AKS and EKRA Enforcement

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AKS and EKRA Similarities and Differences

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THE AKS: BREAKING IT DOWN

- AKS prohibits knowingly and willfully:
  - Offering, paying, soliciting, or receiving (by anyone, including non-providers)
  - Anything of value ("**remuneration**") (directly or indirectly, in cash or in kind)
  - In return for or to induce 1) **referrals;** 2) purchasing, leasing, ordering; or 3) **arranging for or recommending** purchasing, leasing, or ordering of
  - Items or services paid for, in whole or in part, by a **federal health care program**
- **Bottom Line: No payments to induce referrals or purchases of federal health care program items and services**

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THE AKS: BREAKING IT DOWN (CONT.)

- Note: Anti-Kickback Statute (unlike Stark Law) is not just concerned with referrals
  - Purchase, lease or order – means even common and unremarkable inducements by manufacturers, wholesalers, retailers, health care suppliers, facilities, providers and practitioners and others can implicate the AKS; examples include:
    - Discounts, rebates, and value-added items and services by manufacturers or wholesalers
    - Routine waiver of patient's cost-sharing by a hospital or medical practice
    - Patient assistance program funded by one or more pharma companies
  - Arranging for or recommending the purchase, order or lease – means even common and unremarkable payments to group purchasing organizations (i.e., administrative fees) and payments to sales and marketing organizations implicate the AKS

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THE AKS: ENFORCEMENT PENALTIES

AKS Enforcement Exists in Three Forms	
Criminal	AKS is a criminal statute: Felony subject to up to $100,000 fine and 10 years in prison
Civil	Civil prosecution under False Claims Act: • Up to 3 times damages and $27,018 penalty per claim • Settlements typically range 2-3 times damages • Corporate Integrity Agreement (CIA) with HHS Office of Inspector General (OIG)
Administrative	• Civil money penalties of up to 3 times amount of kickback and $112,131 per kickback • Exclusion from participation in federal health care programs

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AKS ANALYTICAL FRAMEWORK: PURPOSE OF AKS IS TO PREVENT FOUR PROBLEMS

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AKS: THE ONE PURPOSE TEST AND INTENT

- Courts have incorporated a "one purpose" test to the AKS' intent question
  - Is "one purpose" to induce referrals?
  - Other legitimate purposes do not cure
  - Some circuits, such as the First, adopted a "primary" purpose test
- Evaluating the commercial reasonableness of an arrangement often can help analyze this test
- Indicia of intent – found in emails, texts, financial projections, board materials, etc.

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AKS: STATUTORY AND REGULATORY "SAFE HARBORS"

- Protect certain arrangements even if intent is to induce referrals
- Must meet all elements
- Voluntary
- Narrowly drafted
- Many of OIG's safe harbors were created in the 1990s
- Few deal expressly with patient remuneration

STATUTORY EXCEPTIONS (42 USC § 1320a-7b(b)(3))

- Discounts / Price Reductions
- Employee Compensation
- GPO Arrangements
- Coinsurance Waivers by FQHCs
- HHS Specified Practices (i.e., Safe Harbors)
- Certain Risk Sharing Arrangements
- Pharmacy Part-D Cost-Sharing Waivers
- Remuneration Between FQHCs and MA Organizations
- Remuneration Between Health Centers and Service Providers
- Discounts on Applicable Drugs Under the Medicare Coverage Gap Discount Program
- Incentive Payments to Beneficiaries under an ACO Beneficiary Incentive Program
- Bona Fide Mental and Behavioral Health Improvement and Maintenance Programs

REGULATORY SAFE HARBORS (42 CFR § 1001.952)

a. Investment Interests
   - Large Investment Safe Harbor
   - Small Investment Safe Harbor
   - Rural Investment Safe Harbor
b. Space Rental
c. Equipment Rental
d. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements
e. Sale of Practice
f. Referral Services
g. Warranties
h. Discounts
i. Employee Compensation
j. Group Purchasing Organizations
k. Certain Waivers of Beneficiary Copayments, Coinsurance, and Deductible Amounts
l. Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
m. Price Reductions Offered to Health Plans
n. Practitioner Recruitment
o. Obstetrical Malpractice Insurance Subsidies
p. Investments in Group Practices
q. Cooperative Hospital Services Organizations
r. ASCs
   - Surgeon-Owned ASCs
   - Single-Specialty ASCs
   - Multi-Specialty ASCs
   - Hospital/Physician ASCs
s. Referral Arrangements for Specialty Services
t. Price Reductions Offered to Eligible Managed Care Organizations
u. Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations
v. Ambulance Replenishing
w. Health Centers
x. Electronic Prescribing Items and Services
y. Electronic Health Records Items and Services
z. Federally Qualified Health Centers and MAOs

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REGULATORY SAFE HARBORS (CONT.)

aa. Medicare Coverage Gap Discount Program
bb. Local Transportation
ee. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency
ff. Value-Based Arrangements With Substantial Downside Financial Risk
gg. Value-Based Arrangements With Full Financial Risk
hh. Arrangements For Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency
ii. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives
jj. Cybersecurity Technology and Related Services
kk. ACO Beneficiary Incentive Program

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HOW DOES THE AKS APPLY?

- Employment
- Service Line management
- Joint Ventures
- Value-Based Arrangements
- Medical director/coverage
- Product design and development
- Consultants / speakers' bureau
- Research grants or payments for collecting data
- Samples
- Medical education sessions
- Gifts / entertainment / meals
- Product discounts and rebates / other price concessions
- Sales and marketing
- Clinical decision support tools
- Patient engagement activities
- Charitable donations
- Patient support – hubs/prior authorization/appeals

HOW TO MANAGE AKS RISK

- Training
- Training
- Training
- Monitoring and auditing
- Internal reporting and investigations
- Conflict of interest reporting
- Contract approval process
- Asking for an Advisory Opinion
- Seek legislative changes

State EQUIVALENT LAWS

- AKS applicable only to **federal health care program** payors
- Some states have state-equivalent AKS statutes that apply broadly to **all payors**
- Other states have AKS laws that are limited to **Medicaid**
  - State laws prohibit bribes, kickbacks, referral fees, and other conduct
  - Some are applicable only to certain providers (physicians, dentists)
  - Sometimes separate patient brokering laws
- Compliance with federal safe harbor/exception will usually (but not always) be protected under state law

STATES WITH ALL-PAYOR AKS OR BROAD SELF-REFERRAL LAWS:

- California
- Colorado
- Florida
- Massachusetts
- Maryland
- Michigan
- New Jersey
- New York
- Ohio
- Oklahoma
- Pennsylvania
- South Carolina
- Tennessee
- Texas

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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
  - SUPPORT Act § 1822: The Eliminating Kickbacks in Recovery Act (EKRA)

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EKRA – 18 U.S.C. § 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

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EKRA TERMS DEFINED

- **Health Care Benefit Program** – The term "health care benefit program" has the meaning given the term in 18 U.S.C. 24(b).
- **Recovery Home** – Shared Living Environment centered on peer support and connection to services that promote sustained recovery from substance use disorders. 18 U.S.C. § 220(e)(5)
- **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.18 U.S.C. § 220(e)(2)
- **Laboratory** – 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 U.S.C. § 220(e)(4); 42 U.S.C. § 263a(a). [a facility for the testing of materials derived from the human body, such as urine and blood sample, for the purpose of providing information for the diagnosis, prevention, or treatment of addiction].
- **Remuneration** – Any kickback, bribe, or rebate, directly or indirectly, covertly or overtly, in cash or in kind. 18 U.S.C. § 220(a).

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EKRA SAFE HARBORS

EKRA defines seven statutory safe harbors and no regulatory safe harbors:

1. Properly disclosed discounts in price;
2. Payments to employees that do not vary based on referrals;
3. Part D drug discounts;
4. Payments that comply with the Anti-Kickback Statute safe harbor for personal services;
5. Co-insurance and copay waivers that are not routinely provided;
6. payments to federally qualified health clinics; and
7. payments under defined or approved alternative payment models.

18 U.S.C. 220(b)(1)-(7)

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EKRA EXCEPTIONS: EMPLOYEES AND CONTRACTORS

- EKRA's exception is narrower than the 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
  - Pre-2021 version of the AKS personal services and management contracts safe harbor
    - Means the aggregate compensation needs to be set in advance.
    - 2021 revision changed the requirement to the compensation methodology needs to be set in advance
- Federal AKS:
  - Payments made by an employer to *bona fide* employees for the provision of covered items and services
  - Independent contractors are covered by the personal services and management contracts SH

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EKRA vs. Federal AKS Summary

	EKRA	Federal AKS
Applies to:	Health care benefit program business (includes private payors)	Federal health care program business (does not include exclusively private payors)
Prohibits:	Referrals of patients or patronage and in exchange for using	Referrals of individuals and arrange for/recommend purchasing etc.
Covered Referrals:	To recovery homes, clinical treatment facilities, and laboratories	For any item or services payable in whole or in part under a Federal health care program
Penalties:	Up to $200,000, 10 years imprisonment, or both	Up to $100,000, 10 years imprisonment, or both
Protection for Payments to *Bona Fide* Employees	Limited protection	Broad protection

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SALES AND MARKETING

- The AKS covers sales and marketing activities under the "arrange for or recommend" prong
- OIG has labeled marketing as "technical violation" that often does not merit prosecution
- AKS
  - Employment safe harbor protects legit employee arrangements
  - Independent contractor marketers are common, but not likely safe harbored if commission or other variable fee
- EKRA
  - More restrictive employment exception than AKS
  - Uses the pre-2021 personal services safe harbor
  - Note that EKRA exceptions function the same as AKS safe harbors – not falling within in one is not a per se violation.

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INDEPENDENT CONTRACTOR ENFORCEMENT IN LABS

- Genotox, a Texas laboratory, agreed to pay at least $5.9 million to resolve FCA allegations that it paid percent-of-revenue-based commissions to independently contracted sales reps and third-party marketing firms to arrange for or recommend its labs in violation of the AKS.
  - The settlement also addresses allegations that the laboratory submitted claims to federal health care programs for lab tests that did not meet coverage requirements, specifically tests prescribed to all of a physician's patients under routine "blanket" or standing orders.
  - The laboratory provided "custom profile" order forms to prescribers that let them pre-select certain tests to be performed on their patients on a general, as opposed to a patient-specific, basis.
  - The laboratory also entered into a five-year corporate integrity agreement with OIG.
  - To resolve parallel criminal proceedings, the lab entered into an 18 month Deferred Prosecution Agreement with the US Attorneys' Office for the Western District of Texas
  - https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and

INDEPENDENT CONTRACTOR ENFORCEMENT IN LABS

- **U.S. v. Mallory**, 988 F.3d 730 (4th Cir. 2021)
  - Appeal of jury verdict; held that a lab's commission-based payments to a marketing firm and that firm's commission-based payments to its independent contractor sales representatives violated the AKS
    - Case also included allegations of paying excessive "processing and handling" fees to physicians to induce ordering the lab's tests
  - Court agrees with DOJ's asserted position that the AKS prohibits commission payments to independent contractor sales agents
    - The court discussed the preamble regarding employment but ignored other language regarding marketing and OIG's longstanding marketing factors

EKRA'S SCOPE

S&G Labs Hawaii, LLC vs. Graves (D. Haw.)

EKRA does not apply to commission-based sales arrangements when the employee markets a lab's tests to ordering providers and other sources of lab referrals, but not to individuals who receive the lab services

versus

US vs. Schena (N.D. Cal.)

EKRA does not require direct interaction between the marketer and the individual using the lab; plain meaning of "to induce a referral of an individual" extends to where a marketer causes an individual to obtain a referral from a physician

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SALES AND MARKETING - QUESTIONS TO ASK AND NOTABLE INFORMATION

- What is the compensation structure and trigger and how close or attenuated is that trigger from the delivery of a reimbursable item or service?
- Is the marketer a health care professional or in a position of trust for a beneficiary?
- Who is the intended target?
  - Are federal patients targeted? All prospective patients? B2B?
- What item or service is being marketed?
  Separately billed or bundled?
- What is the nature of the marketing?
  In-person, telemarketing, TV, internet, etc.

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CURRENT STATE OF MARKETING COMPENSATION

- Many organizations have paid, and continue to pay, independent contractor sales agents (and employees) on a commission basis
  - Relying on OIG marketing factors and that numerous CIAs involving marketing did not prohibit commission payments to independent contractors
- *Mallory* and *Genotox* arguably had "plus factors" present
- Takeaways:
  - Carefully consider marketing relationships
  - Evaluate employment as an option
  - Note application of EKRA and state laws (which DOJ has pursued through the Travel Act)
  - Ensure arrangement otherwise not raise concerns (e.g. physician payments)

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Criminal AKS and EKRA Enforcement

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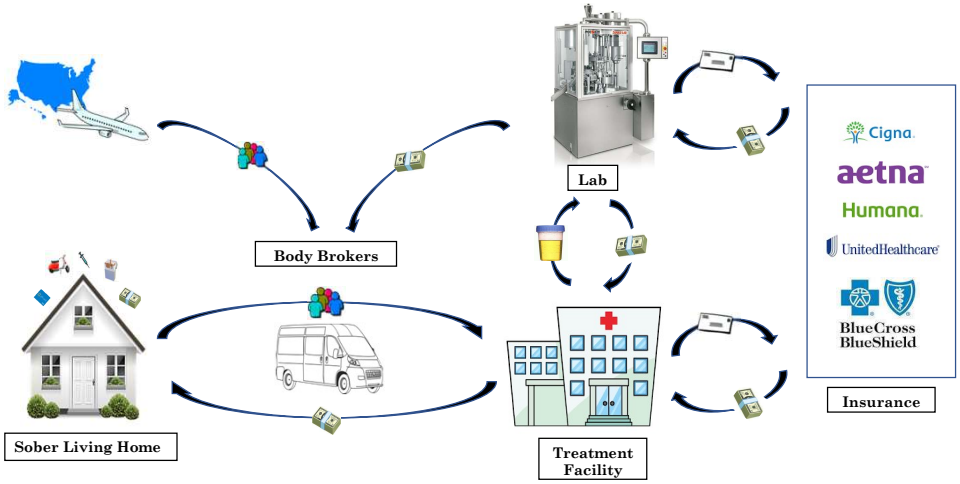
The Problem: Health Care Fraud and Brokering of Addicted Patients



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Basic Terms & Recovery—How It Should Work

- Addict must want to become sober—sober living environment, abstinence, and treatment.
- **Sober Home:** Sober living environment. Like a halfway house.
- **Treatment Center/Facility:** Place where therapy and treatment is provided.
- **Substance Abuse/Addiction Treatment:** Clinical therapy to reinforce abstinence, develop coping skills, identify underlying reasons for substance abuse.
  - **Medically assisted detoxification ("Detox"):** Medically supervised withdrawal from drugs or alcohol, designed to treat acute withdrawal symptoms. Not a treatment, but first step that prepares client for treatment.
  - **Partial Hospitalization Program ("PHP"):** Requires client to report for treatment 5 days a week for 6 to 8 hours a day. Can last 2 weeks to 3 months.
  - **Intensive Outpatient Program ("IOP"):** Requires client to report for treatment 3 to 5 days a week for 4 to 6 hours a day. Can last 30 to 60 days, and then transition to outpatient treatment.
  - **Outpatient Treatment ("OP"):** Requires client to report for treatment 1 to 3 days a week for 1 to 3 hours a session. Can last several months.
- **Medications**: Buprenorphine, Suboxone, benzodiazepines ("benzos")
- **Urinalysis ("UA") Testing:** Designed to monitor sobriety and medications.

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Red Flags Indicating Possible Fraud

- Citizen Complaints
- SIU Referrals
- Code Enforcement Referrals
- Increase in Drug Overdoses
- New Facilities – 100% Capacity
- Solicitation of Addicts; Addicts from out of state
- Co-ed Housing
- Billing for UAs 3 or 4 times per week
- Vans to Various Laboratories/Treatment Centers
- Social Media Activity/Marketing
- Suboxone/Benzos prescribed together and in bulk

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Urinalysis—Point of Care Testing

- POC testing involves collecting the patient's urine in a cup
- The specimen is analyzed using a color-banded or numbered dipstick enabling visual results. (E.g., "+" or "–")
- Tests for 9 to 13 panels.
- Cups cost between $5 and $10 each and can be easily read.

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FLORIDA -- F.S.S. 817.505 Patient Brokering Statute

(1) UNLAWFUL TO:

(A) OFFER OR PAY…TO INDUCE THE REFERRAL OF PATIENTS OR PATRONAGE TO OR FROM A HEALTH CARE PROVIDER/FACILITY;

(B) SOLICIT OR RECEIVE PAYMENT…IN RETURN FOR REFERRING PATIENTS OR **PATRONAGE** TO OR FROM A HEALTH CARE PROVIDER /FACILITY;

(C) SOLICIT OR RECEIVE ANY PAYMENT… IN RETURN FOR TREATMENT FROM A HEALTH CARE PROVIDER OR HEALTH CARE FACILITY; OR

(D) AID, ABET, ADVISE, OR OTHERWISE PARTICIPATE IN THE ABOVE CONDUCT.

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Urinalysis—Lab-Based Testing

- Lab-based urine drug testing uses liquid chromatography-mass spectrometry and/or gas chromatography to analyze the specimen.
- Highly sensitive, accurate, and definitive in identifying substances (e.g., synthetic opioid) and metabolites.

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One Cup of Urine

Test Date	CPT	Drug Tested	Billed
3/11/2014	80154	BENZODIAZEPINES	$ 381.45
3/11/2014	83925	OPIATE(S), DRUG AND METABOLITES, EACH PROCEDURE	$ 1,283.52
3/11/2014	83789	MASS SPECTROMETRY AND TANDEM MASS SPECTROMETRY (MS, MS/MS), ANALYTE [illegible]ERE SPECIFIED; QU	$ 1,116.90
3/11/2014	82542	COLUMN CHROMATOGRAPHY/MASS SPECTOMETRY (EG, GC/MS, OR HPLC/MS), AN[illegible]OT EL[illegible]WHERE SPECIFIED;	$ 297.84
3/11/2014	82646	DIHYDROCODEINONE	$ 85.17
3/11/2014	82649	DIHYDROMORPHINONE	$ 106.02
3/11/2014	80166	DOXEPIN	$ 127.80
3/11/2014	80299	QUANTITATION OF DRUG, NOT ELSEWHERE SPECIFIED	$ 169.47
3/11/2014	80184	PHENOBARBITAL	$ 47.22
3/11/2014	83992	PHENCYCLIDINE (PCP)	$ 60.60
3/11/2014	80182	NORTRIPTYLINE	$ 55.89
3/11/2014	83840	METHADONE	$ 134.70
3/11/2014	83805	MEPROBAMATE	$ 145.38
3/11/2014	82145	AMPHETAMINE OR METHAMPHETAMINE	$ 192.24
3/11/2014	80160	DESIPRAMINE	$ 70.98
3/11/2014	82492	CHROMATOGRAPHY, QUA[illegible]T[illegible]LUMN (EG, GAS LIQUID OR HPLC); MULTIPLE ANALYTES, SINGLE STATIO	$ 74.46
3/11/2014	82205	BARBITURATES, NOT ELSEWHERE SPECIFIED	$ 47.22
3/11/2014	82520	COCAINE OR METABOLITE	$ 62.49
3/11/2014	80152	AMITRIPTYLINE	$ 73.83
3/11/2014	80174	IMIPRAMINE	$ 70.98
3/11/2014	82570	CREATININE; OTHER SOURCE	$ 80.00
3/11/2014	84311	SPECTROPHOTOMETRY, ANALYTE NOT ELSEWHERE SPECIFIED	$ 28.83
3/11/2014	83986	PH, BODY FLUID, EXCEPT BLOOD	$ 30.00
3/11/2014	81003	URINALYSIS, BY DIP STICK OR TABLET REAGENT FOR BILIRUBIN, GLUCOSE, HEMOGLOBIN, KETONES, LEUKOCYTES,	$ 9.18
3/11/2014	83925	OPIATE(S), DRUG AND METABOLITES, EACH PROCEDURE	$ 721.98
3/11/2014	83789	MASS SPECTROMETRY AND TANDEM MASS SPECTROMETRY (MS, MS/MS), ANALYTE NOT ELSEWHERE SPECIFIED; QU	$ 819.06
			$6,293.21

$6,392.21

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C.D. Cal. & S.D. Fla. Sober Homes

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FOR IMMEDIATE RELEASE Wednesday, September 30, 2020

National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses

Largest Health Care Fraud and Opioid Enforcement Action in Department of Justice History

Acting Assistant Attorney General Brian C. Rabbitt of the Justice Department's Criminal Division, Assistant Director Calvin Shivers of the FBI's Criminal Investigative Division, Deputy Inspector General Gary Cantrell of the Department of Health and Human Services Office of Inspector General (HHS-OIG) and Assistant Administrator Tim McDermott of the Drug Enforcement Administration (DEA) today announced a historic nationwide enforcement action involving 345 charged defendants across 51 federal districts, including more than 100 doctors, nurses and other licensed medical professionals.

These defendants have been charged with submitting more than $6 billion in false and fraudulent claims to federal health care programs and private insurers, including more than $4.5 billion connected to telemedicine, more than $845 million connected to substance abuse treatment facilities, or "sober homes," and more than $806 million connected to other health care fraud and illegal opioid distribution schemes across the country.

Today's enforcement actions were led and coordinated by the Criminal Division, Fraud Section's Health Care Fraud Unit, in conjunction with its Health Care Fraud and Appalachian Regional Prescription Opioid (ARPO) Strike Force program, and its core partners, the U.S. Attorneys' Offices, HHS-OIG, FBI, and DEA, as part of the department's ongoing efforts to combat the devastating effects of health care fraud and the opioid epidemic. The cases announced today are being prosecuted by Health Care Fraud and ARPO Strike Force teams from the Criminal Division's Fraud Section, along with 43 U.S. Attorneys' Offices nationwide, and agents from HHS-OIG, FBI, DEA, and other various federal and state law enforcement agencies.

"Sober Homes" Cases

The "sober homes" cases announced today include charges against more than a dozen criminal defendants in connection with more than $845 million of allegedly false and fraudulent claims for tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. The subjects of the charges include physicians, owners and operators of substance abuse treatment facilities, as well as patient recruiters (referred to in the industry as "body brokers"). These individuals are alleged to have participated in schemes involving the payment of illegal kickbacks and bribes for the referral of scores of patients to substance abuse treatment facilities; those patients were subjected to medically unnecessary drug testing – often billing thousands of dollars for a single test – and therapy sessions that were frequently not provided, and which resulted in millions of dollars of false and fraudulent claims being submitted to private insurers. Medical professionals also allegedly prescribed medically unnecessary controlled substances and other medications to these patients, sometimes to entice them to stay at the facility. The patients were then often discharged and admitted to other treatment facilities, or referred to other laboratories and clinics, in exchange for more kickbacks.

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RECENT EKRA CASES

- From July 2020 – January 2021, with a takedown in September 2020, the Fraud Section (National Rapid Response Strike Force, Miami Strike Force, and Los Angeles Strike Force, and the United States Attorney's Office in the SDFL and CDCA), indicted four cases and charged 16 individuals.

Three of these cases included EKRA charges:

- **US v Markovich et al.**, 21-CR-60020 (SDFL). An approximately $112 million-dollar alleged addiction treatment fraud scheme. Charges include a 371 Conspiracy to violate EKRA, and substantive EKRA counts, against 5 Defendants for paying patients, recruiters, and laboratories kickbacks. (2 Defendants pled to a 371 Conspiracy to Violate EKRA).
- **US v Port, et al.**, 19-CR-20583 (SDFL) Superseding indictment in an approximately $75 million alleged addiction treatment fraud scheme. Charges include a 371 Conspiracy to violate EKRA against 2 defendants, and substantive EKRA counts against 1 Defendant, involving paying patients, recruiter, and laboratories. (1 Defendant pled to a 371 Conspiracy to Violate EKRA).
- **US v. Greiss**, 20-CR- 00131 (CDCA). Patient recruiter in Los Angeles area involving millions in billings, charged with a 371 Conspiracy to violate EKRA, and substantive counts.

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RECENT EKRA CASES

U.S. v. Schena et al., Case No. 20-CR-00425-EJD (N.D.C.A.)(Three Defendants Convicted of EKRA Charges).

- On May 18, 2021, in a Superseding Indictment, in the first criminal securities fraud prosecution related to the COVID-19 pandemic brought by the Department of Justice, Mark Schena, the owner and operator of Arrayit Corporation was charged with, in addition to conspiracy to commit health care fraud and three counts of securities fraud, conspiracy to violate EKRA by paying and receiving kickbacks and substantive EKRA counts of paying and receiving kickbacks for referrals to clinical testing laboratories for allergy and COVID-19 testing, which resulted in more than $69 million being billed to Medicare, Medicaid, Tricare, and private insurance companies. Schena was convicted at trial in September 2022.
- Two other defendants in related cases pled guilty to EKRA charges as well.

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OTHER EKRA CASES – FRAUD SECTION

SDFL:

- **U.S. v BAKHSHI**, (21-CR-60212), One Defendant charged by information with a 371 conspiracy to violate EKRA. The Defendant has pled guilty.

CDCA:

- **U.S. v. GONZALEZ,** (21-CR-00120)**:** One defendant charged by information with one count of offering and paying kickbacks in violation of EKRA. The defendant has pled guilty.

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OTHER EKRA CASES

- **United States v Merced** (20-CR-00006) (E.D. Kentucky). The defendant, a manager of a substance abuse treatment facility, solicited kickbacks from the CEO of a urine drug testing laboratory in exchange for the clinic's business (i.e, urine samples for tests). Defendant pled guilty in early 2020. We believe this is the first conviction for criminal EKRA charges in a case brought by the DOJ.
- **United States v. Dickau** (20-CR-783) (D.N.J.) Defendant pled guilty to Information charging a 371 Conspiracy to violate EKRA. Defendant was owner/operator of a clinical treatment facility who bribed patients to attend, and paid at least $5,000 per referral to a marketing company.
- Pre-EKRA Kickbacks Case: **United States v. Snyder, et al**., (18-CR-80111) (SDFL). Travel Act Charges based on kickbacks scheme at clinical treatment facility and recovery home.

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Recent Civil AKS Settlements and Enforcement Actions

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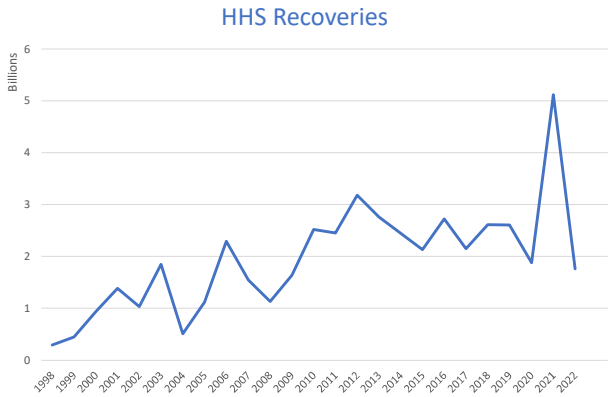
ENFORCEMENT TRENDS: FALSE CLAIMS ACT RECOVERIES

FY 2022 Total FCA Recoveries: $2.2 Billion

$ 1.7 Billion from healthcare cases

First year in which declined cases had higher recovery than intervened and non-qui tam

351 total settlements and judgments (HHS and non-HHS), the 2nd highest number



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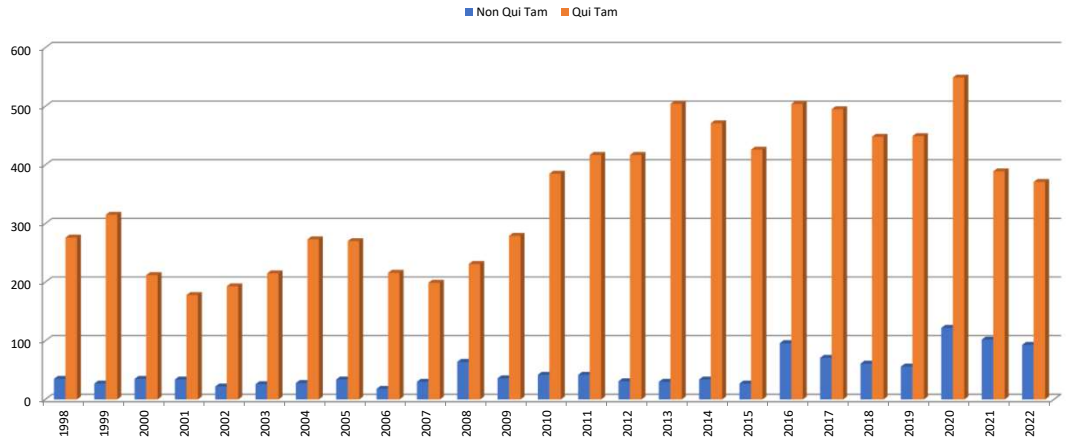
ENFORCEMENT TRENDS: NUMBER OF FILED HHS FCA CASES



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NOTABLE ENFORCEMENT ACTIONS AND TRENDS

- Anti-Kickback Statute cases examine many types of alleged remuneration, including:
  - Ownership profits and investment distributions
  - Consulting and medical director fees
  - Speaker honoraria, speaker training fees, consulting fees and meals
  - Direct bill arrangements
  - Group practice lab revenue distributions
- Urine drug testing / medically unnecessary services
  - Often with a telehealth component

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INVESTMENT/OWNERSHIP DISTRIBUTIONS

- Lab-related investment distributions (2022)
  - Over $32 million in settlements for alleged kickbacks disguised as investment returns from management services organizations (MSOs) in exchange for ordering laboratory tests from **Rockdale Hospital dba Little River Healthcare (Little River), True Health Diagnostics LLC (True Health), and/or Boston Heart Diagnostics Corporation (Boston Heart)**.
  - Little River allegedly funded the remuneration to certain doctors, in the form of volume-based commissions paid to independent contractor recruiters, who used MSOs to pay numerous doctors for their referrals. The MSO payments to the doctors were allegedly disguised as investment returns but in fact were based on, and offered in exchange for, the doctors' referrals.
  - Settling parties included:
    - 33 Texas physicians
    - 2 healthcare executives
    - 1 laboratory

https://www.justice.gov/opa/pr/fifteen-texas-doctors-agree-pay-over-28-million-settle-kickback-allegations

INVESTMENT/OWNERSHIP DISTRIBUTIONS

Physician-Owned Distributors (PODs) in South Dakota (2021)

- Over $33 million in settlements with hospital, two PODs, one medical device manufacturer, and one physician
- HHS-OIG excluded physician and PODs from federal healthcare programs for 6 years

https://www.justice.gov/opa/pr/neurosurgeon-and-two-affiliated-companies-agree-pay-44-million-settle-health-care-fraud

Reliance Medical PODs (2022)

- Over $10.25 million in settlements with medical device manufacturer, two PODs, and POD owners
- Latest settlement occurred after the first day of trial

https://www.justice.gov/opa/pr/department-justice-settles-lawsuit-against-spine-device-distributor-and-its-owners-alleging

INVESTMENT/OWNERSHIP DISTRIBUTIONS

Physician-Owned Hospital in Texas (2021)

- $18.2M settlement alleging **Flower Mound Hospital** violated AKS and Stark by taking into account the volume or value of certain physicians' referrals when it
  (1) selected the physicians to whom the shares would be resold and
  (2) determined the number of shares each physician would receive.

https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations

Hospital, Management Company, and Physician Group in Oklahoma (2020)

- $72.3 million settlement alleging **Oklahoma City Hospital** and management company provided improper remuneration to physicians, including equity buyback provisions and preferential investment opportunities

https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal

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INVESTMENT AND BUSINESS INTEGRATION

In 2022, DOJ intervened in an ongoing *qui tam* suit against **Methodist Le Bonheur Healthcare** and **Methodist Healthcare Memphis Hospitals**, a health system, that purchased substantially all outpatient locations of the largest oncology practice in the Memphis area.

- At the time of the arrangement, the health system lacked a comprehensive cancer treatment center.
- The health system also engaged the oncology practice to provide management services to the health system's adult oncology service line.
- DOJ alleged, among other things, that the health system (a) paid the oncology practice for certain services that it was supposed to, but did not, provide; and (b) double-paid the oncology practice for management services it had performed.
- Motions continue to enforce settlement in principle by DOJ (2023)

https://www.justice.gov/usao-mdtn/pr/united-states-files-suit-against-methodist-le-bonheur-healthcare-and-methodist

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OFFICE-BASED LABS INVESTMENT AND USE

- In 2022, the United States filed a complaint under the False Claims Act against **Yury Gampel**, a chiropractor, 15 **Modern Vascular** office-based labs located throughout the United States primarily owned by Gampel, and five Modern Vascular-affiliated companies owned by Gampel, for engaging in allegedly illegal financial relationships and transactions.
  - The US alleges that Gampel and the Modern Vascular defendants offered physicians the opportunity to invest in Modern Vascular office-based labs to induce them to refer their Medicare and TRICARE patients to Modern Vascular for the treatment of peripheral arterial disease.
  - The complaint also alleges that Gampel pressured vascular surgeons and interventional radiologists employed at the Modern Vascular office-based labs to increase the number of invasive surgical procedures performed by tracking procedures and setting aggressive weekly and monthly goals for such procedures.

https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-chiropractor-modern-vascular-office

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COMPLIANCE TAKEAWAY: INVESTMENT INTERESTS

- Notable number of cases examining investments and complex business relationships involving physicians
- Pay attention to the regulatory posture of business deals and negotiations
  - Letter of Intent, parties' discussions regardless business goals
  - Small Investment Safe Harbor, 1001.952(a), and ASC safe harbor, 1001.952(r)
  - Special Advisory Bulletin on Contractual Joint Ventures, AO 21-18 and 23-05
- Performance under an arrangement as important, or perhaps more so, than structure

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CONSULTING/MEDICAL DIRECTOR FEES

Oklahoma Home Health Company and Executives (2022)

- $22.9 million settlement for allegedly paying medical director fees to induce home health referrals.
- HHS-OIG excluded company's previous CEO and COO for 5 years.

https://www.justice.gov/usao-wdok/pr/oklahoma-city-home-health-company-and-two-former-corporate-officers-agree-pay-229

California Pain Doctor (2022)

- Paid $271,259.12 to settle allegations that he prescribed drugs to Medicare beneficiaries in return for consulting and speaking fees.

https://www.justice.gov/opa/pr/california-pain-specialist-agrees-settle-alleged-receipt-kickbacks-pharmaceutical-companies

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HOSPITAL – PHYSICIAN ARRANGEMENTS

- **Covenant**, a regional hospital system, and two physicians paid over $69 million to resolve FCA allegations that:
  - Several medical director arrangements, including Physician A, violated Stark and AKS
  - The employment agreement Physician B did not satisfy Stark exception
  - The hospital forgave rent payments between 2006 and 2009 for one physician
  - The hospital permitted a physician-owned entity to purchase and lease equipment to the hospital through non-arms length arrangements
- The hospital settled in 2021 for $69 million, the case remained sealed while the government investigated Physicians A and B
- In March 2023, Physician A settled for $345,987.54 and Physician B settled for $406,551.15 and the matter was unsealed.

https://www.justice.gov/usao-edmi/pr/covenant-healthcare-system-and-physicians-pay-over-69-million-resolve-false-claims-act

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HOSPITAL-PHYSICIAN ARRANGEMENTS

- On May 31, 2023, DOJ announced that it had reached a settlement with a **Detroit Medical Center** and its current and former owners to pay about $29 million to resolve allegations brought by a *qui tam* relator that the health system caused the submission of false or fraudulent claims to Medicare in violation of the FCA.
  - The government alleged that between 2014 and 2017, two hospitals operated by the health system provided the services of employed mid-level practitioners at either no cost or below fair market value to select physicians, thereby violating the AKS.
  - The government also alleged that the health system selected the physicians receiving the mid-level practitioner services to induce them to refer more Medicare patients to the health system's facilities.
  - https://www.justice.gov/opa/pr/detroit-medical-center-vanguard-health-systems-and-tenet-healthcare-corporation-agree-pay
- On June 15, 2023, **St. Francis Physician Services, Inc., St. Francis Hospital, and Bon Secours St. Francis Health System, Inc.,** (collectively, "St. Francis"), owner and operator of the St. Francis healthcare system agreed to pay $36.5 million to resolve allegations that it violated the False Claims Act, the Federal Stark Law, and the Federal Anti-Kickback Statute ("AKS") by making payments to orthopedic surgeons that were tied to the volume or value of referrals.
  - The government alleged that St. Francis caused the submission of false claims to Medicare and to TRICARE as a result of an unlawful contractual payment structure between St. Francis and Piedmont Orthopedic Associates ("POA"), whereby POA's compensation was tied to the volume or value of the practice's referrals to St. Francis.
  - https://www.justice.gov/usao-sc/pr/st-francis-pay-united-states-365-million-settle-allegations-under-false-claims-act

EYE SURGERY AND CO-MANAGEMENT

- On May 1, 2023, **SouthEast Eye Specialists**, **SouthEast Eye Surgery Center** and the **Eye Surgery Center of Chattanooga** (SEES), agreed to pay the United States and Tennessee $17,000,000 to resolve allegations that they violated the Anti-Kickback Statute by illegally inducing primary-care eye doctors (optometrists) to refer – or steer –patients to SEES for cataract surgeries by providing optometrists a variety of forms of financial remuneration.
  - The lawsuit alleged that SEES used a variety of approaches to secure a stream of referrals by inducing optometrists to refer patients to SEES, including continuing education, meals, sporting events, and inappropriate pre-arranged co-management agreements with optometrists.
  - Https://www.phillipsandcohen.com/southeast-eye-specialists-pays-17-million/
- In March 2023, an ophthalmology provider group, **Arlington Ophthalmology Association, P.L.L.C. d/b/a Kleiman Evangelista Eye Centers** ("K&E"), with offices located in Arlington, Dallas, Plano, Southlake, Mount Pleasant, and Gun Barrel City, Texas, has agreed to pay $2,902,505 to resolve False Claims Act allegations that it offered and paid kickbacks to optometrists to induce referrals of patients who were candidates for cataract surgery.
  - The remuneration purportedly included payments to referring optometrists that were untethered to actual non-Medicare and non-Medicaid covered services for referring cataract patients who received premium intraocular lenses or laser-assisted cataract surgery, guarantees of automatic returns of patients referred, free continuing education courses, invitations to expensive dinners and tickets to professional baseball games in the ophthalmology group's suite.
  - The fees paid to the referring optometrists for patients who received premium lenses or laser-assisted cataract surgery were in addition to the reimbursement the optometrists received from Medicare and Medicaid for performing post-operative care and were allegedly not tied to or commensurate with actual post-operative services specifically attributed to the premium lenses or laser-assisted cataract surgery rendered
  - https://www.justice.gov/usao-edtx/pr/ophthalmology-practice-agrees-pay-over-29-million-settle-kickback-allegations

SPEAKER HONORARIA, CONSULTING FEES AND MEALS

- In 2020, **Novartis** $312 million criminal and $310 million civil payments and entered into a deferred prosecution agreement to settle allegations concerning research grants, free equipment, lavish meals and entertainment
- In 2022 **Biogen** paid $843.8 million in connection with a *qui tam* suit alleging AKS violations involving remuneration to physicians in the form of:
  - Speaker honoraria and associated speaker training fees and meetings
  - Consulting fees and meals furnished to healthcare professionals who spoke at or attended the company's speaker programs
  - Settlement prompted by District Court ruling that a violation of the federal AKS is *per se* a material violation of the FCA and related state false claims act statutes
  - Case declined by DOJ; filed in 2012

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SPECIAL FRAUD ALERT: SPEAKER PROGRAMS

- Special Fraud Alert published Nov. 16, 2020
  - Skeptical of educational value of device and drug company-sponsored speaker programs; many ways for HCPs to obtain info without remuneration.
  - Parties involved in speakers' programs may be subject to increased scrutiny.
  - Cited studies showing that "HCPs who receive remuneration from a company are more likely to prescribe or order that company's products."

87 Fed. Reg. 51,683, 51,684–86 (Aug. 23, 2022).

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SPECIAL FRAUD ALERT HIGHLIGHTS

- High-prescribing speakers
  - Sales and marketing influence selection of speakers
  - Above FMV payment
- Program locations and characteristics
  - Expensive restaurants or venues not conducive to educational programing
  - Alcohol served
  - Attendees have no legitimate reason to attend
  - Little to no substantive information
  - Repeated programs, attendees, and content (e.g., "nothing new")

FREE PRESCRIBING DATA

- In 2022, durable medical equipment manufacturer **Philips RS North America, LLC**, formerly Respironics, Inc., paid $24.75 million to resolve allegations that it knowingly provided unlawful kickbacks to DME suppliers to induce them to select Respironics' respiratory equipment.
  - The inducements allegedly came in the form of physician prescribing data that Respironics provided free of charge yet knew was valuable in assisting DME suppliers' marketing efforts to physicians.
- The CIA
  - Includes both Arrangement Review and Covered Functions provisions
  - Required an Independent Monitor (as opposed to the typical IRO)

https://www.justice.gov/opa/pr/philips-subsidiary-pay-over-24-million-alleged-false-claims-caused-respironics-respiratory

TRIPS AND ENTERTAINMENT

- In February 2023, a federal civil jury returned a verdict in favor of the United States for more than $43 million against Defendants the **Cameron-Ehlen Group, Inc., d/b/a Precision Lens**, and its owner Paul Ehlen
  - The government's FCA case involved claims of kickbacks to ophthalmic surgeons to induce their use of Defendants' products in cataract surgeries reimbursed by Medicare.
    - Multiple examples of trips, including high-end skiing, fishing, golfing, hunting, sporting, and entertainment vacations, often at exclusive destinations.
    - For many of the trips, Precision Lens and Ehlen transported physicians to luxury vacation destinations on private jets.
    - Trips to New York City to see a Broadway musical, the College Football National Championship Game in Miami, Florida, and the Masters golf tournament in Augusta, Georgia.
    - Precision Lens and Ehlen also sold frequent flyer miles to their physician customers at a significant discount, enabling the physicians to take personal and business trips at well below fair market value.
  - Precision and Ehlen claimed various defenses, including that the trips were related to friendships and not to induce referrals

https://www.justice.gov/usao-mn/pr/federal-jury-finds-precision-lens-and-owner-paul-ehlen-liable-paying-kickbacks-violation

GIFTS AND ENTERTAINMENT

- In June 2023, **Alta Vista Healthcare & Wellness Centre, LLC** (Alta Vista), a skilled nursing facility in Riverside, California, and its management company, Rockport Healthcare Services (Rockport), have agreed to pay the United States and California a total of $3.825 million to resolve allegations that they submitted and caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce patient referrals.
  - The settlement amount was negotiated based on Alta Vista's and Rockport's lack of ability to pay.
- Allegations:
  - From 2009 through 2019, Alta Vista, under the direction and control of Rockport, gave certain physicians extravagant gifts, including expensive dinners for the physicians and their spouses, golf trips, limousine rides, massages, e-reader tablets, and gift cards worth up to $1,000.
  - Paid these physicians monthly stipends of $2,500 to $4,000, purportedly for their services as medical directors. At least one purpose of these gifts and payments was to induce these physicians to refer patients to Alta Vista.
- https://www.justice.gov/opa/pr/california-skilled-nursing-facility-and-management-company-agree-pay-3825-million-settle

COMPLIANCE TAKEAWAY – PHYSICIAN RELATIONSHIPS

- The government and relators have a longstanding focus on physician financial relationships given their gate-keeper role in creating healthcare expenses
- At the same time, industry and physician collaboration can serve important purposes
- Need to ensure payments are FMV for legitimately needed services
- Examine whether items offered has "substantial independent value"
- Close scrutiny of travel, entertainment

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DIRECT BILL ARRANGEMENTS, URINE DRUG TESTING

- In September 2021, U.S. District Court for the District of South Carolina entered default judgments for the United States totaling $136,025,077 against **Oaktree Medical Centre P.C. (Oaktree), FirstChoice Healthcare P.C. (FirstChoice), Labsource LLC (Labsource), Pain Management Associates of the Carolinas LLC (PMA of the Carolinas) and Pain Management Associates of North Carolina P.C. (PMA of North Carolina)**
  - Judgments against chiropractor, pain management clinics, urine drug testing laboratories, and substance abuse counseling center.
  - Alleged "direct bill" kickbacks and Stark violation to HCPs:
    - Lab offered HCPs opportunity to bill private insurers for lab's urine drug tests.
    - HCPs paid lab a fee for lab to run the tests; received higher reimbursement from insurers.
    - Lab offered HCPs the profit-making opportunity to induce HCPs' referrals of federal beneficiaries to lab.
  - Chiropractor pleaded guilty to conspiring to pay kickbacks and to defraud healthcare programs.

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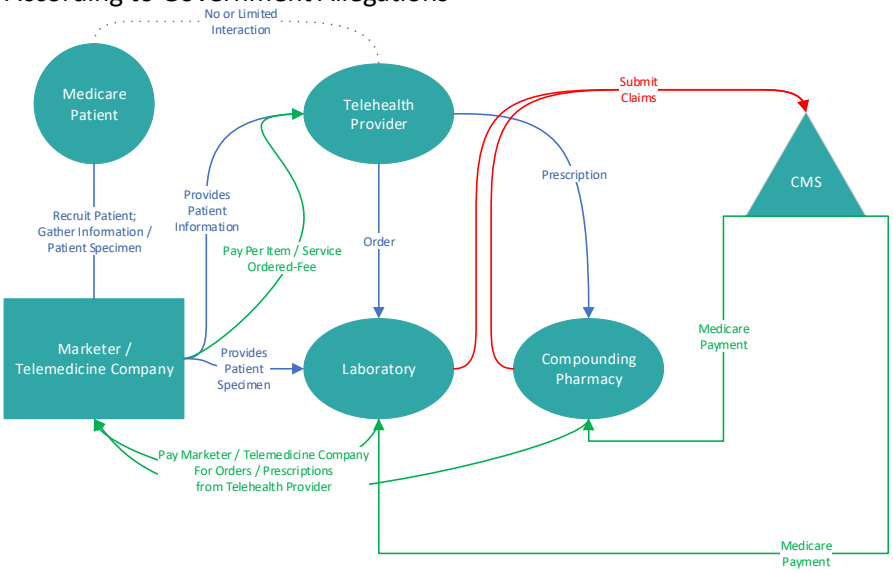
ENFORCEMENT FOCUS ON "TELEFRAUD"

Structure According to Government Allegations



OIG SPECIAL FRAUD ALERT

OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies (July 20, 2022)

- Focus: Alleged schemes involving companies that purport to provide telehealth, telemedicine, or telemarketing services ("Telemedicine Companies") and kickback payments to physicians and nonphysician practitioners ("Practitioners") to generate orders or prescriptions for medically unnecessary durable medical equipment ("DME"), genetic testing, wound care items, or prescription medications that result in fraudulent federal health care program ("FHCP") claims.
- In many arrangements, the Telemedicine Company pays Practitioners in exchange for ordering or prescribing items or services (1) for purported patients with whom the Practitioners have limited, if any, interaction, and (2) without regard to medical necessity.
- Release coincided with a nationwide coordinated law enforcement action.
    - DOJ announced criminal charges against 36 defendants for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and DME schemes. https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud
    - Reflects continuing focus on telemedicine enforcement, following 2019's Operation Brace Yourself, 2019's Operation Double Helix, 2020's Operation Rubberstamp, and the 2021 National Health Care Fraud Enforcement Action (which had a material telemedicine component).

OIG SPECIAL FRAUD ALERT

Suspect Telemedicine Characteristics

1. Patients are identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call centers, health fairs and/or through internet, television or social media by advertising free or low out-of-pocket cost items or services.
2. Practitioners are not provided an opportunity to interact with the patient or gather the information needed from patients to meaningfully assess them and determine the medical necessity of the prescribed items or services.
3. Compensation paid to Practitioners is based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.
4. The Telemedicine Company only furnishes services to FHCP beneficiaries and does not accept insurance from other payors (e.g., a commercial plan).
5. The Telemedicine Company claims to provide services to individuals who are not FHCP beneficiaries but actually bills FHCPs.
6. The Telemedicine Company provides only one product or class of services (e.g., genetic testing, DME or other specific items or services), potentially restricting a Practitioner's treatment options to a predetermined course of treatment.
7. The Telemedicine Company does not expect, provide information to enable, or require practitioners to follow up with patients.

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COMPLIANCE TAKEAWAY – SERVICE DELIVERY AND MEDICAL NECESSITY

- Growing scrutiny of testing and telehealth services, especially due to explosion of services during pandemic
- Understand medical coverage rules
- Maintain documentation showing medical necessity
- Diligence telehealth and other business partners/vendors
  - Many new companies created with little experience operating within the healthcare regulatory environment

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AKS-Related False Claims Act Caselaw Developments and Cases to Watch

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CASE LAW DEVELOPMENTS: CO-PAY ASSISTANCE PROGRAMS

- **Pfizer, Inc. v. United States Department of Health and Human Services et al.**, No. 21-2764 (2nd Cir. July 25, 2022)
  - Affirmed district court denial of Pfizer's request for declaration that its co-pay assistance programs would not violate the AKS and BIS
  - OIG issued a negative advisory opinion on one of the programs; Pfizer sued, arguing that the AKS required "corrupt intent"
    - For example, Pfizer argued that the statute's inclusion of the phrase "any remuneration … to induce" implies a quid pro quo that "improperly or corruptly" skews the patient's decision-making
  - The Court rejected Pfizer's argument, holding that the term "induce" is "neutral with regard to intent," and "willfully" requires only "a voluntary, intentional violation of a known legal duty," not "corrupt intent."
- Note: The court found that "to induce" requires enticement or persuasion to take an action
  - The *Bingham* FMV theory – that a FMV payment simply entices or persuades a person to perform the service for which payment is made, without more left to entice referrals
  - Suggests must be a link between the payment and inducement to make the referral

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LITIGATION ON ADVISORY OPINION 22-19 COST-SHARING SUBSIDIES, PREMIUMS

- **Pharmaceutical Coalition for Patient Access (PCPA)** sued OIG and other federal agencies in E.D. Va seeking declaratory judgment and injunctive relief in connection with AO 22-19, arguing:
  - No AKS violation because no *quid pro quo* and no "corrupt exchange"
  - OIG acted arbitrarily and capriciously because OIG:
    - Approved other assistance programs that had fewer safeguards than PCPA's proposed program
    - Failed to follow prior OIG guidance that has not been withdrawn
  - OIG violated PCPA's First Amendment Rights
- Litigation may have impacts regarding the interpretation of what is required for an AKS violation

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WHAT IS THE CORRECT CAUSATION STANDARD FOR AKS-BASED FCA CASES?

- **U.S. v. Regeneron Pharmaceuticals Inc.**, No. 1:20-cv-11217 (D. Mass. 2023)
  - U.S. brought suit against Regeneron, the manufacturer of Eylea, alleging that Regeneron improperly directed millions of dollars to the Chronic Disease Fund—a purportedly independent charitable foundation—to subsidize patient copays for Eylea.
    - Specifically, the government alleged that the purpose of the foundation was to induce physicians to increase prescriptions and that these actions violated the AKS and caused the submission of false claims.
  - The court ruled on both sides' motions for partial summary judgment, finding:
    - The "resulting from" requirement in the AKS requires but-for causation, and
    - There was enough evidence for the government to attempt to prove a causal connection between the donations and kickbacks received by providers.
  - 42 U.S.C. § 1320a-7b(g): Any claim for Medicare reimbursement "that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."

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WHAT IS THE CORRECT CAUSATION STANDARD FOR AKS-BASED FCA CASES?

- **U.S. v Teva Pharmaceuticals**, No. 1:20-cv-11548 (D. Mass. 2023)
- Question on appeal asks the First Circuit to take a side on the requisite causation requirement for AKS violations to trigger FCA liability
  - Allegations concern the copay charitable assistance program for Copaxone, a multiple sclerosis drug
- In July 2023 D. Mass held:
  1. The causation requirement for a FCA violation predicated on a kickback prohibited by the AKS is, although ill-defined, less exacting than even a "but for" causation analysis;
  2. Allegedly false statements made in the context of alleged kickbacks to federal payor programs like Medicare are *per se* material; and
  3. Damages in an alleged kickback scheme encompass the full measure of what the government paid to the defendant, irrespective of any value the defendant provided
- In August 2023, the court took the rare step of allowing FCA defendant to pursue an interlocutory appeal arising from the summary judgment stage of an FCA case because:
  - (1) the "resulting from" language is a "controlling question of law as to which there is substantial ground for difference of opinion" and
  - (2) an immediate appeal could "materially advance the ultimate termination" of the litigation.

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CIRCUIT SPLIT – "RESULTING FROM"

"But for" Causation Standard

3rd Circuit - *Greenfield*

- Plaintiff must prove only "a ***link*** between the alleged kickbacks and the medical care received."
- Plaintiff need not "show that a kickback ***directly influenced*** a patient's decision to use a particular medical provider," but must demonstrate "***some connection*** between a kickback and a subsequent reimbursement claim."

8th Circuit - *Cairns*

- "[W]hen a plaintiff seeks to establish falsity or fraud…it must prove that a defendant would not have included particular 'items or services' but for the illegal kickbacks"
- **But-for** causation standard is the "default" or "background" rule against which Congress legislates

6th Circuit - *Martin*

- Followed *Cairns*; adopted a **but-for** causation standard
- Noted that "[t]he ordinary meaning of 'resulting from' is but-for causation," and legislative history does not "overcome the ordinary meaning of the text"

D. Mass - *Regeneron*

- "Resulting from" language requires a finding that the appropriate standard is **but-for** causation
- Government must prove that alleged kickbacks related to Eylea had a **direct connection** to false claims

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Thank you

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