



The SUPPORT for Patients and Communities Act: What You Need to Know About the New Law's Expansion of Criminal Laws Against Paying for Referrals ("EKRA")

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Presented by:
Antonio Pozos
215.988.3327 | antonio.pozos@dbr.com

Drinker Biddle

Goals for Today

Understand the New Crimes and Penalties Included in the SUPPORT for Patients and Communities Act, Specifically, the Elimination of Kickbacks in Recovery Act of 2018 (“EKRA”)

Recognize Practices and Situations that Increase the Risk of Government Scrutiny

Learn How to Address Those Risks Before they Become Enforcement Problems

Core Law Enforcement Tools

Health Care Fraud and Conspiracy (18 U.S.C. §§ 1347, 1349)

- Billing for Services Not Rendered, Not Necessary, or Both
- Up to 10 Years in Prison, Fine of up to \$250,000 (or 2x Gain or Loss)

Federal Anti-Kickback Statute (“AKS”) (42 U.S.C. § 1320a-7b)

- Illegal to Pay for Referrals Reimbursed by Federal Health Care Programs
- Up to 10 years in Prison, Fine of Up to \$100,000

State Anti-Kickback Statutes

- Florida Patient Brokering Act (Fla. Stat. § 817.505)
 - Criminal: No Government Payor Requirement
- California Insurance Fraud Prevention Act (Ins. Code § 1871.7)
 - \$10,000 Civil Penalty, Treble Damages, Injunctive Relief, Disgorgement

The Travel Act (18 U.S.C. § 1952)

- Illegal to Cross State Lines, Use the Mail, or Any “Facility in Interstate or Foreign Commerce” to Further, or With the Intent to Promote or Carry on, “Any Unlawful Activity” – Includes Bribery

What is the New Law and Why Does it Matter?

The SUPPORT Act (Public Law No: 115-271) Gives Law Enforcement Powerful New Tools to Prosecute Recovery Residence Operators

§ 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.

Who Will Be Enforcing the New Law?



Federal Law Enforcement

- U.S. Attorney's Offices
- U.S. Department of Justice
- FBI, HHS-OIG, DEA

What About Payments to Employees/Contractors?

Anti-Kickback Statute and the “Bona Fide” Employee “Safe Harbor”

- AKS Does Not Prohibit Payments To an Employee “(who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.”
 - 42 U.S.C. § 1320a-7b(b)(3)(B); *see also* 42 C.F.R. § 1001.952(i)
- Minority: “Safe Harbor” Allows Companies to Pay “Bona Fide” Employees for Patient Referrals
 - *See e.g. United States v. Crinel*, 2015 WL 3755896 (E.D. La. June 16, 2015).
- Majority: Companies May Not Pay for Referrals; May Only Pay For Covered Services
 - *See e.g. United States v. Borrasi*, 639 F.3d 774, 781 (7th Cir. 2011); *United States v. Jackson*, 220 Fed. Appx. 317 (5th Cir. 2007); *United States v. Starks*, 157 F.3d 833, 836, 839 (11th Cir. 1998).



What About Payments to Employees/Contractors?

The “Safe Harbor” Under the SUPPORT Act/EKRA

- Addresses Ambiguities in the AKS Employee Safe Harbor
- Authorizes payments “made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, **if the employee’s payment is not determined by or does not vary by** –
 - (A) the **number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;**
 - (B) the **number of tests or procedures performed;** or
 - (C) the **amount billed to or received** from, in whole or in part, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.”
- **What this means:** Under EKRA, Cannot Pay Employees Based on the Volume or Value Of Referrals in Private Insurance Cases



What About Waiving Copayments?

Copayments and Premium Assistance

- Active Area – Not Just For Substance Abuse Treatment

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE Thursday, December 6, 2018

Drug Maker Actelion Agrees to Pay \$360 Million to Resolve False Claims Act Liability for Paying Kickbacks

Pharmaceutical company Actelion Pharmaceuticals US, Inc. (Actelion), based in South San Francisco, California, has agreed to pay \$360 million to resolve claims that it illegally used a foundation as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension drugs, in violation of the False Claims Act, the Justice Department announced today.

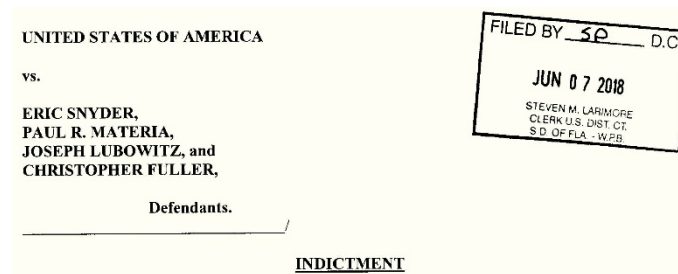
- SUPPORT Act/EKRA
 - Allows “a waiver or a discount ... of any coinsurance or copayment by a health care benefit program if --
 - (a) the waiver or discount is not routinely provided; and
 - (b) the waiver or discount is provided in good faith.”
 - Does Not Authorize Paying Private Insurance Premiums for Patients/Residents



What About Providing Other Benefits to Patients, Such As Discounted Rents, Travel?

Not Authorized by the “Safe Harbors”

- Government Likely to Take the Position that these Benefits Are Illegal



6. To obtain residents for HWT and patients for RLR, the defendants provided kickbacks and bribes in the form of free or reduced rent, payment for travel, and other benefits to individuals with insurance who agreed to reside at HWT, and to attend drug treatment, often in the form of PHP and/or IOP sessions, and submit to regular and random drug testing (typically three or more times per week) at RLR, so members of the conspiracy could bill the substance abuse treatment and testing to the residents' Insurance Plans.

What About Payments from Treatment Providers to Referral Sources for Services?

Government Suspicious of Payments to Referral Sources for Administrative Services

- Does the provider really need you to do this work?
- Is this work that your employees are qualified to do?
- Is any part of the payment meant to pay for referrals?

SUPPORT Act/EKRA Safe Harbor for Personal Services and Management Contracts

- Allows “payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of Section 100.952(d) of title 42, Code of Federal Regulations, as in effect on the date of enactment of this section.”



What About Payments from Treatment Providers to Referral Sources for Services?

What is 42 C.F.R. § 1001.952(d) and What Does it Require?

- Extensive Rules for “Personal Services and Management Contracts”
 - In writing and signed by the parties;
 - Covers and specifies all of the services to be provided;
 - Includes schedules for the work to be done and payments to be made (when periodic, sporadic, or on a part time basis);
 - Contract must be for more than 1 year;
 - **Amount to be paid is set in advance, consistent with fair market value, and may not take into account volume or value of referrals;**
 - Services to be performed do not counsel or promote any illegal activity; and
 - Services to be provided are reasonably necessary to accomplish a reasonable business purpose.
 - 42 C.F.R. § 1001.952(d)



What About Payments from Treatment Providers to Referral Sources for Services?

Payments for Administrative and Management Services (Cont.)

- Practical Steps: Documentation and Verification
 - Qualifications of Persons Performing Work
 - Basis for Amount of Payment (“Fair Market Value”)
 - Amounts charged by third parties?
 - Amounts charged to non-health care industry clients?
 - Support for comparing services provided against the amounts charged by third parties?
 - Costs incurred providing the services?
 - Log of Time Spent Performing Work, With Corresponding Services Rendered
 - Verification of Time and Services Reflected in Log
 - Receipts for Expenses Incurred



What About Payments for Marketing and Community Outreach?

Law Enforcement is Often Skeptical of Payments for Marketing and Outreach Services

- Are Outside Personnel Really Necessary?
- Is This Part of Your Normal Business?
- Is This A Cover to Pay for Referrals?

Documentation and Justification

- Contract that Complies With the Rules for “Personal Services and Management Contracts”
- Acknowledgment that Contract and Compensation are Not Based on Volume or Value of Referrals
- Qualifications, Basis for Fair Market Value, Logs and Receipts



What About Transportation Services?

“Safe Harbor” Under Anti-Kickback Statute

- Authorizes “Local Transportation Services,” With Conditions:
 - Availability of the free or discounted local transportation;
 - Must be set forth in a **policy**, that is applied uniformly and consistently; and
 - May not be related to the past or anticipated **volume or value** of Federal health care program business.
 - Services may not be air, luxury, or ambulance-level transportation;
 - Services may not be **publicly marketed or advertised**;
 - Health care items and services may not be advertised during the transportation;
 - Drivers or others arranging for transportation may not be paid on a **per-beneficiary-transported basis**;
 - The individual transported must be an **established patient** of (1) the provider providing the transportation, if a provider or supplier of health care services, and (2) the provider or supplier to or from which the individual is being transported;
 - Travel may not exceed 25 miles from the health care provider, or 50 miles in a rural area.
 - Transportation must be for medically necessary items and services; and
 - Service provider must **bear all costs** of transportation, and may not “shift the burden of these costs onto any Federal health care program, other payors, or individuals.”
 - See 42 C.F.R. § 1001.952(bb)(1); see also 42 C.F.R. § 1001.952(bb)(2) (shuttle services).

What About Transportation Services?

SUPPORT Act/EKRA Does Not (Yet) Contain Similar Exception

- Ways to Seek Clarification
 - Rulemaking
 - SUPPORT Act Gives Attorney General Authority to Create Further “Safe Harbors,” In Consultation with Secretary of Health and Human Services
 - Advisory Opinion
 - Option Available through HHS-OIG
 - See also Advisory Opinion No. 15-13
 - Predated adoption of AKS safe harbor for transport.
 - Approved proposal by health system to operate shuttle van circuits between medical center, hospital, ambulatory surgery center and designated pickup locations.
 - Found that the value of the transportation, \$10 per transport or \$50 on an annual basis, could implicate the Anti-Kickback Statute.
 - But, found that proposed arrangement presented a minimal risk of fraud and abuse, and would therefore not be subject to an enforcement action.
 - Conditions largely followed AKS safe harbor regulations for local transportation services.

Does My Corporate Structure Affect What I Can Do, and Still Comply with the SUPPORT Act?

Corporate Structure Unlikely to Affect Prosecutions of Individuals Under SUPPORT Act/EKRA

- SUPPORT Act Prohibits Illegal “Remuneration,” Regardless of Whether Paid “Directly or Indirectly, Overtly or Covertly, in Cash or In Kind”
- Government’s Rationale: Companies Act Through People



Compliance Best Practices

They Can Work!

Quality Compliance Programs Can Help, Even When they Do Not Prevent All Misconduct

- Can Influence Whether the Government Brings a Case Against a Company:
 - Showing that company has “adopted and implemented a truly effective compliance program” may “result in decision to charge only the corporation’s employees and agents or to mitigate charges or sanctions against the corporation.”
 - Justice Manual § 9-28.800 – Corporate Compliance Programs

Compliance Best Practices

Quality Compliance Programs Can Benefit a Company, Even When they Do Not Prevent All Misconduct

- Can Also Reduce Fines and Other Penalties
 - U.S. Sentencing Guidelines for Business Organizations Reward Compliance Programs.
 - Programs must be “reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct.”
 - But, “[t]he failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.”
 - U.S. Sentencing Guidelines, § 8B2.1 (Effective Compliance and Ethics Program)

Written Compliance Policies & Procedures

Adopt Written Standards of Conduct and Compliance Policies

- First Element of HHS-OIG's Guidance on Compliance Programs
- Should be Provided to All Employees, Contractors, and Others with Privileges at Your Facility
- Standards of Conduct:
 - Statement of the Company's Principles, Staff Expectations, and Basic Legal Principles Governing Company
- Policies:
 - More Detailed, Tailored to Risk Areas
 - Quality of Care and Residents' Rights
 - Prohibitions Against Accepting Things of Value in Exchange for Referrals

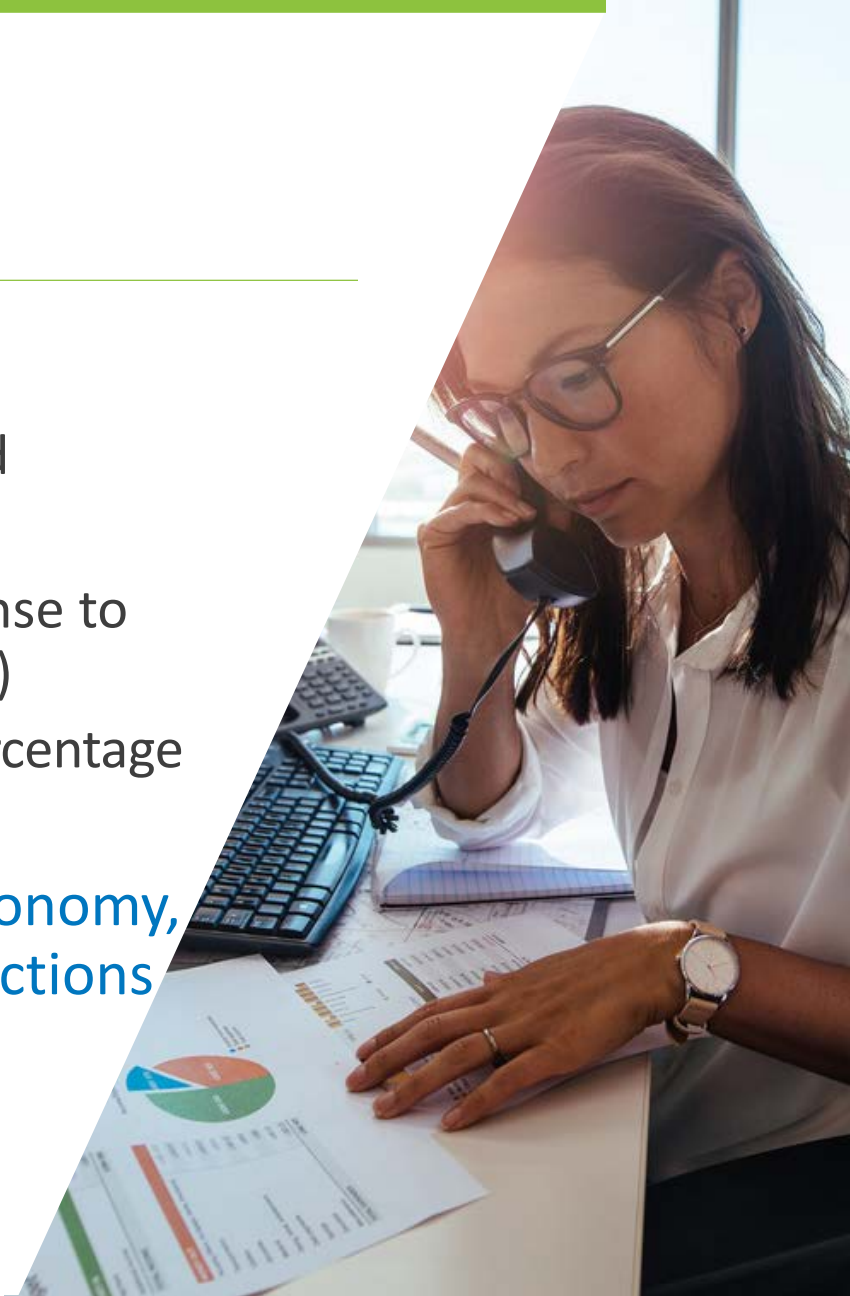


The Chief Compliance Officer

Responsibilities of CCO

- Organizations of All Sizes Should Identify Compliance Lead
- Formality Will Depend on Size of Organization
- Develops Policies, Advises Management, Oversees Response to Compliance Issues (with Advice of Counsel When Needed)
- CCOs with Multiple Responsibilities: Identify Minimum Percentage of CCO's Time on Compliance Issues in Job Description

Justice Department Compliance Guidance Emphasizes Autonomy, Empowerment, Funding and Resources of Compliance Functions



Training

Training Should Be Regular, Interactive

- Emphasis on Comprehension, Not Simply Completion

Enhanced Training for Employees in High Risk Functions

- Heightened SUPPORT Act Training for Marketing, Purchasing, Accounts Payable/Receivable, and H.R. Responsibilities

Ensure Employees Know Where to Go for Help

- Both Direct and Anonymous/Confidential Methods for Reporting and Seeking Guidance
 - U.S. Sentencing Guidelines, § 8B2.1(b)(5)(C)



Empowering Staff to Report Misconduct

Programs Cannot Succeed Without Staff Participation

- Clear Processes for Staff to Raise Concerns
- Strong Policy Against Retaliating Against Employees Who Report Wrongdoing
- Established Processes for Reviewing, Documenting the Resolution of, Concerns
 - Who is Responsible for Reviewing Reports?
 - Who is Responsible for Conducting Internal Investigation?
 - What is the Process for Documenting Findings, and Any Remedial Steps to be Taken?
 - Who is Responsible for Preventing Retaliation?
 - How Regularly Will the Board be Briefed?
- Audit/Review Process to Ensure Appropriate Implementation
 - Who is Responsible for Ensuring that Reviews are Conducted Appropriately?
 - Who is Responsible for Ensuring that Any Remedial Steps are Actually Implemented?



Accountability and Discipline

Government is Very Interested in How the Company Responds to the Discovery of Misconduct

- What disciplinary actions were taken, and when?
- Were managers held accountable for misconduct that occurred under their supervision?

Government is Also Interested in Whether Companies Incentivize Compliance and Ethical Behavior

- Are ethical and compliance considerations factored into compensation, promotions?



Best Practices for Departing Employees

Exit Interview

- Ask Departing Employees if They Are Aware of Illegal or Unethical Conduct
- Carefully Document the Employee's Response, and Investigate if Appropriate

Ask Employees to Certify That They Have Reported Any Potentially Inappropriate Conduct

- Encourages Departing Employees to be Forthcoming
- Limits Employee's Ability to Make New Allegations in the Future

Ask Employee to Sign Release of All Claims Against the Company

- Note: Release Cannot Prohibit Employee from Cooperating with Authorities



Questions?

Antonio M. Pozos

Partner

Philadelphia
(215) 988-3327
Antonio.Pozos@dbr.com

Antonio M. Pozos represents clients in criminal litigation, internal investigations, government investigations, and related civil proceedings, with a particular emphasis on the health care industry, foreign corruption, public corruption, and cross-border disputes. He is an experienced trial lawyer and former federal prosecutor.

[Learn More at: drinkerbiddle.com/people/p/pozos-antonio-m](https://www.drinkerbiddle.com/people/p/pozos-antonio-m)

Thank You

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