HANDOUT FOR THE PRESENTATION FROM H WESTLEY CLARK, MD, JD, PMH, DFASAM

"FEDERAL RULES AND GUARDRAILS FOR SUCCESSFUL ADOPTION OF CONTINGENCY MANAGEMENT"

A. MOTIVATIONAL INCENTIVE POLICY GROUP GUARDRAILS

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.

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

Guardrails:

- 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[i]

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

HHS Office of Inspector General Fact Sheet

Final Rule: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements
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BACKGROUND

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) is publishing a final rule (Final Rule), "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements." This Final Rule is part of HHS's Regulatory Sprint to Coordinated Care (Regulatory Sprint), which aims to reduce regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination.

HHS has identified the broad reach of the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the civil monetary penalty (CMP) law provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP), 42 U.S.C. § 1320a- 7a(a)(5), as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care across care settings in both the Federal health care programs and commercial sector.

The Federal anti-kickback statute provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid. Health care providers and others may voluntarily seek to comply with statutory and regulatory safe harbors so that they have the assurance that their business practices will not be subject to sanctions under the anti-kickback statute. To receive safe harbor protection, an arrangement must squarely meet

each requirement of an applicable safe harbor. However, failure to fit in a safe harbor does not mean that an arrangement violates the Federal anti-kickback statute. Arrangements that do not fit in a safe harbor are analyzed on a case-by-case basis, including whether the parties had the requisite intent. Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.

The Beneficiary Inducements CMP provides for the imposition of CMPs against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.

OIG promulgated a Notice of Proposed Rulemaking (NPRM) on October 17, 2019.[1] OIG coordinated with the Centers for Medicare & Medicaid Services (CMS), which also issued an NPRM in October 2019, and is concurrently issuing a final rule in connection with the Regulatory Sprint. In response to OIG's NPRM, we received 337 public comments, which

provided information regarding whether the proposals in the NPRM would effectively remove barriers to coordinated and value-based care and include the appropriate safeguards to protect Federal health care programs and patients.

1 *See* 84 Fed. Reg. 55,694 (Oct. 17, 2019), *available at* https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the; *see also* OIG, HHS Office of Inspector General Fact Sheet, Notice of Proposed Rulemaking OIG-0936-AA10-p (Oct. 2019), *available at* https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf.

The Final Rule

The Final Rule implements seven new safe harbors, modifies four existing safe harbors, and codifies one new exception under the Beneficiary Inducements CMP. The Final Rule modifies and clarifies the NPRM in response to comments and as explained in the preamble to the Final Rule. For example, the Final Rule clarifies how medical device manufacturers and durable medical equipment companies may participate in protected care coordination arrangements that involve digital health technology; lowers the level of "downside" financial risk parties must assume to qualify under the new safe harbor for value-based arrangements with substantial downside financial risk; and, in recognition of the urgent problem of cyber threats to the health care industry, broadens the new safe harbor for cybersecurity technology and services to cover remuneration in the form of cybersecurity-related hardware.

To safeguard against inappropriate incentives, the Final Rule incorporates additional limitations on parties seeking safe harbor protection under the patient engagement and support safe harbor, such as a fixed dollar cap on protected tools and supports provided to patients and enhanced restrictions on marketing and patient recruitment. As proposed, certain categories of entities that are not typically on the front lines of care coordination and pose a higher risk of fraud or abuse, such as pharmaceutical manufacturers and compounding pharmacies, are ineligible to use the new safe harbors for value-based arrangements, outcomes-based payments, and patient engagement and support. Click here for more information about ineligible entities under these safe harbors. Ineligible entities may be able to use other new or modified safe harbors if an arrangement satisfies all applicable conditions.

Subject to definitions and conditions set forth in the regulations in the Final Rule, the final safe harbor regulations protect:

- *Value-Based Arrangements*. Three new safe harbors for certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordinated and managed patient care:
    - Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (§ 1001.952(ee));

- Value-Based Arrangements With Substantial Downside Financial Risk (§ 1001.952(ff)); and
- Value-Based Arrangements With Full Financial Risk (§ 1001.952(gg)).

These new safe harbors vary by the type of remuneration protected, level of financial risk assumed by the parties, and safeguards included as safe harbor conditions.

- *Patient Engagement and Support*. A new safe harbor (§ 1001.952(hh)) for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency.
- *CMS-Sponsored Models*. A new safe harbor (§ 1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model (as defined in the Final Rule), which should reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.
- *Cybersecurity Technology and Services*. A new safe harbor (§ 1001.952(jj)) for donations of cybersecurity technology and services.
- *Electronic Health Records Items and Services*. Modifications to the existing safe harbor for electronic health records items and services (§ 1001.952(y)) to add protections for certain related cybersecurity technology, to update provisions regarding interoperability, and to remove the sunset date.
- *Outcomes-Based Payments and Part-Time Arrangements*. Modifications to the existing safe harbor for personal services and management contracts (§ 1001.952(d)) to add flexibility for certain outcomes-based payments and part-time arrangements.
- *Warranties*. Modifications to the existing safe harbor for warranties (§ 1001.952(g)) to revise the definition of "warranty" and provide protection for bundled warranties for one or more items and related services.
- *Local Transportation*. Modifications to the existing safe harbor for local transportation (§ 1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for patients discharged

from an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours.

- *Accountable Care Organization (ACO) Beneficiary Incentive Programs*. Codification of the statutory exception to the definition of "remuneration" under the anti-kickback statute related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).

Subject to definitions and conditions set forth in the regulations in the Final Rule, the final exception regulations under the Beneficiary Inducements CMP protect:

- *Telehealth for In-Home Dialysis*. An amendment to the definition of "remuneration" in the CMP rules at 42 C.F.R. § 1003.110 interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.

Readers are directed to the Final Rule for the regulations we are finalizing and further explanation of the regulations.

EKRA and CM

(Are They Related?)

The Eliminating Kickbacks in Recovery Act (EKRA)

EKRA is relatively new, having been passed as a part of the SUPPORT Act of 2018. EKRA is primarily managed by DOJ, with input from OIG. As you may know, EKRA is a law designed to fight patient brokering and recovery profiteering. . EKRA prohibits accepting or paying kickbacks for referrals to recovery homes, clinical treatment facilities, or laboratories.

While the Anti-Kick Back Statute, the CMP-BI, Physician Self-Referral Act, and the False Claims Act would be the primary concern for CM providers, EKRA could also be implicated in CM.

EKRA could be implicated in situations subcontracts are negotiated with: (1) toxicology suppliers/laboratories, (2) gift card vendors, (3) App vendors, (4) mobile phone vendors, or (5) any sub-contract where a kick-back is possible..

In addition to these practices, it should be noted the EKRA applies to both public and private commercial insurance, unlike the Anti-Kickback Statute which only applies to federal health care programs.

There have been two cases at the federal district court level attempting to interpret EKRA: (1) S & G Labs Hawaii vs. Darren Graves, and (2) United States of America vs. Mark Schena of Arrayit Corporation. Since both of these cases involved the interpretation of the new law, there were only mildly enlightening.

Recovery Home Scams

In May of 2022, DOJ through its New Jersey Office reported the first conviction under EKRA. In that announcement, a California man was sent to prison for 15 months for his role in a multi-state recovery home patient brokering scheme.

In this case patients addicted to heroin and other drugs were bribed to enter into drug rehabilitation centers, generating fees from those facilities. In the conviction The indicted and convicted doctor from West Hills, California pled gusty to one count of conspiracy to violate EKRA. The doctor paid a fee for each patient referral.

Wrong Way to Negotiate Lab Contracts

In February 2020, an 80 year old office manager of a substance abuse treatment clinic in Jackson, Kentucky pleaded guilty to soliciting kickbacks from the CEO of a toxicology lab in exchange for urine drug test referrals in violation of EKRA

EKRA, of course, covers a range of "sins". In S & G Labs v Darren Graves, the Court examined whiter the compensation paid by S&G Labs to an employee violated EKRA. The Court found that the commission-based compensation structure used for the employee did not violate EKRA because the employee interacted with the actual providers, but not the the individuals whose samples were tested. This case was narrowly decided, leaving the question of commission based employee compensation still up in the air.

With technology driven SUD treatment, including CM, misadventure exists in the realm of

urine toxicology, gift card management, and patient referral kickbacks.

US v. Markovich

It should be noted that in 2020, the case US v Markovich, a Florida jury returned a verdict convicting two owners of addiction treatment facilities for, among things, conspiracy to violate EKRA. There, the EKRA violations included:
(1) giving illegal drugs to patients before admission and readmission to cause the patients to test positive for drugs and qualify for the highest and most expensive level of care,
(2) paying patients and providing them free transportation, including long-distance flights to the addiction treatment facility,
(3) Splitting fees with clinical laboratories that performed laboratory tests on patients referred from the addiction treatment facility, and
(4) Using social media to target potential patients by offering them cash to go to the addiction treatment facility.

While items 1 and 4 in the Markovich case are clearly of concern, items 2 and 4 invoke considerations of the implementation of CM. Regarding item 2, the view that CM Incentives are not income or remuneration must continue to be emphasized. S & G Labs makes it clear the EKRA does not define remuneration, giving the feds and the states license to do so broadly. It is best to head this issue off at the pass, before some prosecutor decides that incentive are illegal reimbursements.

Regarding item 4 in the Markovich case, I'm trying to track down the details, but it is important not to go hog wild in promoting CM on social media. Any emphasis on the incentives, especially cash or cash like, would undoubtedly be seen as violating EKRA and the Civil-Monetary Penalties, Beneficiary Inducements ACT.

EKRA is still new law, its interpretation is still evolving,, but given the reputation of SUD programs, and the skepticism about "paying addicts", the guard rails are our best bet to keep things legal and treatment oriented.

SUMMARY

Fortunately, the OIG has weighed in on CM. Adequately managed CM itself with the guard rails that meet the OIG's concerns should be more than sufficient to survive scrutiny from both the OIG and the DOJ. It is the subcontracts used as a part of the infrastructure of CM that could be a potential problem.

As a result, we need to remind interested parties that the EKRA law prohibits any recovery home, clinical treatment facility, or laboratory from paying kickbacks to **anyone.** EKRA applies to all laboratories whether or not they perform substance abuse testing. EKRA has an expansive reach that is still being determined by prosecutors from DOJ.