April 20, 2021

The Motivational Incentives Policy Group

Leadership

H. Westley Clark, MD, JD, MPH, DFASAM
Dean's Executive Professor of Public Health
Santa Clara University
Santa Clara, California

Mady Chalk, PhD, MSW
Principal & Managing Director
The Chalk Group
Washington,
District of Columbia

Carol McDaid
Principal
Capitol Decisions, Inc.
Washington,
District of Columbia

Richard Rawson, PhD
Emeritus Professor, UCLA
Los Angeles, California
Research Professor,
University of Vermont
Burlington, Vermont

Sarah A. Wattenberg, MSW
Director, Quality and Addiction Services
National Association for Behavioral Healthcare
Bethesda, Maryland

RECOMMENDED SAFEGUARDS FOR EFFECTIVE CONTINGENCY MANAGEMENT in SUBSTANCE USE DISORDERS Under the CMS 1115 Waiver Program

The Biden Administration has announced its first year priorities for addressing the nation's substance use epidemics, which include advancing adoption of Contingency Management (CM).[1] Given that CM is the best evidenced, most effective treatment for Stimulant Use Disorder, which is undergoing dramatic increases in prevalence and rates of overdose, a number of specific safeguards are recommended for implementing CM in CMS 1115 Waiver programs by states. As the U.S. Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) notes, *"…we recognize that research shows that contingency management interventions are the most effective currently available treatment for stimulant use disorders."* The OIG's recent Final Rule does not ban CM and does not place a ceiling on the amount of incentives, either.[2]

CM incentives are specifically focused on patient care; therefore, implementation should underscore, "the importance of quality of care, the health care provider's medical judgment, and the patient's relationship with their provider in developing plans for treatment and care."

Evidence-based CM incentives *do not consist of or allow for* payments for referrals, marketing, or inducements to patients to select a particular provider. Incentives to patients should be provided for the purpose of enhancing access, quality or benefits from approved healthcare services – particularly practices that have public health as well as clinical health relevance. Elsewhere in healthcare, such incentives are established as acceptable, e.g., with Hepatitis B vaccine.

1. **What is NOT permissible**:
   a. Incentives that result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.
   b. Advertising patient incentives to recruit patients or steer patients away from other providers.
   c. Using incentives for the purpose of increasing fees.
   d. Inadequate protection against fraud.

2. **What IS permissible:**
   a. Incentives that have a direct connection to the coordination and management of care of the target population including for participation in community-based services that are recommended by the patient's licensed health care.
   b. Digital health technology, e.g., remote patient monitoring and telehealth
   c. CM incentives for which the payer only pays when the desired health outcome occurs – attendance, objective, validated measures consistent with treatment (e.g., attendance, abstinent drug tests, and other confirmed behavioral measures).
   d. Advancing goals, as determined by the patient's licensed health provider, of: (i) Adherence to a treatment regimen; (ii) adherence to a drug regimen; (iii) adherence to a follow-up care plan; (iv) management of a disease or condition; (v) improvement in measurable evidence-based health outcomes for the patient or the target patient population; or (vi) ensuring patient safety.

CMS-sponsored Models, such as the 1115 Waiver Program, ACO Beneficiary Incentive Programs, and value-based or risk-based contracting systems may specify patient incentives for CM that offer flexibility and options. The OIG confirms that health-related technology and patient health-related monitoring tools and supports can be protected remuneration. For instance, a smartphone that facilitates telehealth services with a patient's licensed health care professional, or a platform or software that facilitates telehealth services, may be a protected form of remuneration.

Direct Connection to Care: The tool or support furnished to the patient *must have a "direct connection to the coordination and management of care* of the target patient population." In other words, not a "reasonable connection" but rather a direct connection "which empowers patients to fully participate in the care coordination activities." CM incentives for patient behavioral efforts that are objectively verified are eligible, including: appointment attendance, medication self-administration, substance testing results, community reinforcement participation, cognitive behavioral therapy effort, peer recovery coaching participation, etc.

The following guardrails should be implemented to protect against fraud and abuse:

Guardrails[3]:

- ☐ Research-validated evidence-based practices
- ☐ Formal implementation using a written protocol
- ☐ Rewards should not exceed $200/month/per patient
- ☐ Each patient must have a documented clinical diagnosis
- ☐ Each patient's care plan must be documented in the record by a licensed health care professional/clinician
- ☐ Individualized care plans should document specific behavioral targets, amounts and schedules
- ☐ For each patient, a complete, written accounting of every payment, its purpose, the related behavioral expectation and the patient's actual effort for which the reward has been received. For example, the documentation should specifically record the appointments expected and attended, each substance test that was expected and whether the result was consistent or inconsistent with the intended medical expectations (i.e., harm reduction, abstinence and/or adherence to any medications that have been prescribed). Gift or monetary incentives and their distribution must be accurately inventoried.
- ☐ Ongoing attention to and audit-ready processes for backroom functions (e.g., electronic health records, attendance records, established accounting procedures, etc.)
- ☐ Clear protections to avoid using incentives for recruitment (e.g., no advertisements) or suggestions of rebates, refunds, or kick-back offers

[1] The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One [Internet]. Washington, D.C.: U.S. Office of National Drug Control Policy; 2021 Apr [cited 2021 Apr 4] p. 11. Available from: https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf

[2] 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 [Internet]. Federal Register. 2020 [cited 2021 Apr 4]. Available from: https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

[3] Knopf A. CM, only effective treatment for stimulants, on the ropes as methamphetamine surges. *Alcoholism & Drug Abuse Weekly*. 2020;32(23):1-3.