

Contingency Management for the Treatment of Substance Use Disorders: Enhancing Access, Quality, and Program Integrity for an Evidence-Based Intervention

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

November 7, 2023

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EXECUTIVE SUMMARY

Stimulants represent a major and growing threat in the overdose crisis (1). Contingency management (CM) -- a psychosocial intervention that involves reinforcing abstinence from substances, as well as reinforcing other recovery-related behaviors -- is widely considered the most effective treatment for stimulant use disorder, and also has evidence as an effective treatment for alcohol, cannabis, and tobacco use disorders and as an effective adjunctive intervention to medications for opioid use disorder (MOUD) (2-4). While CM has been successfully implemented nationwide by the U.S. Department of Veterans Affairs (VA) and is permitted under several U.S. Department of Health and Human Services (HHS) grant programs and Medicaid demonstrations in California and Washington, it remains underutilized (5-8).

Several barriers limit the uptake of CM, including concerns about the potential application of certain federal fraud and abuse laws; limited funding and reimbursement opportunities; program restrictions on substance use disorders (SUDs) for which CM can be used; knowledge, attitudes and stigma related to CM; importance of strict fidelity to treatment protocols; limited access to training and mentoring; and workforce challenges (5, 8-13). Major barriers include concerns about the potential application of certain federal fraud and abuse laws, a \$75 annual limit on the value of cumulative per client CM incentives in HHS grant programs, and misconceptions about CM.

There are many opportunities for entities overseeing CM implementation -- including, among others, regulators at the federal, state, Tribal, local, and territorial levels -- to overcome barriers to CM access, strengthen the quality of CM services, and promote program integrity. Key opportunities include ensuring the implementation of and fidelity to evidence-based treatment protocols, clarifying the application of certain federal fraud and abuse laws to CM incentives, disseminating best practices on CM implementation, raising incentive limits in federal grant programs to enable evidence-based CM delivery, and conducting evaluations of CM implemented in real-world settings (see **Box 1** for recommendations) (5, 9, 14). Importantly, to promote program integrity and effectiveness, CM incentives should take the form of vouchers for items and services that support client well-being and recovery -- not cash payments.

Ultimately, there is immense need to expand the implementation of CM, as it has tremendous potential to address the nation's high rate of overdose deaths and, in particular, the increasing rate of stimulant-involved overdose deaths.

Box 1. Summary of HHS Recommendations to Entities Overseeing Contingency Management Implementation for Improving Access and Quality and for Strengthening Program Integrity

Clinical Approach

1. Require that providers adhere to established, evidence-based, efficacious treatment protocols that incorporate objective verification of incentivized behaviors.
2. Establish voucher- and prize-based CM incentive magnitudes that are sufficiently high to reinforce recovery-related behaviors as demonstrated in the literature.
 - a. If operational factors necessitate limits on cumulative per client incentive values, ensure that these limits allow for evidence-based incentive values and minimize the likelihood of premature treatment discontinuation.

Box 1 (continued)

3. Require the use of treatment protocols of at least 12 weeks duration when abstinence or treatment attendance are the incentivized behaviors.
4. Select incentives that are perceived as valuable to clients, including items, services, and vouchers or gift cards with purchase restrictions. Certain restrictions on incentives may be needed to effectively support recovery, mitigate risks of incentive diversion and misuse, and promote equity for clients. Due to this need, cash and unrestricted cash equivalents should be disallowed as incentives.
 - a. Recommended restrictions on incentives include:
 - Weapons;
 - Intoxicants (e.g., alcohol);
 - Over-the-counter preparations containing possible intoxicants (e.g., dextromethorphan);
 - Tobacco products;
 - Pornographic materials;
 - Gambling-related items (e.g., lottery tickets);
 - Enhanced or expedited access to SUD treatment or recovery support services; and
 - Parenting time.
5. Implement treatment protocols in which opportunities to receive incentives occur with sufficient frequency to effectively reinforce the desired behavior.
 - a. Abstinence: twice or thrice weekly.
 - b. Treatment session attendance: at least once weekly.
 - c. Medication adherence (for medications administered monthly): once monthly.
6. Provide incentives immediately after the incentivized behavior is verified. For abstinence as an incentivized behavior, this requires the use of rapid point-of-care (POC) drug tests.
7. Consider prioritizing stimulant use disorder for CM over other SUDs, based on CM's superior efficacy relative to other treatments for stimulant use disorder, its more robust evidence base for stimulant use disorder compared to other SUDs, the lack of Food and Drug Administration (FDA)-approved medications for stimulant use disorder, and the growing contribution of stimulants to overdose deaths. Targeting a broader set of SUDs with CM can, however, be a better strategy for certain communities depending on their needs.
8. Select incentivized behaviors that are appropriate for the substances being targeted, based on currently available drug testing technologies and medications.
 - a. Abstinence: stimulant and cannabis use disorders.
 - Abstinence should be objectively verified using rapid POC tests waived under the Clinical Laboratory Improvement Amendments of 1998 ("CLIA").
 - b. Treatment session attendance: stimulant, opioid, cannabis, alcohol, and tobacco use disorders.
 - c. Medication adherence (for long-acting medications): opioid use disorder (OUD).
9. Offer CM as part of a continuum of evidence-based treatment options and services for SUDs, as appropriate for the populations being served.
10. Consider using telehealth as a strategy to expand access to CM when SUD treatment session attendance is the incentivized behavior.

Box 1 (continued)

Provider and Organizational Standards

11. Implement the following training and coaching requirements for CM providers:
 - a. CM providers must receive CM-specific training before offering CM, as well as ongoing coaching throughout their time delivering CM.
 - b. CM coaches must receive CM-specific training prior to coaching.
 - c. CM providers and coaches must receive regular continuing education on CM.
12. Permit any health care provider authorized to provide SUD treatment services to deliver CM. At this time, it is not recommended that peer support specialists be permitted to deliver CM.
13. Require that each office or facility providing CM designate one or more CM Champions, and that CM Champions receive training on evidence-based practices (EBPs) and periodic continuing education.
14. Consider requiring the development and approval of a readiness attestation before organizations may begin providing CM.
15. Require frequent monitoring of fidelity to EBPs using robust documentation systems and use the findings to implement program improvements and to target additional training and coaching investments.

Policy Opportunities

16. Align any limits on the value of incentives with the research evidence to maximize CM effectiveness.
17. Provide guidance or other clarifications that explain permissible CM activities under potentially applicable federal fraud and abuse laws to ensure maximum access to CM. In accordance with section 4127 of the Consolidated Appropriations Act, 2023, the HHS Office of Inspector General (OIG) and HHS are considering proposing a safe harbor for evidence-based CM incentives, which would include any parameters for such a safe harbor.
18. Publish and disseminate best practices for the implementation of CM in diverse settings.
19. Provide information that is tailored to different stakeholders to address misconceptions about CM.
20. Support research to further optimize CM delivery, including on areas such as repeat courses of treatment, optimal duration of treatment, and best practices for treating children and adolescents.
21. Conduct implementation and outcome evaluations of CM to ensure that practices that have enabled CM to be successful in research trials are optimally translated into real-world practice, as well as to identify new practices that promote effective CM implementation.
22. **Implementation of CM that aligns with the existing evidence base should not be delayed while further research on optimizing CM delivery is conducted.**

INTRODUCTION

The drug overdose crisis continues to worsen, with provisional data predicting over 110,000 overdose deaths in 2022 (15). Many overdoses involve polysubstance use (16). Synthetic opioids such as fentanyl remain the major driver of overdose deaths, but stimulants, particularly methamphetamine, also play a prominent role: in 2022, based on provisional data, cocaine was involved in nearly one in four overdose deaths, while psychostimulants with abuse potential (e.g., methamphetamine) were involved in nearly one in three overdose deaths (17). Stimulants are also the fastest-growing category of substances involved in overdose deaths. Between 2020 and 2021, the rate of deaths involving psychostimulants with abuse potential, such as methamphetamine, increased 34% -- a more rapid rate of increase than for overdose deaths involving opioids (18). There are currently no FDA-approved medications to treat stimulant use disorders, and naloxone -- the opioid overdose reversal medication that has saved countless lives -- does not reverse stimulant overdoses (19, 20). The most effective available treatment for stimulant use disorder is CM, a behaviorally based clinical intervention.

CM is an evidence-based psychosocial therapy for the treatment of stimulant use disorder, as well as a variety of other SUDs, that is supported by three decades of research (2-4, 21-25). It involves providing incentives to people to reinforce desired behaviors that promote recovery from SUDs, such as abstinence from substance use, SUD treatment attendance, and adherence to medications for SUDs. VA began implementing CM for stimulant use disorder and other SUDs in 2011, and now has a successful nationwide program that has been well described in the research literature (26). CM is currently permitted under several HHS grant programs (e.g., Substance Abuse and Mental Health Services Administration's [SAMHSA's] State Opioid Response (SOR) and Tribal Opioid Response Grants, and the Health Resources and Services Administration's Rural Communities Opioid Response Program's Psychostimulant Support Program). In 2021, the Centers for Medicare & Medicaid Services (CMS) approved California as the first state to offer Medicaid coverage of CM for stimulant use disorder through a Section 1115 demonstration (27); in June 2023, CMS also approved Washington State's request to offer Medicaid coverage of CM for SUDs through its Section 1115 renewal. Delaware, Montana and West Virginia have submitted requests for coverage in their respective Section 1115 demonstrations.^a In addition, Community Reinforcement Approach (CRA)^b + Vouchers, which combines a community reinforcement approach with a voucher component (i.e., CM) that provides incentives for remaining in treatment and sustaining cocaine abstinence, has been rated as a promising practice by Title IV-E Prevention Services Clearinghouse, and is therefore a permitted use of Title IV-E Prevention Service Program funds (28, 29).

Despite CM's great potential and demonstrated effectiveness in improving the health and well-being of many people with SUDs, this proven treatment remains underutilized (5-8). Expanding access to high-quality CM services for the treatment of SUDs represents an important opportunity to accelerate efforts to address the overdose crisis, as well as the other substantial public health harms and costs related to untreated SUDs (e.g., cancers, infectious diseases, cardiovascular disease, oral health, cirrhosis of the

^a For more information about Section 1115 demonstrations, visit <https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html>.

^b CRA "uses a range of recreational, familial, social, and vocational reinforcers, along with material incentives, to make a non-drug-using lifestyle more rewarding than substance use." For more information, see National Institute on Drug Abuse's (NIDA's) *Principles of Drug Addiction Treatment: A Research-Based Guide* (Third Edition) at <https://archives.nida.nih.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition>.

liver, accidental injury) (30). State officials, health care delivery organizations and providers are eager to expand effective treatments for people who have had few options and have expressed the need for guidance and other policy actions to support broader implementation of CM in particular (9, 31-33).

In recognition of this opportunity, and to guide efforts by federal, state, local governments and other stakeholders, Section 4127 of the Consolidated Appropriations Act, 2023 (42 U.S.C. § 1320a-7d(a)(3)(B)), included a requirement for the Secretary and the Inspector General to “submit to Congress recommendations... for improving access to evidence-based contingency management interventions while ensuring quality of care, ensuring fidelity to evidence-based practices, and including strong program integrity safeguards that prevent increased waste, fraud, and abuse and prevent medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program.”

To respond to this provision, the HHS Workgroup on Implementation Strategies for Contingency Management, which included representatives from OIG who provided technical assistance in the Workgroup and on this report, has prepared this Report to Congress, which discusses opportunities and considerations for entities overseeing CM implementation, including regulators at the federal, state, Tribal, local and territorial levels; funders (e.g., grant making agencies, insurance companies); health care organizations; and health care providers. This report was informed by the published literature on CM for the treatment of SUDs and expert perspectives based on CM implementation experience at the time of issuance. The report also includes the perspectives of HHS and VA subject matter experts and insights from prior listening sessions with leading CM researchers, practitioners with experience implementing CM in real-world settings (including HHS grantees), professional associations, and people with lived experience, as well as contributions from OIG to address potential or perceived fraud and abuse concerns. Importantly, as the research evidence for CM, implementation experience, and the technology underlying components of CM interventions (e.g., drug tests, mobile applications) evolve, the opportunities and considerations highlighted in this report should be updated accordingly.

WHAT IS CONTINGENCY MANAGEMENT?

CM is a behaviorally based clinical intervention where tangible reinforcers (e.g., gift cards, vouchers, prizes, other items of value) are given to clients contingent on objective evidence of a specific, incentivized behavior(s) (i.e., evidence obtained from standard, unbiased measures that can be independently verified, such as drug test results and attendance records) (2). When used for SUDs, CM incentives are a form of treatment because their purpose is to reinforce abstinence from substances, and reinforce other recovery-oriented behaviors, such as attendance at SUD treatment sessions (e.g., group therapy, counseling) and medication adherence (21, 34, 35). Receiving incentives for reducing substance use or engaging in SUD treatment can help people become more aware and self-accountable regarding their substance use, further supporting their recovery (36).

Treatment Approach

Before starting CM, the clinician will discuss the goals of CM with the client and how it works. If clinicians have the resources to offer different kinds of incentives (e.g., vouchers or gift cards redeemable for specific needs, such as food or transportation), they should ask the client which kinds of incentives are most appealing and most likely to motivate the client to reduce their substance use

and/or continue engaging in treatment (37). A typical CM session consists of the following elements (24, 38):

- Brief discussion of any substance use and cravings since the initial visit or prior CM session.
- If the previous session was missed, a brief discussion of whether the absence was unexcused or excused (because this determination affects the schedule of reinforcement).
- Verification that the incentivized behavior was achieved.
 - Where abstinence is the incentivized behavior, this is confirmed through a rapid POC drug test.
 - Where treatment attendance is the incentivized behavior, this is confirmed through review of treatment attendance records.
 - Where adherence to long-acting MOUD is the incentivized behavior, this is confirmed through administration of the medication by a clinician and clinical documentation of administration.
- If the incentivized behavior was achieved, incentives are provided using one of the reinforcement methods described below.
- If the incentivized behavior was not achieved, no incentive is provided.
- Brief discussion of how the individual plans to use the incentives, with positive verbal reinforcement and reminder of upcoming CM sessions.

The two evidence-based reinforcement methods most commonly used in real-world treatment protocols are prize-based and voucher-based CM, in which incentives are assigned monetary values, but are not disbursed as cash.

1. Prize-based: This is exemplified in the “fishbowl” model, in which people demonstrating the incentivized behavior receive draws from a fishbowl, either in a set number (e.g., one draw for each substance-negative drug test) or with an escalating schedule (e.g., one draw for the first negative sample, two draws for the second consecutive negative sample, three draws for the third, and so on) (37, 39). A typical fishbowl comprises 500 prize tickets, about half of which have monetary value and half of which have no monetary value (the latter prize tickets typically state “good job”). Prize amounts indicated on prize tickets that have monetary value vary in magnitude, typically from \$1 to \$100,^c with the majority of such prize tickets showing the smallest magnitude (\$1), a smaller number providing larger magnitude (e.g., \$20) prizes, and one slip in the bowl for the maximum prize (\$100). Prize amounts are then provided to the person in the form of gift certificates or in-kind prizes with the corresponding value. When the incentivized behavior is not achieved, no draws are received; and in protocols with an escalating draw schedule, draws are “reset” to one for the next time the incentivized behavior is achieved. Prize tickets are replaced after each draw so the probability of receiving a prize ticket with monetary value is always the same across clients for any draw.
2. Voucher-based: Voucher-based methods offer a set reinforcement amount when people successfully complete incentivized behaviors (e.g., \$2 per substance-negative drug test) and

^c While these are typical ranges reported in the research literature over the years, more recent studies (e.g., Rash 2023 (37)) have noted that higher incentive amounts may be necessary to preserve the effectiveness of CM in settings where other economic factors (e.g., cost of living) may limit the range of items for which lower-value prize tickets in the \$1-\$2 range can be redeemed. VA, for example, is raising the value of small prizes from \$1 to \$3 in its prize-based protocol.

typically escalate by a prescribed amount (e.g. \$0.50), with repeated performance of the behavior (e.g., \$2 for first negative drug test, \$2.50 for second consecutive negative drug test, \$3 for third, and so on), but “reset” to \$0 when the incentivized behavior is not achieved (e.g., a substance-positive drug test).^d Variations on the voucher-based protocol in which “points” are received after successful completion of incentivized behaviors, which can later be exchanged for items or services of value, have also been found to be effective (40).

Both prize-based and voucher-based protocols generate moderate effect sizes on treatment outcomes with no differences in outcomes noted in head-to-head comparisons of these two methods (41-44). Examples of efficacious study protocols are available through the NIDA Clinical Trials Network dissemination library.^e

Evidence Base for CM for Treating SUDs

CM has three decades of research demonstrating its long-term efficacy for treating a variety of SUDs, including stimulant, opioid, cannabis, alcohol, and tobacco use disorders, as well as concurrent SUDs (3, 14, 35, 42, 45-50). In studies comparing CM with other psychosocial interventions for SUD (e.g., cognitive behavioral therapy [CBT], motivational enhancement therapy),^f CM produced significantly higher abstinence rates over the course of treatment, higher retention in treatment, and higher abstinence self-efficacy (51-55). CM is also effective in producing abstinence that persists at least one year following treatment, either alone or in combination with other evidence-based behavioral therapies for SUDs (3, 4, 49). CM is effective in diverse client populations, including people with concurrent mental disorders, people experiencing homelessness, justice-involved populations, and racially and socioeconomically diverse populations (56-64).

In addition to SUDs, CM has been shown to effectively treat multiple different medical conditions through encouraging and reinforcing health-promoting behaviors. For example, CM has been used to improve adherence to blood-glucose monitoring among young people with diabetes, and to improve mental health outcomes among elementary school-aged children (65, 66). Researchers have noted, however, that there are unique aspects of SUD pathology -- such as how SUDs affect the brain’s reward system and decision-making processes -- that might contribute to the efficacy of CM in treating SUDs in particular (67).

SUDs co-opt and disrupt brain circuitry involved in learning (or reinforcement of) behaviors that produce a reward, such as feelings of pleasure or relief from pain. As a result of this, in people with SUD, the immediate positive feelings from substance use continue to become reinforced by the brain’s reward circuitry over time, as well as the cues associated with past substance use -- in other words, people, places, or feelings can become linked with past substance use in ways that motivate people to seek

^d The incentive amounts here are provided as an example -- larger incentive amounts have also been used in voucher-based protocols.

^e For more information, please visit <http://ctndisseminationslibrary.org>.

^f CBT helps individuals to “learn to identify and correct problematic behaviors by applying a range of different skills that can be used to stop drug [use] and to address a range of other problems that often co-occur with it.” Motivational enhancement therapy “helps individuals resolve their ambivalence about engaging in treatment and stopping their drug use... [by evoking] rapid and internally motivated change.” For more information, see NIDA’s *Principles of Drug Addiction Treatment: A Research-Based Guide* (Third Edition) at <https://archives.nida.nih.gov/sites/default/files/podat-3rdEd-508.pdf>.

substances in the future when they are exposed to those cues. As SUD develops, there is progressive disruption of the brain's reward circuitry: the brain becomes more sensitive to the cue-driven expectation of substances and their rewarding effects. At the same time, the brain becomes *less* sensitive to the actual rewards from substance-taking (e.g., euphoria, positive physical sensations), as well as to the satisfaction from *non-substance* rewards (e.g., food, prizes, previously fulfilling activities) (68, 69). There is also evidence that people with SUD have changes to their brains' self-regulation circuitry (anatomically in the prefrontal cortex) that normally helps us avoid risky or self-destructive behaviors, resist temptation (such as taking substances), and delay gratification (69, 70).

CM is thought to help repair these disrupted brain circuits, and thus to help people with SUD recover in several ways. First, by offering positive reinforcement for abstinence and other recovery-related activities (e.g., treatment attendance, medication adherence) via concrete and immediate incentives, CM can compete with and displace the reinforcement associated with substance use (71, 72), helping to reorient the brain's reward circuitry toward non-substance rewards (73). In doing so, CM also engages clients' decision-making processes in a way that improves their ability to conceptualize and act on non-substance options that produce positive outcomes (74). As noted above, there is evidence that people with SUDs experience changes to their brains' self-regulation circuitry that lead to a stronger preference for immediate rewards over delayed gratification (termed "delay discounting") -- the immediacy with which CM incentives are provided after achieving a desired behavior is therefore part of what makes the treatment effective in reinforcing healthful behaviors, relative to substance use. Finally, CM also helps the brain to heal through the treatment's impacts on abstinence from substances. Many studies show that abstinence from substances can at least partially reverse the substance-induced deficits in the brain's reward and self-regulation circuits. In people with stimulant use disorders, for example, abstinence is associated with a recovery of some measures of normal brain activity (75, 76), as well as a recovery of brain gray-matter tissue in self-regulation circuitry (70). There is evidence from both brain imaging and studies of brain neurotransmitter activity that among people with cocaine use disorder who were able to reduce their substance use after treatment with CM, there is some recovery of normal brain activity in the reward and self-regulation networks that have been disrupted by addiction (77, 78).

The evidence base for CM for specific SUDs is described below:

- **Stimulant use disorder**: CM is effective at reducing stimulant use and is among the most effective available treatments for stimulant use disorder, for which there are no FDA-approved medications (2-4). CM is superior to other psychosocial interventions for stimulant use disorder -- it is about twice as effective as alternative treatments such as CBT, counseling, and motivational interviewing (79). While CM is effective as a standalone treatment for stimulant use disorders, its efficacy may be enhanced when combined with other evidence-based treatments such as CRA (45).
- **Opioid use disorder (OUD)**: FDA-approved MOUD (i.e., buprenorphine, methadone, extended-release naltrexone) are highly effective first-line therapies (80), so current clinical guidelines note that **CM should not be considered a substitute for MOUD and should not be used as a first-line intervention for OUD**. CM can, however, be an effective adjunct to MOUD. An analysis of 60 clinical trials conducted over more than three decades found that for people receiving MOUD, CM performed better than standard care for producing MOUD adherence and end-of-medication abstinence from opioids as well as polysubstance use (81).

- Cannabis use disorder: CM has moderate effectiveness in reducing cannabis use and decreasing the severity of cannabis use disorder, when implemented alongside CBT and/or motivational enhancement therapy (82).
- Alcohol use disorder: CM is an effective treatment for alcohol use disorder, with studies identifying substantial reductions in both the frequency and amount of alcohol consumption, as well as significant increases in abstinence (39, 61, 83-86).
- Tobacco use disorder: CM is effective in increasing smoking cessation rates. In an analysis of 30 clinical trials, participants who received CM for tobacco smoking cessation were 50% more likely, on average, to discontinue smoking by 6 months than those who received usual care and/or a cessation intervention without contingent rewards (48). Another analysis included in this study found that the impact was highest in studies of pregnant women: those who received CM for smoking cessation were more than twice as likely to quit and remain smoke-free 6 months after childbirth, compared with those treated through usual care and/or non-contingent smoking cessation programs. A systematic review also found that among pregnant women, CM was superior to motivational interviewing, CBT, mindfulness, and hypnosis in reducing smoking (87).

There are important differences by SUD in the specific types of incentivized behaviors (e.g., abstinence, treatment attendance) that are recommended for CM protocols under current clinical guidelines -- this is discussed further below under “Incentivized Behaviors.”

By reducing substance use and improving engagement in SUD treatment, CM -- when provided alone and in conjunction with other interventions -- has also been shown to reduce the complications of substance use and promote better health outcomes, including improved cardiovascular health among individuals with stimulant use disorder (as evidenced by lower coronary plaque burden and lower levels of plasma endothelin-1, a biomarker for cardiovascular disease) (88), a reduction in high-risk sexual behaviors among people who use drugs (55), and suppression of HIV among men with HIV and stimulant use disorder (89). CM is also associated with positive social outcomes that are important to SUD recovery; one study found that, in addition to reducing stimulant use and improving other psychiatric-related outcomes, CM led to improvements in employment status and in family and social relationships (54).

Case Study: The Veterans’ Health System’s Successful Nationwide CM Program

The VA has included CM among its evidence-based SUD treatment options since 2011, and as of 2019, more than 100 VA medical centers offered CM (26), representing the largest-scale implementation of CM to date (22). Most participating centers offer abstinence as an incentivized behavior, while a smaller proportion offer treatment attendance. All programs in the VA system employ the “fishbowl” (i.e., prize-based) method to offer incentives that vary in scope and size (see “Using Evidence-Based Treatment Protocols” below), from a simple note saying, “Good job!” to prize coupons valued at \$1 to \$100.[§] The average value of incentives over 12 weeks is equivalent to approximately \$200 per veteran, and prize coupons can be redeemed for merchandise at any Veterans Canteen Service retail store, cafeteria, or coffee shop. Published VA protocols include check-ins 2-3 times weekly, with use of onsite rapid POC tests to check for abstinence and offer incentives immediately following a negative test (21). A 2018

[§] As discussed later in this document, VA plans to increase the value of these prize coupons.

study found that the majority of participating VA centers demonstrated a high degree of fidelity to evidence-based practices for CM (21). As of the publication of this report, more than 6,300 veterans have received CM through the VA. Among the nearly 82,000 urine samples that these veterans collectively submitted for abstinence-based CM, more than 90% have tested negative for the target substance (most commonly stimulants, and sometimes cannabis), comparable with rates observed in clinical trials (22, 90).

Several features of the VA's nationwide initiative have contributed to the high levels of uptake by practitioners, high quality of CM services, and positive client outcomes. These include a robust CM-specific training curriculum for practitioners; pre-implementation planning calls for VA sites interested in offering CM to prepare for and support the design of effective interventions; routine assessment of service quality and fidelity to evidence-based practices; and post-implementation CM coaching calls to further enhance quality and fidelity (21, 22, 24, 25).

The VA's experience and results are a striking indicator of the potential value of implementing CM more broadly across the nation's health care system, and for the potential recovery of people living with very difficult-to-treat SUDs.

CM works by helping people to make health-promoting changes in their lives that would otherwise be very difficult because of the impacts of SUDs on the brain. Attitudes that people with SUDs should simply be able to stop using substances are prevalent, as are opinions that substance use reflects a personal or moral failing and that people with SUDs are therefore less deserving of treatment and recovery supports. But these views are often shaped by stigma and a misunderstanding of the scientific evidence on how untreated SUDs affect the brain. Chronic substance use can lead to profound neurobiological changes that disrupt the brain's reward system and impair decision-making abilities, which collectively reinforce continued substance use (69, 70). Without addressing these harmful effects of substance use through treatment and recovery services, people with SUDs face substantially greater challenges than the general population in pursuing health-promoting behaviors. CM addresses this by helping to recalibrate the brain's reward system toward recovery-related behaviors (e.g., abstinence, treatment attendance, medication adherence) through incentives that make these behaviors more immediately and concretely rewarding (71-74).

CM holds people accountable for meeting their recovery goals, including reduced substance use. CM reinforces recovery-related behaviors that are in the client's best interest and holds individuals accountable for meeting recovery goals. In abstinence-based CM protocols, people do not receive an incentive unless they test negative for the target substance. In CM protocols that reinforce treatment attendance or medication adherence, people do not receive an incentive unless they engage in treatment.

Abstinence-based CM protocols mitigate the likelihood of diversion. The risk of clients diverting their incentives toward obtaining substances is low; for example, one study found that clients who received cash (which lacks diversion controls recommended by HHS later in this report) as an incentive did not increase their substance use, compared with clients who received non-cash incentives (91). Meanwhile, abstinence-based CM protocols *mitigate* the likelihood of diversion because clients who use a target substance will not receive an incentive after a positive test, and in CM protocols that escalate the value of incentives, their incentive amount in subsequent CM sessions could reset to a lower value. Nonetheless, HHS recommends various safeguards to prevent diversion by clients or staff and promote program integrity, such as adhering to evidence-based treatment protocols; maintaining proper clinical documentation; implementing appropriate accounting and security measures; and disallowing certain incentive types, such as cash payments and unrestricted cash equivalents (further discussion of recommended restrictions on incentive types occurs later in the report).

The abstinence effects of CM can last even after the treatment is completed. Studies have consistently found that the effects of CM on abstinence persist after treatment is completed (49). Furthermore, CM is among the most effective treatments for promoting lengthier periods of abstinence during treatment, which is associated with a greater likelihood for long-term abstinence following treatment (44, 92-95). In addition, evidence has consistently demonstrated that external reinforcement of recovery-related behaviors does not diminish internal motivation (96). CM reinforces the patient’s efforts at living without the target substance and the longer that period, the greater the likelihood that the patient will begin to experience reinforcements aside from CM to sustain their recovery.

BARRIERS

Despite its robust empirical support, CM has encountered numerous barriers to widespread implementation in clinical settings. Barriers include concerns about the potential application of certain federal fraud and abuse laws; limited funding and reimbursement opportunities (9, 97); program restrictions on SUDs for which CM can be used; knowledge, attitudes and stigma related to CM (8, 10-12, 98); importance of strict fidelity to treatment protocols (13); limited access to training and mentoring in CM (11); and workforce challenges. This section highlights the most significant barriers to implementing CM programs in clinical practice as identified by the existing research and stakeholder feedback.

Concerns Regarding the Potential Application of Federal Fraud and Abuse Laws

Practitioners’ concerns regarding the application of certain federal fraud and abuse laws to CM incentives have chilled the wider implementation of CM (9, 67, 97, 99), and such concerns have been explicitly identified by HHS grantees as a barrier to delivering CM. Specifically, stakeholders have raised concerns that they could face criminal and monetary penalties under the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)), the civil monetary penalty provision prohibiting inducements to beneficiaries (“Beneficiary Inducements CMP”, 42 U.S.C. § 1320a-7a(a)(5)), or both in connection with providing CM incentives to a client who receives federally billable services from the same provider (5, 7, 100).

Practitioners’ concerns stem from the breadth of the prohibitions set forth in the federal anti-kickback statute and Beneficiary Inducements CMP and uncertainty regarding how those laws would apply to CM interventions involving federal health care program beneficiaries. The federal anti-kickback statute is a broad, intent-based criminal statute that, as a general matter, prohibits the exchange of anything of value for Medicare, Medicaid, and other federal health care program referrals (including self-referrals by federal health care program enrollees) or purchasing items or services paid for by Medicare, Medicaid, or other federal health care programs. The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers anything of value to a Medicare or state health care program beneficiary that the person offering or transferring remuneration knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). Whether or not CM incentives implicate -- and potentially violate -- these two laws would require an assessment of all of the facts and circumstances of the CM program, including the intent of the practitioner providing the CM incentive. Stakeholders have explained that the need to assess compliance with these laws on a case-by-case basis has contributed to uncertainty and confusion regarding what types of CM arrangements are legally permissible.

In addition, there is a widespread belief among stakeholders that guidance from OIG in connection with the federal anti-kickback statute and Beneficiary Inducements CMP limits CM incentives to a \$75 annual value. While OIG has explained that this is a misunderstanding of its guidance and that “[t]here is no OIG-imposed \$75 limitation on contingency management program incentives,” OIG also has stated that “[c]ontingency 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” (101). Again, stakeholders have raised concerns that the lack of legal certainty created by the necessity for case-by-case assessments has hindered broader use of CM incentives. As discussed further in the following section, HHS grants that support CM disallow the use of grant funds for CM incentives that exceed a \$75 annual value threshold -- which studies show is too low to be effective -- to prevent cases of non-compliance with the Beneficiary Inducements CMP. Finally, stakeholders also have expressed confusion about whether advertising that they offer CM as a treatment would potentially result in liability under the federal anti-kickback statute or Beneficiary Inducements CMP.

In short, stakeholders have identified their concerns regarding the potential application of the federal anti-kickback statute and Beneficiary Inducements CMP, and the lack of certainty about whether CM incentives could be subject to criminal and monetary penalties, as a primary regulatory barrier to the increased implementation of CM. These concerns have similarly been raised by CM researchers and implementers in the published literature (9, 97).

Insufficient Reimbursement and Funding Limitations

Insufficient reimbursement and funding limitations are among the most frequently cited barriers to the implementation of CM in clinical settings (5, 42, 102, 103). With few exceptions, CM is generally not reimbursed by public or private insurance programs. Providers therefore largely rely on grants to finance CM interventions, raising concerns about sustainability of CM programs beyond the life of the grant. In addition, a major limitation of federal grants has been their restriction on the level of funding that can be allocated toward CM incentives. HHS grants restrict the use of funds for CM incentives to a limit of \$75 per client, per year through sub-regulatory grant requirements.^h This limit has been widely cited as non-evidence-based and an impediment to the delivery of effective CM protocols (9). As discussed in detail in a subsequent section of this report (“Opportunities to Improve Access and Quality and Strengthen Program Integrity”), the current scientific evidence clearly demonstrates that higher-value CM incentives are necessary to achieve positive behavior changes (3, 21, 104, 105). The *average* range

^h HHS agencies established a \$75 annual value limit for grant-funded CM incentives based on OIG guidance related to gifts of nominal value that are permissible under the Beneficiary Inducements CMP. This guidance includes a \$75 annual, aggregate limit per beneficiary on the value of gifts (i.e., in-kind items or services, not cash payments), among other restrictions. Although this guidance does not directly pertain to CM incentives, OIG has noted that CM incentive arrangements may implicate the federal anti-kickback statute, the Beneficiary Inducements CMP, or both (101). However, CM incentives that implicate one or both of these statutes are not necessarily illegal; compliance depends on the specific facts of each arrangement, which must be analyzed on a case-by-case basis unless the arrangement satisfies an existing safe harbor or exception. Therefore, agencies have opted to retain the \$75 annual value limit to prevent cases of non-compliance with the Beneficiary Inducements CMP. For more information about OIG’s guidance on gifts of nominal value, visit <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2006053221-hi-oigpolicystatementgiftsofnominalvalue.pdf>.

of distributed CM incentives that have been found to be effective in the research literature over the years, during a typical 12-week treatment protocol, amounts to \$300-\$600 per client.ⁱ

Echoing this concern, among HHS grantees the \$75 CM incentive value limit is the most frequently cited barrier to the wider implementation of CM and is noted to be among the most significant obstacles to the delivery of effective, evidence-based CM interventions. The SAMHSA SOR Program Office reports that, as of the publication of this report, at least 40 states^j across geographically diverse regions of the United States have requested an increase in the HHS grant limit for CM incentives, citing it as a barrier to the use of evidence-based treatment protocols. Several states have even communicated an unwillingness to implement CM using SOR funds unless the incentive limit is raised to an evidence-based amount. HHS grantees note that the current CM incentive limit has made it more challenging to engage and retain clients in their CM programs, and even makes providers reluctant to offer CM due to concerns that it precludes fidelity to effective protocols.

Financial limitations hinder other aspects of CM delivery as well, such as staff training and program administration (2, 103). As an example, HHS grantees noted that developing an infrastructure to safely store CM incentives prior to their disbursement to clients and to track disbursement is essential to safeguarding program integrity but often requires additional resources. Financial limitations are particularly pronounced in publicly funded treatment programs, which often struggle to obtain sufficient resources to implement and sustain evidence-based practices (40).

Program Restrictions on SUDs for Which CM Can Be Used

As discussed above, CM is an effective treatment for stimulant, cannabis, alcohol, and tobacco use disorders, and is also an effective adjunctive treatment to MOUD. Funding entities typically restrict the use of CM, however, to only a subset of these conditions for various programmatic or statutory reasons. Several HHS grantees identified such restrictions as a barrier to implementing CM. Since establishing a new CM program often requires significant time, resources, and redesign of clinical workflows, grantees noted that clinicians were more hesitant to undertake such investments when the application of CM was limited to a narrower set of SUDs. Other stakeholders noted that, as a result of changing substance use patterns and increasing adulterants in the drug supply, clinicians are increasingly encountering polysubstance use. Under these conditions, stakeholders have expressed concern that narrowly limiting the application of CM to specific types of SUDs means that many people who could benefit from CM would not be eligible to receive it, especially since CM can be, and is, used successfully for people who engage in polysubstance use.

Knowledge, Attitudes, and Stigma Related to CM

As discussed earlier in this report, stigmatizing attitudes and inaccurate beliefs about CM are common -- among clinicians, community stakeholders, and even clients -- and can also pose barriers to implementation. Among clinicians, some express ethical concerns related to the use of incentives, viewing them as coercive, manipulative, or even fostering dependence on external rewards (102, 106),

ⁱ As previously noted, more recent studies (e.g., Rash, 2023 (37)) indicate that higher incentive amounts may be necessary to preserve the effectiveness of CM in settings where other economic factors (e.g., cost of living) limit the range of items for which incentives can be redeemed.

^j In SAMHSA's SOR grant program, states are the grant recipients that then allocate funds among government and non-governmental entities.

even despite evidence that CM does not diminish internal motivation for recovery (96). Other clinicians might have limited understanding or knowledge of CM, preventing proper integration and execution of CM programs (107). Furthermore, the belief that other established treatment approaches are already sufficient can deter clinicians from adopting new evidence-based practices, including CM (108). HHS grantees also noted that stigma and misinformation about CM among non-clinical staff working in organizations seeking to implement CM can be a barrier to adoption.

HHS grantees also identified a lack of understanding of CM, negative attitudes toward incentives, and broader stigma toward people who use substances as barriers to obtaining adoption and acceptance from community stakeholders in areas where CM programs are being implemented. Finally, grantees noted that clients themselves might have negative biases about receiving incentives for recovery, or skepticism of the effectiveness of CM.

Importance of Strict Fidelity to Treatment Protocols

Fidelity refers to the degree to which an intervention is delivered as intended by its developers (109). High fidelity is essential for achieving the desired outcomes of an intervention, but for many interventions, maintaining fidelity can be difficult in real-world clinical settings (110), and CM is no exception. As discussed in detail in a subsequent section of this report (“Opportunities to Improve Access and Quality and Strengthen Program Integrity”), strict fidelity to treatment protocols is particularly important for CM in order to ensure effectiveness, safeguard program integrity, and prevent negative unintended consequences. This is because deviation from evidence-based protocols might lead to reinforcement of negative or harmful behaviors, rather than the desired positive behaviors (see section on “Incentive Timing” for an example). Because CM treatment protocols differ considerably from many other behavioral therapies, however, promoting fidelity may require redesign of clinic workflows, additional investments in quality assessment and assurance processes, staff training, and ongoing provider supervision and support (40, 111-113). These changes may be costly or challenging to implement and can therefore be a barrier to wider adoption of CM and delivery of high-quality CM (103).

Limited Access to Robust Training and Mentoring Programs

Provider training and ongoing support and supervision are noted by experts to be essential elements of maintaining fidelity to CM treatment protocols (112). Studies have demonstrated that in addition to equipping providers with information on the principles of CM, detailed education on the implementation of CM in clinical settings and ongoing training opportunities are necessary to promote adoption of evidence-based CM (2, 114). Real-world CM programs vary, however, in the extent to which they incorporate provider training and continued supervision and support (5). This has been attributed to limited access to training on CM principles and techniques (42), as well as to limited information about the specific format that education on CM should take (61).

Workforce Challenges

A number of HHS grantees identified broader behavioral health workforce challenges as also being a barrier to implementing CM. They noted that implementing CM with fidelity can be labor-intensive, not only for the clinicians who deliver the intervention, but also for non-clinical staff who help support program administration, monitoring, and quality assurance. In the current environment of workforce

shortages, recruiting sufficient staff to implement CM with fidelity can therefore pose a challenge in certain communities.

OPPORTUNITIES TO IMPROVE ACCESS AND QUALITY AND STRENGTHEN PROGRAM INTEGRITY

Mitigating and eliminating barriers to the broader implementation of evidence-based CM can expand access to this highly effective treatment for SUDs. In addition, enhancing the quality of CM interventions and strengthening program integrity through fidelity to evidence-based practices can improve health outcomes among people with SUDs who receive CM. Fortunately, there are many opportunities for clinicians, educators, health care administrators, and policymakers to take action to help overcome barriers to CM implementation and achieve these goals.

This section considers such opportunities, including approaches that clinicians can use to enhance the clinical delivery and quality of CM, organizational strategies to promote evidence-based practices and safeguard program integrity, and policy opportunities to further enhance and support these efforts.

Enhancing Clinical Approaches to CM Delivery

Using Evidence-Based Treatment Protocols

The use of established, evidence-based treatment protocols represents a critical opportunity for entities overseeing CM implementation to both enhance the quality of CM and safeguard program integrity (5, 21, 115). As noted earlier, the most commonly used CM treatment protocols are the prize-based and voucher-based protocols. Both have been extensively researched and proven to be efficacious, with no differences in outcomes noted in head-to-head comparisons of these two methods of CM (41-44).

Selecting either the prize-based or voucher-based model depends on several factors:

1. **Organizations' capacity to ensure fidelity to EBPs for specific models** (e.g., some stakeholders have noted that the fixed incentive amounts in the voucher-based model may be easier to implement than the probabilistic nature of incentives in the prize-based model).
2. **Funding available for incentives**, as the average per client incentive amount across a population of CM participants is typically lower for the prize-based than for the voucher-based model (94, 116, 117), but the variability of prize-based CM can result in amounts that are substantially lower or higher than the average for individual clients (see the "Incentive Magnitude" section below for more information). Consequently, budgeting for incentive costs and adhering to incentive caps could be more challenging in prize-based CM than in voucher-based CM.
3. **Client preferences for a particular model** (e.g., some clients may be more motivated by the predictable nature of the voucher-based model or the unpredictable nature of the prize-based model).

Regardless of the specific protocol used, CM incentives should only be provided to a person when there is objective verification of the incentivized behavior (e.g., through drug test results, verification of

attendance at a treatment session, verification of medication adherence) (21, 38, 118). Objective verification of incentivized behaviors is essential to the effectiveness of CM in treating SUDs, because it ensures that only recovery-related behaviors are reinforced. It is also important for safeguarding program integrity.

Clients' understanding of the treatment protocol and participation in treatment planning are also important to clinical effectiveness. Providers should consider reviewing the CM protocol and any applicable clinical agreements jointly with clients to promote engagement in decision-making (e.g., selecting an incentivized behavior) and ensure they understand the specifics of the protocol, such as how achievement of an incentivized behavior is assessed and what to expect if an incentivized behavior is or is not achieved (32, 38).

In summary, entities overseeing CM implementation should therefore require that providers adhere to established, efficacious treatment protocols, and also require objective verification of incentivized behaviors.

Incentive Magnitude

The current scientific evidence demonstrates that the value of an incentive is important in eliciting positive outcomes, with higher-value incentives generally more effective at leading to positive behavioral changes than lower-value incentives (3, 21, 38, 104, 105).

- The *average* range of distributed CM incentives that have been found to be effective in the research literature is \$100-\$200 per client monthly. Over the course of a typical 12-week treatment protocol, this amounts to an average range of distributed incentives with a value equivalent to \$300-\$600 (typically disbursed as vouchers, not cash). However, the average value of distributed incentives per person is generally lower than the *maximum* value available per client, due to missed CM sessions, positive drug tests, and the probabilistic nature of incentives in the prize-based model.
- *Maximum* possible values that have been used in the literature differ based on the type of CM protocol:
 - In a typical voucher-based CM protocol, clients can receive a *maximum* of \$1,000 worth of incentives over 12 weeks if they achieve the incentivized behavior 100% of the time (e.g., 100% of their drug tests are negative).
 - Prize-based CM attempts to lower the costs of the incentives through the introduction of probabilistic receipt and variability in prize magnitude. In a typical prize-based CM protocol, clients can receive an *expected maximum* of \$250-\$450 over 12 weeks (94, 116, 117), if they achieve the incentivized behavior 100% of the time. As previously noted, in prize-based CM, clients earn a prize draw each time they meet a treatment goal, with hundreds of prizes valued at \$1-\$20 and at least one prize valued at \$100. The prize-based model is effective despite having a lower average value of distributed incentives than the voucher-based protocol because, over the course of their treatment, clients have the

chance to receive incentives that amount to a cumulative value that is substantially higher than the average disbursed.^k

Setting a cap on cumulative incentive values per client is often necessary from an operational standpoint due to budget constraints (e.g., in grant programs). However, setting a cap that is too low risks jeopardizing the success of the intervention; studies have found that CM protocols involving higher-value incentives are generally more effective than those involving lower-value incentives (3), and that setting incentive values too low can render CM ineffective (119).

When setting a cap on cumulative incentives per client in the context of prize-based protocols, additional care must be taken to ensure that clients who draw high-value prize tickets are not forced to discontinue treatment prematurely because, as a result of the high-value prize, they have exceeded the incentive cap prior to the end of the treatment protocol. For these reasons, entities overseeing CM implementation that would like to set a cap on cumulative incentive values per client should be guided by the expected maximum value of incentives that can be received (21).

Stakeholders have noted additional factors that might be considered in determining the value of CM incentives, such as regional variations in the cost of living. Importantly, for treatment of a given SUD, stakeholders emphasized that people with similar levels of clinical severity should have equal opportunities to receive incentives for achieving the desired behaviors, and that entities overseeing CM implementation should monitor for and address inequities in incentive magnitudes that are unrelated to individuals' underlying SUD severity.

In summary, entities overseeing CM implementation should be aware that higher incentive magnitudes are more effective in reinforcing recovery-related behaviors and abstinence from substances; CM incentive limits should therefore exceed the average effective range of \$100-\$200 monthly per client.

Adequate Duration of Treatment

The typical duration of CM treatment protocols incentivizing abstinence or treatment attendance that have been examined in the research literature is 12 weeks. Some studies demonstrate that longer protocols (typically 18 or 24 weeks) are associated with a higher likelihood of abstinence up to one year following treatment (49). **Entities overseeing CM implementation should therefore require the use of a treatment protocol of at least 12 weeks duration.**

^k These incentive ranges are largely derived from studies conducted between 1994 and 2014. More recent studies have noted that higher incentive amounts may be necessary to preserve the effectiveness of CM in settings where other economic factors (e.g., cost of living) may limit the range of items for which restricted cash-equivalent incentives (i.e., vouchers, gift cards) can be redeemed. For example, Rash (2023) recommends an expected maximum prize-based CM incentive magnitude in the range of \$385-\$533 for a 12-week protocol (37). Accordingly, VA will soon raise the value of small prizes in its prize-based CM protocol from \$1 to \$3, which raises the expected maximum CM incentive from \$364 to ~\$501. Practitioners implementing voucher-based CM protocols may wish to consider adjusting CM incentive limits accordingly.

Incentive Type

A range of CM incentive types has been used in research and treatment settings, including gift cards, transportation vouchers, food, food coupons, clothing, electronic equipment, and recreational items (e.g., movie passes, sports equipment) among others (3, 39, 120). In some CM protocols, specific incentives are chosen in advance by participants to support greater client engagement. The effectiveness of CM depends upon incentives being perceived as valuable to participants; therefore, versatile, cash-equivalent incentives (i.e., gift cards, vouchers that can be redeemed for a wide array of goods and services) may have broader appeal among clients than specific items (121). Stakeholders also emphasized that community and cultural factors are key considerations when selecting incentive types, as they may also influence which types of incentives are most appealing to clients.

At the same time, certain restrictions on incentive types may be necessary to safeguard program integrity. Stakeholders with CM implementation experience noted, for example, that cash incentives and *unrestricted* cash-equivalent incentives (i.e., checks or similar items that can be readily exchanged for cash with no restrictions on their use) are more challenging for CM programs to monitor and track, making it more difficult to identify and prevent diversion and misuse.

Stakeholders also emphasized that it is of paramount importance that incentives should not interfere with or undermine a client's recovery or pose additional health or safety risks. Accordingly, for CM programs offering cash-equivalent incentives that can be exchanged for other items (e.g., vouchers, gift cards), stakeholders recommended incorporating safeguards to prevent these incentives from being exchanged for cash (e.g., assigning vouchers/gift cards to named clients and not permitting them to be redeemed by individuals other than the named client), and instituting restrictions on the types of purchases for which these CM incentives could be used. Such "restricted cash-equivalent" incentives are often preferred to cash or unrestricted cash-equivalent incentives in the interests of client safety and program integrity. Categories of items and services that stakeholders believed should be restricted from CM incentives included:

- Weapons.
- Intoxicants (e.g., alcohol).
- Over-the-counter preparations containing possible intoxicants (e.g., dextromethorphan).
- Tobacco products.
- Pornographic materials.
- Gambling-related items (e.g., lottery tickets).

Stakeholders described the rationale for such restrictions as preventing incentives from enabling harm to the client or others, and preventing incentives from exacerbating co-occurring SUDs or other conditions and behaviors that are frequently associated with SUDs and may complicate recovery (e.g., gambling disorder, compulsive sexual behavior) (116, 122-130).

Stakeholders and HHS subject matter experts also suggested two additional types of incentives that should be disallowed:

- **Enhanced or expedited access to SUD treatment or recovery support services**, as people with SUDs should have equitable access to other treatments (including medications) and recovery

support services regardless of their participation in CM and regardless of whether they achieve an incentivized behavior.

- **Parenting time** (i.e., time spent by a child with a non-custodial parent), as decisions about parenting time should be made solely on the basis of a child's interests and should be withheld only if there is a direct or immediate concern for the child's safety.

The dual goals of effectively promoting recovery and protecting program integrity therefore imply a need for some restrictions on the types of CM incentives that can be offered, and how they can be used. A growing number of providers have explored technological approaches to implementing such restrictions, particularly for cash-equivalent incentives: for example, "smart debit cards" and gift cards that restrict certain purchases, as well as web-based and smartphone-based applications that disburse incentives directly to participants and track incentive amounts received (21, 27, 100, 131-133). However, some people without reliable Internet access or a smartphone, or with lower technological literacy, might face challenges in using digital and web-based interfaces to access their incentives. Participants' needs and access to technology should therefore also be considered in determining the type of CM incentives to offer and the method of incentive disbursement.

In summary, entities overseeing CM implementation should require certain restrictions on the types of items and services that can be incentives, and the types of purchases that can be made with CM incentives, to support clients' recovery and mitigate risks of incentive diversion and misuse. The need for such restrictions implies that cash and unrestricted cash equivalents should not be used as CM incentives.

Incentive Timing

The timing of reinforcers significantly impacts their effectiveness. More frequent opportunities for incentives tend to produce stronger reinforcement (134). At the same time, the frequency of assessment and incentive delivery should be weighed against the burdens on program resources, staff, and clients. When abstinence is the incentivized behavior, client assessments (and therefore opportunities for incentives) should be aligned with the detection window of the target substance by POC testing. CM protocols that have been examined in the literature typically assess desired behaviors and provide the opportunity to earn an incentive 2-3 times per week when the desired behavior is abstinence (21, 135), and weekly when the desired behavior is treatment attendance (38).

When an incentivized behavior is achieved, immediacy of incentive provision is critical to the effectiveness of CM (3, 21, 135). Entities overseeing CM should require that CM incentives be provided to the person immediately following verification of the desired behavior for two reasons. First, people tend to devalue incentives the longer that they must wait for them as a result of "delay discounting," which some evidence suggests is more pronounced in people with SUDs and correlates with the severity of the disorder (12, 64). Delaying the delivery of incentives following confirmation of the desired behavior therefore reduces their value and the effectiveness of CM. Second, when abstinence is the desired behavior, delaying the delivery of incentives to await laboratory-based drug testing, which may take hours to days, introduces a risk that people may resume substance use in the interim between administration of the drug test and receiving the delayed CM incentive for a negative result. In this case, receipt of the CM incentive might reinforce substance use instead of abstinence (136). Given that immediate provision of CM incentives is essential to evidence-based practice, entities overseeing CM implementation that permit abstinence as an incentivized behavior should therefore require the use of

rapid POC drug tests that have a high level of accuracy to confirm that abstinence was achieved, and should require that incentives are provided immediately after testing. One noteworthy exception is for tobacco use disorder, as there is evidence to support the provision of a one-time “end-of-treatment” incentive (i.e., a one-time incentive provided after an individual has completed their entire smoking cessation program), in addition to immediate incentives provided during the CM treatment course each time the incentivized behavior is achieved (137).

In summary, entities overseeing CM implementation should ensure that opportunities to receive incentives occur frequently enough to effectively reinforce desired behaviors (typically at least weekly when treatment attendance is incentivized, and at least 2-3 times weekly when abstinence is incentivized). Entities should also require that incentives be provided immediately after an incentivized behavior is verified -- to incentivize abstinence, rapid POC testing must therefore be used.

Determining Which SUDs to Target and Designating Appropriate Incentivized Behaviors

CM has been shown to be effective in treating stimulant, opioid, cannabis, alcohol, tobacco, and concurrent SUDs (3, 14, 35, 42, 45-50). Eligibility for CM should depend on whether an individual has one or more of the above SUDs, determined based on clinical history. Stakeholders with experience implementing CM cautioned that a positive drug test should never be required for enrollment into treatment that includes CM, as it may incentivize substance use.

Entities may choose to offer CM for any SUDs for which it is effective, or instead restrict its use to a subset of SUDs. A number of factors may inform this decision, including but not limited to:

- Restrictions from the funding source because certain funders target only a subset of SUDs.
- The desire to pilot CM with a limited subset of SUDs so that implementation practices can be refined before expanding it to more SUDs.
- Comparative efficacy of CM for different SUDs and treatment modalities, as well as the existence of other treatments; for example, stimulant use disorder is often prioritized for CM because, for this condition, the CM evidence base is strongest, CM is the most effective treatment, and there are currently no FDA-approved medications.
- Community needs, because substance use patterns vary widely across different communities and, therefore, so does the prevalence of different types of SUDs and polysubstance use; the accessibility of other evidence-based treatments to address specific SUDs may also vary across communities and influence how CM is targeted.
- Ability to conduct rapid POC drug tests, if abstinence is selected as the incentivized behavior.
- Implementation and scaling considerations; for example, some HHS grantees noted that providers were more enthusiastic to implement CM when it could be used for multiple SUDs, as this would allow their investments in CM infrastructure and workflows to have even greater positive impact.

In summary, entities overseeing CM implementation should consider prioritizing stimulant use disorder for CM based on its superior efficacy relative to other treatments for stimulant use disorder, the more robust evidence base for stimulant use disorder compared with other SUDs, the lack of FDA-approved medications for stimulant use disorder, and the growing contribution of stimulants to overdose deaths. Targeting a broader set of SUDs for CM can, however, be a better strategy for certain communities depending on their needs.

Incentivized Behaviors

Abstinence from substances is a commonly incentivized behavior in CM for SUDs. Other incentivized behaviors in CM include attendance at clinically indicated SUD treatment sessions (e.g., counseling, group therapy sessions, other behavioral treatments), adherence to medication for SUDs, and, for some people, adherence to medical services related to prevention and treatment of other conditions that are common medical complications of SUDs (e.g., hepatitis, HIV, tuberculosis) (21, 138). Whichever desired behavior is selected, it is critical that objective evidence of the desired behavior be used to determine whether a CM incentive can be provided (21, 38, 118). Where abstinence is the desired behavior, as previously discussed, entities overseeing CM implementation should require rapid POC drug tests to produce objective evidence.

Use of abstinence as an incentivized behavior produces moderate to large treatment effects for both abstinence and treatment attendance; use of treatment attendance as an incentivized behavior produces moderate to large effects on treatment attendance, but small effects on abstinence (139). For this reason, entities overseeing CM implementation might consider encouraging the use of abstinence as an incentivized behavior when clinically indicated and acceptable to the client. However, use of abstinence as an incentivized behavior requires:

1. The availability of an accurate, CLIA-waived rapid POC test for the substance of focus.^l
2. That the rapid POC test can detect recent use of the substance.
3. That the window of detection for the substance is at least 2-3 days, such that twice or thrice-weekly in-person testing would be sufficient to identify recent substance use.

Abstinence may not be a feasible incentivized behavior for CM participants who are taking necessary medications that could cause false positive test results, as this may prevent the accurate verification of abstinence (140). In these cases, treatment attendance or medication adherence may be a more appropriate incentivized behavior. Abstinence also may not be the preferred incentivized behavior for people whose drug test results could be used for non-clinical purposes or otherwise have unintended consequences (e.g., some states mandate reporting of prenatal substance exposure, and this information can subsequently be used in criminal proceedings).^m

The ability to use abstinence as an incentivized behavior therefore depends both on testing technology and safety considerations related to the promotion of abstinence. These factors differ by SUD as described below:

1. Stimulant use disorder: **Stimulant use disorder is well-suited for the use of abstinence as an incentivized behavior.** Rapid POC urine tests for stimulants demonstrate a high degree of sensitivity for these drugs up to 2-3 days following use, thereby allowing for twice-weekly

^l HHS recommends using CLIA-waived, rapid POC tests to confirm abstinence, as CLIA-waived tests must be simple, must have a low risk of error, and can be administered and interpreted by individuals without additional specialized training.

^m HHS also notes that participation in CM activities more broadly -- irrespective of the type of incentivized behavior -- should be voluntary, and participation in and of itself should not result in any punitive or negative consequences for the participant.

assessment of abstinence as the incentivized behavior (21). Cocaine metabolites, amphetamine and methamphetamine should be included in urine testing protocols.

2. **OUUD: Abstinence should not be used as an incentivized behavior in CM for OUD, for several reasons.** First, MOUD are the gold standard treatment for OUD (141). Second, as people abstain from using opioids for longer periods of time, their tolerance to opioids decreases and their risk of opioid-induced respiratory depression upon resuming use increases, leaving them more vulnerable to overdose in the event that opioid use recurs (142-144). Recurrence of use in the setting of long periods of abstinence therefore poses a higher risk for opioids than for other substances. Third, current rapid POC urine tests for opioids do not reliably identify fentanyl and its analogues, and do not reliably distinguish opioid agonists and partial agonists used for OUD treatment (i.e., methadone, buprenorphine) from other opioids (145-148). Abstinence from opioids, particularly among people taking MOUD, therefore cannot be accurately ascertained with current rapid POC testing technology.
3. **Cannabis use disorder: Abstinence can be used as an incentivized behavior for cannabis use disorder, although a modified protocol may be necessary** (149, 150). Cannabis can have a long window of detection (e.g., 4-6 weeks) in rapid POC urine drug tests even after use is discontinued, which complicates the use of abstinence as an incentivized behavior in CM treatment for cannabis use disorder (151). However, the VA has developed and successfully implemented a modified CM abstinence protocol for cannabis use disorder in which clients receive one draw per urine sample until either four weeks have elapsed since treatment began or a urine drug test is negative, whichever comes first. After the client's first negative urine drug test for cannabis (i.e., after the "washout" period is complete), there is an immediate escalation to five draws offered, and thereafter rapid POC urine tests are used to assess abstinence twice weekly.
4. **Alcohol use disorder: Abstinence and/or reduced use of alcohol should not be used as an incentivized behavior in CM for alcohol use disorder in non-research settings at this time, due to limitations in current testing technology.** The most widely available method to test for abstinence from alcohol is a breath test, which can only detect metabolites of alcohol for up to 12 hours after consumption. Therefore, the frequency of testing that would be required to verify continuous abstinence from alcohol with this method (i.e., twice daily) is prohibitively burdensome in real-world settings (21, 35). While recent studies have used novel detection methods -- including a wearable sensor that detects alcohol in sweat, and a urine test for a long-lasting alcohol metabolite -- to assess the impact of CM on abstinence from alcohol, more research is needed to confirm that these newer testing technologies can be feasibly implemented in real-world settings and with similarly promising findings (86, 152, 153).
5. **Tobacco use disorder: Abstinence from tobacco should not be used as an incentivized behavior in CM for tobacco use disorder in non-research settings at this time, due to limitations in current testing technology.** The best method for assessing abstinence from tobacco is via breath tests that measure carbon monoxide, but because of the short half-life of carbon monoxide, multiple tests per day would be needed to verify sustained abstinence, which is prohibitively burdensome in real-world settings (154). Urine cotinine tests have been explored as an alternative but are currently not recommended because nicotine replacement therapy and nicotine consumption from e-cigarettes may cause false positive results (155).

The recommendations above are based on the application of CM in real-world settings using currently available drug testing technologies. In research and similar settings where newer technologies are being evaluated, it may be appropriate to test whether abstinence can feasibly be used as an incentivized behavior for a broader set of SUDs. Given the rapidly evolving landscape of drug testing technologies, it is very likely that abstinence as an incentivized behavior will be recommended to treat additional SUDs in real-world settings in the future.

For any of the above SUDs, attendance at evidence-based, clinically indicated and medically necessary psychosocial treatment sessions can be used as an incentivized behavior.

| | Abstinence | Treatment Session Attendance | Medication Adherence** |
|------------------------|-------------------|-------------------------------------|--------------------------------|
| Stimulant use disorder | Yes | Yes | — |
| Opioid use disorder | No | Yes | Yes |
| Cannabis use disorder | Yes [†] | Yes | — |
| Alcohol use disorder | No | Yes | Can be considered [‡] |
| Tobacco use disorder | No | Yes | No |

* This table features information on incentivized behaviors that are readily implementable in outpatient settings considering current practical limitations with specimen testing technologies and methods of verifying medication administration. However, abstinence and medication adherence have been used as incentivized behaviors in research trials for all applicable SUDs listed above.

** Due to limitations in current technologies for objectively verifying medication administration remotely, the use of medication adherence as an incentivized behavior is recommended only for medications that are administered by a health care provider. For the treatment of SUDs, this includes two long-acting injectable medications: buprenorphine and naltrexone.

† Due to the long window of detection for cannabis following chronic use, a modified abstinence protocol that allows a washout period may be necessary, as described above.

‡ Studies on CM to incentivize adherence to long-acting injectable naltrexone have not been conducted for alcohol as the target substance, but it could be considered as a strategy to encourage treatment engagement and retention.

Adherence to SUD medications has also been studied as a CM incentivized behavior in research trials. Such studies have evaluated whether CM can reinforce adherence to methadone, oral naltrexone, extended-release injectable naltrexone (XR-naltrexone), oral or sublingual buprenorphine, and extended-release injectable buprenorphine (BUP-ER), with promising results (81, 156-164). An important challenge in translating these research findings to real-world clinical settings, however, is the feasibility of objectively verifying medication administration. For long-acting injectable SUD medications that are administered monthly, which include BUP-ER for OUD and XR-naltrexone for OUD and alcohol use disorder, because medication administration is already performed by a health care provider, adherence can be objectively assessed without imposing additional burdens on clients or providers. Emerging evidence on the efficacy of CM for reinforcing adherence to long-acting injectable SUD medications has been promising (156, 157, 163) -- further research can inform how to optimally implement such protocols in real-world settings. For medications that are administered daily, however, direct observation of self-administration in-person may not be feasible because of the burden it places on patients and the challenges providers face in adjusting clinical workflows to accommodate this frequency of visits. There is emerging evidence related to the use of digital health technology (e.g.,

mobile applications) to objectively verify medication adherence remotely in CM protocols (164-166), but more research and experience is needed before this can be recommended in real-world clinical settings.

In summary, entities overseeing CM implementation should ensure that the incentivized behaviors selected are appropriate for the substances targeted, based on currently available drug testing technology. Abstinence may be reinforced for stimulant and cannabis use disorder, and it should be objectively verified twice or thrice-weekly with a CLIA-waived rapid POC test (a modified protocol may be needed for cannabis use disorder; see description above). Attendance at treatment sessions may be reinforced for any SUD. Medication adherence may be reinforced for two long-acting injectable medications: buprenorphine and naltrexone for OUD.

CM as Part of a Comprehensive Treatment Plan

While CM is effective as a standalone treatment, its effectiveness may be enhanced when combined with other evidence-based treatments and recovery support services (45). In addition, given the high prevalence of polysubstance use, people receiving CM as treatment for one type of SUD may still benefit from additional treatment modalities targeted at other comorbid SUDs. For these reasons, CM is most often offered in conjunction with other evidence-based SUD treatments (e.g., medications, CBT, CRA) and recovery support services; CM can be considered an additional evidence-based treatment option to complement, rather than replace, other effective treatments. HHS recognizes that a variety of psychological and community methods can effectively promote treatment and recovery-related behaviors on their own, and in combination with CM to act synergistically, and these methods can be delivered through a combination of technological and interpersonal means. In addition, collaboration among treatment and recovery support services providers can help ensure that treatment is coordinated with other supports to address SUDs and improve the overall health and well-being of CM participants.

In summary, CM outcomes may be optimized when it is offered as part of a continuum of evidence-based treatment options and services for SUDs, as appropriate for the populations being served.

Polysubstance Use

Polysubstance use is prevalent and has been increasing in recent years. Experience with CM in the context of polysubstance use suggests that for each person, the primary substance (i.e., the substance with the most significant negative impacts on health and functioning) should be identified and prioritized for treatment via CM. Depending on the primary substance, either attendance at treatment sessions, medication adherence, or abstinence may be appropriate incentivized behaviors (see above). If abstinence is the incentivized behavior, CM incentives are more likely to be effective when provided for abstinence from a single substance (typically the primary substance) or single substance class like stimulants (i.e., inclusive of cocaine, amphetamine, and methamphetamine), rather than abstinence from multiple substances or substance classes at once (21). Individuals should receive appropriate evidence-based treatments for other non-primary substances used, and these may be provided concurrently with, or following, CM. In situations where it is challenging to differentiate the harms attributable to each substance and to designate a primary substance, the decision of which substance(s) to prioritize for treatment via CM may be informed by the availability of alternative effective therapies and shared decision-making between the client and treating provider.

In summary, CM can be adapted to successfully treat polysubstance use challenges.

Courses of Treatment

There is insufficient evidence to inform whether repeated courses of CM following recurrence of substance use produce superior outcomes relative to alternative treatments. In the absence of such evidence, implementers have taken varying approaches to repeat courses of CM.ⁿ

Additional research is needed to understand the circumstances under which providing repeat courses of CM might improve client outcomes. Regardless, a provider seeing a new patient with SUD should make every reasonable effort to determine the person's treatment history including the receipt of CM based on self-reporting and medical records that are legally and operationally accessible.

In summary, understanding under what circumstances repeat courses of CM improve client outcomes is an important area for additional investigation.

Telehealth and Remote Provision of CM Incentives

There is a strong evidence base supporting the delivery of specific behavioral therapies via telehealth, which is recognized as an important strategy for expanding access to underutilized, evidence-based behavioral health services more broadly (167-169). The availability of mobile applications and other electronic platforms that allow the disbursement of CM incentives remotely and immediately has introduced the possibility of more broadly delivering CM interventions via telehealth, and there is growing evidence from such remote and hybrid CM models (132, 170-173). Delivering CM by telehealth is an appropriate option to expand access to this effective therapy in CM protocols that incentivize SUD treatment attendance, provided that the research evidence supports the delivery of the specific SUD treatment modalities used (e.g., CBT) via telehealth and related technologies, and provided that incentives can be disbursed to clients remotely and immediately via a mobile application or other electronic platform.

In CM protocols that incentivize abstinence, the need to conduct rapid POC drug testing to verify abstinence and the need for a health care provider to review the results in real time complicates the delivery of CM via telehealth. Remote assessment of abstinence via telehealth, facilitated by the use of self-administered oral fluid rapid POC tests, or self-administered breath tests for alcohol or tobacco metabolites, is currently being investigated as a strategy to increase access to CM by reducing distance-related barriers to in-person care (172, 174). At this time, given the limited availability of CLIA-waived, self-administered rapid POC drug tests that would be needed to enable remote verification of abstinence, and the limited evidence on their application to remote CM in real-world settings, entities

ⁿ For example, in the VA system CM is generally intended to be a one-time intervention, with repeat courses permissible only if: (1) at least 12 months have elapsed since the completion or discontinuation of the client's last CM course; (2) the treating clinician believes that, based on changes in the client's clinical status, circumstances, or environment, a repeat course of CM is now more likely to achieve sustained benefit (e.g., if during a previous CM course, the client was experiencing an acute destabilizing stressor that has now resolved, such as housing instability); and (3) other evidence-based treatment options (e.g., medication, other clinically indicated behavioral therapies) have been considered or attempted, but anticipated to be less effective than a second course of CM. For example, even though CBT for SUD is an evidence-based treatment of stimulant use disorder, it may be considered less effective than a second course of CM for a client with cognitive deficits that limit their ability to participate fully in CBT (e.g., it may be challenging to complete a functional analysis of behavior with such a client due to deficits in recall of the circumstances associated with an episode of use).

overseeing CM implementation should require rapid POC drug testing in-person. As testing technologies evolve and the evidence for delivering CM via telehealth grows, it is likely that abstinence-based CM protocols can also be recommended for delivery via telehealth in the future. Similarly, there are technological limitations to remotely assessing medication adherence. Therefore, outside of research settings, entities overseeing CM implementation should limit the use of CM for medication adherence to medications that are administered by clinicians (i.e., long-acting injectables).

In summary, entities overseeing CM implementation should consider using telehealth as a strategy to expand access to CM protocols that incentivize SUD treatment attendance. For CM protocols that incentivize abstinence, at this time it is recommended that rapid POC drug testing to verify abstinence be conducted in-person. For CM protocols that incentivize medication adherence, at this time it is recommended that outside of research settings, implementation should be limited to long-acting injectable medications.

Eligible Age Groups

The majority of CM research involves adult populations, although a growing body of literature has found CM holds promise in treating cannabis use disorder and tobacco use disorder among adolescents, especially when implemented alongside other evidence-based interventions (175, 176). Additional research evidence is needed to determine which components and design features of CM interventions are most efficacious in younger populations, including how best to involve parents/guardians.

Provider and Organizational Standards to Promote Evidence-Based Practices for CM

Provider Eligibility

CM interventions that have been described in the research literature and implemented in real-world settings have been delivered by a range of different provider types. In the absence of evidence demonstrating superior efficacy of CM delivered by any specific provider type, it is reasonable for CM to be delivered by any health care provider who is authorized to provide SUD treatment services in a given state, according to applicable state licensing, certification, and scope-of-practice laws and regulations.

CM is not typically delivered by peer support specialists, because it falls outside their traditional scope of activities and it may place them in a role of authority that conflicts with the peer-to-peer relationship. Peer support specialists are still important members of the overall SUD care team and may provide other services to individuals receiving CM as authorized by the state in which they practice. There is ongoing research into the potential effectiveness of peer-delivered CM to improve engagement in SUD treatment.

In summary, entities overseeing CM implementation can designate any health care provider authorized to administer SUD treatment services to deliver CM. At this time, it is not recommended that peer support specialists be permitted to deliver CM.

Provider Training and Coaching

The evidence-based manner in which CM is delivered is central to outcomes; strict adherence to the treatment protocol is necessary to maximize effectiveness and to avoid unintended harms to clients. This makes CM-specific provider training and regular, ongoing coaching essential. In the context of CM,

HHS considers coaching to include supervision of providers' CM implementation plans and protocols; regular reviews to assess fidelity to evidence-based practices and hear providers' challenges and concerns; and feedback to providers to help address their concerns, offer guidance, and improve fidelity to evidence-based practices. Studies have found that ongoing coaching on CM implementation is both valued by providers and associated with higher adoption of evidence-based CM practices (5, 21, 112, 114, 177, 178). Stakeholders also emphasized the key importance of training and coaching to engage more providers in delivering CM, improve the quality and effectiveness of CM delivery, and strengthen program integrity through increased adherence to evidence-based protocols.

There is insufficient evidence to recommend any one specific format or duration for training and coaching (22). Stakeholders with CM research and implementation experience, however, have highlighted the following components as important to provider training:

- Evidence-based CM protocols, including incentivized behaviors, incentive types and magnitudes, the importance of immediate incentive provision upon verification of the incentivized behavior, frequency of incentive provision, and treatment duration.
- Objective methods to verify whether an incentivized behavior has been achieved, including rapid POC drug tests in cases where abstinence is the incentivized behavior.
- Importance of strict fidelity to evidence-based protocols and to the behavioral principles on which those protocols are based (e.g., operant conditioning).
- The neurobiological basis of CM's efficacy.
- Coordination and integration with other evidence-based treatments.
- Culturally informed practices, and adaptations that are appropriate to diverse communities.
- Approaches to educating prospective clients on CM.
- Documentation and data collection standards to support fidelity adherence and monitoring for quality assurance.
- Roles and responsibilities of staff involved in the provision of CM.
- Oversight of the security and accounting of incentives.
- Processes to identify and rectify deviations from EBPs (e.g., via enhanced provider coaching).
- Relevant legal requirements for CM delivery, including the application of federal fraud and abuse laws and regulations.

In summary, entities overseeing CM implementation should require that CM providers receive CM-specific training before offering CM, as well as ongoing coaching throughout their time delivering CM. CM coaches should be required to receive CM-specific training prior to coaching, and both providers and coaches should be required to receive regular continuing education on CM.

CM Champions

Stakeholders with CM research and implementation experience strongly recommended that organizations implementing CM designate one or more individuals to act as "champions" for CM implementation, noting that this coordination role is important for promoting fidelity to evidence-based practices and also for monitoring and enforcing protocols to prevent diversion and misuse of CM incentives. In real-world settings, typical responsibilities of CM Champions include (27, 179):

- Overseeing implementation of CM activities at their facility or office.
- Securing the necessary training for clinicians and staff.

- Monitoring for fidelity to EBPs.
- Connecting providers of CM with coaching as needed (see above).
- Monitoring the safe storage of tangible CM incentives and approving the release of incentives based on objective evidence of achieving the desired behavior.^o
- Documentation and record-keeping related to the disbursement of CM incentives.

In summary, entities overseeing CM implementation should require that each office or facility providing CM designate one or more CM Champions, and that CM Champions receive training on EBPs and periodic continuing education, as described in the previous section.

Readiness Attestation

Stakeholders with CM research and implementation experience also identified as valuable the development of a “readiness attestation” by organizations seeking to implement CM. A readiness attestation describes an organization’s plan for implementing CM and monitoring fidelity to EBPs -- typical components include a description of:

- The role of the CM Champion(s).
- CM-incentivized behaviors and approach to verification.
- The type of CM incentives to be offered.
- Processes for documenting and monitoring fidelity to EBPs.
- How training and coaching requirements will be met.
- Any safeguards they are using to mitigate the risk of diversion or misuse of CM incentives.

Stakeholders noted that the process of developing a readiness attestation can be helpful to organizations to effectively plan and prepare for implementing CM and can also be a helpful tool for funding and regulatory entities overseeing SUD treatment delivery to verify that implementing organizations have the necessary infrastructure and processes to deliver CM with fidelity. In addition, the development of a readiness attestation offers a valuable opportunity for organizations to engage key community stakeholders to ensure that their implementation of CM is culturally informed and responsive to the needs of diverse and vulnerable communities. For example, Tribal consultation is highly recommended for organizations seeking to serve Tribes.

In summary, entities overseeing CM implementation should consider requiring the development and approval of a readiness attestation prior to offering CM.

Monitoring Fidelity to EBPs

Monitoring fidelity to EBPs was identified by stakeholders with CM research and implementation experience as a critical function for organizations delivering CM. Published research studies also find that systematically monitoring fidelity to EBPs and taking steps to address deviations from recommended practices can enhance CM quality (22, 180, 181). Stakeholders recommended that organizations offering CM conduct frequent and regular reviews of clinician and staff fidelity to CM treatment protocols, in addition to regular supervision.

^o Offices/facilities providing CM may need to designate more than one CM Champion to ensure that someone who is authorized to release incentives is available to do so promptly when the desired behavior is verified.

- Stakeholders noted that robust clinical documentation and data collection systems can assist with monitoring fidelity to EBPs and help to safeguard against fraud and abuse. Specific strategies recommended included: Requiring clear documentation in the medical record of the treatment plan, including all instances in which the person received or did not receive CM incentives and on what basis (i.e., whether attainment of the incentivized behavior was objectively confirmed), and the amount of incentives disbursed.
- Requiring that providers offering CM use an accounting system to track disbursement of incentives, that can be audited as necessary.
- Encouraging organizations delivering CM to use benchmarks to assess provider and program-level fidelity to EBPs and to help identify where enhanced training or coaching is needed.
 - Examples of program-level performance benchmarks used in the VA include 90% of specimen samples testing negative for the drugs of focus, and 50% of CM sessions attended, across all clients that the provider treats (22).

In cases where fidelity is not achieved, stakeholders with CM research and implementation experience recommended that providers receive coaching or further training to help identify the reasons for deviation from the protocol and steps they can take to improve treatment fidelity.

In summary, entities overseeing CM implementation should require frequent monitoring of fidelity to EBPs using robust documentation systems and should use the findings to implement program improvements and target additional training and coaching investments.

Policy Opportunities to Expand Access to CM, Increase Treatment Quality, and Safeguard Program Integrity

Sustainable Funding that Supports Evidence-Based Practices

The need for sustainable funding sources was among the most commonly identified barriers to CM implementation by stakeholders, including HHS grantees. Reimbursement for CM among insurers in the United States is currently extremely rare -- one important policy opportunity to expand access to CM is therefore for insurers to consider how CM and its components can be reimbursed through existing fee-for-service and value-based payment arrangements (9).

While acknowledging the importance of more sustainable funding sources for CM such as insurance, stakeholders also emphasized that grants remain the major source of funding for CM programs at present and are likely to remain an essential source of funding in the coming years due to the slow pace of adoption by insurers, and that certain components of CM interventions might not lend themselves as readily to reimbursement under existing insurance frameworks (e.g., provider training and coaching). Grants therefore represent a critical policy opportunity to expand access to CM. For funding organizations, ensuring that grants' policies -- and in particular, policies that limit the magnitude of CM incentives -- align with EBPs for CM is an important strategy to support treatment quality.

In light of the robust scientific evidence demonstrating that higher-value incentives are necessary to improve treatment outcomes, federal agencies and other funders should consider aligning funding limits with the research evidence to maximize CM effectiveness.

Reducing Uncertainty Regarding the Potential Application of Certain Federal Fraud and Abuse Laws

to CM Incentives

Stakeholders, including HHS grantees, identified concerns regarding the potential application of certain federal fraud and abuse laws as an ongoing barrier to implementing CM. Similar concerns are documented in the research literature (9, 97, 103). Compliance with the applicable federal fraud and abuse laws is currently assessed on a case-by-case basis for any CM program, leading to stakeholder uncertainty regarding potential criminal or monetary liability under these laws. Stakeholders expressed that unambiguous and certain protection for specified CM incentives would offer greater clarity to providers and would facilitate wider implementation of CM programs.

OIG and HHS are planning next steps to address the barrier to CM implementation stemming from stakeholders' concerns that CM incentives could be subject to criminal and monetary penalties under certain federal fraud and abuse laws, including conducting the review required by 42 U.S.C. § 1320a-7d(a)(3) on whether to establish a safe harbor for evidence-based CM incentives.

Disseminating Best Practices for CM Implementation

Stakeholders with CM implementation experience, including HHS grantees, expressed that having clear and more readily available guidance for CM implementation and fidelity to EBPs would help to support high-quality treatment delivery and program integrity. In particular, they noted that practical information about how to adapt clinic workflows (e.g., protocol templates), how to manage and store CM incentives, use of technology to support CM delivery (e.g., mobile applications), and how to adapt delivery to different populations and settings would be of value. This recommendation has also been echoed in the research literature (9).

Publishing and disseminating best practices for the implementation of CM in diverse settings therefore represents an important policy opportunity for organizations engaged in research and guideline dissemination to help support the broader adoption of EBPs and program integrity safeguards.

Addressing Misconceptions About CM

As previously noted, despite the three decades of research supporting the effectiveness of CM for a variety of SUDs and across diverse populations, the treatment is still commonly misunderstood, mischaracterized and often stigmatized as a result. Stakeholders have noted that this has hindered adoption by providers and acceptance by communities and even clients. As with SUD treatment and recovery support services more broadly, sharing accurate information about CM in a manner that is tailored to different stakeholders (e.g., providers and other entities overseeing SUD treatment, clients, family and community members) and messaging that addresses common misconceptions about CM represents an important policy opportunity for organizations with a prominent messaging role and platform to support broader access. For example, in addition to promoting fidelity to evidence-based practices, training workshops for clinical leaders have been found to be an effective strategy for addressing misconceptions about CM (25).

Supporting Further Research and Evaluation

A wide body of research has demonstrated that CM is a highly effective SUD treatment, and CM is considered an established, evidence-based practice by HHS. As with all health care and recovery support

interventions, there remain certain areas where additional research may help optimize the implementation of CM, particularly in light of emerging technologies that have potential applications to CM delivery (e.g., novel methods of drug testing, digital applications). This report has noted several areas where additional research can help to further optimize CM delivery, including on repeat courses of treatment, optimal duration of treatment, best practices for treating children and adolescents, and best practices for cultural adaptation to optimally serve specific populations (e.g., Tribal communities).

Supporting such research, as well as implementation and outcome evaluations, represents a policy opportunity to ensure that the practices that have enabled CM to be successful in research trials are optimally translated into real-world practice, as well as to identify new practices that promote effective CM implementation.

Most importantly, HHS emphasizes that implementation of CM that aligns with the existing evidence base need not be delayed while further research on optimizing CM delivery is conducted. **The severity of the overdose crisis necessitates greater focus on effective approaches to address its evolving threats, for which CM stands among the most promising.**

CONCLUSION

CM is an established, evidence-based treatment for a variety of SUDs, and is the most effective currently available treatment for stimulant use disorder, which represents the fastest-growing category of substances involved in overdose deaths. CM remains underutilized, but as this report describes, there are numerous opportunities for health care providers, organizations delivering CM, entities that are overseeing the implementation of CM, as well as research, education, communications, funding, and regulatory entities to support broader access to high-quality CM through clinical, organizational, funding and policy strategies (see **Box 1** for summary of recommendations). Accelerating our collective efforts to address the overdose crisis using all available effective tools is imperative to save lives and support recovery from SUDs -- CM can help advance our progress.

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ACRONYMS

| | |
|---------------|---|
| BUP-ER | Extended-Release Injectable Buprenorphine |
| CBT | Cognitive Behavioral Therapy |
| CLIA | Clinical Laboratory Improvement Amendments of 1998 |
| CM | Contingency Management |
| CMP | Civil Monetary Penalty |
| CMS | Centers for Medicare & Medicaid Services |
| CRA | Community Reinforcement Approach |
| EBP | Evidence-Based Practices |
| FDA | Food and Drug Administration |
| HHS | U.S. Department of Health and Human Services |
| MOUD | Medications for Opioid Use Disorder |
| NIDA | National Institute on Drug Abuse |
| OIG | HHS Office of Inspector General |
| OD | Opioid Use Disorder |
| POC | Point-of-Care |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SOR | State Opioid Response |
| SUD | Substance Use Disorder |
| VA | U.S. Department of Veterans Affairs |
| XR-naltrexone | Extended-Release Injectable Naltrexone |



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

200 Independence Avenue SW
Washington, D.C. 20201

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