



December 6, 2021

Miriam E. Delphin-Rittmon, Ph.D.  
Assistant Secretary for Mental Health and Substance Use  
Chair, Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC)  
c/o Tracy Goss, ISUDCC Designated Federal Officer  
U.S. Department of Health and Human Services (HHS)  
Substance Abuse and Mental Health Services Administration (SAMHSA)  
5600 Fishers Lane, 13E37B  
Rockville, MD 20857

*Via email to Tracy.Goss@samhsa.hhs.gov*

**Subject: Areas for Improved Federal Coordination**

Dear Dr. Delphin-Rittmon and Committee Members:

This letter is in response to the ISUDCC [Federal Register Notice](#) dated October 19, 2021. The Center for U.S. Policy (CUSP) would like to provide the ISUDCC our recommendations for improving federal coordination as related to substance use disorder (SUD) prevention, interventions, treatment, harm reduction, and recovery support.

CUSP is a nonpartisan, 501(c)(3) not-for-profit research and education organization. Our 2021 and 2022 issue priorities include reducing substance use disorders and their consequences, including drug poisonings. We are home to the [Finding the ‘ME’ in Treatment](#), [Warm Handoff](#), and [Prescriber Safety](#) initiatives. Our recommendations to the ISUDCC are structured under those headings. We will also make recommendations related to state and local opioid litigation proceeds.

**Finding the ‘ME’ in Treatment**

It is essential that Americans have access to individualized health care, including for SUD. The COVID-19 public health emergency has shown that digital health supports the personalization of treatment services. Digital health is especially important to Americans in medically underserved communities and persons whose health requires them to avoid potential exposure to infections in health care facilities.

In response to the COVID-19 public health emergency, HHS and the Department of Justice (DOJ) have temporarily reduced regulatory barriers to medications for opioid use disorder (MOUD). **We recommend that HHS and DOJ follow rulemaking procedures to extend MOUD flexibilities after the COVID-19 public health emergency ends.** More information on this recommendation is detailed in “[Extending Pandemic Flexibilities for Opioid Use Disorder Treatment: Authorities and Methods](#),” published by Bridget C.E. Dooling & Laura Stanley in the *Minnesota Law Review*.

Center for U.S. Policy

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Similarly, over the past 20 years, the Office of National Drug Control Policy (ONDCP), National Institute on Drug Abuse (NIDA), and Food and Drug Administration (FDA) have supported the development of, access to, and coverage of evidence-based digital treatments for substance use and mental health disorders.<sup>1</sup> Prescription digital therapeutics (PDTs) are evidence-based medical interventions using software that can be accessed on a tablet or smartphone to prevent, manage, or treat a range of diseases and disorders.<sup>2</sup> As of November 22, 2021, the FDA had cleared seven PDTs for conditions including SUD, ADHD, and insomnia.<sup>3</sup> MassHealth recently enacted a policy enabling program participants to access PDTs for SUDs as covered benefits.<sup>4</sup> **We recommend that HHS enable Medicare and Medicaid participants to access PDTs for substance use and mental health disorders as covered benefits.**

## **Warm Handoff and Community Paramedicine**

A SUD warm handoff is the process of transitioning a patient with SUD from an intercept point, such as an emergency department, to a treatment provider once the patient is stable.<sup>5</sup> Warm handoffs provide a pathway to treatment and recovery for persons with SUDs and can decrease the risk of SUD progression and drug poisoning.<sup>6</sup> According to Dr. Nora Volkow, the Director of NIDA, “It is crucial that acute care physicians, and the health care systems in which they practice, become aware of the importance of ensuring that patients are screened for OUD and, if OUD is detected, that they receive OUD treatment, ideally by initiating them on buprenorphine before they are released.”<sup>7</sup> **To ensure that most U.S. hospitals conduct SUD warm handoffs, we recommend that HHS require Medicare- and Medicaid-participating hospitals and non-participating hospitals that provide covered emergency services to implement SUD warm handoff policies and programs, and have a practitioner who is federally qualified to prescribe buprenorphine for OUD on duty or on call at all times.**

Community paramedicine (CP) programs are an extension of emergency medical services that cover gaps in health care services.<sup>8</sup> CP programs provide follow-up services after a health emergency to support access to care and prevent repeat incidents.<sup>9</sup> They can empower advanced EMS professionals to intervene and activate community resources for individuals who use substances and may benefit from supportive services. CP programs can help people who use substances by dispensing naloxone, arranging for bridge medication between an emergency incident and an appointment with an SUD treatment provider, and connecting individuals with social services, such as food assistance and violence- or substance-free housing.<sup>10</sup> **HHS and the**

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<sup>1</sup> <https://pcssnow.org/wp-content/uploads/2021/09/Aklin-PCSS-Webinar-9.30.21-final-003.pdf>

<sup>2</sup> [https://dtxalliance.org/wp-content/uploads/2021/01/DTA\\_DTx-Definition-and-Core-Principles.pdf](https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf)

<sup>3</sup> <https://aimedalliance.org/wp-content/uploads/2021/12/Executive-Summary-Addressing-Chronic-Diseases-Mental-Health-and-Substance-Use-In-America-Optimizing-Care-with-PDTs.pdf>; <https://centerforuspolicy.org/mass-medicare-covers-digital-therapeutics/>

<sup>4</sup> <https://mhdل.pharmacy.services.conduent.com/MHDL/pubdownloadpdfupdates.do?id=6896>

<sup>5</sup> <http://d-scholarship.pitt.edu/29950/1/IOPOpioidReport2016.pdf>

<sup>6</sup> <https://dcbalaw.com/wp-content/uploads/2019/01/WarmHandoffsBarnesMcClughen.pdf>

<sup>7</sup> <https://www.drugabuse.gov/about-nida/noras-blog/2019/08/emergency-departments-can-help-prevent-opioid-overdoses>

<sup>8</sup> <https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/ems-and-disaster-preparedness/ems-resources/mih-cp-primer-2016.pdf>

<sup>9</sup> <https://impactcarolina.org/wp-content/uploads/FINAL-Community-Paramedicine-Overview.pdf>

<sup>10</sup> <https://impactcarolina.org/wp-content/uploads/FINAL-Community-Paramedicine-Overview.pdf>

**Department of Homeland Security should coordinate to provide grant funding to enable EMS agencies to implement and improve CP programs that address SUD. Additionally, HHS should require that all federally regulated health plans cover health services provided by community paramedics.**

## **Prescriber Safety**

We appreciate that the Biden-Harris Administration has prioritized expanding access to evidence-based treatment for SUD.<sup>11</sup> For patients to have access to SUD medications, including methadone and buprenorphine for OUD, it is essential that authorized prescribers feel confident and safe in prescribing or dispensing those medications.

The DOJ has implemented an aggressive effort to shut down rogue controlled-medication prescribers and pharmacists.<sup>12</sup> As part of this effort, however, the DOJ has raided, searched, and investigated a past president of the American Academy of Pain Medicine (AAPM), the editor-in-chief of the Practical Pain Management medical journal, a past president of the American Society of Addiction Medicine (ASAM), and a past president of ASAM's affiliate, the Tennessee Society of Addiction Medicine.<sup>13</sup>

DOJ's priority of prosecuting controlled-medication prescribers creates fear and reluctance among health care professionals. This chilling effect undermines congressional and Biden-Harris Administration efforts to expand access to medications to treat OUD.<sup>14</sup> **To improve access to evidence-based treatment for OUD, the administration should require federal law enforcement to obtain a referral from the appropriate state health-profession licensing board before instituting, aiding in, or defending an investigation or criminal or civil action against a prescriber or dispenser of FDA-approved medications in which medical need or patient care, including the prescribing or dispensing of medications, is at issue.**

More information on the DOJ's enforcement actions, their unintended consequences, and our policy recommendation is detailed in "[A More Sensible Surge: Ending DOJ's Indiscriminate Raids of Healthcare Providers](#)," published by CUSP's chairman in the American University Washington College of Law's *Legislation & Policy Brief*.

## **Opioid Litigation Proceeds**

Our organization wishes to thank ONDCP for the work it has conducted to date to ensure that state and local opioid litigation proceeds are directed toward prospective SUD prevention, treatment, harm reduction, and recovery support services. **We recommend that the DOJ not pursue refunds to the federal government of any portion of state or local opioid litigation proceeds.**

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<sup>11</sup> <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>

<sup>12</sup> <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1071&context=lpb>

<sup>13</sup> <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1071&context=lpb>

<sup>14</sup> <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1071&context=lpb>

Finally, we direct the ISUDCC to the [\*Principles for the Use of Funds from the Opioid Litigation\*](#), published by the Johns Hopkins Bloomberg School of Public Health, and the [\*Model Opioid Litigation Proceeds Act\*](#), developed with support from ONDCP by the Legislative Analysis and Public Policy Association, the O'Neill Institute for National & Global Health Law at Georgetown University Law Center, the Center for U.S. Policy, and Brown & Weinraub, PLLC. **We recommend that each state opioid litigation proceeds law and every opioid litigation settlement reflect the public health priorities set forth in the model act.**

Thank you for the opportunity to share our perspective. Please contact me at 202-743-5771 if you would like more information on our organization or our recommendations.

Sincerely,



Michael C. Barnes  
Chairman