

# Understanding & Mitigating Anti-Kickback Risk Through Data Analytics

*Presented to the Members of the Dental Trade Alliance*

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# Meet the Presenters



**ED BUTHUSIEM**  
Managing Director, BRG



**BRIAN HOYT**  
Managing Director, BRG

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# Discussion Topics

- **Overview of the Anti-Kickback Statute**
- **The Importance of Mitigating Anti-Kickback Risk**
- **How Dental Companies Can Mitigate Anti-Kickback Risk & The Importance of Data Analytics**

# WHAT IS THE ANTI-KICKBACK STATUTE?



# The Anti-Kickback Statute

## Overview

The **Anti-Kickback Statute** (“AKS”) is a **criminal prohibition** against payments, whether direct or indirect, made purposefully to **induce or reward** the referral or generation of federal health care business.

- The AKS addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for—or recommending—the purchase, lease, or ordering of any item or service reimbursable in whole or part by a **federal health care program** (*i.e.*, no quid pro quo transactions).
- At its heart, the AKS is an anti-corruption statute designed to protect federal health care program beneficiaries from the **influence of money** on referral decisions.
- Many common business activities in the dental sector—including, for example, sales, marketing, discounting, and purchaser relations—are subject to **heightened scrutiny** under the AKS.
- Thus, doing anything to promote products to dentists participating in federal health care programs presents an **inherent risk**.
- To that end, dental manufacturers must take measures to mitigate the risk of violating the AKS when engaging in promotional activities directed at federal health care program participants.

*The nexus required to prosecute a dental manufacturer pursuant to the AKS is*  
**PARTICIPATION IN A FEDERAL HEALTH CARE PROGRAM.**

Without this connection, there is no federally-actionable offense.

# The Anti-Kickback Statute

42 U.S.C. 1320a-7b(b)

(1)

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—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a **Federal health care program**, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

(2)

Whoever knowingly and willfully **offers or pays any remuneration (including any kickback, bribe, or rebate)** directly or indirectly, overtly or covertly, in cash or in kind **to any person to induce such person—**

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a **Federal health care program**, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

# The Anti-Kickback Statute

## “Federal Health Care Programs” Defined

**REMEMBER:** The nexus required to prosecute a dental manufacturer pursuant to the AKS is **participation in a federal health care program.**

1. **Medicare:** Medicare is a federal and state government health insurance program that primarily covers **recipients over 65 years old** as well as certain groups of younger Americans with **special disability status** for conditions such as end stage renal disease. Medicare contains four main program elements that cover inpatient hospital stays, outpatient physician services, nursing and home care, prescription drug purchases, among other costs. Parts of Medicare are administered through private insurers who contract with the government to serve as sponsors for the program.
2. **Medicaid:** Medicaid is a national health insurance program that covers costs for Americans with **low income**. Eligibility requirements vary from state to state, but are generally based on a measure of gross income as well as non-financial requirements such as pregnancy and parenting status.
3. **VA:** The VA Health Administration is a federal program that provides extensive health care services to **US military veterans and their families**. Services covered include primary care, specialty care, and mental health treatment.
4. **TRICARE:** Tricare provides health insurance to **active military personnel and their families**. In addition to coverage for standard primary care, Tricare also confers benefits for dental care and other services.
5. **IHS:** The Indian Health Service (IHS) provides medical services to **Native Americans and Alaska Native people** recognized by the Federal Government.
6. **CHIP:** The Children’s Health Insurance Program (CHIP) is a federal program that provides **supplementary health benefits to children of low-income families**. The program is designed to help families that are not eligible for other programs such as Medicare and Medicaid but have incomes too low to provide adequate coverage for their children.

**IN ADDITION TO POTENTIAL FINES AND JAIL TIME FOR VIOLATING THE AKS, DENTAL COMPANIES MAY ALSO FACE EXCLUSION FROM REIMBURSEMENT BY THESE FEDERAL HEALTH CARE PROGRAMS.**



# The Anti-Kickback Risk Statute

## “Remuneration” Defined

The AKS defines **remuneration** broadly as: “the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value (FMV).”

**Remuneration** includes kickbacks, which can take many forms in the dental industry, such as:

- Paying referral fees to a dentist
- Paying speaker fees to a dentist to promote a product in excess of FMV
- Paying SPIFs to dealer reps based on increasing sales to customers
- Leasing equipment to a dental practice beyond 90 days, at rates less than FMV
- Providing an excessive number of samples to a dental practice, which later resells them



**Fair Market Value** is the value for a good or service that is negotiated between a hypothetical buyer and seller at **arms length**.

**Kickbacks** can lead to:

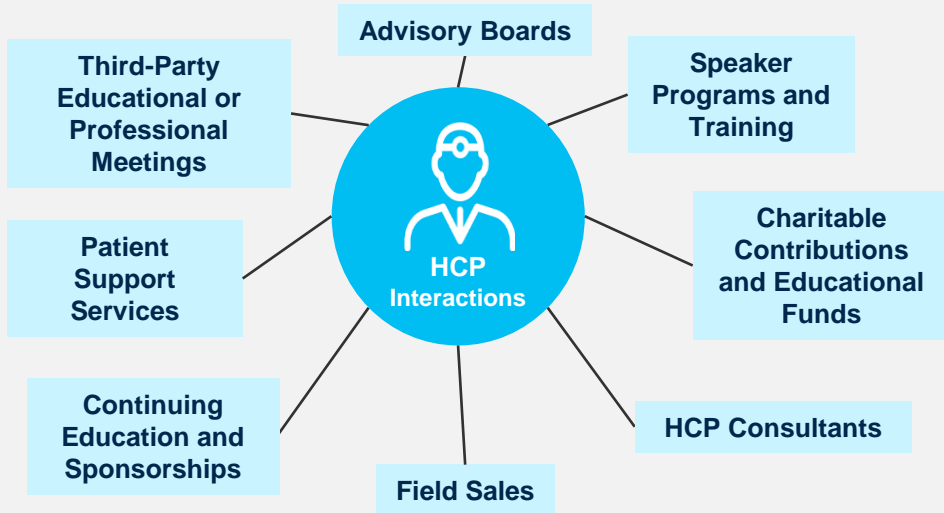
- Overutilization
- Increased program costs
- Corruption of medical decision-making
- Patient steering
- Unfair competition

# The Anti-Kickback Risk Statute

## Recognizing Different Provider Types

### Providers Accepting Only Commercial Insurance

Providing remuneration to HCPs that do not participate in federal health care programs in exchange for conducting business-related activities will not trigger AKS violations.



**OKAY!**

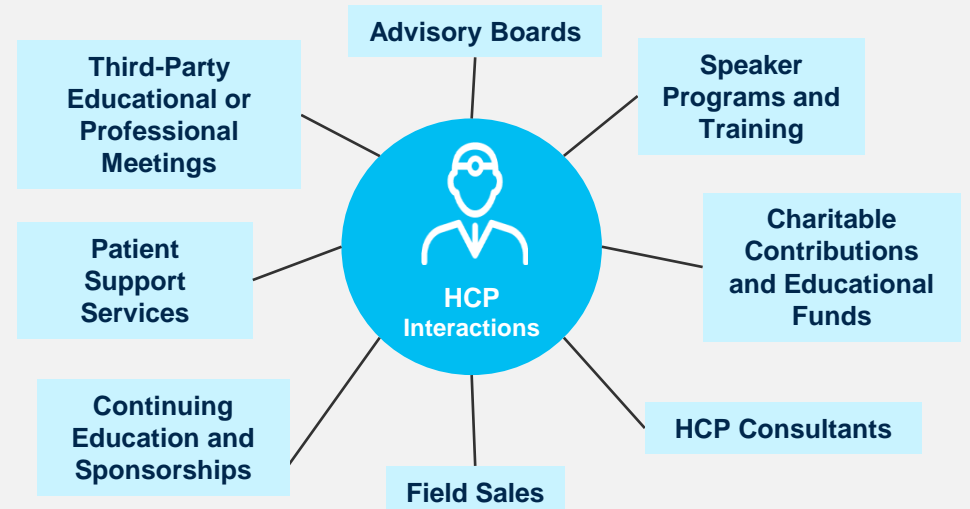
**39%**

of U.S. Dentists Participate in Medicaid or CHIP according to the ADA

*...Only a fraction of enrolled HCPs receive payment from FHCPs.*

### Providers Enrolled in and Actively Receiving Payments From Federal Health Care Programs

Providing remuneration to HCPs that are enrolled in and actively receive payments from federal health care programs in exchange for conducting business-related activities may trigger AKS violations in the absence of appropriate compliance controls and consideration.

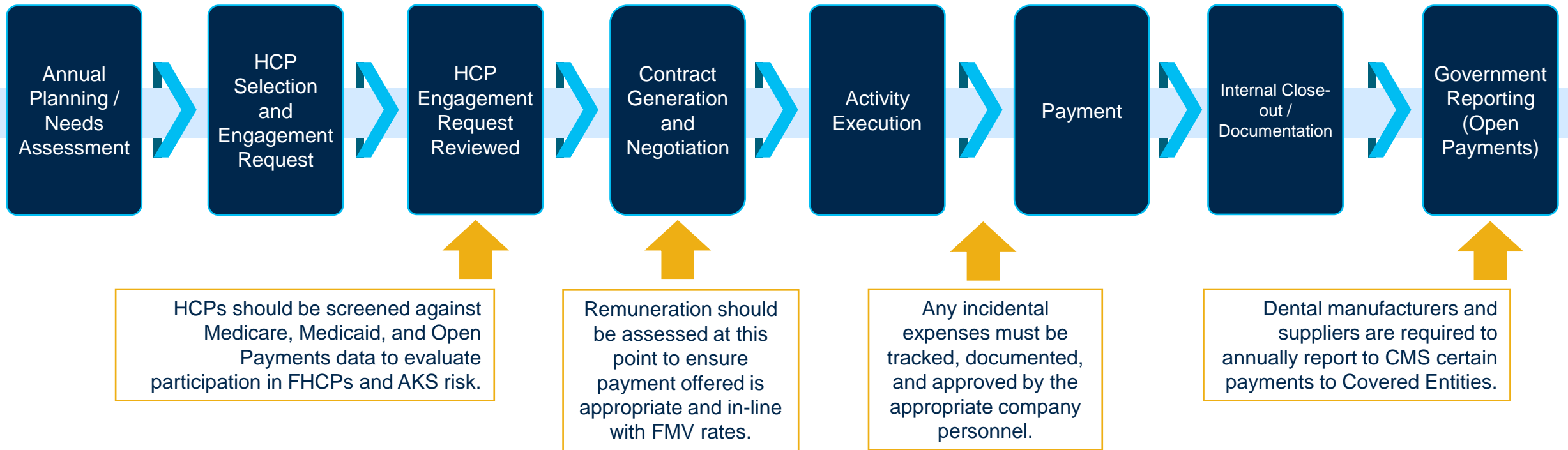


**USE CAUTION**

# The Anti-Kickback Risk Statute

## *The Provider Payment Process*

Companies may engage an HCP for a number of appropriate business-related activities, given that there is a **legitimate need** for the services, remuneration is in-line with **Fair Market Value** (FMV), all steps of the engagement are **thoroughly documented**, and payments to covered entities are reported to **CMS Open Payments**, as required. A formalized, robust HCP engagement process is critical to ensuring payments by dental manufacturers and suppliers to HCPs are compliant with federal and state regulations:



# AKS Safe Harbor Regulations

## Overview

Not all referrals or interactions with beneficiaries of federal health care programs violate the AKS. The “**Safe Harbor**” **regulations** describe various payment and business practices that, although they potentially implicate the AKS, are not treated as offenses under the statute. In other words, a company **will not risk federal prosecution** pursuant to the AKS if its activity meets the requirements of a safe harbor, which include:

- Bona Fide Employment Relationships
- Personal Service Arrangements
- Lease or Rental of Office Space or Equipment
- Referral Services
- Group Purchasing Organizations
- Discounts
- Investment Interests
- Waivers of Copayments, Coinsurance, and Deductibles
- Warranties
- Price Reductions
- Sale of Health Care Practice

*A discussion of the Safe Harbors most relevant to DTA Members is set forth in the following slides.*

# AKS Safe Harbor Regulations

## *Bona Fide Employment Relationship*

**Bona Fide Employment Relationships** qualify for safe harbor protection under Section 1128B of the Social Security Act (which is home to the AKS). As explained by the OIG, the AKS “exempts from its reach ‘any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.’” For the purposes of the AKS, **employment status** is determined based upon the applicable common law principles that typically evaluate factors such as:



The level of control the employer exerts over the employee



The timing and method of payment (e.g., bi-monthly paychecks vs. invoicing)



The location and tools or equipment used by the employee during work hours

# AKS Safe Harbor Regulations

## *Personal Service Arrangements*

**Personal Service Arrangements** that **do not** qualify as bona fide employment relationships qualify for safe harbor protection under the AKS if they satisfy seven specific conditions outlined in Section 1128B. The ability to satisfy those conditions is of paramount importance in considering the use of **HCPs as consultants**. The conditions to qualify for this safe harbor are:

1. A written contract that is currently in force
2. All bi-directional terms of service are contemplated in the agreement
3. Service intervals are described (periodic, if not full time)
4. Contract term not less than one year (e.g., no “one day” agreements)
5. The aggregate compensation paid to the HCP over the term of the agreement is:
  - I. set in advance,
  - II. is **consistent with fair market value in arms-length transactions**, and
  - III. is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
6. No promotional activities violate state or federal laws
7. The **aggregate services** contracted for **do not exceed** those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services

# AKS Safe Harbor Regulations

## *Lease or Rental of Office Space or Equipment*

The safe harbor regulations contain near-identical provisions insulating **agreements for the lease or rental of office space and equipment** that satisfy certain conditions. A lease or rental agreement will not trigger AKS liability if:

The parties have a written and signed lease or rental agreement that specifies the premises or items covered by the lease

The term of the lease is for not less than a year

The aggregate rental charge is set in advance consistent with fair market value and does not take into account the volume or value of any referrals or business between the parties

The lease or rental agreement specifies the schedule for the lease or rental

The scope lease or rental agreement is no greater than is reasonably necessary for commercial purposes

# AKS Safe Harbor Regulations

## Referral Services

Despite the Anti-Kickback Statute’s express intent to prohibit payments for referrals, payments of “remuneration” to referral services are **permitted** under certain circumstances. The “**Referral Services**” safe harbor provides:

**‘[R]emuneration’ does not include any payment or exchange of anything of value between an individual or entity (‘participant’) and another entity serving as a referral service (‘referral service’), as long as all of the following four standards are met –**

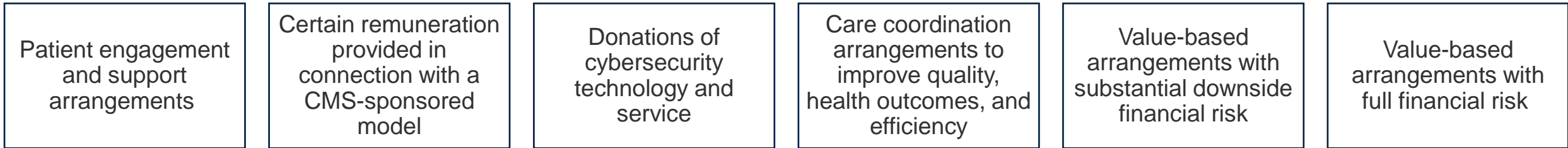
1. The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.
2. Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants and is based only on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.
3. The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.
4. The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service –
  - i. The manner in which it selects the group of participants in the referral service to which it could make a referral
  - ii. Whether the participant has paid a fee to the referral service;
  - iii. The manner in which it selects a particular participant from this group for that person;
  - iv. The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and
  - v. The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.



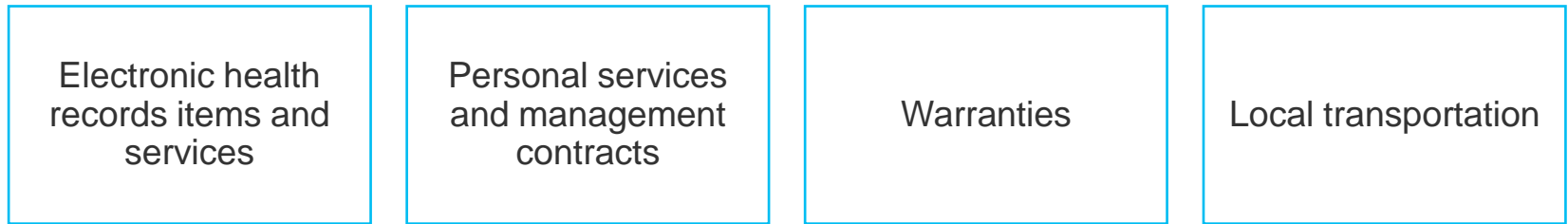
# AKS Safe Harbor Regulations

## Recent Updates

In October 2019, HHS OIG released a Proposed Rule to add **new safe harbor protections** for certain **coordinated care** and associated **value-based arrangements** with HCPs. The new safe harbors are intended to support:



The Proposed Rule also included proposed **modifications to the existing safe harbors** for:



Another important update to be aware of is the **November 2019 changes by CMS to Open Payments reporting requirements**. Effective as of January 1, 2021 for all reporting submitted on or after January 1, 2022, the Medicare Physician Fee Schedule (PFS) Final Rule expands the scope of the Open Payments program by implementing a **broader definition of a Covered Recipient** to include physician assistants, nurse practitioners, clinical nurse specialists; certified registered nurse anesthetists; and certified nurse midwives. Published in the Federal Register on November 1, 2019, the PFS Final Rule updates payment policies, payment rates, and other provisions for services furnished under the Medicare PFS on or after January 1, 2020. The Final Rule also added **three new payment categories** for transparency reporting purposes: **(1) Debt Forgiveness**, **(2) Long-Term Medical Supply or Device Loans**, and **(3) Acquisitions**.

# WHY IS IT IMPORTANT TO **MITIGATE** ANTI-KICKBACK RISK?

# The Anti-Kickback Statute

## Enforcement Actions

The federal government is aggressive and particularly active in pursuing suspected violations of the AKS against healthcare entities. It has an array of **enforcement tools** at its disposal, which may be overlapping.

LEAST SEVERE

+ *Fines & Penalties*

MOST SEVERE

1. Declination

5. CIA / IRO Monitor

7. DPA / No  
DOJ Monitor?

9. Probation\*

3. Consent Decree

2. Declination w/  
disgorgement

6. NPA / IRO Monitor

10. Exclusion from  
Federal Programs

4. NPA / No Monitor

8. DPA / DOJ Monitor

\*In 2018 a federal judge in the District of Massachusetts sentenced Aegerion Pharmaceuticals, Inc. to three (3) years probation in conjunction with the company's plea agreement related to marketing practices, kickbacks, and data privacy violations. In addition to the DPA / Consent Decree / CIA monitor, Aegerion must also report to a probation officer with the Federal Bureau of Prisons on a prescribed interval. See Form 8-K dated January 30, 2018. *Novelion Therapeutics, Inc.* Available online at [www.sec.gov/edgar.shtml](http://www.sec.gov/edgar.shtml).

# The Anti-Kickback Statute

## Sources of Investigations and Enforcement Actions

### Qui Tam Relator

- A **qui tam relator** is a “whistleblower” who brings attention to the fraud within their organization.
- Qui tam relators identify alleged overpayments made by the government to a private organization as a result of a false claim or kickback scheme resulting from improper activities.
- Alternatively, qui tam relators may reveal that their organization withheld money that should have been paid to the government.
- The US Government may, or may not, join suit with qui tam relators.

### DOJ Strike Force

- The **Medicare Fraud Strike Force** combines resources of federal agencies and uses data analytics to identify potential instances of health care fraud, waste, and abuse, and have prosecuted cases involving over \$14 billion in losses to Medicare.
- DOJ recently announced the formation of a new strike force, the **Procurement Collusion Strike Force** (PCSF), dedicated to “deterring, detecting, investigating, and prosecuting antitrust crimes.” The application to life sciences manufacturers who participate in the Federal Supply Schedule (“FSS”) is particularly relevant; especially on balance with the intensified focus on prescription drug pricing and healthcare costs more generally.

### Self-Disclosure

- The OIG maintains several **self-disclosure processes** that apply to health care providers, contractors, and grant recipients.
- Self-disclosure protocol gives these providers and organizations the opportunity to proactively identify areas of potential fraud and avoid incurring the large costs of becoming subject to a government investigation.
- Self-disclosures often result from results of internal auditing and monitoring, or internal reports of potential misconduct through investigative channels.

# The Anti-Kickback Statute

## *Enforcement Actions against Manufacturers and Suppliers*

### CASE STUDY #1

In a December 2015 settlement agreement with the DOJ, Coloplast Corp. paid **\$3.1 million** to resolve allegations that it paid kickbacks to numerous suppliers to induce them to convert patients to Coloplast products.

Under Coloplast's SPIF program, the company offered funding for cash incentives paid to suppliers' sales personnel in exchange for product conversions. The DOJ also alleged that Coloplast offered rebates or price concessions contingent on suppliers' participation in promotional campaigns on the company's behalf.

### CASE STUDY #2

Hollister, Inc. and its supplier Byram Healthcare collectively paid **\$20.9 million** in an April 2016 settlement agreement in connection with the Hollister SPIF program. The DOJ alleged that Hollister was disguising the payments of cash incentives to suppliers' sales personnel as "marketing funding." The DOJ pegged as an illegal kickback Hollister's "catalog funding" program, which involved yearly payments to suppliers to encourage recommendation of Hollister products to patients during the calendar year. The DOJ asserted that these payments by Hollister were designed to "convert" patients from competitors' products to their own, and were then billed to federal health care programs.

### CASE STUDY #3

In January 2017, MB2 Dental Solutions and 21 of its pediatric dental affiliates agreed to an **\$8,450,000** settlement with the DOJ and the State of Texas Medicaid Program after allegations of violating the False Claims Act (FCA) and Anti-Kickback Statute (AKS). The DOJ's allegations were initially filed under the qui tam "whistleblower" protections of the FCA, and contain three central components: (1) MB2 knowingly submitted false claims for pediatric single-surface fillings that were not performed, (2) paid kickbacks to Medicaid beneficiaries and marketing entities, and (3) intentionally used incorrect Medicaid provider numbers to misrepresent the dentist who performed various procedures.

# HOW CAN DENTAL COMPANIES MITIGATE ANTI-KICKBACK RISK?



# Mitigating Anti-Kickback Risk

## *Risk Assessment and Management Programs*

**REMEMBER:** The nexus required to prosecute a dental manufacturer pursuant to the AKS is **participation in a federal health care program.**

To avoid legal, financial, operational, or reputational damage, companies must ensure a comprehensive understanding of their specific compliance risk portfolio, assess the potential damage to the business posed by each risk, and then allocate the appropriate level of resources to manage the highest risk areas.

Built-for-purpose Risk Assessment and Management Program (RAMP) processes lead with strong risk identification and evolution processes to ensure a company's limited resources are keenly aware of all material healthcare compliance risks, that they have been evaluated critically and holistically, and that the resulting work plan is informed by a true understanding of the company's highest risk management priorities. This folds into a cycle that repeats annually with continued maintenance and oversight from compliance.



# Mitigating Anti-Kickback Risk

## *Compliance Standards & RAMP*

In the current complex operating environment, regulators *expect* companies to address compliance risks by establishing a regular compliance risk assessment process and implementing responsive risk management actions. This sentiment is evidenced by the references to risk assessment, identification, mitigation, and management throughout the pertinent compliance standards.

- The **OIG's 2003 Compliance Program Guidance**, which delineates the Seven Elements of an Effective Compliance Program, describes the expectation for a comprehensive program to include “risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems.”
- In its recently revised **Guidance on Evaluating Corporate Compliance Programs**, the **DOJ** describes compliance risk assessment and risk management as “the starting point for a prosecutor’s evaluation of whether a company has a well-designed compliance program” and is therefore eligible for cooperation credit. Specifically, prosecutors are instructed to understand “how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks.”
- The 2018 **Federal Sentencing Guidelines** explain that an effective compliance program should periodically assess the risk of criminal conduct and take steps to design, implement, or modify activities to reduce the risks identified through this process.
- A proactive, standardized risk assessment processes is a common requirement in **CIAs and other enforcement agreements** across the pharmaceutical, medical device, and dental industries.



# Mitigating Anti-Kickback Risk

## *Using Data to Inform FMV Analysis*

Among other requirements that must be satisfied to fulfill the objectives of the Anti-Kickback Statute “safe harbors”, a Fair Market Value must be ascribed to any transaction between a dental manufacturer or supplier and another party (such as a healthcare professional) **who is in a position to purchase, recommend, refer or prescribe a product that is eligible for reimbursement by US federal health care programs** (e.g., Medicare, Medicaid).

**Fair Market Value** is defined as the compensation that would be included in a services agreement as a result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the service agreement (the “**arm’s length transaction**” test). Additional consideration for **commercial reasonableness** should be applied to the transaction as well. To be deemed reasonable, the purpose must be reasonably calculated to further the business of the lessee or purchaser. Space, equipment, or services that the lessee or purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives should all be factored into FMV compensation, where applicable.



# Mitigating Anti-Kickback Risk

## *Hallmarks of a Robust FMV Analysis*



**Data-driven assessments** customized to the company's business structure, policies and procedures, activities, and needs.



**Multi-disciplinary approach** incorporating professionals with training in statistics, economics, accounting and public policy.



**Consideration and incorporation of key regulatory drivers, industry guidance, valuation principles and industry best practices.**



**Holistic analysis of the commercial reasonableness** of a transaction through benchmarking, market research, and econometric analysis.



**Reliance on multiple publicly available and/or subscription level transaction-specific datasets** in addition to qualitative econometric research (e.g., salary datasets).



**Periodic updates** based on market fluctuations or changes in the business that expand the types of transactions the company would like to consider.

# Mitigating Anti-Kickback Risk

## *Data-Driven FMV Analysis Methodology*

To conduct an FMV Assessment, BRG procures custom dataset(s) dependent on the type of transaction under analysis. Using this data as a basis point, BRG develops a financial model to determine Fair Market Value by cost type.

### Step 1: Characterize

**CHARACTERIZE** the company's activities related to the transaction type.

### Step 2: Determine Factors

**DETERMINE** factors to include in dataset based on the determinants driving cost for specific transaction. **Cross-reference** these factors with industry benchmarks.

### Step 3: Create Calculator

**CREATE** an integrated FMV Calculator to evaluate rates/costs submitted, as compared to weighted factors adjusted for therapeutic area and country of origin or transaction location.

### Step 4: Test and Calibrate

**TEST** and **CALIBRATE** transaction type-specific FMV Calculator. Conduct User Acceptance Testing.

# Mitigating Anti-Kickback Risk

## Key Levers for FMV Analyses

### COMPANY POLICES AND PROCEDURES

Assessment of a company's business model, compliance processes, and the scope of activities / transactions contemplated enriches understanding of the nature and purpose of the transaction, and thus, the appropriate FMV.

### COMPANY HISTORICAL PAYMENT DATA

It is important to understand the company's standard payment practices to ensure FMV is assessed consistently and gain insight into how different transactions are valued at the company.

### RELEVANT LITERATURE AND INDUSTRY STANDARDS

This information informs opinions of what is believed to be a commercially reasonable cost associated with a transaction.

### LENGTH OF ACTIVITY / TRANSACTION

The expected and standard amount of time spent completing an activity or other transaction is essential to determining ultimate payment.



### OVERHEAD

Overhead costs associated with the transaction should be accounted for in FMV analysis.

### COMPLEXITY OF ACTIVITY / TRANSACTION

Different transaction / activity types must be examined in the context of their affect on FMV.

### PAYMENT RECIPIENT SALARY AND TAX INFORMATION

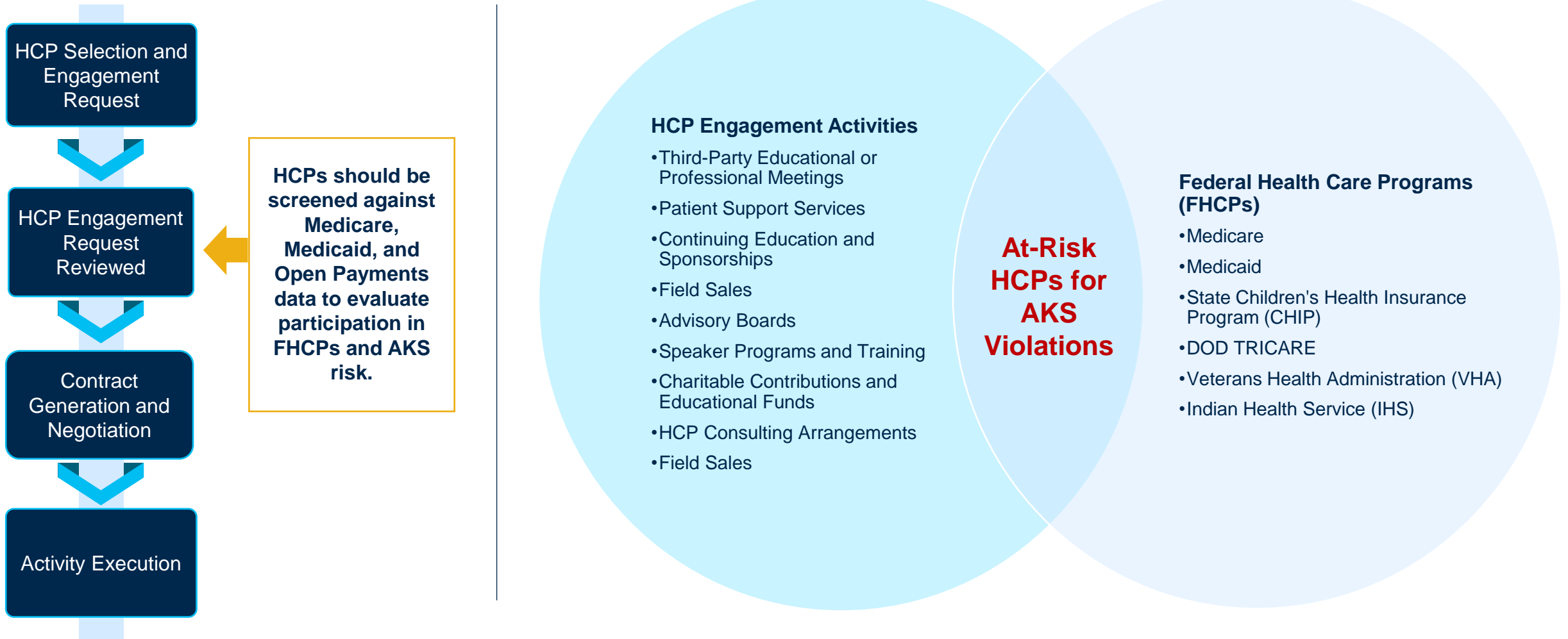
Depending on the transaction type, FMV determination may require review of HCP's tax documents by a professional accountant.

### THIRD PARTY DATA

Depending on the transaction type, third party data incorporated into the analysis may include **Global Data, Salary Survey Data and Pay Differentials, NIH Reporter, Standard Travel Expense Data, and Literature Review.**

# Mitigating Anti-Kickback Risk

## Review – HCP Participation in FHCPs





# ASK THE AUDIENCE!



**DO YOU KNOW HOW MANY OF YOUR  
CUSTOMERS RECEIVE FUNDS FROM  
FEDERAL HEALTH CARE PROGRAMS?**

**a. YES**

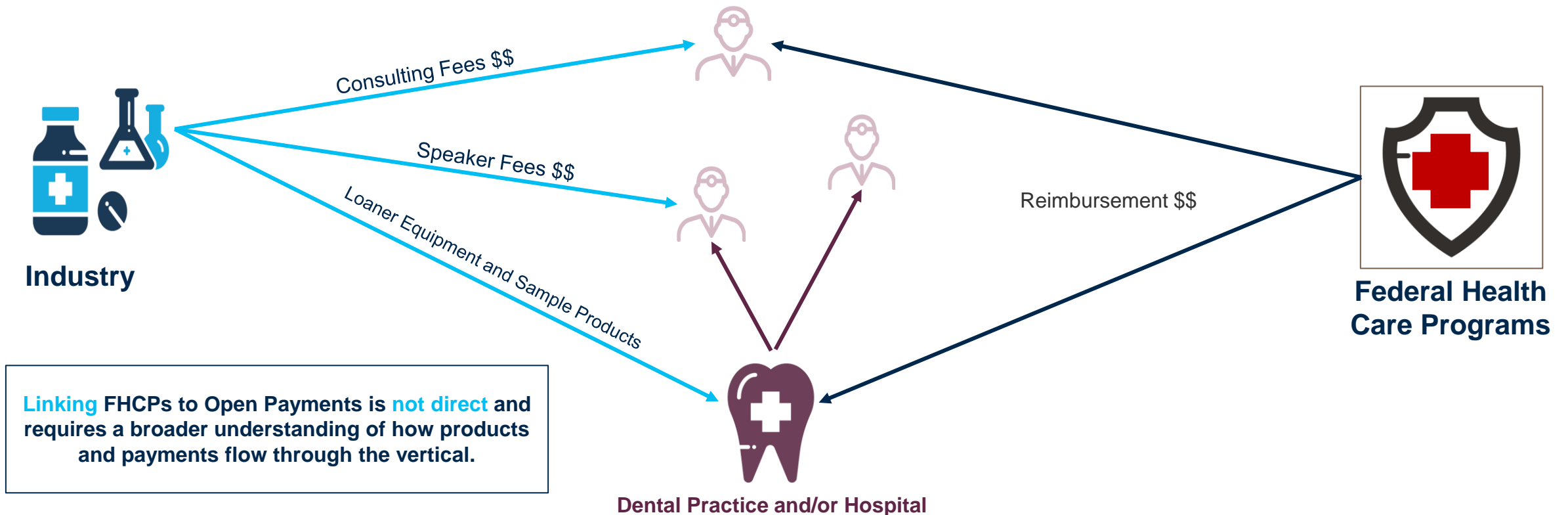
**b. NO**



# Mitigating Anti-Kickback Risk

## Using Data to Understand HCP Participation in FHCPs

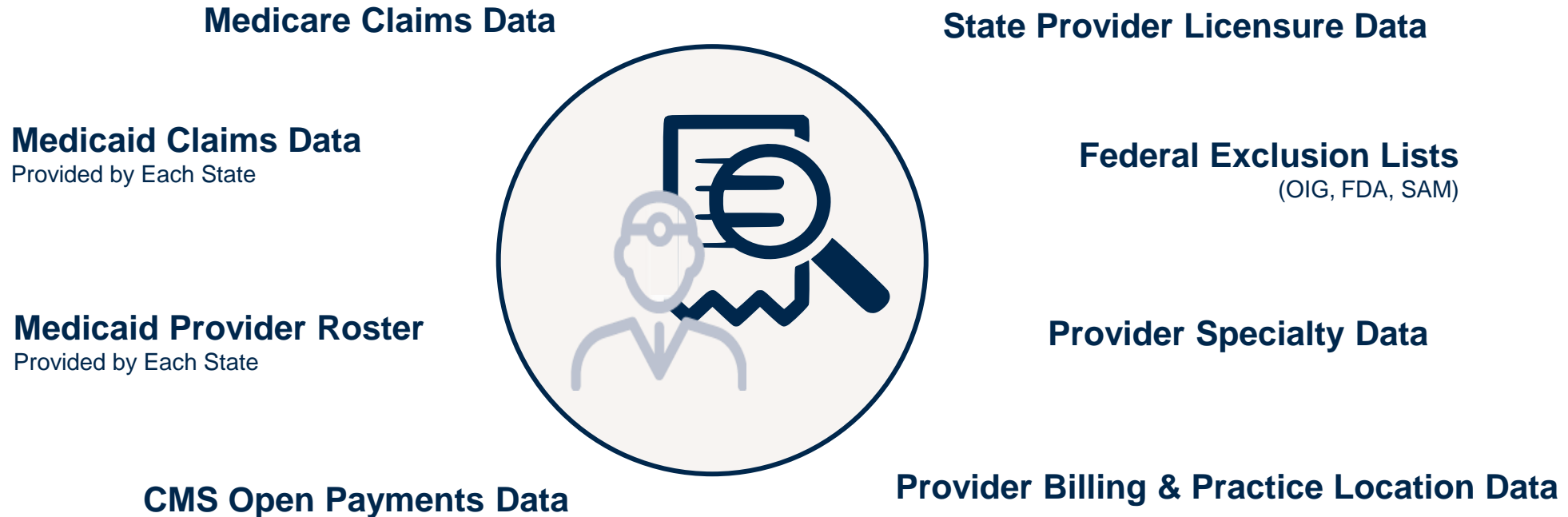
Dentists and other HCPs can receive payments and other transfers of value from industry **directly** from dental supplies manufacturers and distributors or **indirectly** via transfers of value received by their place of practice. Claims data can elucidate both the direct and indirect payments in order to provide companies with a **full picture of the risk** involved with doing business.



# Mitigating Anti-Kickback Risk

## *Data-Driven HCP Participation Analysis*

A comprehensive, data-driven analysis of kickback risk requires **validating and linking structured and unstructured data** across multiple sources. From the aggregated information, companies can **gain actionable insights** at both the provider and practice levels to **assess and manage risk** across provider specialties and geographies.



**Industry experts, experienced data scientists/analysts, and advanced technology providers must collaborate to carry out and interpret data-driven AKS risk assessments for dental supplies manufacturers and distributors.**



**QUESTIONS?**

