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Dr. Rahul Gupta

Director of National Drug Control Policy

White House Office of National Drug Control Policy

December 19, 2022

Dear Dr. Gupta,

The signatories to this letter are individuals and organizations from across the country concerned with the availability of and equitable access to evidence-based treatment options for substance use disorder. As providers, researchers, and advocates in the field, we share in the ONDCP's concern over the steady rise of overdose deaths (ODs) across the country over the past several years; particularly the substantial increase in deaths related to stimulant use.¹ Accordingly, we write in response to the ONDCP's National Drug Control Strategy and Plan to Address Methamphetamine Supply, Use, and Consequences. With the growing crisis of stimulant use and stimulant-involved ODs, we applaud the ONDCP's attention to contingency management (CM) in its recent plans. More specifically, we wish to highlight some additional considerations not addressed in the strategy, in hopes that they will contribute to a more comprehensive landscape of support for CM.

While stimulant use and stimulant-involved fatal ODs have impacted the whole country, we also wish to name their disproportionate harm on low-income and rural communities, and communities of color. The staggering climb in psychostimulant-involved ODs is felt keenly in rural counties, where the age-adjusted rate of such deaths was 1.4 times higher than in urban counties in 2019.² Systemic racism and inequities in access to treatment mean that, despite substantively similar rates of past-year cocaine use, Black Americans were twice as likely to die from a cocaine-involved overdose compared to their white counterparts in 2019.³ Psychostimulant and opioid co-involved OD rates during the same year were more than 1.5 times higher for Indigenous persons as compared to white persons.⁴ In addition to these fatal consequences, substance use also has devastating lifelong impacts on communities of color: Black and Latinx people make up 30% of the U.S. population but 77% of the population federally incarcerated for drug offenses; and even without incarceration a drug conviction may place a lifetime bar on an

¹ Substance Abuse and Mental Health Services Administration, *Treatment of Stimulant Use Disorders*, 4 (2020).

² Holly Hedegaard & Merianne Rose Spencer, Nat'l. Ctr. for Health Statistics, *Urban-Rural Differences in Drug Overdose Death Rates, 1999-2019*. NCHS Data Brief No. 403 (2021).

³ Centers for Disease Control and Prevention, *Cocaine and Psychostimulant-involved Overdose Deaths Disproportionately Affect Racial and Ethnic Minority Groups*, <https://www.cdc.gov/drugoverdose/featured-topics/psychostimulant-cocaine-race-ethnic-minorities.html>.

⁴ Kariisa Mbabazi et al., *Drug Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential Among Racial and Ethnic Groups- United States, 2004-2019*, 227 DRUG AND ALCOHOL DEPENDENCE (2021).

individual's access to public benefits, economic opportunities, and political life,⁵ as well as limit access to child care, housing, connection to loved ones and transportation.

There is an enormous and unequal burden of pain and punishment associated with substance use disorder generally and stimulant use specifically. A more equitable path forward, one rooted in harm reduction, evidence-based substance use disorder and mental health treatment, and multiple pathways to recovery is vital. In recent decades, CM has emerged as the most effective evidence-based practice to combat Stimulant Use Disorder and has demonstrated robust outcomes including reduction or cessation of drug use and longer retention in treatment.⁶

Despite the demonstrated effectiveness of CM, policy barriers have thus far stifled its inclusion alongside other evidence-based treatment options for substance use disorder in federal health care programs. As the ONDCP identified in the Plan, the landscape around the Anti-Kickback Statute and Beneficiary Inducement CMP is murky, and merits attention to ensure that CM providers have the guidance they need to set up safe and effective CM programs.

While we are encouraged by the ONDCP's attention to policy barriers faced by would-be CM providers, we also urge the ONDCP to look ahead to the next set of barriers: those that might limit uptake or create unintended consequences for patients seeking CM treatment. In particular, we encourage the ONDCP to work with the Internal Revenue Service (IRS) to establish clear guidelines regarding the tax treatment of cash incentives received as part of CM, and to work with agencies that administer public benefits to establish clear guidelines on how the receipt of cash incentives as part of CM might affect an individual's benefits eligibility.

While a growing number of states are utilizing Medicaid waiver flexibilities to pilot short-term CM interventions, waiver flexibility cannot be relied on in perpetuity; we encourage the ONDCP to use this time as an opportunity to clear policy barriers for more sustainable interventions moving forward. In short, we urge the ONDCP to consider its role in creating meaningful access to this evidence-based treatment, making it intuitive and transparent for both providers and patients.

We urge the ONDCP to work with HHS to issue guidance on safeguards and best practices against fraud and abuse in CM programs.

In its 2020 Rulemaking, HHS explicitly declined to extend patient engagement and support safe harbor protections to cash and cash-equivalent incentives through CM, opting instead to examine each program on a case-by-case basis. While HHS has elsewhere opined that it would not enforce the Anti-Kickback Statute and Beneficiary Inducements CMP against two requestors,⁷ the absence of generalizable guidance

⁵ Drug Policy Alliance, *The Drug War, Mass Incarceration, and Race*, https://www.unodc.org/documents/ungass2016/Contributions/Civil/DrugPolicyAlliance/DPA_Fact_Sheet_Drug_War_Mass_Incarceration_and_Race_June2015.pdf (2015).

⁶ Dominick DePhilippis et al., *The National Implementation of Contingency Management (CM) in the Department of Veterans Affairs: Attendance at CM Sessions and Substance Use Outcomes*. DRUG ALCOHOL DEPEND. 2018.

⁷ See *Advisory Opinion 22-04*, U.S. Department of Health and Human Services Office of Inspector General (Mar. 2, 2022) (determining that although a digital health platform's participation in a CM model implicated both the Anti-Kickback Statute

produced by these methods continues to hinder the growth of CM across the country. With only advisory opinions to form the basis of future CM program development, would-be providers face a choice: design a program closely aligned with that of prior requestors to lessen the possibility of enforcement; or risk investment in a program that could lead to penalties under the Anti-Kickback Statute and Beneficiary Inducements CMP. This uncertainty stifles program development and access to evidence-based CM programs, and limits innovation by encouraging fidelity to the limited examples of programs on which HHS has opined.

The uncertain landscape between HHS advisory opinions also raises equity concerns. More sophisticated organizations will always be better positioned to navigate the legal and regulatory processes inherent in this uncharted territory, able to bring their programs into alignment with advisory opinions or accept the risk of penalties and subsequent program modification. Organizations with less support however, especially organizations led by people of color, smaller organizations, and rural groups, may lack the ability either to achieve alignment with advisory opinions or accept the risk that accompanies charting a new course.

We urge the ONDCP to work with HHS to issue clear, generalizable guidelines on safeguards and best practices to mitigate the risk of fraud and abuse that might lead to penalties under the Anti-Kickback Statute and Beneficiary Inducements CMP. Doing so will ensure that would-be providers of CM across the country have a clear roadmap that enables them to move forward in program development with lower risk of reprisal. This guidance would not substitute for the case-by-case assessments still required under the Anti-Kickback Statute and Beneficiary Inducements CMP, but would provide an initial framework for all would-be providers.

In developing this guidance, we encourage the ONDCP and HHS to focus their attention on guardrails and procedures that can accommodate and encourage further developments in the field of CM. Like any medical treatment, the efficacy of CM is strengthened by ongoing research into the appropriate value of incentives, duration of treatment, and components of the treatment protocol. As the research base grows, healthcare providers and other experts in the field will be the ones best situated to make determinations on the course of patients' treatment. The role of policymakers should not be to hinder the growth of the field, but to develop clear and thorough procedures that minimize the risk of fraud and abuse by, for example, requiring providers to document the clinical reasoning and evidence base behind particular courses of treatment.

While the ONDCP rightly identified the Anti-Kickback Statute and Beneficiary Inducements CMP as key policy barriers preventing the diffusion of CM programs, we also encourage forward-thinking considerations to clear policy barriers that might undermine the implementation of programs once established. We urge the ONDCP to consider the experience of CM from the perspective of a patient, and

and the Beneficiary Inducements CMP, the risk of fraud and abuse was low because (1) the Requestor did not bill Federal Health Programs directly; (2) Incentives were dispersed through a smart debit delivery system that protected against abuse; (3) Incentives were protocol-driven and part of an evidence-based treatment model; and (4) Incentive amounts were relatively low, both individually and in the aggregate.)

to be thoughtful about removing obstacles and mitigating risks that might prevent individuals from receiving this crucial treatment. Accordingly:

We urge the ONDCP to work with the Substance Abuse and Mental Health Services Administration (SAMHSA) to remove ineffective and unnecessary limits to federally-funded programs.

Five decades of research have produced evidence indicating that the effectiveness of CM is moderated by the value of incentives, with an average incentive total in research studies exceeding \$500 per participant,⁸ and lower incentive values proving less effective or ineffective in achieving target behaviors.⁹ Despite this evidence, SAMHSA SOR grant announcements, as recently as FY22, cap CM programs at \$15 per incentive and \$75 per patient annually.¹⁰ To hold a program out as contingency management while divorcing it from proven incentive levels sets programs and patients up for failure. It invests federal funding into a program model that is neither supported by evidence nor required by the most recent OIG opinions, which stress the importance of program guardrails other than inflexible ceilings.

SAMHSA's grant portfolio represents a substantial amount of federal investment in substance use disorder treatment, and its policies are a reflection of the administration's priorities in this space. With CM as one of the ONDCP's stated priorities in the treatment of substance use disorder, we encourage the ONDCP to ensure that federal agencies like SAMHSA are not needlessly erecting barriers to its maximally successful implementation.

We urge the ONDCP to work with the IRS to issue guidance differentiating between CM incentives and income.

As CM incentives have growing flexibility to be set at clinically proven levels, attention must be paid to the potential for adverse consequences to patients as a result of the classification of these incentives. The IRS has yet to comment on the classification of incentives received as part of CM treatment for tax purposes. However, it is clear from other guidance that the IRS recognizes the difference between (1) income, and (2) medical treatment. Consistent with this approach, we encourage the ONDCP to work with the IRS to issue guidance that differentiates between income and CM incentives, thereby removing the barrier of confusion and burdensome tax-reporting requirements at all levels for this medical treatment.

⁸ Richard Rawson et al., *Treatment for Individuals who Use Stimulants*, 23 (2021). https://mataccesspoints.org/wp-content/uploads/2021/04/TRUST_Therapist_Guide.pdf.

⁹ Lussier, J.P., Heil, S.H., Mongeon, J.A., Badger, G.J. and Higgins, S.T. (2006), *A meta-analysis of voucher-based reinforcement therapy for substance use disorders*. *Addiction*, 101: 192-203.

¹⁰ DEP'T OF HEALTH & HUMAN SERV., SUBSTANCE USE & MENTAL HEALTH ADMIN., *FY 2022 State Opioid Response Grants Notice of Funding Opportunity*, No. TI-22-005, 59-60 (2022).

Taxable income includes all income from all sources, minus certain deductions.¹¹ Individuals who receive income in the form of a prize or award have a duty to report any amount in their tax filings, and providers of gifts or awards to an individual totaling \$600 or more in one year must issue that individual a 1099-MISC form.¹² If CM incentives were to be classified as prizes or awards, this requirement would create barriers for protocols, providers, and patients. Firstly, CM protocols may be deliberately designed to avoid the administrative burden of issuing 1099-MISC forms and engaging with IRS obligations. In fact, some existing CM protocols already are, despite evidence that CM is most effective at higher total incentive values.¹³ Second, this classification would plunge CM providers into counselling on a subject far outside their area of expertise as patients seek help navigating the tax implication of their medical care. Lastly and most significantly, individuals who receive prizes or awards have a duty to report them, regardless of the total amount. Were CM incentives to be classified in this manner, it would mean that any patient who received CM treatment would have to accept responsibility for new tax reporting obligations.

Individuals battling substance use disorder may experience concurrent challenges including unstable housing and employment, interpersonal conflict, and/or mental health struggles. Tax obligations are likely to present an insurmountable logistical burden among such competing priorities. Legal consequence for failure to report, itself a concerning outcome, could also deter people from engaging in CM treatment altogether.

Notwithstanding the above-referenced harms of classifying CM incentives as income, the strongest argument against the position is that it goes against agency precedent. While the IRS has yet to comment on this area specifically, it is clear from other guidance that the agency considers carefully the impact that income determinations might have on access to healthcare. For example, the IRS differentiates between prizes or awards and expenses related to medical treatment. The IRS defines medical expenses as “payments for the diagnosis, cure, mitigation, treatment, or prevention of disease, or payments for treatments affecting any structure or function of the body.”¹⁴ Such expenses must be “primarily to alleviate or prevent a physical or mental disability or illness,” not “merely beneficial to general health.”¹⁵ One key consideration between medical expenses and other wellness programs is the presence or absence of a medical diagnosis: where the IRS excludes weight-loss treatments generally from its definition of medical expenses, it includes weight loss programs for a specific disease diagnosed by a physician.¹⁶ As an evidence-based treatment meant primarily to alleviate a diagnosed substance use disorder, CM is clearly more closely aligned with medical expenses than prizes, and ought to be classified as such.

¹¹ 26 I.R.C. § 61; 26 I.R.C. §63(a); 26 I.R.C. § 74(a).

¹² *About Form 1099-MISC, Miscellaneous Income*, Internal Rev. Serv., <https://www.irs.gov/forms-pubs/about-form-1099-misc>.

¹³ Richard Rawson et al., *Treatment for Individuals who Use Stimulants*, 23 (2021). https://mataccesspoints.org/wp-content/uploads/2021/04/TRUST_Therapist_Guide.pdf.

¹⁴ *Topic No. 502 Medical and Dental Expenses*, INTERNAL REV. SERV., <https://www.irs.gov/taxtopics/tc502>.

¹⁵ INTERNAL REV. SERV., PUBLICATION 502, MEDICAL AND DENTAL EXPENSES (2020), https://www.irs.gov/publications/p502#en_US_2020_publink1000178851.

¹⁶ INTERNAL REV. SERV., PUBLICATION 502, MEDICAL AND DENTAL EXPENSES (2020), https://www.irs.gov/publications/p502#en_US_2020_publink1000178851.

While cash incentives as a component of medical treatment are a subject on which the IRS has yet to provide guidance, it is clear that the IRS does not intend for healthcare to impose tax obligations on providers or patients. Guidance from the IRS to differentiate between CM incentives and income would have the immediate effect of placing decisions on the total amount of incentive over the course of treatment in the hands of providers and protocol developers, allowing those decisions to be guided by evidence rather than tax obligations.

We urge the ONDCP to work with agencies that administer public benefits to issue guidance differentiating between CM incentives and income or assets for the purposes of benefits eligibility.

We also wish to draw the ONDCP's attention to the potential impact of CM incentives on patients' eligibility for public benefits. Much like IRS guidance, we encourage the ONDCP to work with federal and state agencies that administer means-tested public benefits to develop consistent guidance setting CM incentives apart from income and assets used in eligibility determinations. Such guidance will ensure that patients and their families will not be forced, needlessly so, to make impossible choices between mental health care, primary care, substance use disorder treatment and food, shelter, or other basic needs.

The existence of a 'Benefits Cliff,' an amount of earned income that renders a household ineligible for public benefits but fails to adequately compensate for the loss of those benefits, is a well-documented consequence of safety net programs with meagre asset limits.¹⁷ Households are often forced to make difficult decisions, foregoing additional earned income in order to remain eligible for needed assistance.¹⁸ Without guidance that sets CM incentives apart from these eligibility calculations, people with physical or mental health struggles and substance use disorder may be forced to choose between benefits and medical treatment. The result will be an unbearable cost-benefit analysis that burdens not only patients, but providers as well. Individuals with substance use disorder may be deterred from evidence-based treatment by the loss of other needs-sustaining support. This would also create additional treatment eligibility criteria that CM providers may be insufficiently resourced to respond to. In addition to diagnosing a substance use disorder and determining whether CM would be clinically indicated for a particular patient, the provider would need to determine whether the treatment would put the patient at risk of a benefits loss.

In developing guidance across public benefit categories, the approach to medical care and services in SSI is instructive. Medical care and services, including in some instances cash and in-kind assistance, are not considered income for the purposes of income determinations in this program.¹⁹ This reflects an intuitive approach to healthcare treatment: that it should be a stabilizing force in a patient's life, not at odds with other necessary supports. We encourage the inclusion of CM incentives under this category for SSI calculations, and under similar guidance across public benefit programs.

¹⁷ See, eg. *Introduction to Benefits Cliffs and Public Assistance Programs*, NAT'L CONFERENCE OF STATE LEGISLATURES, <https://www.ncsl.org/research/human-services/benefits-cliffs.aspx> (2022)

¹⁸ *While the full scope of mean-tested public benefits is broad and variable depending on location, we note that basic needs such as food; housing; emergency cash assistance; health care coverage; utility assistance; and subsidized childcare, not just for the individual earner but often at the household level, hang in the balance were incentives to be counted as income for the purposes of benefits eligibility.*

¹⁹ 20 C.F.R. § 416.1103

Simply put, clear differentiation between income and cash incentives as a component of CM are vital to the successful functioning of this treatment for those who need it most. If incentives are considered income for tax or benefits purposes, economically disadvantaged patients will be denied meaningful access to promising treatment. In the interest of health equity, we strongly encourage the ONDCP to work quickly across agencies and develop clear guidance that sets CM incentives apart from income and assets.

Our country faces a multi-faceted stimulant use crisis that disproportionately harms communities of color, and rural and low-income communities. No one intervention will solve this crisis, but evidence-based treatment for stimulant use disorder is an undeniable piece of the solution. CM stands poised as the most promising treatment available for people dependent on stimulants, but we must first create a policy landscape that allows it to thrive. We applaud the ONDCP for its efforts, and encourage continued collaboration across agencies to develop policies that recognize CM incentives for what they are: a critical component of an evidence-based medical intervention.

We would be happy to work with the ONDCP to further address any of the comments above. If you have any further questions, please reach out to Erin McCrady (emccrady@law.harvard.edu) at the Center for Health Law and Policy Innovation of Harvard Law School.

Respectfully submitted by the undersigned organizations and individuals:

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American Society of Addiction Medicine
Association for Behavioral Health and Wellness
C4 Recovery Foundation
Center for Health Law and Policy Innovation of Harvard Law School
Drug Policy Alliance
The Kennedy Forum
Montana Primary Care Association
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National Association of Addiction Treatment Providers
National Harm Reduction Coalition

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