
ELIMINATING KICKBACKS IN RECOVERY ACT OF 2018

EKRA – A NEW ANTI-KICKBACK LAW

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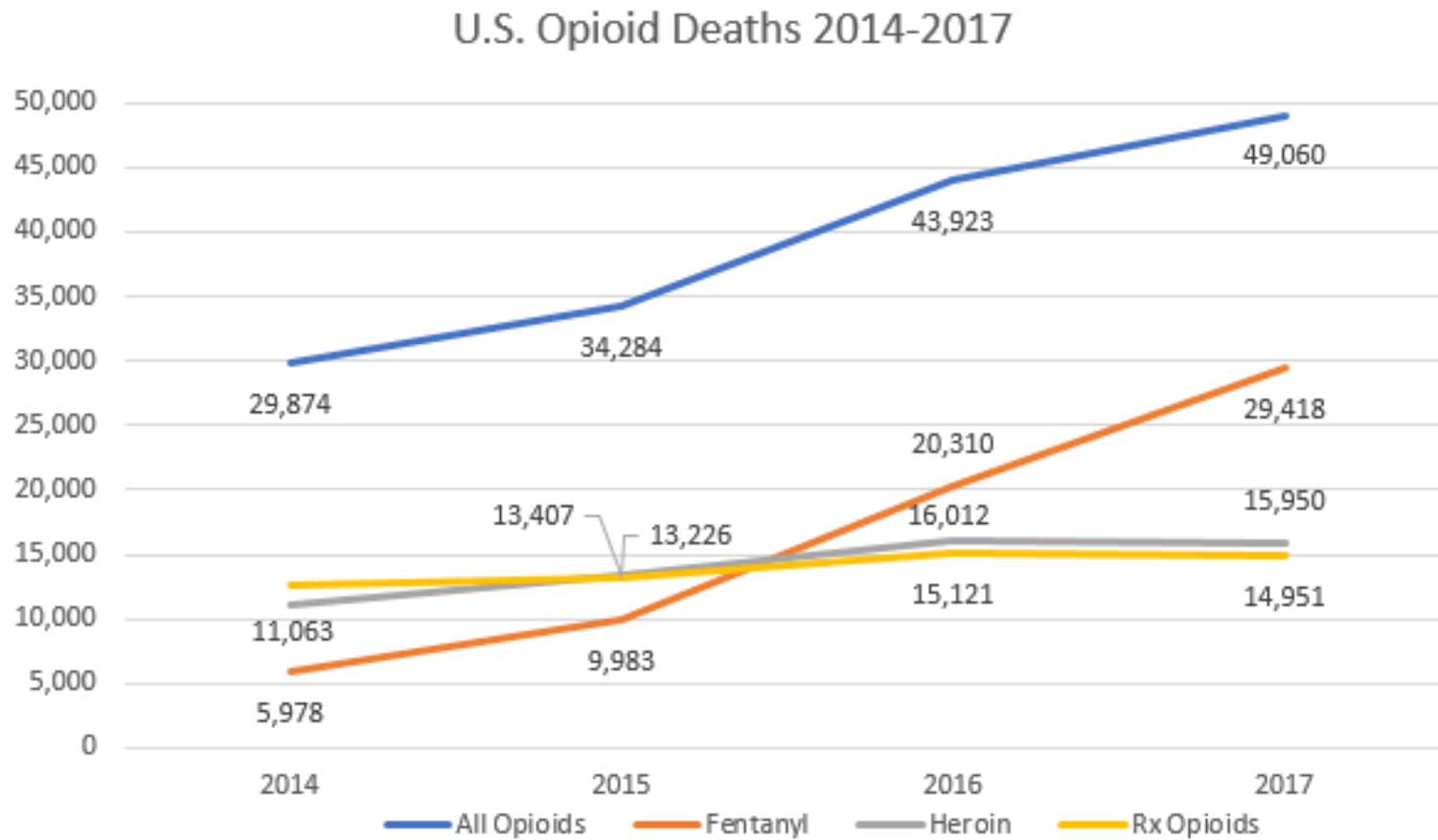
WHAT IS EKRA?

- Congress' attempt to prohibit people from referring substance abuse patients to recovery homes, clinical treatment facilities and laboratories in exchange for kickbacks

CONGRESSIONAL INTENT



TARGET: OPIOIDS



THE OPIOID EPIDEMIC BY THE NUMBERS



130+

People died every day from
opioid-related drug overdoses³
(estimated)



11.4 m

People misused
prescription opioids¹



47,600

People died from
overdosing on opioids²



2.1 million

People had an opioid use
disorder¹



886,000

People used heroin¹



81,000

People used heroin
for the first time¹



2 million

People misused prescription
opioids for the first time¹



15,482

Deaths attributed to
overdosing on heroin²



28,466

Deaths attributed to
overdosing on synthetic
opioids other than
methadone²

SOURCES

1. 2017 National Survey on Drug Use and Health, Mortality in the United States, 2016
2. NCHS Data Brief No. 293, December 2017
3. NCHS, National Vital Statistics System. Estimates for 2017 and 2018 are based on provisional data.

THE SUPPORT ACT

- **The “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act”**
- **Large number of separate “Acts”**
 - 120 different “Acts”
- **Health industry sectors impacted by the Support Act:**
 - just about everyone
- **EKRA is just one of the 120 Acts in the Support Act**
 - Last minute addition to the Support Act (!)
 - Controversy regarding its vetting

THE POINT OF EKRA

- Prohibit individuals from referring substance abuse patients, in exchange for kickbacks to recovery homes, clinical facilities, and laboratories
- Congressional concerns: patient brokering and referrals to substandard or fraudulent providers

WHERE TO FIND EKRA

- 18 U.S.C. Section § 220
- Where to find the law on the internet:
 - [http://uscode.house.gov/view.xhtml?req=\(title:18%20section:220%20edition:prelim\)](http://uscode.house.gov/view.xhtml?req=(title:18%20section:220%20edition:prelim))

THE LANGUAGE OF EKRA

(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-

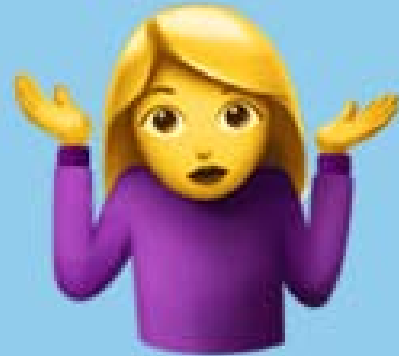
(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

(2) pays or offers 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, shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

WHAT IS COVERED BY EKRA?



THE LANGUAGE OF EKRA –HEALTH CARE BENEFIT PROGRAM

(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 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

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“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.”
 - 18 U.S.C. § 24

PAYORS OR JUST GOVERNMENT PAYORS?

- EKRA is an “all payor” statute
 - It applies to all payors, not just government payors
 - Typically regulated by state governments, not the federal government
 - Raises compliance challenges

THE LANGUAGE OF EKRA – SOLICITS OR RECEIVES

(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 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

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THE LANGUAGE OF EKRA – PAYS OR OFFERS

(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 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

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THE LANGUAGE OF EKRA – CASH OR IN KIND

(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 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) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, **in cash or in kind**-

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THE LANGUAGE OF EKRA - REFERRALS

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(2) pays or offers 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, shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

THE LANGUAGE OF EKRA – ENTITIES COVERED

(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-

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RECOVERY CENTERS

- “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.
 - 18 USC § 220 (e)(5)

CLINICAL TREATMENT FACILITY

- “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.
 - 18 USC § 220 (e)(2)

LABORATORIES



LABORATORIES

- Laboratories are 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.”
 - 18 USC § 220
 - 42 USC § 263a

WHAT LABORATORIES ARE COVERED BY EKRA?

- Thrown into the statute at the last minute
- The language of EKRA is not limited to toxicology providers
- All clinical laboratories potentially affected by the new law
- Potentially targets marketing arrangements that might have been acceptable before EKRA became the law
 - Compensation to employees based on the number of individuals referred to the lab?
 - Compensation to marketing employees based on the number of tests or procedures performed?
 - Compensation to marketing employees based on the amount billed or received by the payors?

CRIMINAL PENALTIES

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(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.

- “for each occurrence”

EKRA EXCEPTIONS

- (1) discounts obtained by service providers, if disclosed and reflected in the costs claimed;
- (2) payments made by an employer to an employee / independent contractors as long as those payments are unrelated to referrals, tests, amounts billed;
- (3) discounts by drug manufacturers provided under the Medicare coverage gap discount program;
- (4) payments to agents that meet the personal services and management contracts safe harbor under the federal Anti-Kickback Statute set forth at 42 U.S.C. § 1320a-7b(b) (AKS);
- (5) waivers or discounts of coinsurance / copayments by a health care benefit program, if the waiver is not routinely provided and it is provided in good faith;
- (6) certain remuneration between healthcare entities and an individual related to the availability / quality of services provided to medically underserved populations;
- (7) remuneration made pursuant to alternative payment models (or other models HHS determines are necessary for care coordination or value-based care); and
- (8) any other regulatory safe harbor that the Attorney General and HHS determine are clarifications of the other exceptions.

RELATIONSHIP TO ANTI KICKBACK STATUTE

- The Anti Kickback Statute:
 - makes it improper for anyone to solicit, receive, offer or pay remuneration in exchange for referring patients to receive certain services that are paid for by the government.
 - 42 U.S.C. § 1320a-7b(b)
- Relationship to EKRA?
 - EKRA viewed as an expansion of Anti Kickback Statute
 - AKS and EKRA exceptions do not entirely overlap
 - EKRA exceptions look more narrow than AKS exceptions
 - Arrangements prohibited by AKS not subject to additional EKRA liability
- No reference to STARK in EKRA

WHAT IF YOUR STATE HAS A SIMILAR LAW?

- EKRA shall “not be construed to occupy the field in which any provisions of EKRA operate to the exclusion of state laws on the same subject matter.”
- If your state has a law that deals with similar issues, does the state law apply or does EKRA preempt the state law?
- What if state laws are inconsistent with EKRA?

WHAT IS NEXT?

- Potential for new regulations interpreting EKRA, and particularly the exceptions
 - Will regulations address state / federal confusion?
 - Will regulations address intersection of EKRA, AKS and STARK?
- Will the Federal Government reduce the scope of EKRA?
- New tool for prosecutors – who will be the first guinea pigs?
- Case law interpretations

PRACTICAL ADVICE

- Criminal penalties are very serious
- Expect and budget for increased compliance costs
- Review financial relationships, especially for laboratories
 - Collect contracts and other related documents
 - Raise the issue with internal compliance personnel
- Be mindful of all financial relationships, not just marketing arrangements
 - Employees & Independent Contractors
- If in doubt, lean toward conservative approach
- Get legal help in reviewing those relationships

CONCLUSION

- Our webinar has been recorded, and materials will be available on our blog:
 - <https://www.hhhealthlawblog.com/>
- Additional questions?



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THANK YOU