf
- 36. Fashler, S.R., Cooper, L.K., Oosenbrug, E.D., Burns, L.C., Razavi, S., Goldberg, L., & Katz, J. (2016). Systematic Review of Multidisciplinary Chronic Pain Treatment Facilities. *Pain Res Manag.*, 2016:5960987. doi: 10.1155/2016/5960987.
- Davis, C.S. (2021). The Purdue Pharma Opioid Settlement Accountability, or Just the Cost of Doing Business? N Engl J Med. doi: 10.1056/NEJMp2033382
- Achenback, J. (2020). Johnson & Johnson, three other companies close in on \$26 billion deal on opioid litigation. Washington Post. Retrieved from https://www.washingtonpost.com/health/opioid-settlement-drug-distributors/2020/11/05/6a8da214-1fc7-11eb-b532-05c751cd5dc2_story.html
- Johns Hopkins Bloomberg School of Public Health. Opioid principles. Retrieved from https://opioidprinciples.jhsph.edu/principle-4-focus-on-racial-equity/

Authors

This brief was produced by the Penn LDI Opioids Working Group. Authors include Shoshana Aronowitz, Molly Candon, Peggy Compton, Austin Kilaru, Margaret Lowenstein, Zachary Meisel, Jeanmarie Perrone, and Janet Weiner. The authors thank Rachel Werner for her insightful review and comments. Please contact pennldi-info@wharton.upenn.edu with questions.

About Penn LDI

The Leonard Davis Institute of Health Economics at the University of Pennsylvania catalyzes and facilitates multidisciplinary research and educational programs, shaping and expanding the knowledge required to improve population health, the health care system, and health policy. Learn more at Idi.upenn.edu.

About the Center for Addiction Medicine and Policy

The Penn Medicine Center for Addiction Medicine and Policy (CAMP) strives to substantially mitigate harms from substance use, regionally and nationally, through clinical education, substance use treatment, and research. Learn more at penncamp.org.