

Trends in Behavioral Health

Webinar Series



Marketing Best Practices in Light of the
SUPPORT for Patients and Communities Act

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presented by



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Agenda

- Overview of the Eliminating Kickbacks in Recovery Act (EKRA)
- Relevant terminology
- Exceptions to EKRA
- Related California laws
- The existing fraud and abuse landscape
- How EKRA fits into the existing framework
- Application to laboratories
- What companies should do now

Why Does This Matter?

- Shift from cash-pay to insurance reimbursement
- Post-ACA explosive growth of the industry
- State regulatory departments playing catch up
- State legislatures under pressure to tighten laws
- Growing number of large payor (Anthem, Blue Shied, Health Net, Aetna, Cigna, United) Special Investigations Unit (SIU) investigations, task forces, referrals to criminal prosecutors
- Demonstrated public interest in operations of addiction treatment programs



Understanding the Enforcement Players

- State regulators
 - DHCS and other licensing agencies that oversee operations
 - Department of Insurance
- Payor SIUs (Anthem, Blue Shield, Aetna, Cigna, Health Net, UnitedHealth)
 - Referrals to local district attorneys for criminal prosecution
 - Large self-funded employer plans (federally regulated under ERISA)
- Federal regulators
 - OIG/Medicare/Medi-Cal when federal claims are involved
 - CMS oversight of ACA implementation
 - FBI Support of State Investigations (Conspiracy to commit Honest Services Mail Fraud, 18 U.S.C. § 371; Honest Services Mail Fraud, 18 U.S.C. § 1341 and 1346; Travel Act, 18 U.S.C. § 1952)

State/Local Investigating Agencies



State Department of Justice



State Professional Licensing Agencies



State Facility Licensing Agencies



State Department of Insurance



Local D.A. / Law Enforcement

Federal Investigating Agencies



Department of Health & Human Services (HHS)



U.S. Department of Justice (DOJ)



Federal Bureau of Investigations (FBI)



Office of the Inspector General (OIG)



Local U.S. Attorney's Offices



Centers for Medicare & Medicaid Services (CMS)

The SUPPORT Act

- On October 24, 2018, President Trump signed into law the SUPPORT for Patients and Communities Act
- The SUPPORT Act is a comprehensive bill designed to address the current opioid crisis
- Section 8122 of The Support Act is referred to as the “Eliminating Kickbacks in Recovery Act of 2018” or “EKRA”
- EKRA is codified at 18 U.S.C. § 220



The Eliminating Kickbacks in Recovery Act of 2018

- Unless an exception applies, EKRA prohibits knowingly and willfully
 - (1) soliciting or receiving any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
 - (2) paying or offering any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
 - (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
 - (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory
- Violations of EKRA may result in a fine of up to \$200,000 and/or imprisonment of up to 10 years, for each occurrence



Definitions

- “Clinical treatment facility” means a medical setting , other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law
- “Recovery home” means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders



Terminology & Concepts

- Remuneration

- Cash
- Gifts
- Cash equivalents
- Anything of value

- Inducement

- Something intended to persuade someone

- Kickbacks

- The act of giving remuneration in order to induce a patient referral

- Patient Brokering

- The act of sending a patient to a particular program in exchange for remuneration



Exception for Bona Fide Employment Relationships

- EKRA has an exception for payments made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
 - (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
 - (B) the number of tests or procedures performed; or
 - (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory
- Bonuses should not be paid based on successful admissions and should not be related to the value or volume of referrals
- Payment for marketing services must be based on the fair market value of the services provided to the facility at a commercially reasonable rate

Exception for Personal Services and Management Contracts

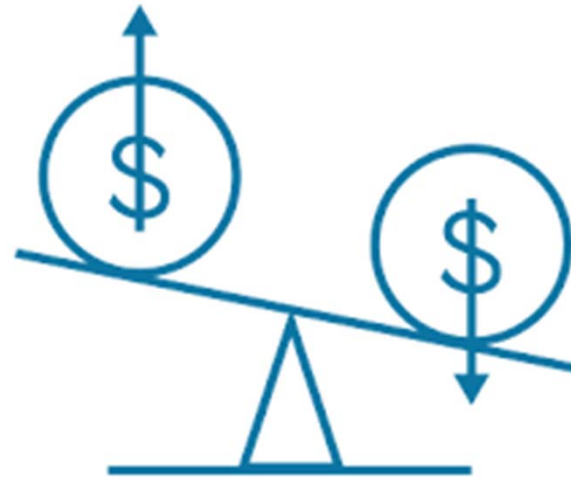
- EKRA has an exception for payments pursuant to a personal services or management contracts that meet the following requirements:
 - (1) The agreement is in writing and signed by the parties
 - (2) The agreement covers all of the services the provided for the term of the agreement and specifies the services to be provided
 - (3) If the agreement is intended to provide for the services on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals

Exception for Personal Services and Management Contracts

- (4) The term of the agreement is for not less than one year
- (5) The aggregate compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties
- (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services

Fair Market Value

- What are other employers paying?
 - Same relevant services
 - Similar geography
 - Similar cost of living
 - Employment pool



Commercial Reasonableness

- Compensation Relationship
 - Is the aggregate payment for the services consistent with practices in other places?
 - Considering aggregate compensation, and in the absence of referrals, would the relationship make sense?



Bed Vouchers

- Any sort of quid pro quo arrangement between businesses with regard to patient services is considered a kickback and prohibited under EKRA



Call Centers

- Treatment programs can operate their own call centers (subject to avoidance of deceptive practices), but paying outside call centers on a per patient basis for the value or volume of referrals is illegal
- Paying for the volume of call center or marketing services utilized at a commercially reasonable price is ok



Prohibition on Inducements

- EKRA prohibits offering anything of value to patients in exchange for using the services of the recovery home, clinical treatment facility, or laboratory
- Programs may not pay for a patient's travel to the facility
- Programs should not waive deductibles, co-insurance, and co-payments without determining whether the patient has a genuine and documented financial need
- Outpatient programs should not offer free or reduced rent at a sober home that they operate if the patient attends the IOP program



California SB 1228 Prohibits Patient Brokering

- SB 1228 went into effect on January 1, 2019 and prohibits patient brokering
- The California Department of Health Care Services (DHCS) recently issued its Information Notice 19-002, which provides guidance regarding compliance with SB 1228



California – New Disclosure Requirements

- Pursuant to a new law (Health and Safety Code § 11833.05(a)), licensed and/or certified addiction treatment programs are required to disclose the following information to DHCS:
 - Ownership or control of, or financial interest in, a recovery residence.
 - Any contractual relationship with an entity that regularly provides professional services or addiction treatment or recovery services to clients of programs licensed or certified by the department, if the entity is not part of the program licensed or certified by the department.



Additional California Laws

California Insurance Code section 750

- Prohibits any person who processes/presents/negotiates claims under policies of insurance from offering and accepting anything of value for the referral of clients
- Crime punishable by imprisonment in county jail and a fine of up to \$50,000

California Insurance Code section 1871.7

- Prohibits employing another person to procure clients whose claims will be the basis of a claim against an insurer
- Fine of \$5,000 to \$10,000, plus an assessment of up to three times the amount of each claim for compensation

California Health & Safety Code section 445

- Prohibits payments for referrals to “health-related facilities”
- Misdemeanor and may be punished by imprisonment in the county jail and/or a fine of up to \$5,000

Existing Fraud and Abuse Landscape

■ Anti-Kickback Statute



- a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).



- Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.



- Applies only to items and services payable under the Federal health care programs.

■ Existing Safe Harbors

How Does EKRA fit into Existing Framework?

18 U.S.C. section 220

Makes it illegal, with respect to services covered by a **health care benefit program**, in or affecting interstate or foreign commerce, to knowingly and willfully solicit, receive, offer, or pay any “remuneration” in return for referring a patient to, inducing a referral of an individual to (or in exchange for an individual using the services of a):

- **Recovery home**
- **Clinical treatment facility, or**
- **Laboratory**

How Does EKRA fit in?



- Statute addressed *prohibited* conduct but what about *permitted* conduct?



- Some of the safe harbors are consistent with the Anti-Kickback Statute (e.g., personal services) while others are not (e.g., employment).



- What does “refer a patient or patronage” or “use of services” mean?

What about Laboratories?



On its face, “laboratory” is defined very broadly in EKRA



“a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” 42 U.S.C. 263a



Not only limited to drug abuse-related testing



EKRA shall not apply to conduct that is *prohibited* under the Anti-Kickback

What Should Companies Do Now?



- Take careful, thoughtful steps to:
 - Review all existing arrangements with vendors and substance abuse treatment facilities
 - Review and audit physician prescription practices
 - Review and audit marketing activities
 - Examine employment relationships and compensation structures
- Consider how to fix or unwind potentially improper arrangements
- Consider if there are there any steps to mitigate exposure?
- Consider conducting this review with counsel under privilege
- Develop a compliance program

Questions?



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Upcoming Webinars

Office-Based Opioid Treatment: What You Need to Know: Trends in Behavioral Health Webinar Series

When: April 4, 2019 from 12:00 p.m. - 1:00 p.m. EST

For more information and to register, please visit www.ebglaw.com/events.



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