LABS, RECOVERY HOMES, AND CLINICAL TREATMENT FACILITIES, OH MY!
FOLLOW US DOWN THE EKRA BRICK ROAD

James A. Cannatti III, Partner
Tony Maida, Partner

ROADMAP

- Legislative Context
- Statutory Prohibition
- Exceptions and Comparison to the Federal AKS
- Open Questions
- Proposed Analytical Framework
THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT

- H.R. 6: The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
  - Bipartisan response to Nation's Opioid Epidemic
  - Over 50 separate bills, over 250 pages
  - Most provisions directly relate to opioid and substance abuse issues
  - Became effective on 10/24/2018

§ 8122: “ELIMINATING KICKBACKS IN RECOVERY ACT OF 2018” (“EKRA”), 18 USC 220

- Creates a new federal crime for paying “kickbacks” for referrals to recovery homes, clinical treatment facilities, and laboratories
- Violations would be punishable with criminal penalties, including monetary fines, imprisonment, or both
- EKRA does not preempt the federal anti-kickback statute (“Federal AKS”) or state laws on the same subject matter
EKRA LEGISLATIVE HISTORY

- It appears that EKRA originated out of a concern with certain “body broker” activity in connection with substance use disorder treatment centers and a perceived gap in federal law that could address that activity.
- “Patient brokering” or “body brokering” is a scheme in which the sober home, treatment center, or other provider pays third parties a “finder’s fee” for each patient that enters treatment.
- Oftentimes, these payments accompany providers accused of billing for unnecessary procedures or substandard treatment.

EKRA LEGISLATIVE HISTORY (CONT.)

- In a July 13, 2017 letter, a bi-partisan group of chair and ranking members of the House Committee on Energy and Commerce and certain subcommittees wrote to the Secretary of HHS raising several questions about the topic, including “are there adequate anti-kickback protections that would make [patient] brokering a violation of federal law?”
In response, HHS stated that “[t]o date, abusive payment arrangements involving opioid addiction treatment centers primarily have affected private health insurance plans . . . . The [Federal AKS] applies only to federal health care programs; it does not apply to privately insured patients.

Senators Rubio and Klobuchar, co-sponsors of a Senate version of the law, explained that EKRA would help prevent patient brokering and health care fraud

- “Too many Americans suffering as a result of the opioid epidemic are exploited by bad actors seeking to make a profit from addiction….This bill will help stop the cash flow for middlemen involved in illicit sober homes and paid referrals.” – Sen. Rubio
- “When people are struggling with addiction, their focus should be on getting well, not worrying whether the treatment facilities are trying to take advantage of them to make more money.” – Sen. Klobuchar

Emerging Theme: Preventing exploitation of vulnerable patients seeking addiction treatment by being misdirected to substandard providers by brokers
PRIOR PATIENT BROKERING LANDSCAPE

- DOJ has used other criminal statutes to pursue patient brokering, including
  - The Travel Act, 18 U.S.C. § 1952
  - Wire Fraud, 18 U.S.C. § 1343
  - Healthcare Fraud, 18 U.S.C. § 347
- Some states specifically prohibit patient brokering
  - Florida’s Palm Beach County has created a Sober Home Task Force to investigate patient brokering, resulting in more than 40 indictments and dozens of convictions to date under the Florida Patient Brokering Act
  - Texas Treatment Facilities Marketing and Admission Practices Act
    - Prohibits compensation to sales and marketing staff based upon: (i) patient admissions; (ii) calls/contacts with patients or non-physician referral sources; or (iii) determinations regarding length of inpatient stay
    - Requires sales and marketing personnel to identify themselves as working for the Texas-licensed facility

6 more arrested in sober home patient brokering crackdown

Patient-brokering case is county’s first to go to trial
ROADMAP

- Legislative Context
- Statutory Prohibition
- Exceptions and Comparison to the Federal AKS
- Open Questions
- Proposed Analytical Framework

EKRA – 18 USC 220

- For any services covered by a health care benefit program
- Whoever knowingly and willfully
  - Solicits or receives 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
  - Pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
    - to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
    - in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory
- Penalty: Fines of not more than $200,000, imprisonment of not more than 10 years, or both, for each occurrence
EKRA DEFINITIONS:
HEALTH CARE BENEFIT PROGRAM

- Any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract
  - Federal health care programs
  - Private insurance
  - Self-pay?

EKRA DEFINITIONS: RECOVERY HOME AND CLINICAL TREATMENT FACILITY

- Recovery Home: 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

- Clinical Treatment Facility: 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
EKRA DEFINITIONS: LABORATORY

- Labs are defined by reference to the CLIA statute, 42 U.S.C. § 263a
- This broad definition means that all laboratories, not just laboratories that perform toxicology screening, are subject to EKRA

ROADMAP

- Legislative Context
- Statutory Prohibition
- Exceptions and Comparison to the Federal AKS
- Open Questions
- Proposed Analytical Framework
EKRA EXCEPTIONS: SAME AS THE FEDERAL AKS

- Personal services and management contracts
- Discounts or other reductions in price obtained by a provider
- Discounts in drug prices from manufacturers under the Medicare Medigap program
- Remuneration provided to a federally qualified health center

EKRA EXCEPTIONS: PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Note that the statute permits payments made by a principal to an agent as compensation for services of the agent under an arrangement that meets the Federal AKS safe harbor ("SH") for personal services and management contracts, 42 CFR 1001.952(d), (as in effect on the date of enactment)
  - The Federal AKS SH is narrowly drafted to require aggregate payments be set in advance and that, in part-time arrangements, the agreement specify the schedule that services will be performed
  - If the Federal AKS SH were amended in the future, EKRA's exception would continue to follow the old version
EKRA EXCEPTION:
PATIENT COPAY WAIVERS AND DISCOUNTS

- EKRA’s exception appears to be broader than OIG’s guidance on the Federal AKS/Beneficiary Inducement Statute (“BIS”)
- EKRA:
  - Not routinely provided and provided in good faith
  - “Good faith” applies to waiver/discount generally
  - Advertising not prohibited
- Federal AKS/BIS:
  - Not routinely provided and provided after good faith determination that individual is in financial need or failure of reasonable collection efforts
  - “Good faith” applies to the financial need determination
  - No advertising copay waivers
  - See 42 CFR 1003.110 (remuneration definition)

EKRA EXCEPTION:
ALTERNATIVE PAYMENT MODELS

- This exception is not contained in the Federal AKS
- EKRA’s exception protects remuneration paid pursuant to an alternative payment model or pursuant to a payment arrangement used by a state, health insurance issuer, or group health plan “if the HHS Secretary has determined that such arrangement is necessary for care coordination or value-based care”
EKRA EXCEPTIONS:
EMPLOYEES AND CONTRACTORS

- EKRA’s exception provides more narrow protection for employee compensation than the Federal AKS
- EKRA:
  - Payments made by an employer to bona fide employees and independent contractors if the payment is not determined by or does not vary by:
    - the number of individuals referred;
    - the number of tests or procedures performed; or
    - the amount billed to or received from, in part or in whole, from a health care benefit program from the individuals referred
- Federal AKS:
  - Payments made by an employer to bona fide employees for the provision of covered items and services, 42 USC 1320a-7b(b)(3)(B), 42 CFR 1001.952(i)
  - Independent contractors are covered by the personal services and management contracts SH, 42 CFR 1001.952(d)

FUTURE RULE-MAKING

- Under EKRA, the Attorney General (in consultation with the Secretary of Health and Human Services) may, by regulation, clarify the statutory exceptions and create new exceptions
- This structure is opposite from the Federal AKS where the HHS Secretary may create new exceptions by regulation, in consultation with the Attorney General
FEDERAL AND STATE PREEMPTION

- Federal preemption: EKRA does “not apply to conduct that is prohibited under [the Federal AKS]”
  - The effect of this language is limited to preventing prosecution under both statutes for conduct involving federal health care programs
  - Conversely, the statute appears to allow prosecution under EKRA for conduct that is permitted under the AKS

- State preemption: EKRA is not to be construed to “occupy the field” to the exclusion of state laws on the same subject matter
  - Thus, states remain free to enact and enforce more stringent state laws on the topics covered by EKRA

---

### EKRA VS. FEDERAL AKS SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>EKRA</th>
<th>Federal AKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applies to:</td>
<td>Health care benefit program business (includes private payors)</td>
<td>Federal health care program business (excludes private payors)</td>
</tr>
<tr>
<td>Prohibits:</td>
<td>Referrals of patients or patronage and in exchange for using</td>
<td>Referrals of patients and arrange for/recommend purchasing</td>
</tr>
<tr>
<td>Covered Referrals:</td>
<td>To recovery homes, clinical treatment facilities, and laboratories</td>
<td>For any item or services payable by a Federal health care program</td>
</tr>
<tr>
<td>Penalties:</td>
<td>Up to $200,000, 10 years imprisonment, or both</td>
<td>Up to $100,000, 10 years imprisonment, or both</td>
</tr>
<tr>
<td>Protection for Payments to Bona Fide Employees</td>
<td>Limited protection</td>
<td>Broad protection</td>
</tr>
</tbody>
</table>
DOES EKRA APPLY TO MARKETING ARRANGEMENTS IN THE SAME WAY AS THE FEDERAL AKS?

- Meaning of "in exchange for ... using" and "patronage" vs. "arrange for or recommend"
- OIG described marketing as a “technical violation” of AKS that does not normally warrant prosecution and has developed a multifactor analysis for marketing arrangements that examines:
  - The nature and amount of compensation
  - The marketer’s identity and relationship to audience (“white coat”)
  - The nature of the marketing
  - The item/service being marketed
  - The target audience
HOW CAN AFFECTED PROVIDERS PAY EMPLOYEES BONUSES, ESPECIALLY SALES PERSONNEL?

- EKRA employment exception does not protect payments based on:
  - the number of individuals referred;
  - the number of tests or procedures performed; or
  - the amount billed to or received from, in part or in whole, from a health care benefit program from the individuals referred

- What about:
  - Net profit targets
  - EBITDA targets
  - Call wait times
  - Cost containment
  - Job performance criteria

WHAT IS THE SCOPE OF PERMITTED PATIENT ARRANGEMENTS?

- EKRA's copay waiver exception requires that the waiver be “non-routine” and “in good faith”

- OIG has stated that $15 per instance/$75 per year nominal remuneration is permitted under the beneficiary inducement statute
  - Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (December 7, 2016)
  - Can providers rely on this “nominal value” exception as a guidepost under EKRA?

- Can providers use the free or discounted transportation safe harbor or the promotes access to care exception as models for appropriate arrangements?
LOCAL TRANSPORTATION SAFE HARBOR
42 CFR 1001.952(bb)

- Made available by an “eligible entity”
  - “Eligible entity” means any individual or entity, except for those (or family members or others acting on their behalf) that primarily supply health care items
- The eligible entity that makes the transportation services available bears the cost of the free or discounted transportation and does not shift the burden of these costs to any federal health care program, other payors, or individuals
- The eligible entity establishes a transportation policy and applies it uniformly and consistently
- Drivers and others arranging for the transportation are not paid on a per-beneficiary-transported basis

LOCAL TRANSPORTATION SAFE HARBOR
42 CFR 1001.952(bb) CON’T

- Transportation only made available to:
  - An established patient of the eligible entity that is providing the transportation, if the eligible entity is a provider or supplier of services and an established patient of the provider or supplier to or from which the patient is being transported
    - “Established patient” means a person who has selected and initiated contact to schedule an appointment with a provider or supplier or who has previously attended an appointment with the provider or supplier
- Transportation is:
  - Within 25 miles of the provider or supplier to or from which the patient would be transported (or with 50 miles if the patient resides in a rural area)
  - For the purpose of obtaining medically necessary items and services
  - Not determined in a manner related to past or anticipated volume or value of federal health care program business
  - Not luxury, air, or ambulance-level
  - Not publicly marketed or advertised and no marketing occurs during transportation or by drivers
PROMOTES ACCESS TO CARE BIS EXCEPTION
42 CFR 1003.110

- Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—
  - Being unlikely to interfere with, or skew, clinical decision making;
  - Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
  - Not raising patient safety or quality-of-care concerns

WHY DOES EKRA APPLY TO ALL LABS?
HOW DO COMMON LAB ACTIVITIES FARE UNDER EKRA?

- Why Labs:
  - It is likely that the government’s scrutiny of urine drug testing billing contributed to the inclusion of labs in EKRA
  - However, EKRA is not, on its terms, limited to urine drug testing labs

- Common Lab Activities:
  - Phlebotomist in the physician’s office who only collects specimens for the lab
  - Supply specimen collection devices for sending specimens to the lab
    - Under an AKS analysis, neither of these activities constitute “remuneration” to the physician
    - The same analysis should apply to EKRA because Congress used the same term
ROADMAP

- Legislative Context
- Statutory Prohibition
- Exceptions and Comparison to the Federal AKS
- Open Questions
- Proposed Analytical Framework

PROPOSED ANALYTICAL FRAMEWORK

Preventing Exploitation of Substance Abuse Patients

- Increased Health Care Costs
- Overutilization of Care
- Corruption of Medical Decision-making
- Unfair Competition

Fair market value payment, unrelated to referrals, for legitimate and commercially reasonable services
QUESTIONS?

James A. Cannatti III  
• 202-756-8866
• jcannatti@mwe.com

Tony Maida  
• 212-547-5492
• tmaida@mwe.com