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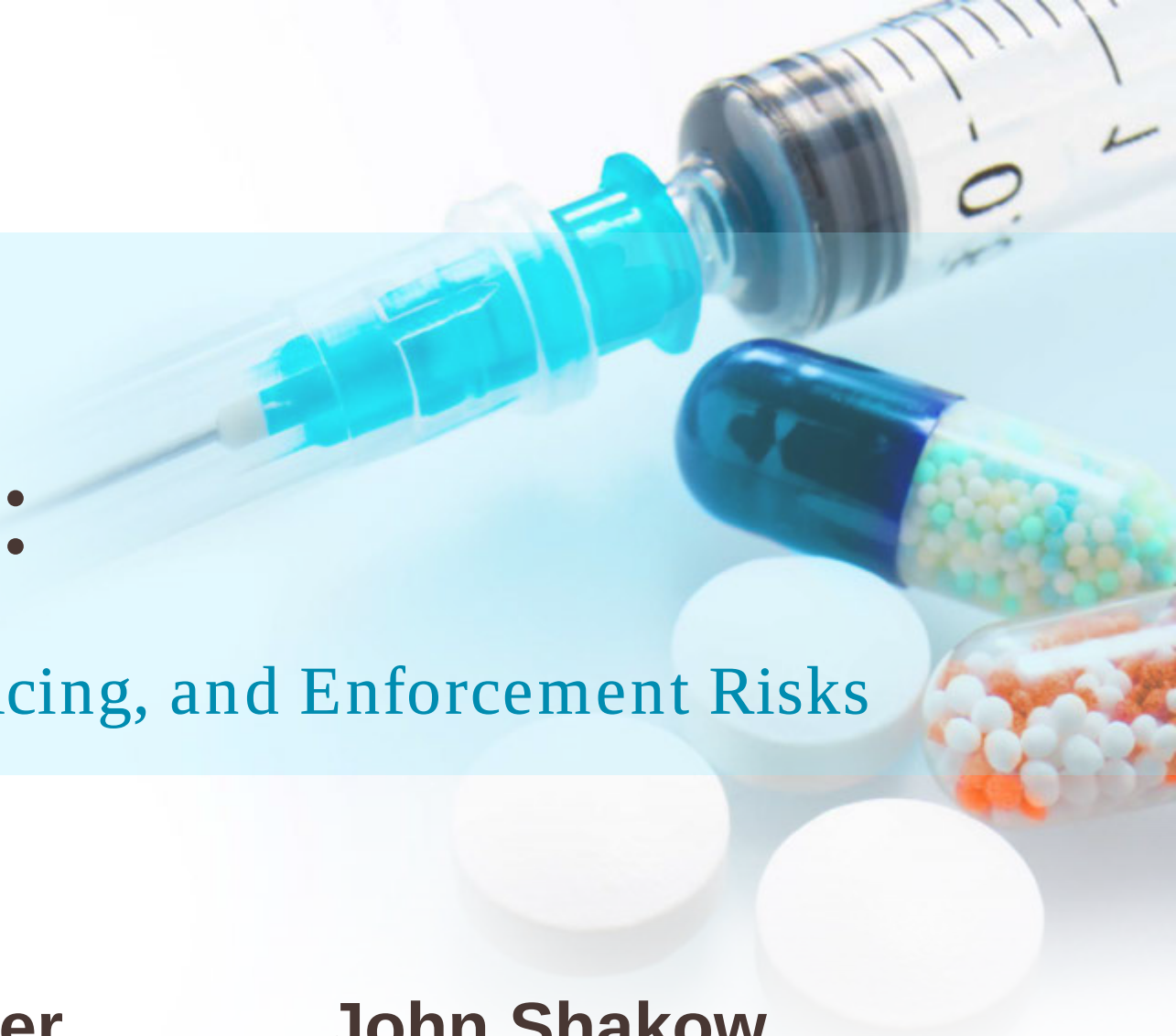

Service Fees to Channel Partners:

Understanding Anti-Kickback, Pricing, and Enforcement Risks

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Agenda

Common Types of Service Fees Paid to Channel Partners

Key Legal Considerations:

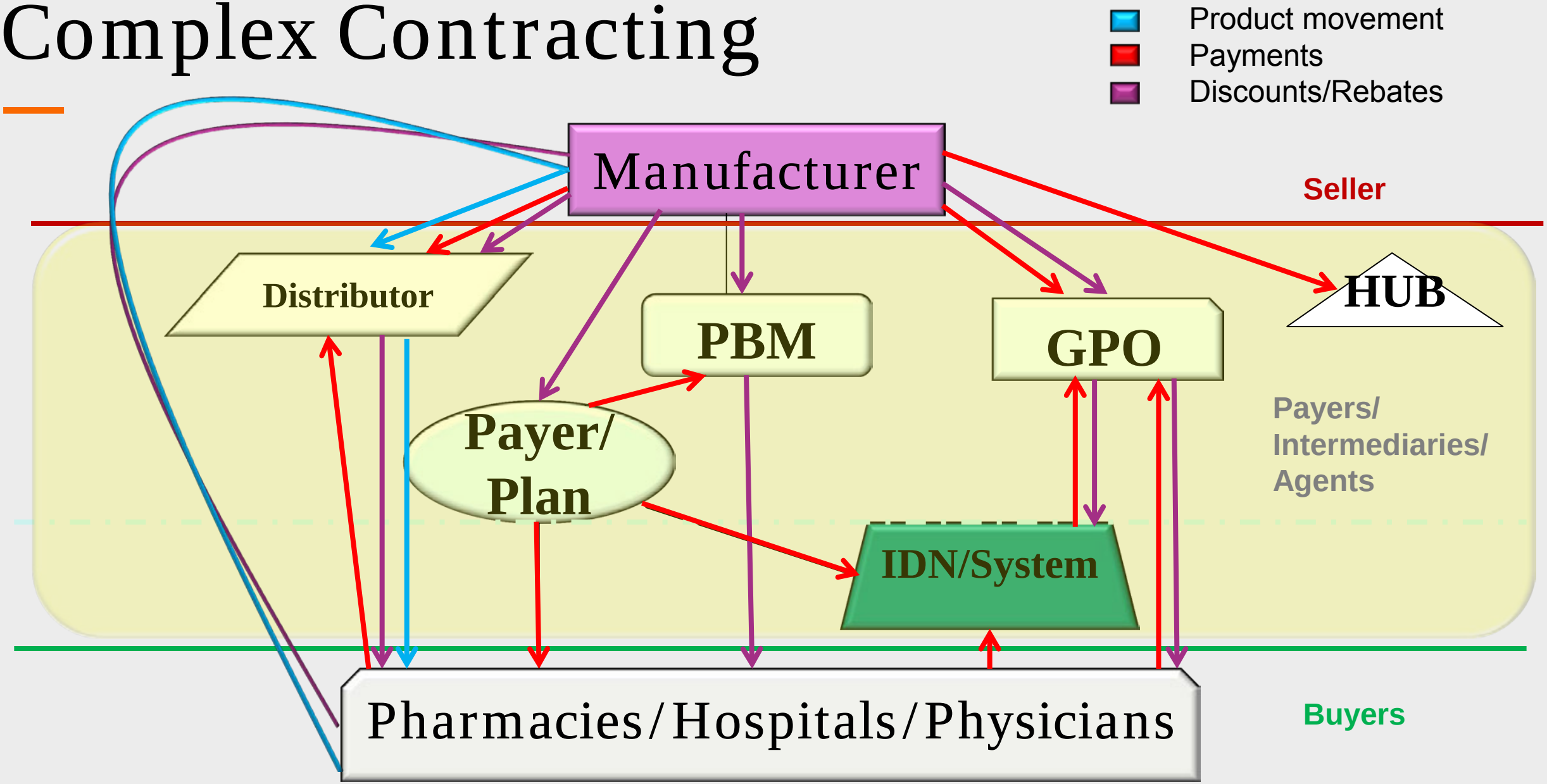
- Government Pricing
- Anti-Kickback Statute (AKS)

Factual Considerations & Enforcement Analysis

- Type of Channel Partner
- Fair Market Value Analysis
- Basis for Services

Takeaways and Recommendations

Complex Contracting



Recipe for Investigations

Ingredients:

- Political Drivers
- Economic Motivations
- Legal Uncertainty
- Lack of Transparency/Understanding
- Poor Communications/Documentation

Potential for Enforcement

Priority at the top

Prosecutors' cynical world-view:

- Complex, opaque relationships
- Understood by few
- "Middlemen" profiting + customers/ gov't pay more = illegal

No clear safe harbor

Prosecution tools:

- Breadth of AKS/"one purpose test"
- FCA damages/threat of exclusion

Government Focus on Pricing

HHS Secretary Alex Azar, March 5, 2018:

In both healthcare services and pharmaceuticals, the huge gaps between the list price and the actual price are notorious. . . .***This thicket of negotiated discounts makes it impossible to recognize and reward value, and too often generates profits for middlemen rather than savings for patients***.

So this administration is calling on . . . drug companies and pharmacies, to become more transparent about pricing and outcomes of their services and products. And if that doesn't happen, ***we have plenty of levers to pull that would help drive this change***.

Types of Channel Partner Relationships

Payor/PBM	Entities that establish **formulary** and thereby influence prescribing
GPO/HUB	Entities acting as **agents** that have a commercial purpose
Pharmacy/IDN	Customers that are actual **purchasers** of product

Examples of Paid Services

Data	Care Coordination	REMS	Patient Communication
Reimbursement Information	Benefits Investigations	PA and Appeals Support	Triage to Specialty Pharmacy
Inventory Management	Days on Hand	Returns Management	Call Center Services

Government Pricing Considerations

Service Fees and Government Pricing

***Bona Fide* Service Fee test**

- A regulatory test, first articulated in 2004, governs GP treatment of service/admin fees
- Four *qualitative* prongs
- One *quantitative* prong
- Only those fees to AMP/BP/ASP eligible customers need to be assessed for GP

Service Fees and Government Pricing

***Bona Fide* Service Fee test**

Fees that "pass" the BFSF test are ignored in Medicare and Medicaid

Fees that "fail" the BFSF test

- May set a new Best Price
- Reduce AMP
- Reduce ASP
- Indeterminate effect on 340B

Service Fees and Government Pricing

Bona Fide Service Fee test

Qualitative prongs:

- *Bona fide*, itemized service
- Performed on behalf of the manufacturer
- Manufacturer would otherwise perform
- Not passed on in whole or in part to a client of the service-providing entity

Service Fees and Government Pricing

Bona Fide Service Fee test

- Quantitative prong: fair market value
- CMS has given manufacturers great latitude in the determination of FMV
- FMV as a snapshot of a moment in time
- Percent-of-sales fees and FMV

Service Fees and Government Pricing

Bona Fide Service Fee test

- Most manufacturers *bifurcate* fees that satisfy the qualitative elements but exceed FMV
- That is, a fee can be *bona fide* to a point, then not
- Government pricing can handle a fee in excess of FMV by treating the excess as a discount

Service Fees and Government Pricing

The includable fees "test" for NFAMP/FSS

Merchant middleman fees are generally included in NFAMP if they are

- Percent of sales incentive fees to achieve the manufacturer's business goals,
- Not generally imposed on all manufacturers, or
- Pricing/promotion discounts to make drugs more attractive in the market

Service Fees and Government Pricing

Streck Litigation

- Multi-year, multi-district *qui tam* litigation
- Questioning the application of the BFSF test to wholesaler service fees in AMP
- Were the manufacturers reckless?
- Quality of the FMV measurements?
- Intersection of an aggressive plaintiff and opaque requirements

Service Fees and Government Pricing

Minimize service fee risk in GP

- Perform contemporaneous analysis of agreements with service fee provisions
- Undertake objective analysis of all prongs
- Document findings in GP files

Fraud and Abuse Considerations

Anti-Kickback Statute

42 U.S.C. § 1320a-7b(b)

Makes it illegal to pay (or offer) or accept anything of value in exchange for:

- referring Medicare/Medicaid program patients or other federal health care program patients or business
- purchasing or ordering Medicare/Medicaid covered items
- arranging for others to make such referrals/purchases/orders
- recommending that others make such referrals/purchases/orders

Anti-Kickback Statute

Channel Partners

Service fees

Purchase, prescribe, recommend or arrange for prescriptions

Pharma Manufacturer

Personal Services Contracts Safe Harbor

Requirements:

- Written agreement of at least one year
- Defined services
- Aggregate compensation set in advance
- Consistent with fair market value
- Not be determined in a manner that takes into account the volume or value of referrals or business otherwise generated
- Commercially reasonable services

GPO Safe Harbor

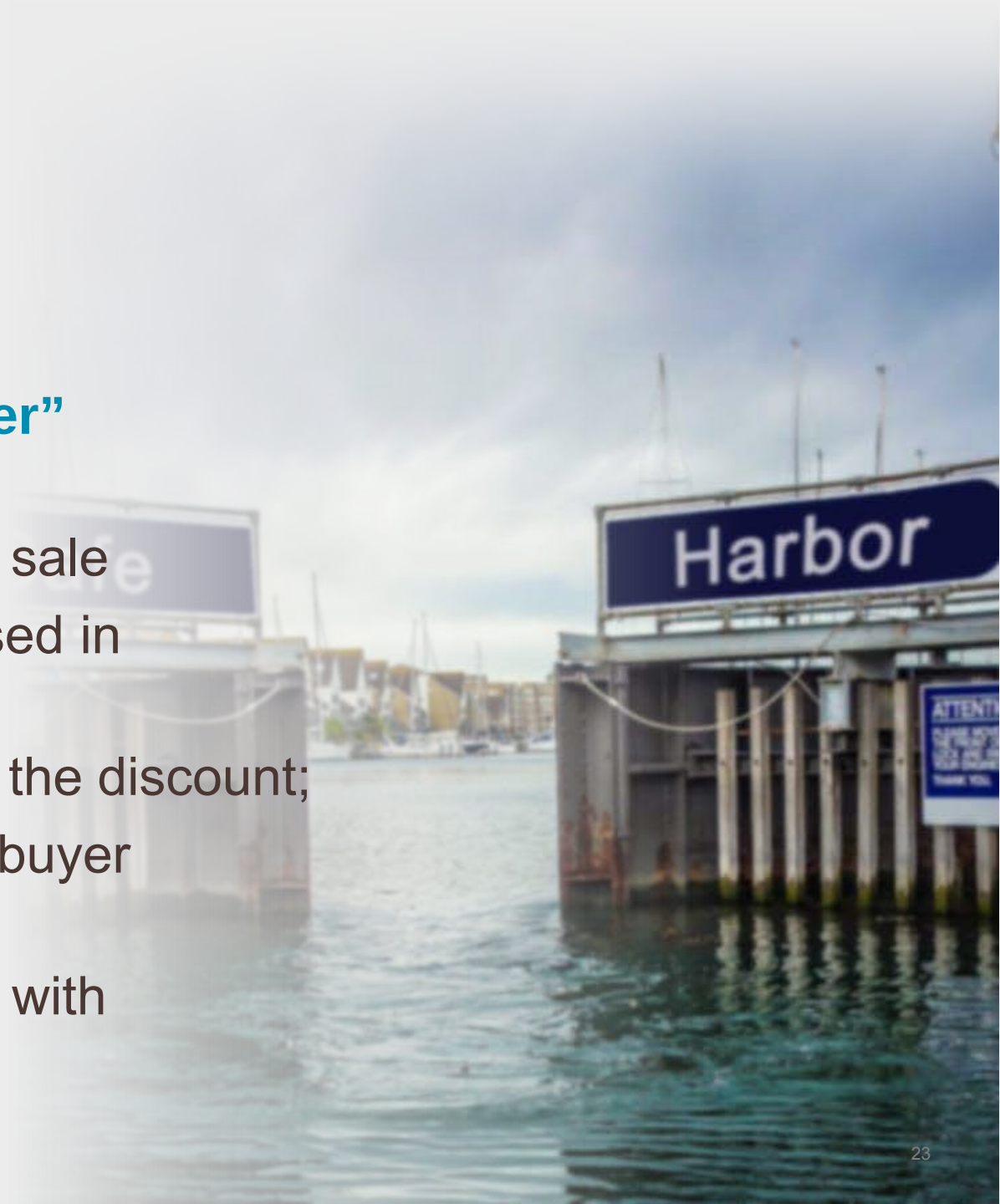
Requirements:

- GPO = entity authorized to act as a purchasing agent
- Protects payments to a GPO for administrative services in conjunction with the administration of sales and discounts to GPO members
- GPO must have a written agreement with its members with different terms if:
  - Fees are 3% or less, or
  - Fees are more than 3%

Discount Safe Harbor

Requirements:

- Must be offered from a seller to a **"buyer"** of a product
- Must be made at (or before) the time of sale
- Rebate terms must be fixed and disclosed in writing to the buyer at the time of sale
- Buyers must fully and accurately report the discount;
- Sellers must provide information to the buyer to allow accurately reporting
- Buyers must provide federal authorities with requested information



Navigating the Divide Between Price Reporting, Fraud and Abuse, and Business Need

Fair Market Value (FMV)

OIG Definition:

> "Fair market value means the value that would be assigned to the item or service in question by individuals or entities who have an arms-length relationship and who have no ability to influence referrals of any health care business to each other."

Used for both AKS and government price reporting purposes

Price Reporting – Bona Fide Service Fees

> *"Bona fide service fees mean fees paid by a manufacturer to an entity, that represent fair market value of a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."*
>
> *— 42 C.F.R. § 414.802*

AKS Basis for Services

- Safe harbor compliant?
- Legitimate commercial or clinical purpose, other than driving scripts?
- Would the services otherwise be performed by the channel partner?
- Type of services that a manufacturer would be expected to purchase?
- Will services actually be used?
- Are the fees fair market value?

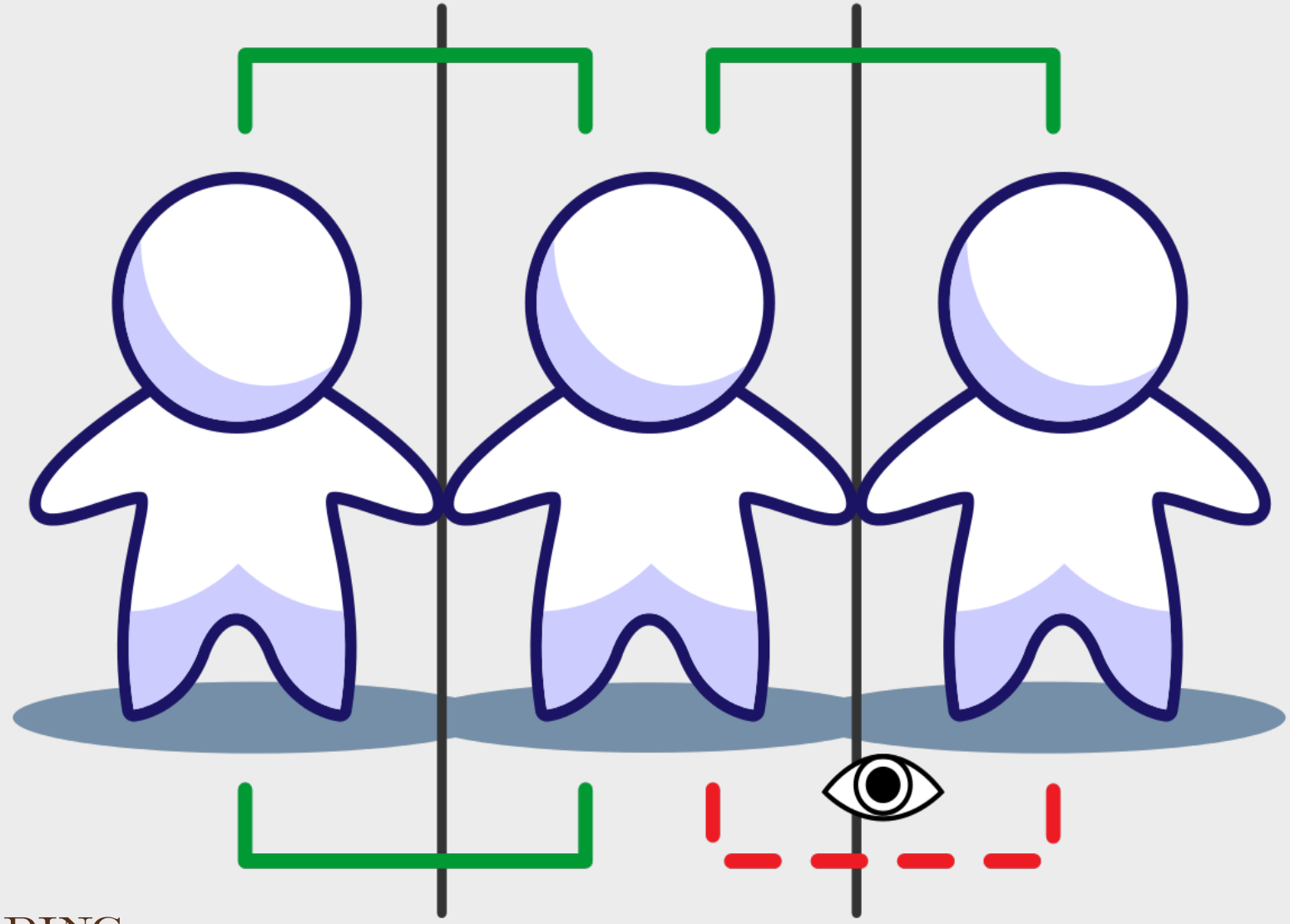
AKS – Service Fees

Non-bona fide services are inherently suspect

Non-bona fide services may include services:

- not required by the purchaser
- not performed as contracted
- not ordinarily performed in absence of the payment arrangement

Channel Partner Service Relationships



Types of Channel Partner Relationships

Legal/compliance risks vary depending upon the channel:

Payor/PBM

- Service fees could be a form of discount for government price reporting purposes
- Risk that fees could be viewed as remuneration in return for arranging for product to be prescribed through formulary management

GPO/HUB

- Fees to GPOs (not hubs) could have government pricing implications
- Entities act as an agent of the manufacturer and their actions can be attributed to the manufacturer

Pharmacy/IDN

- Service fees could be a form of discount for government price reporting purposes
- Any service fees could be viewed as remuneration in return for script fills or purchases

No safe harbor protection is likely in any channel

Payor/PBM Case Example

AstraZeneca (Feb. 2015)

- $7.9 million settlement
- Resolved allegations that AstraZeneca agreed to provide remuneration to a PBM in exchange for maintaining “sole and exclusive” status on certain formularies and through other marketing PBM activities

OIG Guidance on PBM Rebates

"Formularies are a well-established tool for the effective management of drug benefits... So long as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.

— HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (May 2003)

OIG Guidance on PBM Rebates

> *"However, as federal program expenditures for, and coverage of, outpatient pharmaceuticals increase, scrutiny under the anti-kickback statute has also increased. Several practices appear to have the potential for abuse... Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor.*
>
> *— HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (May 2003)*

Payor/PBM Risks

- Safe harbors may not apply
- Rebates intended to induce services or actions, may be viewed as service fees
- Is there a bona fide service?
- Is formulary decision-making independent or steered?
- Communications may refer to arrangements improperly (e.g., “buying market share”)

GPO/HUB Case Example

Pfizer (May 2018)

- Settlement announced May 24, 2018
- Pfizer agreed to pay $23.85M to "resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation"
- Pfizer case focused on company's use of a pharmacy HUB to interact with the charitable foundation

GPO/HUB Risks

- Could the manufacturer provide the service directly?
- Is the service *bona fide*?
- Is there safe harbor protection?
- Contracts may not define services
- Agent activities may not be properly overseen or policed

Pharmacy/IDN Case Example

Novartis (Nov. 2015)

- $370 Million Civil Fraud Settlement with DOJ and Southern District of New York
- Allegations that volume discount and market-share rebate agreements with pharmacies constituted illegal inducements to switch patients to the manufacturer's drug
- Agreements were subject to un-memorialized requirements (oral agreements) that made the discounts and rebates contingent upon efforts to aggressively switch patients and increase market share
- No allegations that discount and rebate agreements were not valid on their face, but rather that they were not discounts by payments for services

Core vs. Enhanced Services

Whether a service is "core" or "enhanced" may vary based on the business model and practices of a particular channel partner

Core Services?	Enhanced Services?
Benefits verification	Welcome kit distribution
Product dispensing	REMS requirements
Patient management services	Patient assistance programs
Distribution of patient information	Enhanced patient management services • In-home nursing assistance • Adherence/ compliance programs
Patient education/counseling, including adverse events	Data reporting
Payor/insurance information and counseling	Expedited prior authorization services
Product shipment	Refill reminders

Pharmacy/IDN Risks

- These are payments to customers
- Services may be the customer's own responsibility
- Consider the PhRMA Code
- Discounts may not be protected if used to pay for services

Recommended Courses of Action

Legal Challenges For Enforcers

- **Causation:** FCA liability only when "cause" false claims to be presented
- **Intent:** mere hope for or expectation of referrals collateral to legitimate motive for financial arrangement ≠ improper inducement
- **Materiality:** Gov't knowledge plus payment = strong evidence of immateriality

Key Questions to Ask

- What kinds of services can be sought?
- What kinds of payments or discounts can be offered?
- What is the purpose of the payments or discounts?
- What are the roles and responsibilities of the parties (with and without the services being performed)?
- Can a business need be demonstrated and documented, including FMV and proof of performance?
- What other relationships are in place with the channel partner and its affiliates?
- How will the arrangement be communicated?

Recommendations

- Document the need for every service
- Conduct an FMV assessment
- Evaluate for both ASP and AKS
- Use strong written agreements
- Stick to the script with communications

Recommendations

- Evaluate enforcement risks
- Develop clear policy
- Seek independent review
- Ensure that the services are used
- Audit and monitor
- Enforce and remediate

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Questions?

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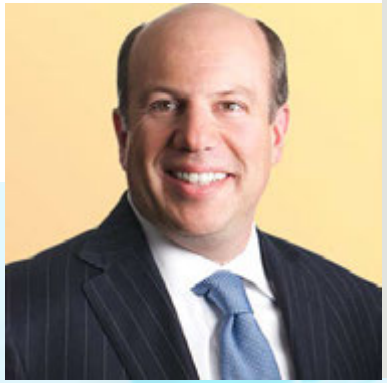

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