CONTINGENCY MANAGEMENT

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INTRODUCTION

Medications are an essential tool for treating substance use disorder, particularly for disorders involving opioid use. For some conditions like stimulant use disorder, however, there are not any Food and Drug Administration (FDA)-approved medications available. Contingency management, a form of psychosocial therapy extensively studied in recent years, but not commonly used to treat substance use disorder in the United States, may fill some of the void. Recent changes in federal policy, delineated below, removed certain barriers—some more perceived than actual—that limited the wider adoption of contingency management for stimulant use disorder treatment. In response, several states introduced new contingency management programs. As a result, it is likely that this form of substance use disorder treatment will become more prominent in the U.S. in the future.

WHAT IS CONTINGENCY MANAGEMENT?

Contingency management is a behavioral therapy that reinforces or rewards positive behavioral change. Often, mental health professionals use contingency management alongside other methods of treatment. Psychologists coined the term in the 1930s, with researchers testing it to treat alcohol use disorder as early as the 1960s. In the context of substance use disorder treatment, patients typically receive something of monetary value to incentivize abstinence from drug use. The incentivized behaviors might be negative drug tests, reaching sobriety milestones, attending treatment, or taking medication(s). The aim of contingency management is to reverse the neurobiological basis of addiction. Prolonged drug use "rewires" the brain's reward system; contingency management combats this by overriding the system with competing incentives. Where successful, patients desire the rewards that go with treatment more than the "reward" that accompanies drug use.

There are seven key aspects or principles to successful contingency management treatment:

- **Target behavior.** This is the specific, observable behavior that the patient should start (if a positive behavior) or stop (if a negative behavior).
- **Target population.** The subset of the population in treatment for which contingency management is the most helpful or effective. These may be new patients or patients that struggled to sustain recovery in the past.
- **Choice of incentive.** The reward must be something of genuine interest to the patient, not a symbolic token.
- **Amount of incentive.** The incentive must be large enough to entice the patient without overly depleting the program's resources.
- **Frequency of reinforcement**. Whether rewards prove more effective given after each instance of positive behavior, or less frequently, depends on the patient.
- **Timing of reinforcement.** Ideally, a patient should receive the reward immediately after engaging in, or not engaging in (if applicable), the target behavior.
- **Duration of reinforcement.** Contingency management should last until the patient can sustain recovery even after rewards are removed. The length of time will vary from patient to patient.

The method of rewarding positive behavior usually follows one of two models. Under the on-site prizes or "fishbowl" method, patients earn opportunities to draw slips of paper from a bowl to win a random prize of varying value. This includes earning multiple draws as a reward for consistent positive behavior. Although this method contains an element of chance, studies suggest this method does not promote gambling behavior. The second method is voucher-based reinforcement. Under this method, patients receive prizes with a monetary value, like gift cards, with the value of the vouchers increasing over time as positive behavior continues.

Research shows that contingency management works in many contexts, such as in promoting weight loss and smoking cessation. Studies in the 1990s demonstrated that it also helps patients with cocaine use disorder. Between 1970 and 2014, researchers conducted over 100 randomized-controlled trials demonstrating the effectiveness of contingency management in treating a variety of substance use disorders. Moreover, nine meta-analyses performed during the past two decades used the combined data from multiple studies to find positive results from contingency management treatment. These results suggest that contingency management reduces the use of stimulants, opioids, cannabis, nicotine, and other substances. Therefore, either alone or in combination with other treatments, contingency management appears to help patients reduce drug use and continue with treatment longer than traditional substance use treatment. Despite these positive outcomes, however, fewer than 10 percent of substance use disorder treatment programs in the U.S. make routine use of contingency management in their practices.

GOVERNMENT POLICY AND CONTINGENCY MANAGEMENT

Except for one notable exception in the Veterans Administration (VA) delineated below, there is widespread reluctance in the United States to employ contingency management. Much of the reluctance stems from concerns that providing contingency management could violate: (1) federal or state anti-kickback laws, which prohibit healthcare providers from paying patients to seek treatment; or (2) section 1128A(a)(5) of the Social Security Act (otherwise known as the "Beneficiary Inducements CMP"), which provides for the imposition of civil monetary penalties (*i.e.,* CMP) against any person who offers or transfers remuneration to a Medicare or state health care program beneficiary that the benefactor knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services.[1]

According to a Congressional committee report accompanying the enactment of the Beneficiary Inducements CMP, Congress intended that inexpensive gifts of nominal value be permitted under the law. In 2000, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) issued guidance interpreting "nominal value" as no more than $10 per item or $50 in the aggregate per patient on an annual basis. The OIG increased these amounts to $15 and $75, respectively, in 2016. As a result of these OIG directives, the Centers for Medicare and Medicaid Services (CMS) placed an annual limit of $75 on incentives to patients, including contingency management, an amount that many treatment practitioners consider too small to be effective.

In 2021, the Biden-Harris Administration's Office of National Drug Control Policy announced that, among its year one priorities, it sought to "[i]dentify and address policy barriers related to contingency management interventions (motivational incentives) for stimulant use disorder."[2] Shortly before this, in December 2020, the OIG issued new regulations concerning changes to "safe harbors" (*i.e*., exceptions) to the federal anti-kickback statute and Beneficiary Inducements CMP rules. While the OIG did not add contingency management as a safe harbor under the anti-kickback statute, it addressed several "misunderstandings" about the effect of prior OIG guidance, pointing to the need for case-by-case evaluation of any such proposed contingency management program:

[1] The Federal anti-kickback statute is codified at 42 U.S.C. 1320a–7b(b), while the Beneficiary Inducements CMP is codified at 42 U.S.C. 1320a–7a(a)(5).

[2] "The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One." *Executive Office of the President, Office of National Drug Control Policy*, at 3, April 1, 2021. https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf.

After weighing the potential benefits of contingency management and other programs designed to motivate beneficial behavioral change with the potential risks to program integrity—and understanding that many of these programs involve cash and cash-equivalent payments to patients—we are not expanding the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes. This does not mean that all such cash or cash-equivalent payments are unlawful, but they would be subject to case-by-case analysis under the federal anti-kickback statute and Beneficiary Inducements CMP.

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Gifts that implicate the Beneficiary Inducements CMP that exceed these dollar limits are not prohibited but are analyzed on a case-by-case basis for compliance under the statute. We highlight, however, that this nominal value guidance applies to the value of in-kind items and services, not to the value of incentive payments in the form of cash or cash equivalents. In other words, cash and cash-equivalent payments under $75 would not be covered by this guidance.

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There is no OIG-imposed $75 limitation on contingency management program incentives. Rather, the federal anti-kickback statute may constrain the ability of individuals or entities to offer contingency management program incentives of any value to federal health care program beneficiaries, depending on the facts of the arrangement. Moreover, in-kind incentives above the $75 annual, aggregate limit, and all cash or cash-equivalent incentives regardless of the amount, must be analyzed on the basis of their specific facts for compliance with the Beneficiary Inducements CMP.[3]

More recently, in March 2022, the OIG released an advisory opinion regarding DynamiCare Health, a Boston-based therapeutics company that includes contingency management therapy among its treatments. DynamiCare offers its patients up to $599 per year in financial incentives in small increments ($1- $3) and sought reassurance from the OIG that it would not be charged for violations of either the anti-kickback statute or Beneficiary Inducements CMP.[4] The OIG concluded that DynamiCare would not face any criminal or civil penalties, as the requisite intent to violate either law is not present.[5] This opinion only applies to the specific elements and protocols of DynamiCare's program, but the answer may encourage other health providers to follow its example.

Interestingly, and in contrast to CMS policy, starting in 2011, the VA provided funds to support training and initial implementation for contingency management nationwide for substance use disorder treatment. During the 12 years since implementation, more than 6,000 veterans from 119 VA facilities received contingency management via a 12-week program in which two urine samples are obtained per week. The VA reports that 92 percent of the samples test negative for the targeted substance.

Moreover, since 2021, several states introduced contingency management therapy as a Medicaid benefit through Section 1115 Medicaid waivers. These waivers give states greater flexibility to achieve the objectives of the Medicaid program by approving novel or experimental projects that are consistent with federal policies and do not increase federal expenditures. With greater assurance that these programs do not *per se* violate federal law, states

[3] "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," *Office of Inspector General, Department of Health and Human Services*, 85 Fed. Reg. 77684, 77791-92 (Dec. 2, 2020), https://www.federalregister.gov/d/2020-26072.

[4] Presumably, DynamiCare chose $599 for the upper limit of annual incentives because a payer does not have to create a 1099-MISC for the recipient (and thus report that income to the IRS) for payments of less than $600 in a year.

[5] OIG reached its conclusion based solely on a lack of intent to violate the law. It expressly found that DynamiCare's contingency management program "would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present," and "may generate prohibited remuneration under the Beneficiary Inducements CMP."

are moving forward and obtaining federal approval. So far, California, Montana, Washington, and West Virginia have sought coverage for contingency management in their Medicaid waivers. If contingency management programs in these states are approved by CMS and prove effective, more states will likely follow.

CONCLUSION

Contingency management is a well-studied and effective method for treating substance use disorder, but for years, it received little support in the United States from state or federal governments. No explicit legal obstacle prohibits it, but concerns about violating anti-kickback laws discouraged government entities and private insurers from employing it more extensively. With the release of new, clarifying legal guidance, this period of hesitancy may be ending. Several states requested approval from the federal government to include coverage for contingency management in their own state Medicaid programs, and it is probable that more will follow suit. Contingency management may soon become a key part of the national toolkit in fighting the overdose epidemic in the United States.

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The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

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