



Anti-Kickback Developments

Health Care Enforcement Compliance Conference

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Office of Counsel to the Inspector General

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Agenda

- **OIG Notice of Proposed Rulemaking**
- **New OIG Advisory Opinions**
- **Criminal Enforcement and Policy Developments**
- **Civil Enforcement and Policy Developments**

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Disclaimer

All panelists do not intend to say anything that binds, is attributed to, or is on behalf of their respective organizations, clients or customers (if applicable), colleagues, relatives, friends, neighbors, or acquaintances.

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Anti-Kickback Statute (“AKS”)

- The AKS prohibits knowingly and willfully:
 - Offering, paying, soliciting, or receiving
 - Anything of value (“remuneration”) (direct or indirect, 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
 - Items or services paid for, in whole or in part, by a federal health care program
- “One purpose” test: if any one purpose is improper, other legitimate purposes may not carry the day

Bottom Line: No payments to induce referrals or orders of items and services

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AKS: Enforcement Penalties

AKS enforcement exists in three forms	
Criminal	AKS is a criminal statute <ul style="list-style-type: none">Felony subject to up to \$100,000 fine and ten years in prison
Civil	Civil prosecution under FCA: <ul style="list-style-type: none">Up to 3 times damages and \$22,363 penalty per claimSettlements typically range 2-3 times damagesCIA with OIG
Administrative	<ul style="list-style-type: none">Civil money penalties of up to 3 times amount of kickback and \$100,000 per kickbackExclusion from participation in Federal health care programs ("FHCP")

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OIG's Notice of Proposal Rulemaking – the HHS Regulatory Sprint to Coordinated Care

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HHS' Regulatory Sprint to Coordinated Care

Departmental Priority

- Launched in 2018, with release of RFIs by CMS and OIG

Objectives

- Facilitate coordinated care
- Accelerate the transition to “value-based care”

Scope

- **OIG:** Federal anti-kickback statute; beneficiary inducements civil monetary penalty provision
- **CMS:** Physician self-referral law
- **SAMHSA:** 42 C.F.R. Part 2
- **OCR:** HIPAA

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Balancing Innovation with Protection Against Fraud and Abuse



- Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the healthcare industry.
- OIG’s goal is to finalize safe harbors that protect arrangements that foster beneficial care coordination and promote value, while also protecting programs and beneficiaries against fraud and abuse harms.
- The anti-kickback statute as a “backstop” protection.

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Concerns Raised

- The anti-kickback statute and beneficiary inducements CMP are perceived by some as barriers to innovative care coordination arrangements.
- Care coordination often involves moving patients between providers who may have financial arrangements between them that relate to those patients (e.g., an ACO shared savings arrangement).
- Questions have been raised about a variety of types of potential remuneration, such as—
 - Providing technology infrastructure;
 - Sharing care coordinators;
 - Data systems;
 - Patient engagement arrangements; and
 - Outcomes-based payments.
- Without clear safe harbor protection, some stakeholders assert they are reluctant to innovate (and invest significant resources in new ways of delivering care) and point to heightened litigation risk.

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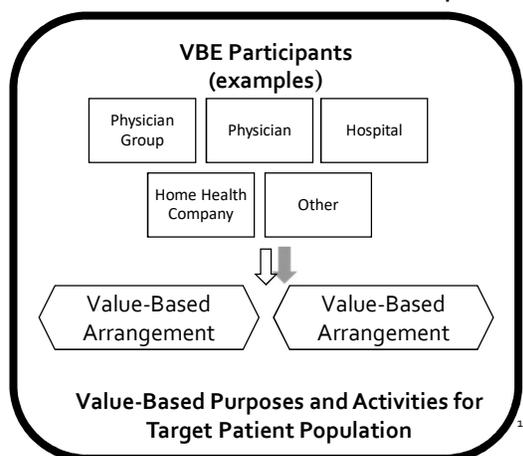
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Value-based Framework

Definitions

- Value-based enterprise (VBE)
- VBE participant
- Value-based purpose
- Value-based activities
- Value-based arrangement
- Target patient population

Illustrative Value-based Enterprise



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Proposed Safe Harbors for Value-based Arrangements

- **New**
 - Full financial risk
 - Substantial downside financial risk
 - Care coordination arrangements to improve quality, health outcomes, and efficiency
- **Revised**
 - Personal services and management contracts and outcomes-based payment arrangements (discussed later in presentation)

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Proposed Value-Based Arrangement Safe Harbors Overview

- **The proposed new safe harbors for value-based arrangements allow greater regulatory flexibility for value-based arrangements that involve downside financial risk:**
 - The “full risk”(e.g., full capitation) and “substantial risk” (e.g., partial capitation) safe harbors include fewer conditions and safeguards than the care coordination arrangements safe harbor.
- **Key proposed safeguards across all three proposed new value-based safe harbors:**
 - Cannot condition remuneration on referrals/business outside of the value-based arrangement
 - No patient marketing/recruitment
 - No inducement to reduce or limit medically necessary services
 - No offer or receipt of an ownership or investment interest
 - Excludes pharma, labs, DMEPOS (per definition of “VBE participant”)
 - Direct connection to coordination and management of care for the target patient population

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Examples of Value-Based Arrangements

Examples of potentially protected arrangements include:

- Performance-based payments
- Gainsharing
- Care coordination items and services
- Health information technology
- Data analytics software
- Quality improvement activities

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Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor

Proposed safeguards specific to the care coordination arrangements safe harbor:

- In-kind remuneration only
- Commercial reasonableness
- Contribution requirement (15 percent)
- Evidence-based outcome measures
- Annual monitoring/assessment by VBE accountable body
- Requires termination of value-based arrangement in defined circumstances

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Patient Engagement and Support Safe Harbor Overview

- Protects **in-kind** remuneration furnished by a “VBE participant” to patients in a “target patient population.” The in-kind remuneration must be:
 - Furnished directly to the patient by a VBE participant
 - Directly connected to the coordination and management of care of the target patient population
 - Recommended by the patient’s licensed healthcare provider and going to advance enumerated clinical goals, *e.g.*, adherence to a treatment regimen
- Aggregate retail value from a VBE participant cannot exceed \$500 per patient per year (absent financial need determination).
- No protection for:
 - Gift cards, cash, cash equivalents
 - Marketing/patient recruitment
 - Medically unnecessary or inappropriate items/services
 - Items/services likely to be diverted, sold, or used for unintended purposes

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Proposed Safe Harbor for CMS-sponsored Model Arrangements and Patient Incentives

- Under proposal, CMS would determine whether the safe harbor applies to the “CMS-sponsored model” (as defined by the proposed rule) on a model-by-model basis.
- Our proposed “universal waiver” would:
 - Simplify and standardize OIG’s approach to fraud and abuse waivers for CMS-sponsored models (*e.g.*, MSSP, BPCI Advanced, CJR)
 - Permit financial arrangements and patient incentives that are consistent with, and not prohibited by, the CMS-sponsored model participation documentation
 - Give parties flexibility to seek protection through existing fraud and abuse waivers or any of the proposed value-based safe harbors

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Proposed Revisions to Personal Services and Management Contracts and Outcomes-based Payment Arrangements Safe Harbor

- Would eliminate requirements that:
 - aggregate compensation be set forth in advance; and
 - parties specify the schedule of part-time arrangements in advance.
- Would establish new protection for “outcomes-based payment” arrangements
 - FMV and commercial reasonableness requirements would apply.
 - To receive a payment, the agent must satisfy one or more specific evidence-based, valid outcome measures that are:
 - Related to:
 - (1) measurably improving, or maintaining the improved, quality of patient care; or
 - (2) appropriately and materially reducing costs to, or growth in expenditures of, payors while improving, or maintaining the improved quality of care for patients; or
 - Selected based upon clinical evidence or credible medical support.

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Other Proposed Protections for Patient Arrangements

- **Local Transportation.** Proposed modifications to the existing safe harbor for local transportation (§ 1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities.
- **Accountable Care Organization (ACO) Beneficiary Incentive Programs.** Codification of the statutory exception to the definition of “remuneration” related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program (§ 1001.952(kk)).
- **Telehealth Technologies for In-Home Dialysis.** A proposed amendment to the definition of “remuneration” in the CMP rules at 42 C.F.R. § 1003.110 interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for “telehealth technologies” furnished to certain in-home dialysis patients.

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Proposals Related to Cybersecurity Technology and Services and Electronic Health Records (EHR) Items and Services

EHR:

- Proposes to make safe harbor permanent (current sunset date is December 31, 2021)
- Would incorporate “cybersecurity technologies” (or similar defined term), while also creating a standalone cybersecurity safe harbor
- Would modernize interoperability requirements

Cyber:

- Would protect donations of cybersecurity technologies and services that are “necessary and used predominantly to implement and maintain effective cybersecurity”
 - Cybersecurity defined as the “process of protecting information by preventing, detecting, and responding to cyberattacks”

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Proposed Revisions to Warranties Safe Harbor

- OIG proposes to modify the warranties safe harbor to:
 - Protect warranties for one or more items and related services upon certain conditions;
 - Exclude beneficiaries from the reporting requirements applicable to buyers; and
 - Define “warranty” directly and not by reference to 15 U.S.C. § 2301(6).

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What Does OIG's Proposed Rule Mean for Me?

Comment:

- Extended comment period of 75 days
- In addition to primary proposals summarized here, OIG solicits comments on a number of alternate proposals (*e.g.*, excluding device manufacturers from value-based and patient engagement and support safe harbors).

Proposed Rule:

- The proposals set forth in OIG's NPRM are not final, and if some or all of the proposals are finalized, they would apply only on a prospective basis.

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Notable OIG Advisory Opinions (2019)

- 19-02
- 19-03
- 19-04

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Promotes Access to Care Exception to the Beneficiary Inducements CMP

The term "remuneration" does not include:

...

- (6) 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—
- (i) Being unlikely to interfere with, or skew, clinical decision making;
 - (ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
 - (iii) Not raising patient safety or quality-of-care concerns.

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Promotes Access to Care?

- **Adv. Op. 19-02 Facts**
 - A pharmaceutical company developed a drug with a sensor embedded in it.
 - When a patient ingests the imbedded sensor, it sends signals to a patch on the patient's abdomen.
 - The information collected by the patch is then transmitted to an app on the patient's smartphone.
 - The requestor proposed to loan a refurbished phone to certain patients who don't have a smartphone for the duration of their drug treatment (use of the phone could not exceed two 12-week periods).
 - The phone would come preprogrammed with only the app and the functionality to make domestic phone calls; it would be unable to download other functions, such as text messaging, a camera, or other apps.
- **Adv. Op. 19-03 Facts**
 - A medical center offered to provide free, in-home follow-up care to certain patients with congestive heart failure and COPD.
 - Patients receive two visits from a community paramedic each week for approximately 30 days following enrollment.
 - Services performed during visits include:
 - Reviewing medication;
 - Ensuring compliance with a discharge plan of care;
 - Monitoring the patient's health care status; and
 - Performing home safety assessments.

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Promotes Access to Care?

- **Adv. Op. 19-02 Analysis**
 - Proposed arrangement would promote access to care because it would improve a qualifying beneficiary's ability to access the full scope of benefits of the drug.
 - Prescribers likely would choose the drug based on its ability to transmit data rather than the possibility of a highly limited-use smartphone being loaned to patients who do not already have one.
- **Adv. Op. 19-03 Analysis**
 - Arrangement does not promote access to care because the full suite of services the medical center offers does not remove a barrier to accessing care.
 - However, OIG found the arrangement to be low risk.
 - Notable safeguards:
 - Arrangement only for existing patients with high risk of inpatient admission/readmission;
 - Patients already must have selected the requestor (or one of its affiliates) for follow-up care;
 - Employee compensation not tied to number of patients in the program; and
 - Arrangement not likely to increase costs to FHCPs or patients.

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Marketing Arrangement

- **Adv. Op. 19-04 Facts**
 - A technology company operates an online platform where people can search and book appointments with healthcare professionals that are listed in a directory.
 - To generate directory results, users can enter criteria, such as their zip code, the type of service they need, and their insurance.
 - In addition to directory results, the requestor also offers sponsored results, which are banner advertisements, clearly labeled as "sponsored."
 - The requestor wanted to charge either per-impression or per-click fees for the sponsored results and either per-click or per-booking fees for the directory results.
- **Adv. Op. 19-04 Analysis**
 - Notable safeguards:
 - The requestor's fees would not exceed fair market value or directly vary with the volume or value of FHCP business generated by the platform.
 - The requestor's advertising activities would not: (i) specifically target Federal health care program beneficiaries; or (ii) relate to any specific items or services users may obtain from healthcare professionals as a result of appointments booked through the platform.
 - Everyone, regardless of insurance status, would be able to access the platform.
 - The requestor would not provide anything of value to Federal health care program beneficiaries.

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Eliminating Kickbacks in Recovery Act and the Travel Act

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EKRA: OVERVIEW

- Introduced late in legislative process for the SUPPORT Act
- Designed to address concerns regarding patient brokering activities relating to treatment for patients addicted to opioids
- Perceived gap in federal laws that are limited to federal health care programs
- But did Congress really mean what they said?

"I know this proposal is well-intentioned in addressing the serious problem of patient brokers who are taking advantage of individuals with opioid use disorders and referring them to substandard or fraudulent providers in exchange for kickbacks. This is an issue, but since the bill was introduced last Tuesday night, multiple stakeholders have raised concerns that the language does not do what we think it does. It may have unintended consequences."

Statement of Representative Pallone
164 Cong. Reg. H9244 (daily ed. Sept. 28, 2018)

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EKRA: Prohibited Conduct

- With respect to services covered by a **health care benefit program**, prohibits soliciting, receiving, paying, offering any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly
 - In return for referring a patient or patronage to, to induce a referral of an individual to, or in exchange for an individual using the services of a
 - Recovery home
 - Clinical treatment facility
 - Laboratory
 - Subject to seven statutory exceptions
 - Violations subject to a fine of up to \$200K or imprisonment of 10 years, or both, for each occurrence

“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, items, or service for which payment may be made under the plan or contract.

Key Point: All-Payor Statute

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EKRA: Covered Facilities

“Recovery Home”

- A shared living environment free from alcohol/illicit drug use, centered on peer support and connection to services that promote sustained recovery from substance abuse disorders

“Clinical Treatment Facility”

- A licensed/certified non-hospital medical setting that provides detox, risk reduction, outpatient treatment, residential treatment, or rehab for substance abuse

“Laboratory”

- Essentially any facility that examines human specimens, regardless of whether the test is related to substance abuse treatment.

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EKRA vs. AKS

	EKRA	AKS
Applies to:	Health care benefit program business (includes private payors)	Federal health care program business (excludes private payors)
Prohibits:	Referrals of patients or patronage <u>and</u> in exchange for using	Referrals of patients <u>and</u> arrange for/recommend purchasing
Covered Referrals:	To recovery homes, clinical treatment facilities, and laboratories	For any item or services payable by 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 <i>Bona Fide</i> Employees	Limited protection	Broad protection

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Travel Act

- Use of the mail, wires, travel/interstate commerce
- With the intent to
 - Distribute proceeds of any unlawful activity
 - Commit any crime of violence to further any unlawful activity
 - Otherwise promote, manage, establish, carry on ... any unlawful activity
- And performs an act or attempts to perform an act
- “Unlawful activity” can be based on a state law violation
- Enacted in 1961 to combat organized crime
- No “fraud” requirement

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Criminal AKS Enforcement, Law, and Policy Update

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U.S. Department of Justice, Criminal Division, Fraud Section

Healthcare Enforcement Compliance Conference – November 3, 2019

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July 2018: Eliminating Kickbacks in Recovery Act (EKRA) Introduced

Amid National Opioid Crisis, Rubio & Klobuchar Introduce Bill to Eliminate Patient Brokering

JUL 20 2018

Washington, D.C. – U.S. Senators Marco Rubio (R-FL) and Amy Klobuchar (D-MN) yesterday introduced the Eliminating Kickbacks in Recovery Act, legislation to prohibit patient brokering by punishing unscrupulous actors that prey on patients seeking treatment in order to exploit the patient's insurance. In May, Rubio introduced legislation to help states, law enforcement, private insurers and patients identify potentially illicit treatment centers and sober homes to ensure those who need treatment are able to find legitimate facilities.

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October 2018: Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

POTUS Enacts Opioids Package with Rubio Provision to Eliminate Patient Brokering

OCT 24 2018

Miami, FL - Today, President Trump signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes several provisions championed by U.S. Senator Marco Rubio (R-FL) to prevent and treat opioid addiction, including the Eliminating Kickbacks in Recovery Act. This provision will help stop payments to middlemen referring patients to illicit sober homes and treatment centers—increasingly a problem in South Florida. The SUPPORT for Patients and Communities Act passed the Senate, 98-1, on October 3.

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18 U.S.C. § 220 - Illegal remunerations for referrals to recovery homes, clinical treatment facilities and laboratories

(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.

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Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, September 27, 2019

Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over \$2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged

Elderly Patients Nationwide Lured into Criminal Scheme; Centers for Program Integrity & Medicare Services Takes Administrative Action against Providers that Submitted Over \$1.7 Billion in Claims

A federal law enforcement action involving fraudulent genetic cancer testing has resulted in charges in five federal districts against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing laboratories (CGx) for their alleged participation in one of the largest health care fraud schemes ever charged. According to the charges, these defendants fraudulently billed Medicare more than \$2.1 billion for these CGx tests. Among those charged today are 10 medical professionals, including nine doctors.

The coordinated federal investigation targeted an alleged scheme involving the payment of illegal kickbacks and bribes by CGx laboratories in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies for expensive cancer genetic tests that were medically unnecessary.

Often, the test results were not provided to the beneficiaries or were worthless to their actual doctors. Some of the defendants allegedly controlled a telemarketing network that lured hundreds of thousands of elderly and/or disabled patients into a criminal scheme that affected victims nationwide. The defendants allegedly paid doctors to prescribe CGx testing, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen.

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Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, April 9, 2019

Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over \$1.2 Billion in Losses

Hundreds of Thousands of Elderly and/or Disabled Patients Nationwide and Abroad Lured into Criminal Scheme; Center for Program Integrity, Center for Medicare Services, Takes Administrative Action Against 130 DME Companies That Submitted Over \$1.7 Billion

One of the largest health care fraud schemes investigated by the FBI and the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG) and prosecuted by the Department of Justice resulted in charges against 24 defendants, including the CEOs, COOs and others associated with five telemedicine companies, the owners of dozens of durable medical equipment (DME) companies and three licensed medical professionals, for their alleged participation in health care fraud schemes involving more than \$1.2 billion in loss, as well as the execution of over 80 search warrants in 17 federal districts. In addition, the Center for Medicare Services, Center for Program Integrity (CMS/CPI) announced today that it took adverse administrative action against 130 DME companies that had submitted over \$1.7 billion in claims and were paid over \$900 million.

The charges announced today target an alleged scheme involving the payment of illegal kickbacks and bribes by DME companies in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies for back, shoulder, wrist and knee braces that are medically unnecessary. Some of the defendants allegedly controlled an international telemarketing network that lured over hundreds of thousands of elderly and/or disabled patients into a criminal scheme that crossed borders, involving call centers in the Philippines and throughout Latin America. The defendants allegedly paid doctors to prescribe DME either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. The proceeds of the fraudulent scheme were allegedly laundered through international shell corporations and used to purchase exotic automobiles, yachts and luxury real estate in the United States and abroad.

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<p>Department of Justice Office of Public Affairs</p>	
FOR IMMEDIATE RELEASE	Friday, April 5, 2019
<p>South Florida Health Care Facility Owner Convicted for Role in Largest Health Care Fraud Scheme Ever Charged by The Department of Justice, Involving \$1.3 Billion in Fraudulent Claims</p>	
<p>A federal jury found a South Florida health care facility owner guilty today for his role in the largest health care fraud scheme ever charged by the Justice Department, involving over \$1.3 billion in fraudulent claims to Medicare and Medicaid for services that were not provided, were not medically necessary or were procured through the payment of kickbacks.</p>	
<p>After an eight-week trial, Philip Esformes, 50, of Miami Beach, Florida, was convicted of one count of conspiracy to defraud the United States, two counts of receipt of kickbacks in connection with a federal health care program, four counts of payment of kickbacks in connection with a federal health care program, one count of conspiracy to commit money laundering, nine counts of money laundering, two counts of conspiracy to commit federal program bribery, and one count of obstruction of justice before U.S. District Judge Robert N. Scola Jr. of the Southern District of Florida. Sentencing has not yet been scheduled.</p>	
<p>According to evidence presented at trial, from approximately January 1998 through July 2016, Esformes led an extensive health care fraud conspiracy involving a network of assisted living facilities and skilled nursing facilities that he owned. Esformes bribed physicians to admit patients into his facilities, and then cycled the patients through his facilities, where they often failed to receive appropriate medical services, or received medically unnecessary services, which were then billed to Medicare and Medicaid, the evidence showed. Several witnesses testified to the poor conditions in the facilities and the inadequate care patients received, which Esformes was able to conceal from authorities by bribing an employee of a Florida state regulator for advance notice of surprise inspections scheduled to take place at his facilities. The evidence further showed that Esformes used his criminal proceeds to make a series of extravagant purchases, including luxury automobiles and a \$360,000 watch. Esformes also used criminal proceeds to bribe the basketball coach at the University of Pennsylvania in exchange for his assistance in gaining admission for his son into the university. Altogether, the evidence established that Esformes personally benefited from the fraud and received in excess of \$37 million.</p>	

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<p>Department of Justice U.S. Attorney's Office Northern District of Texas</p>		<p>SHARE </p>
FOR IMMEDIATE RELEASE	Wednesday, April 10, 2019	
<p>Seven Guilty in Forest Park Healthcare Fraud Trial</p>		
<p>Following four days of deliberations, a federal jury returned guilty verdicts for seven individuals implicated in the Forest Park Medical Center bribery scheme Tuesday evening, announced U.S. Attorney Erin Nealy Cox.</p> <p>Wilton McPherson "Mac" Burt, Jackson Jacob, Douglas Sung Won, Michael Bassem Rimlawi, Shawn Mark Henry, Mrugeshkumar Shah, and Iris Kathleen Forrest were all convicted of conspiracy to pay or receive healthcare bribes.</p>		
<p>Ten other defendants had already pleaded guilty in the \$200 million scheme, designed to induce doctors to steer lucrative patients – particularly those with high-reimbursing, out-of-network private insurance – to the now defunct hospital.</p> <p>Most of the kickbacks, which totaled more than \$40 million, were disguised as consulting fees or "marketing money" doled as a percentage of surgeries each doctor referred to Forest Park.</p> <p>Instead of billing patients for out-of-network co-payments, instituted by insurers to de-incentivize the high costs associated with out-of-network treatment, Forest Park allegedly assured patients they would pay in-network prices. Because they knew insurers wouldn't tolerate such practices, they concealed the patient discounts and wrote off the difference as uncollected "bad debt."</p> <p>Hospital manager Alan Beauchamp, who testified for the government, admitted that Forest Park "bought surgeries," and then "papered it up to make it look good."</p>		

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Department of Justice

U.S. Attorney's Office

District of Massachusetts

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FOR IMMEDIATE RELEASE
Thursday, May 2, 2019

Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy

First successful prosecution of top pharmaceutical executives for crimes related to the prescribing of opioids

BOSTON – The founder and four former executives of Insys Therapeutics Inc. were convicted today by a federal jury in Boston in connection with bribing medical practitioners to prescribe Subsys, a highly-addictive sublingual fentanyl spray intended for cancer patients experiencing breakthrough pain, and for defrauding Medicare and private insurance carriers.

Insys founder and former Executive Chairman John N. Kapoor, 76, of Phoenix, Ariz.; Richard M. Simon, 48, of Seal Beach, Calif., the former National Director of Sales; Sunrise Lee, 38, of Bryant City, Mich., a former Regional Sales Director; Joseph A. Rowan, 45, of Panama City, Fla., a former Regional Sales Director; and Michael J. Gurry, 55, of Scottsdale, Ariz., the former Vice President of Managed Markets, were convicted by a federal jury of RICO conspiracy. Sentencing dates have not yet been set.

Prior to the start of the trial, two other high-level Insys executives pleaded guilty and testified during the trial: Michael Babich, of Scottsdale Ariz., the former CEO and President of the company, and Alec Burlakoff, of Charlotte, N.C., the former Vice President of Sales.

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Relevance of Corporate Compliance Programs to the Investigation and Prosecution of Corporations

- **Determining Whether a Corporate Charge or Resolution is Appropriate**
 - Guilty Plea
 - Deferred Prosecution Agreement (DPA)
 - Non-Prosecution Agreement (NPA)
 - Declination (CEP)
- **Calculating the Appropriate Organizational Criminal Fine**
- **Determining the Appropriate Compliance Obligation**
 - **The type** of compliance obligation that should be imposed
 - Self Reporting
 - Independent Compliance Monitor
 - **The length of time** of the compliance obligation

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**U.S. Department of Justice
Principles of Federal Prosecution of Business Organizations
JM 9-28.000**

1. The nature and seriousness of the offense
2. The pervasiveness of wrongdoing within the corporation
3. The company's history of similar misconduct, including prior enforcement actions against it
4. The corporation's willingness to cooperate, including as to potential wrongdoing by its agents
5. **The adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision**
6. **The corporation's timely and voluntary disclosure of wrongdoing**
7. **The corporation's remedial actions, including any efforts to implement an adequate and effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution**
8. Collateral consequences
9. Adequacy of civil or regulatory enforcement actions
10. Adequacy of the prosecution of responsible individuals

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**U.S. Department of Justice
FCPA Corporate Enforcement Policy - JM 9-47.120**

- Applies in all FCPA cases, principles applied in all Criminal Division cases
- **Credit for Voluntary Self-Disclosure, Full Cooperation, and Timely and Appropriate Remediation**
 - **Presumption of declination** absent aggravating circumstances
 - Involvement by executive management of the company in the misconduct
 - Significant profit to the company in the misconduct
 - Pervasiveness of the misconduct within the company
 - To qualify, the company is required to pay all disgorgement, forfeiture, and/or restitution resulting from the misconduct

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U.S. Department of Justice's FCPA Corporate Enforcement Policy JM 9-47.120

- **Credit for Voluntary Self-Disclosure, Full Cooperation, and Timely and Appropriate Remediation**
 - If criminal resolution is warranted, the Fraud Section:
 - Will accord, or recommend to a sentencing court, a 50% reduction off the low end of the U.S.S.G. fine range, except for recidivists
 - Generally will not require appointment of a monitor if a company has, at the time of the resolution, implemented an effective compliance program
- **Limited Credit for Full Cooperation and Timely and Appropriate Remediation Without Voluntary Self-Disclosure**
 - The company will receive, or the Department will recommend, to a sentencing court, up to a 25% reduction off the low end of the U.S.S.G. fine range

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Criminal Division's Evaluation of Corporate Compliance Programs

U.S. Department of Justice
Criminal Division
Evaluation of Corporate Compliance Programs
(Updated April 2019)

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

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Evaluation of Corporate Compliance Programs

The 3 “Fundamental Questions” in JM 9-28.800 are the Framework

1. “Is the corporation's compliance program well designed?”
2. “Is the program being applied earnestly and in good faith?”
 - In other words, is the program being effectively implemented?
3. “Does the corporation's compliance program work” in practice?

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Criminal Division’s Evaluation of Corporate Compliance Programs - Anti-Kickback Statute Risk

- **Risk Assessment**
 - Risk Management Process
 - Risk-Tailored Resource Allocation
 - Updates and Revisions
- **Third-Party Management**
 - Risk Based and Integrated Processes
 - Appropriate Controls
 - Management of Relationships
 - Real Actions and Consequences

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Selection of Monitors in Criminal Division Matters – (the “Benczkowski Memo”)

October 11, 2018

TO: All Criminal Division Personnel

FROM: Brian A. Benczkowski
Assistant Attorney General 

SUBJECT: Selection of Monitors in Criminal Division Matters

The purpose of this memorandum is to establish standards, policy, and procedures for the selection of monitors in matters being handled by Criminal Division attorneys.¹ This memorandum supplements the guidance provided by the memorandum entitled, “Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations,” issued by then-Acting Deputy Attorney General, Craig S. Morford (hereinafter referred to as the “Morford Memorandum” or “Memorandum”).² The standards, policy, and procedures contained in this memorandum shall apply to all Criminal Division determinations regarding whether a monitor is appropriate in specific cases and to any deferred prosecution agreement (“DPA”), non-prosecution agreement (“NPA”), or plea agreement³ between the Criminal Division and a business organization which requires the retention of a monitor.

In general, the Criminal Division should favor the imposition of a monitor only where there is a demonstrated need for, and clear benefit to be derived from, a monitorship relative to the projected costs and burdens. Where a corporation’s compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will likely not be necessary.

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Civil Enforcement and Policy
Developments

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False Claims Act

- Prohibits **knowingly** presenting, or **causing** to be presented, a claim to the U.S. Government that is **false** or **fraudulent**
- **Knowledge**
 - Actual knowledge
 - Reckless disregard
 - Deliberate ignorance
- **False or Fraudulent**
 - Tainted by non-compliance with another law
 - Not medically necessary
 - Billed item or service billed is not the same as item or service provided

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False Claims Act

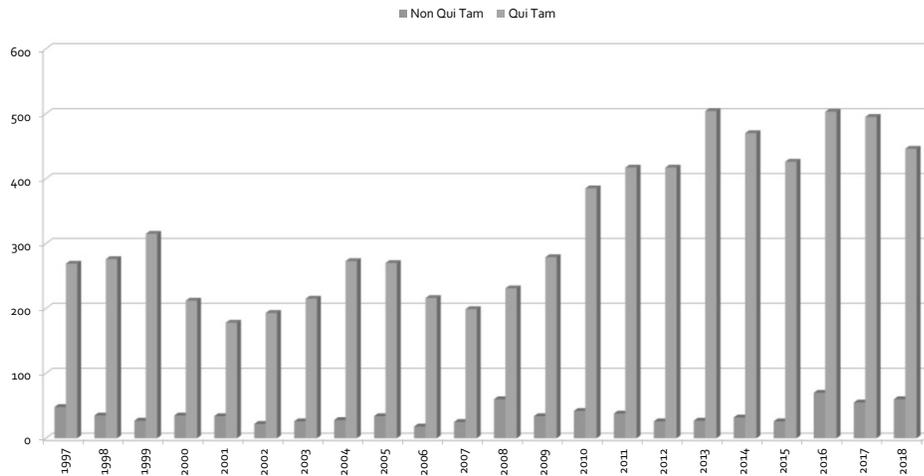
Penalties



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Enforcement Trends: Number of Filed HHS FCA Cases

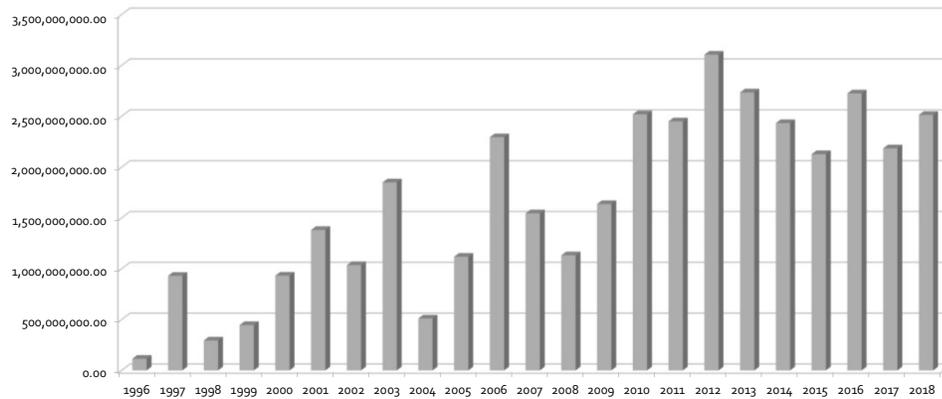


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Enforcement Trends: HHS False Claims Act Recoveries

HHS Recoveries



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Bingham v. HCA

Case No. 1:13-cv-23671 (11th Cir. 2019)

- Relator filed his first amended complaint on August 15 alleging that HCA, through its Centerpoint Medical Center and Aventura Hospital facilities, violated the FCA due to improper space rental arrangements with physicians.
 - Alleged improper developer subsidies that the developer passed onto physician tenants
- The court held that proving fair market value is an essential element for a relator to survive summary judgment and that relators must plead a lack of fair market value consistent with the Rule 9(b) particularity requirement to allege improper remuneration exists in the first place.
- The court's holding is significant for two reasons: (1) it underscores that the plaintiff bears a burden in pleading and proving lack of fair market value, and (2) it suggests that fair market value compensation may be an absolute defense to an AKS allegation.
- **Compliance Takeaway:** Importance of a solid contemporaneous FMV analysis

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Noteworthy FCA Settlements

- Avanti Hospitals, LLC and six owners: \$8.1M for alleged above FMV payments to medical director physician to secure referrals
- MedStar Health: \$35M for alleged improper PSA payments in return for referrals and medically unnecessary stent procedures
- Charitable Foundation Project: Six pharma manufacturers paid a combined total of over \$600M for alleged improper donations to foundations that provide copay assistance. Two foundations also settled for a total of \$6M
- Sanford Health: \$20.25M based on allegations that it submitted claims for devices/surgeries performed by an employed physician who received alleged kickbacks from his physician-owned distributorship
- Molecular Testing Labs: \$1.8M for alleged kickbacks to physician-owned labs
- Cardiology Practice and Physicians: \$1.1M for accepting alleged kickbacks from a genetic testing lab in exchange for ordering tests

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COOPERATION CREDIT

Assistant Attorney General Jody Hunt:

"False Claims Act defendants may merit a more favorable resolution by providing **meaningful assistance** to the Department of Justice—from **voluntary disclosure**, which is the most valuable form of cooperation, to various other efforts, including the **sharing of information gleaned from an internal investigation** and **taking remedial steps through new or improved compliance programs**"

- DOJ guidance on awarding cooperation credit issued on May 7, 2019
- An entity or individual may be awarded cooperation credit for
 - (1) voluntarily disclosing misconduct unknown to the government;
 - Entity or individual awarded cooperation credit for a "proactive, timely, and voluntary self-disclosure"
 - (2) cooperating in an ongoing investigation; or
 - (3) undertaking remedial measures in response to a violation

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COOPERATION CREDIT

- Examples of cooperation during ongoing investigation
 - "Identifying individuals substantially involved in or responsible for the misconduct"
 - "Disclosing relevant facts and identifying opportunities for the government to obtain evidence relevant to the government's investigation that is not in the possession of the entity or individual or not otherwise known to the government"
 - "Preserving, collecting, and disclosing relevant documents and information relating to their provenance beyond existing business practices or legal requirements"
- Examples only; not mandatory or binding on DOJ
- In considering value of voluntary disclosure or cooperation during ongoing investigation, prosecutors are to consider four factors:

Timeliness and voluntariness of the assistance

Truthfulness, completeness, and reliability of any information or testimony provided

Nature and extent of the assistance

Significance and usefulness of the cooperation to the government

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COOPERATION CREDIT

- Examples of individuals or entities undertaking remedial measures in response to a violation
 - **Remediating the root cause of the conduct**
 - **Implementing or improving a compliance program**
 - **Removing those responsible for the misconduct**
- Guidance provides that maximum credit an individual or entity may receive may not result in the government receiving less than “full compensation for the losses caused”

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Civil Enforcement and Policy Punch Line

- The government and relators have a longstanding interest and track record in pursuing AKS issues under the FCA
- Both big and small organizations are pursued
- The government is increasingly requiring specific payments from executives in addition to the organization
- Having a strong compliance program in place to proactively address these issues is important to protect both the organization and the executive team

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