February 16, 2021

Christi A. Grimm
Principal Deputy Inspector General, Office of the Inspector General
Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue SW
Washington, DC 20201

RE: OIG-128-N, Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Ms. Grimm,

The undersigned organizations, which represent healthcare professionals, patients and advocates dedicated to the prevention and treatment of substance use disorder (SUD), write to recommend the creation of a new safe harbor provision to the Federal anti-kickback statute (AKS) to protect the use of cash and cash-equivalent payments offered as part of contingency management (CM) in the treatment of SUD. CM is among the most effective evidence-based psychosocial treatments for SUD. With appropriate safeguards in place to prevent fraud, waste, and abuse, it can and should be made available to all patients receiving SUD treatment.

The Centers for Disease Control and Prevention (CDC) has recently reported an alarming increase in drug overdose deaths, with more than 81,000 overdose deaths reported in the 12-month period ending in May 2020, the highest number of such deaths ever recorded in a 12-month period.[1] This increase has been driven primarily by increases in overdose deaths involving synthetic opioids such as fentanyl, but overdose deaths involving cocaine and psychostimulants, such as methamphetamine, have increased dramatically as well. The rate of drug overdose deaths involving psychostimulants such as methamphetamine increased nearly five-fold between 2012 and 2018,[2] and provisional 12-month counts of overdose deaths involving psychostimulants increased by 34.8% from the 12-months ending in June 2019 compared to the 12-months ending in May 2020.[3] The increase in overdose deaths appears to have accelerated during the Public Health Emergency for COVID-19, reflecting the resulting treatment disruptions, social isolation, and other hardships of the pandemic.

With drug overdose deaths increasing at such a concerning rate, it is imperative that we remove barriers that prevent patients from accessing evidence-based and potentially life-saving SUD treatment services, including federal prohibitions on the use of CM. Particularly in the absence of medications approved to treat SUD involving cocaine or psychostimulants, ensuring access to all evidence-based psychosocial interventions for SUD takes on increasing importance as overdose deaths related to these substances rise.

Contingency Management is an Effective, Evidence-Based Treatment for SUD

CM is an evidence-based, psychosocial intervention that involves giving patients tangible monetary or non-monetary rewards (such as gift cards or vouchers) to reinforce positive behaviors such as treatment adherence (e.g., participation in therapy sessions, attendance at scheduled appointments, medication adherence) or reduced drug use/abstinence from drug use.[4] Federal agencies including the National

Institute on Drug Abuse (NIDA)[5] and the Substance Abuse and Mental Health Services Administration (SAMHSA)[6] recognize CM as an evidence-based and highly effective intervention to increase SUD treatment retention and promote abstinence from drug use. The Food and Drug Administration (FDA) has cleared a mobile medical application that incorporates CM to help increase treatment retention for patients with opioid use disorder (OUD).[7] Moreover, the Department of Veterans Affairs (VA) offers CM across its national health care system, reflecting its position that CM is an effective treatment.[8]

These positions in turn reflect the academic consensus that CM is an effective, evidence-based treatment. Two 2017 meta-analyses concluded that CM is effective in reducing use of a wide variety of substances, including alcohol, tobacco, cannabis, and stimulants, as well as polysubstance use.[9,10] Another meta-analysis of the clinical literature found that more immediate delivery and higher monetary value of rewards are associated with a larger effect on abstinence from drug use.[11]

Importantly, implementation of CM that is done with fidelity to the evidence-based practice never involves payments to providers for referrals or to patients as an inducement; it is structured in such a way as to avoid fraud and abuse.

The Federal Anti-Kickback Statute Impedes the Availability of CM

Despite its demonstrated effectiveness in reducing substance use and promoting SUD treatment retention, CM is rarely available to patients,[12] due in part to federal policy limiting the type and allowable cash value of incentives that can be used.[13] Indeed, the HHS Office of Inspector General (OIG) recognized these limitations in recent rulemaking that proposed protections for certain value-based arrangements, when it decided not to include cash and cash-equivalent payments offered as part of CM interventions or other programs to motivate beneficial behavioral changes in the new patient engagement and support safe harbor.[14] OIG further clarified that its nominal value guidance applies only to in-kind items or services, and not to cash or cash-equivalent payments, as some stakeholders had interpreted it. It concluded,

> The Federal anti-kickback statute may constrain the ability of individuals or entities to offer contingency management program incentives of any value to Federal health care program beneficiaries, depending on the facts of the arrangement… Contingency management incentive arrangements that do not comply with a safe harbor must be analyzed on a case-by-case basis for compliance with the Federal anti-kickback statute and Beneficiary Inducements CMP.

OIG issued such a case-specific advisory opinion 2008.[15] It concluded that a CM program, which was operated in a manner consistent with NIDA and SAMHSA publication, posed low risk of fraud and abuse and would not be an impermissible inducement to obtain covered items and services under section 1128A(a)(5) of the Act. The advisory opinion detailed the characteristics of the CM program that supported its conclusion; these same characteristics could be used to erect guardrails around a new safe harbor for CM to prevent its inappropriate use while expanding its availability beyond value-based enterprises.

Recommendations to Prevent Fraud, Waste, and Abuse

The clinical literature describing evidence-based CM and OIG's 2008 advisory opinion discuss several characteristics of some CM practices that could be understood as proxies for its appropriate clinical use and implemented as constraints on a new safe harbor for CM. Specifically, the safe harbor could require:

- The use of established and validated protocols for the incentives;
- Documentation in the patient's medical record of an established treatment plan that describes the clinical indication and medical necessity for CM (i.e., there is no standing order for CM);
- Documentation that the patient "earned" the incentive through objective, verifiable endpoints such as program participation or negative drug tests; and
- No marketing of CM as the primary or sole intervention offered or advertising the value of incentives provided.

Additionally, the use of automated CM programs, such as FDA-approved or research-validated digital therapeutics that provide CM, can offer similar accountability and program integrity assurance, but the clinical indication and medical necessity of such a program should still be documented in the patient's medical record and the use of such programs should never be marketed to potential patients.

With parameters such as those bulleted above in place, a new safe harbor should be created to allow for the broad implementation of CM as an effective treatment for SUD. When used to promote treatment adherence and abstinence from drug use in a manner consistent with the factors outlined above, CM incentives are clearly distinct from inducements for care. While OIG has offered that evidence-base CM practices do not necessarily implicate the Federal anti-kickback statute and civil monetary penalties (CMP) prohibiting beneficiary inducements, the lack of a safe harbor for this effective treatment option leaves providers to request case-by-case advisory opinions regarding their practices – a time-consuming process that impedes CM availability. Establishing a safe harbor for CM, with guardrails in place to ensure its appropriate use, would allow for the implementation of an established, effective treatment modality for SUD at a time when access to more effective treatment options is desperately needed.

Additional OIG Guidance and/or Regulatory Safe Harbor Needed Under EKRA

Finally, while we understand this solicitation relates only to safe harbors under AKS, the undersigned also urge OIG to issue guidance and/or create a regulatory safe harbor for CM under the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). EKRA makes it a crime to knowingly and willfully solicit, receive, pay, or offer any "remuneration (including any kickback, bribe or rebate)" in return for referrals to, or in exchange for using the services of, a "recovery home, clinical treatment facility or laboratory," and it applies to items and services paid for by government and private health plans.[16] Even with the recommended safe harbor for CM under the AKS, healthcare providers offering CM in accordance with established clinical guidelines and within the recommended guardrails could still face liability under EKRA. Thus, we urge OIG to issue guidance clarifying the permissibility of CM or propose a similar safe harbor for CM under EKRA.

Thank you again for this opportunity to propose a new regulatory safe harbor under the AKS to facilitate access to evidence-based treatment services for patients with SUD. We look forward to continuing to work with HHS and OIG to ensure patients can access life-saving treatment and finally turn the tide on the drug overdose epidemic.

Sincerely,

American Academy of Addiction Psychiatry
American Osteopathic Academy of Addiction Medicine
American Psychiatric Association

American Society of Addiction Medicine
The Kennedy Forum
Live4Lali
National Alliance for Medication Assisted Recovery (NAMA Recovery)
National Association for Behavioral Healthcare
National Association of Addiction Treatment Providers
National Association of Clinical Nurse Specialists
National Council for Behavioral Health
The San Francisco AIDS Foundation
Shatterproof
SMART Recovery
Well Being Trust
Young People in Recovery

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[1] Centers for Disease Control and Prevention (CDC). Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic. December 17, 2020. CDC Health Alert Network. Available at: https://emergency.cdc.gov/han/2020/han00438.asp?ACSTrackingID=USCDC_511-DM44961&ACSTrackingLabel=HAN%20438%20-%20General%20Public&deliveryName=USCDC_511-DM44961 Accessed January 12, 2021

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[16] 18 U.S.C. § 220(a)