

EKRA: Marketing in a New World

G2 Intelligence - Lab Institute 2019

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Laboratory Marketing: The Old World

- ◆ Anti-Kickback Statute
 - ◆ Employment Safe Harbor
(42 C.F.R. 1001.152(i))
- ◆ Healthcare Fraud
 - ◆ All Payors
 - ◆ Aimed at payments to providers

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Laboratory Marketing: The New World

- ◆ On October 24, 2018, President Trump signed the SUPPORT ACT into law
- ◆ Contained the Eliminating Kickbacks in Recovery Act of 2018 (EKRA)
 - ◆ Intent: to prohibit individuals from referring substance abuse patients in exchange for kickbacks to recovery homes, clinical treatment facilities and laboratories.
 - ◆ Language, however, is broader and applies to otherwise legitimate arrangements that complied with existing Federal Law.

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EKRA - INTRODUCTIONS

- ◆ (a) **Offense.** Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully-
 - ◆ (1) solicits or receives any remuneration (including any kickbacks, 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) pays or offers any remuneration (including any kickbacks, 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.
 - ◆ Shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence. 18 USCS § 220

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EKRA - INTRODUCTIONS

EKRA –WHAT IS PROHIBITED?

- ◆ Soliciting or Receiving
 - ◆ Remuneration
 - ◆ Referral
 - ◆ Recovery home, clinical treatment facility, or laboratory
- ◆ Payments or offer of Remuneration
 - ◆ Intent
 - ◆ Induce a referral of an individual; or
 - ◆ In exchange for an individual using a laboratory

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EKRA - INTRODUCTIONS

WHAT IS A LABORATORY?

- ◆ 42 USC 263(a) – A facility for the biological, microbiological, serological, chemical, immuno-hematological, 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.
 - ◆ In otherwords, All Laboratories!

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EKRA - INTRODUCTIONS

WHAT IS A REFERRAL?

- ◆ Similar to AKS, not defined
- ◆ Who can make a referral?
 - ◆ No case law or guidance
 - ◆ “Relevant Decision Makers”?
 - ◆ Advisory Opinion 98-10

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EKRA - INTRODUCTIONS

“RELEVANT DECISION MAKER”

- ◆ Set forth in U.S. v. Miles, 360 7. 3d 472
 - ◆ Payments to P.R. Firm to distribute literature on home health agency
 - ◆ Conviction reversed: Payee not “relevant decision maker.”
 - ◆ Clarified in subsequent cases, including *U.S. v. Shoemaker*.

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EKRA - INTRODUCTIONS

ADV. OPINION 98-10

- ◆ Issued by the HHS OIG in 1998
- ◆ Analyzed an agreement between a sales agency and a medical supply manufacturer
- ◆ 6 Factors
 - ◆ Compensation based on percentage of sales;
 - ◆ Direct billing of a federal healthcare program by the seller for the item or service sold by the sales agent;
 - ◆ Direct contact between the sales agent and physician in a position to order items or services that are then paid for by a federal healthcare program;
 - ◆ Direct contact between the sales agent and federal healthcare program beneficiaries; and
 - ◆ Use of sales agents who are healthcare professionals or persons in a similar position to exert undue influence on purchasers...
 - ◆ Marketing of items or services that are separately reimbursable by a federal healthcare program.

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EKRA - INTRODUCTIONS

RELEVANT EXCEPTIONS

- ◆ Payment by an employer to an employee, or independent contractor (who has bona fide employment relationship or contractual relationship) for employment, if the payment is not determined by or does not vary, by
 - ◆ (a) Number or individuals referred to laboratory
 - ◆ (b) Number of tests performed
 - ◆ (c) The amount billed to or received from health care benefit program
- ◆ Personal Services and Management Contracts

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EKRA - INTRODUCTIONS

AKS V. EKRA

APPLICATION

AKS

Federal healthcare program

"Referral"

"Recommend or Arrange"

ALL Providers & Suppliers

EKRA

All Healthcare programs, including commercial plans

"Referral"

N/A

ONLY recovery homes, residential treatment centers, clinical laboratories

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EKRA - INTRODUCTIONS

AKS V. EKRA

EXCEPTIONS

AKS

Payment to bona fide employee

collected

Personal Services and Management Contracts

Leases

EKRA

Payment to Employee but only if payment does not vary based on number of tests, patients referred, and amount billed or

Personal Services and Management Contracts

N/A

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EKRA – QUESTIONS RAISED

BIG Issues for Laboratories

- ◆ Sales Representative Compensation
- ◆ Accountable Care Organizations
- ◆ Leases

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EKRA – QUESTIONS RAISED

Are Commission-Based Payments Permissible?

- ◆ No Exception/Safe Harbor
- ◆ Some commentators have taken position that by including a statutory exemption for non-commission payments that Congress indicated commission-based compensation is prohibited.
 - ◆ Does the Statute facially prohibit commission-based payments to W-2 personnel?
 - ◆ Does the “otherwise prohibited” language permit it?
 - ◆ Does the omission of “recommending” permit it?

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EKRA – QUESTIONS RAISED

May Clinical Laboratories Participate in Accountable Care Organizations?

- ◆ PPACA authorizes the Sec of HHS to develop fraud and abuse waivers
- ◆ Fraud and abuse waivers only apply to AKS and Stark
- ◆ Donating items and services to ACO, may implicate EKRA

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EKRA – QUESTIONS RAISED

May Laboratories Lease Collection Space Directly From Physician Practices?

- ◆ Laboratories often have a need to maintain a collection office in or near a high-volume practice that necessitates renting space owned by a referring physician or group
- ◆ AKS and the Stark law contain an exception/safe harbors for leases
- ◆ EKRA, however, does not contain a relevant exception
- ◆ Must be to induce a referral
 - ◆ Intent?
 - ◆ General: The person intended to perform the act in question.
 - ◆ Specific: (1) Desire to commit an international unlawful act; and (2) intend for that unlawful act to achieve a specific result.

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EKRA – WHAT DO WE DO NOW?

Compensation Arrangements

The diagram shows a horizontal spectrum. On the left is a green-bordered box containing the word 'SAFE'. In the middle is a grey rectangular box. On the right is a red-bordered box containing the words 'Per Se illegal'. Below the spectrum, a double-headed arrow points from left to right. Above the arrow is the word 'Risk' and below it is the word 'Analysis'.

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EKRA – WHAT DO WE DO NOW?

What is Safe?

- ◆ Bona Fide Employee
 - ◆ Salary
 - ◆ Annual Adjustments
 - ◆ Incentive Compensation not tied to number of test, amount billed or collected
 - ◆ Hours worked
 - ◆ Number of calls, presentations made
 - ◆ Bonus tied to number of accounts signed up
 - ◆ Customer satisfaction surveys

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EKRA – WHAT DO WE DO NOW?

What is Safe? (Cont.)

- ◆ Independent Contractor (EKRA & AKS)
 - ◆ Writing
 - ◆ Fixed fee, Set in advance
 - ◆ Specifies schedule of services
 - ◆ At least one year

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EKRA – WHAT DO WE DO NOW?

What is Grey?

- ◆ Wait and see on treatment of bona fide employees
 - ◆ DOJ Guidance
 - ◆ Congressional clarification
- ◆ Increased monitoring of sales force (audits, certifications), *i.e.* treat arrangements as you treated Pre-EKRA Independent Contractor arrangements
 - ◆ We are not a toxicology lab

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EKRA – WHAT DO WE DO NOW?

Accountable Care Organizations

- ◆ Are donations to ACO indirect Remuneration?
 - ◆ “Induce Referral?”
- ◆ Personal Services & Management Contract Safe Harbor?

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EKRA – WHAT DO WE DO NOW?

Leases

- ◆ No Protection
- ◆ Must show “Intent to Induce”
 - ◆ Level of Intent
 - ◆ Facts & Circumstances
 - ◆ Need for Space
 - ◆ Bargain for

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Questions?

THANK YOU

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