C. The Scope of Permissible Anti-Kickback Discount Arrangements

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The Anti-Kickback Statute
(42 U.S.C. § 1320a-7(b)(b))
(SSA § 1128B(b))
The Anti-Kickback Statute

- Makes it unlawful for any person to:
  - (1) Knowingly and willfully;
  - (2) Offer, pay, solicit or receive;
  - (3) Any remuneration;
  - (4) To induce or in return for
    - a referral or for recommending a referral, or
    - purchasing or recommending or arranging for the purchase;
  - (5) Of covered items or services; and
  - (6) Paid for by any federal health care program.

The Anti-Kickback Statute (Cont.)

- Remuneration includes the transfer of anything of value, in cash or in kind, whether made directly or indirectly, and whether made overtly or covertly.
- Remuneration can include cash, free goods or services, discounts, or otherwise below fair market value items or services.
The Anti-Kickback Statute (Cont.)

- Criminal conviction under the Anti-Kickback Statute requires proof of criminal intent or *scienter*.
- The United States Supreme Court has held that, in the context of the Firearms Owners’ Protection Act, one acts willfully when one acts with a bad purpose, with knowledge that his conduct is unlawful. *Bryan v. United States.*

The Statutory Discount Exception

*(42 U.S.C. § 1320a-7b(b)(3)(A))*

*(SSA § 1128B(b)(3)(A))*

&

**The Regulatory Discount Safe Harbor**

*(42 C.F.R. § 1001.952(h))*
The Statutory Discount Exception

➢ The Anti-Kickback Statute contains an exception for: “a **discount or other reduction in price** obtained by a provider of services or **other entity** under [Medicare or Medicaid] if the reduction in price is **properly disclosed** and **appropriately reflected** in the costs claimed or charges made by the provider or entity under [Medicare or Medicaid].”

The Statutory Discount Exception (Cont.)

“The bill would specifically **exclude the practice of discounting or other reductions** in price from the range of financial transactions to be considered illegal under medicare and medicaid, **but only if such discounts are properly disclosed and reflected in the costs for which reimbursement could be claimed.** The committee included this provision to **ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal.** In fact, the committee would **encourage providers to seek discounts** as a good business practice which results in savings to medicare and medicaid program costs.” (Emphasis added)

The Regulatory Discount Safe Harbor

- In 1991, the OIG promulgated a regulatory safe harbor for purchasing discounts received by providers.

- Discounts given by providers are covered elsewhere.

The Regulatory Discount Safe Harbor (Cont.)

- What Is A “Discount” Under The Safe Harbor:
  - “[T]he term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction.”
The Regulatory Discount Safe Harbor (Cont.)

What Is Not A “Discount” Under The Safe Harbor (seven items identified):

- (i) Cash payment or cash equivalents (except that rebates as defined … this section may be in the form of a check);
- (ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;
- (iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;
- (iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;
- (v) Warranties;
- (vi) Services provided in accordance with a personal or management services contract; or
- (vii) Other remuneration, in cash or in kind, not explicitly described in … this section.
The Regulatory Discount Safe Harbor
(Cont.)

What Is A “Rebate” Under The Safe Harbor:

- “[A] rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.”

The safe harbor established separate disclosure obligations for different types of entities:

- Manufacturers, that furnish goods and services to providers on a discounted basis (“sellers”),
- Providers that buy such goods and services and submit claims to Medicare and Medicaid (“buyers”), and
- Parties that are essentially middlemen who arrange for discounts between buyers and sellers (“offerors”).
The Regulatory Discount Safe Harbor (Cont.)

- The safe harbor’s obligations are further differentiated depending on whether the buyer:
  - Is acting under risk contract;
  - Reports costs on a cost report;
  - Or falls under neither of these categories

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The Regulatory Discount Safe Harbor (Cont.)

- **Buyer Obligations -- risk contracts:**
  - Essentially no reporting obligations
The Regulatory Discount Safe Harbor (Cont.)

Buyer Obligations: the cost report buyers must comply with all of the following:

- (A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;
- (B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;
- (C) The buyer must fully and accurately report the discount in the applicable cost report; and
- (D) The buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

Buyer Obligations: all others must comply with both of the following:

- (A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and
- (B) The buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.
The Regulatory Discount Safe Harbor
(Cont.)

➢ Seller/Offeror Obligations -- defined with reference to the three types of buyers

➢ Risk Contracts:
  ▪ Essentially no reporting obligations

The Regulatory Discount Safe Harbor
(Cont.)

➢ Seller Obligations -- where cost report buyer, seller must comply with either of the following:
  ▪ (A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or
The Regulatory Discount Safe Harbor

(Cont.)

⇒ Seller Obligations -- cost report buyer (Cont.):

- (B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

The Regulatory Discount Safe Harbor

(Cont.)

⇒ Seller Obligations -- for any other buyer, seller must comply with either of the following:

- (A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

- (B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.
The Regulatory Discount Safe Harbor (Cont.)

- **Offeror Obligations** -- where cost report buyer, offeror must comply with both of the following:
  - (A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and
  - (B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

The Regulatory Discount Safe Harbor (Cont.)

- **Offeror Obligations** -- for any other buyer, offeror must comply with both of the following:
  - (A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and
  - (B) The offeror of the discount must refrain from doing anything that would impede the buyer’s or seller’s ability to meet its obligations under this paragraph.
SELECTED ISSUES & THEMES

HOW DO Discounts Implicate the Anti-Kickback Statute and How is this Analysis Informed by the Discount Exception?
How Do Discounts Implicate The Anti-Kickback Statute?

- Remuneration is the lowered price buyer gets to pay -- but no payment to referral source
  - Induce purchase/ordering --
  - Not referrals
- Buy-sell transaction -- no side benefit
- Congress intended the statute not to apply to common, commercially reasonable discounts
- What is corrupting or criminal intent?

How Do Discounts Implicate The Anti-Kickback Statute? (Cont.)

- Did Congress intend to criminalize all discounting practices not meeting the exception?
- Very little case law
- Statutory construction tools may say yes
- Gov’t position → yes
How Do Discounts Implicate The Anti-Kickback Statute? (Cont.)

- Cost report buyers --
  - Probably what Congress was thinking about
  - Likely a false claim
- Other buyers?

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How Do Discounts Implicate The Anti-Kickback Statute? (Cont.)

- Logic would suggest that if the exception fails, the government must prove every element of the offense.
- Conduct that does not fall within the discount exception/safe harbor can be legal if there is no criminal intent.
United States v. Shaw,

- Shaw was charged with conspiracy to violate the federal anti-kickback statute, in violation of 18 U.S.C. § 371, for allegedly conspiring to pay remuneration in the form of rebates, special pricing, entertainment and hunting trips, and write-offs of bad debt to induce dialysis clinics to order clinical laboratory blood testing. (Note: bundled discounts)

- In a motion to dismiss, Shaw argued, among other things, that the statutory discount exception protected the conduct at issue.

- The district court denied the motion.

Shaw (Cont.)

- Court rules discount exception is a “carve-out.”

- “But for the ‘carve-out’ provision, a discount or other reduction in price would fall within the activities prohibited by” the anti-kickback statute. At 113-114.

- “Offering or receiving discounts in order to compete for business does not alone mean that an entity ‘knowingly and willfully’ induced or arranged for referrals or for other business reimbursable under the Medicare or Medicaid programs.” Id. at 120.
**Klaczak v. Consolidated Medical Transport, N.D. Ill. 2006**

- Qui tam relators claimed that hospital defendants violated the Anti-Kickback Statute by knowingly and willfully receiving remuneration -- in the form of discounts -- in exchange for referrals (more on specific fraud theory later)

- The district court granted the hospital defendants’ motion for summary judgment because of “Global Failures of Proof.”
  - No criminal intent
  - No remuneration (more later)
  - Implausible legal theory (more later)

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**Klaczak (Cont.)**

- “Relators' AKS theory. . . is not fairly likened to people personally pocketing bribes, transferred in remote parking lots so others could not see what was transpiring, in return for medical referrals. There is no allegation in this case that anyone, at any of the Defendant Hospitals, personally profited from any alleged transgression of the AKS or any other law. There is no allegation that any services were billed that were not provided, nor that any services were provided. . . that were not medically necessary.”
  At 675.
  - **Note:** Absence of personal gain, recurring theme for court
  - **Note:** The court did state, “This is not to say that such an illicit endeavor could not be proven, if there were a legitimate record to support such a claim.”
BURDEN OF PROOF

Burden of Proof: Shaw

➢ The exception is not an additional element. Shaw court:
  - “Defendant’s argument … relies on the erroneous legal premise that
    the statute requires that the government state in the indictment that
    the defendant’s conduct does not fall within the “discount
    exception…..”  [T]he “discount exception” does not serve as an
    additional element of the criminal offense. It serves, instead, as a
    framework around which arguments of the parties regarding the
    evidentiary issues, such as how the government is to prove beyond a
    reasonable doubt that the defendant acted with the requisite state of
    mind, may be presented during trial.”

➢ Court goes on to make clear the government must prove “all
  the elements of the crime. . . Including the mens rea element,
  must be found beyond a reasonable doubt.”
Burden of Proof:

**The Parties**

- The day of the TAP settlement, the US Attorney’s Office charges individual TAP senior managers and mid-level employees
- With superseding indictment in July 2002, 13 individuals indicted
- One is a physician whose case was severed

Burden of Proof:
*United States v. MacKenzie, et al.* (Cont.)

The charges included

- Samples
  - Inducements
  - FDA violations
- Return to practice un-disclosed discounts
- Discounts
  - Bundled discounts
  - Other
Burden of Proof:
United States v. MacKenzie, et al. (Cont.)

➢ Government Position:
  ▪ “The statutory [exceptions and regulatory] safe harbors are affirmative defenses. . . Affirmative defenses must be raised at trial and asserted by the defendant, and if not raised by the defendants at trial, will be deemed waived. . . If the defendants can adduce evidence at trial that they satisfy each and every element, . . . then they can request that the court instruct on the affirmative defense.”
  
  (Emphasis in original)
  
  - Gov’t reply brief to motions to dismiss, re: discounts (at 10-11):

Source: June 29, 2004 Transcript

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**DIFFERENCE BETWEEN DISCOUNT EXCEPTION AND SAFE HARBOR**

OIG position →

- Safe harbor interprets exception
- Safe harbor does not narrow the scope of the exception
**Exception/ Safe Harbor Independent**

*Shaw*

> “[B]ecause the “discount exception” to the anti-kickback statute is a **separate provision** under which the defendant may claim an exemption from liability under the statute-one that was enacted over a decade before the safe-harbor provisions were first promulgated to provide further protection for health-care-service-and-goods providers from liability under the statute-I will interpret the “discount exception” to the anti-kickback statute in light of those discounting arrangements that the safe-harbor provisions have explicitly deemed protected from criminal liability, but I will not be limited by the definitions imposed by the safe-harbor provisions.” (emphasis added).

**Exception/ Safe Harbor Independent**

*Klaczak*

> “[T]he statutory exception for discounts does not require that Medicare receive the same discount, just that any discount is properly accounted for and disclosed on the cost reports.”

At 680
DISCLOSURE AND REPORTING OBLIGATIONS

United States v. Shaw
Disclosure Obligations

- “The phrase ‘charges made by the . . . entity’ refers to those costs charged to the buyer - provider by the seller - supplier.” *Id* at 120.

- Thus, the seller must properly disclose and appropriately reflect its discounted charges made to the provider-buyer.

- “Both buyer-providers and seller-suppliers are required to ‘properly disclose and appropriately reflect’ the reduction in price [to Medicare and Medicaid] in order to avoid criminal liability.” (Emphasis added). *Id.*
**United States v. MacKenzie, et al.**  
*Rule 29 Motions and Decisions*

1 THE COURT:  
appropriately reflected can simply be it is in  
the invoices that we received. That's appropriately reflected.

8 THE COURT:  
this is a safe harbor  
that is in the nature of an interpretation of the statutory  
safe harbor. So I'm reading it in conjunction with the  
statutory safe harbor, and it tells me what it is that it  
means to "appropriately report."

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**Source: June 29, 2004 Transcript**

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**United States v. MacKenzie, et al.**  
*Rule 29 Motions and Decisions (Cont.)*

20 THE COURT: But what is it that says this is  
appropriate reflection and what isn't? There's nothing, right?

3 THE COURT: Where is the kind of freestanding  
obligation to provide these charges to the secretary? You make  
up your own list, you make up your own form? If you're a  
buyer. Where is it that the secretary is giving you some or  
someone has given you some -- something to fill out?

8 MR. LOUCKS: The HCFA 1500 form, your Honor, has  
this spot for the charge.

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**Source: June 29, 2004 Transcript**

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THE COURT: You mean somewhere says that's where you supposed to put it in the HCFA 1500 form? And really, where is the advice do that? Ordinarily you've got a government form and then you get 15 pages to explain what you're supposed to do with the government form. Where is it that you get that?

MR. LOUCKS: Well, your Honor, there isn't -- I mean, the statute -- I can cite the Court to the legislative history.

THE COURT: We keep talking about this legislative history, and I have to tell you that I really think statutory construction is, you know, a Talmudic undertaking.
The Court (continuing)
24    [But] if you have
25 to -- someone has to go through legislative history of things
1 that somebody couldn't get the votes to put into a statute,
2 then we've got a real problem.
3 So appropriately reflected, you've told me that
4 appropriately reflected means put it on the 1500 form, that
5 sounds, you know, plausible. Apart from you has anybody else
6 said that?

Source: June 29, 2004 Transcript

THE COURT:
11 What we're talking
12 about is a statute with virtually no meaning.

THE COURT:
18 this thing is open
19 to a variety of different interpretations.

Source: June 29, 2004 Transcript
Rule 29 Motions and Decisions (Cont.)

8 THE COURT: To appropriately reflect

18 THE COURT: How do we do that?

19 MR. LOUCKS: Send a letter, put it on a form.

20 THE COURT: Send a letter?

21 MR. LOUCKS: Put it on the form, give them a call.

22 Honestly, this is -- I mean, this is not hard.

Source: June 29, 2004 Transcript

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2 MR. LOUCKS: Send in a letter to the carrier saying

3 my bills this year all had discounts in them, the charges that

4 I got -- and I'm reporting the discounts that I got this past

5 year on all the bills I sent in. That would be safe harbor.

Source: June 29, 2004 Transcript

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Rule 29 Motions and Decisions (Cont.)

5 MR. LOUCKS: If people
6 reported their discounts --
7 THE COURT: In the form of diaries, you say
8 letters, notes, scraps of paper.

Source: June 29, 2004 Transcript

Rule 29 Motions and Decisions (Cont.)

6 THE COURT:
7 You know, the thing is the government has some
8 obligation, doesn't it, to square it's own corners, to get this
9 administrative structure in place?

Source: June 29, 2004 Transcript
Rule 29 Motions and Decisions (Cont.)

THE COURT: What we've done as a matter of policy
in our criminal law is said it has to be a fairly high standard
for the description of what the crime is. . .

It's why we have due process requirements and notice requirements and rules of
lenity and all that sort of thing.

And all I have here is kind of ragtag form of
regulatory regime in this area. Appropriately reflected. We don't know what appropriately means. You tell me it's letters
and phone calls.

Source:  
June 29, 2004
Transcript

IS THERE A FLOOR OR BASE ON A PERMISSIBLE DISCOUNT OFFERED BY A SELLER?
Discount Floor?

- There is nothing in the statutory exception or safe harbor that sets a floor or base below which a discount would become impermissible.
- But logic suggests that an uneconomic discount could suggest the discount is being offered for some other goods.
- In other words, uneconomic discounts raise bundling questions.

Discount Floor? (Cont.)

- In advisory opinions, the OIG has at several times rejected the position that the analysis should be based on marginal costs.
- E.g., Adv. Ops 99-2 involved ambulance discounts offered to nursing homes:
  - Below cost discounts are a factor in determining illegal intent.
  - FN 12: “In this regard, we do not think it sufficient to consider only a supplier's marginal costs. Rather, in determining whether a discount is below cost, we look, for example, at the total of all costs divided by the total number of ambulance trips.”
Discount Floor - *Klaczak*

- Fraud theory (pull through case)
- Discounted Part A ambulance work offered to Hospital defendants as inducement for “affording [Ambulance Defendant] an exclusive or preferred position with respect to Part B transports.”

“[T]he only alleged remuneration is a ‘discount’ for services, which raises the critical question - a discount compared to what?

‘Relators’ initial argument is that a discount off a higher price is something of value for the purposes of the AKS. Relators have not cited any cases in support of this argument, nor have they provided a meaningful conceptual defense of using the Ambulance Defendants’ ‘non-contracted’ or ‘usual and customary’ rates as the proper baseline for assessing whether a price is a ‘discount,’ and thus ‘something of value.’” At 678
Discount Floor - **Klaczak (Cont.)**

- “Relators cannot prove that the Hospital Defendants received remuneration—something of value—without comparing the contracted rates with fair market value.” At 679

- “Relators have not demonstrated that the Medicare allowable rate is equivalent to fair market value for Part A transports.” *Id.*

Discount Floor - **Klaczak (Cont.)**

“Relators suggest, at least at times, that the rates in the contracts were so low that the only reasonable inference to draw is that the Hospital Defendants knew they were receiving illegal remuneration in the form of discounted rates, in violation of federal law, in exchange for referrals. As explained above, this theory fails at the outset because the theory requires a comparison point-no inference can be drawn from “low” prices unless there is some higher price for a similar service to which the Hospital Defendants should have compared the contract rates. In this regard, Relators have adduced no evidence that a 25% discount off “non-contracted” rates (which was the most common discount applied in the CoMed contracts) was so unusual or out of line in the industry that a hospital administrator “must have known”—not just in the sense of negligence, but in the sense to reasonably draw an inference of willful and knowing scienter—that the CoMed discounts were unlawful remuneration illicitly provided in return for referrals.” At 680-681
Discount Floor - Klaczak (Cont.)

- In granting summary judgment, court weighed heavily implausible fraud theory
  - Preferred or first call contracts → Common industry practice
  - No private benefit to individuals
  - No evidence that Hospital Defendants knew what Ambulance Defendants charged Medicare to have any awareness they were being offered a discount

BUNDLED DISCOUNTS (including swapping and pull through)
Bundled Discounts: Definitions

- OIG safe harbor definition:
  “Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service”

- This is more like a pull through definition

- Other definitions of bundled discounts focus more on a direct link or contingency of products A and B bought together.

Bundled Discounts: Definitions (Cont.)

- Medicaid Drug Rebate Statute:
  - Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.
  
  - 42 C.F.R. § 447.502 (Definitions)
Bundled Discounts: Examples

- Purchases of A, B, and C are aggregated toward a threshold for a volume discount to apply
- Must buy multiple products together
- Volume purchases of A allow free, discounted or credits toward purchases/receipt of B
- Disposables/equipment deals

Bundled Discounts: Examples (Cont.)

- IOLs with free disposable surgical packs (Levin)
- Lab scam cases -- addition of ferritin to chem panel
- Free infusion pumps → purchase of enteral nutrition therapy products and related supplies (Operation Headwaters)
- Free car (Bay State)
Bundled Discounts
Swapping/ Pull Through Examples

- Free blood glucose meters → testing supplies
- Discounted Part A work to induce services payable under Part B
  - Ambulance services (*Klaczak*)
  - Lab testing (often nursing home context)
- Rebates, special pricing, entertainment and hunting trips, and write-offs of bad debt → ordering lab testing (*Shaw*)

OIG Position:
Two Problems With Bundled Discounts

- Situation typically is → free or discounted good does not cost money to Medicare
  - PPS
  - Not covered
- If a purchased good is paired with a free good, the free good might be one that cannot be measured and fully reported to Medicare.
- Bundled goods might potentially shift costs among reimbursement systems or distort the true cost of all the items.
**OIG Position (Cont.)**

- But, according to the OIG, in certain circumstances where the net value can be properly reported, bundled discounts do not pose a risk of program abuse.
  - For example, where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment.

**Bundled Discounts & The Safe Harbor**

- 1999 Regulatory "clarification" -- Bundled item must be paid under the same reimbursement methodology.

- 2000 “clarification” & 2002 withdrawal:
  - In October 2000 proposed rule, the OIG indicated that it had made what it described as “technical errors” in the 1999 rule, and proposed eliminating the bundled discount protection where the different bundled items or services are paid under a fee schedule.
  - March 2002 This proposed rule was withdrawn.
OIG View On Swapping/ Pull Through

- Hostility expressed in many places
  - Advisory opinions
  - Risk sharing safe harbor -- no fee for service pull through
    “In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.”
    1001.952(t)(i)(B)

OIG Advisory Opinions

- OIG Advisory Opinion No. 13-07
  - Proposed arrangement in which a device manufacturer would offer customers a tiered discount program on purchases of surgical products – whether or not reimbursable by federal health care programs. The more products purchased, the larger the discount.
  - OIG determined that this structure is distinguishable from a bundled discount where a customer might receive a free surgical pack if the customer purchased five surgical devices.
  - Additionally, the OIG concluded that the arrangement could meet the safe harbor definition of a "discount" and "rebate."
OIG Advisory Opinions (Cont.)

➢ OIG Advisory Opinion No. 14-05

▪ Proposed arrangement in which a pharmaceutical manufacturer would offer any patient with a valid prescription for certain branded products that were not covered by insurance (or covered under a higher cost-sharing tier) because of the availability of a generic equivalent, a discount to purchase the branded product with cash (i.e., claims not submitted to any third party payors).

▪ Manufacturer provides the branded drugs to the pharmacy and pays the pharmacy a flat, per-transaction fee to dispense the drugs to patients.

OIG Advisory Opinions (Cont.)

➢ OIG Advisory Opinion No. 14-05 (Cont.):

▪ OIG determined that the arrangement could implicate the AKS if:
  • The discount induced patients to purchase other products marketed by the manufacturer that reimbursed under federal health care programs; or
  • The discount induced patients to switch to the branded drug and then — if the manufacturer terminated the discount arrangement — use their Part D plan or other federal health care program coverage to subsequently purchase the drug.

▪ However, the OIG concluded that risk under the AKS was "sufficiently low" for the following reasons:
  • The manufacturer certified that it would not use the discount as a vehicle to market other federally reimbursable products.
  • Patients would not be induced to switch to the branded drug and use their Part D plan to obtain coverage of the drug because few federal health care programs currently cover the drug.
**Courts' View on Swapping/ Pull Through Arrangements**

- **U.S. v. Hagstrom, et al.**
  - March 15, 2005, William Hagstrom, CEO of Urocor (publicly traded lab), was indicted for conspiracy in W.D. Oklahoma along with his CFO and VP for marketing.
  - Allegation: AKS prohibits labs from offering discounts to physician-clients for their non-Medicare work as an inducement for their Medicare referrals.
  - Court found the allegations sufficient to go forward to trial as a viable legal theory.
  - On June 30, 2006 the jury acquitted all defendants.

**United States ex rel. Jamison v. McKesson Corp.**
D. Miss. (Sept. 28, 2012)

- In December 2004, Thomas Jamison filed a *qui tam* complaint against various nursing homes and DME suppliers related to enteral nutrition services and supplies arrangements.

- 2003 Transaction Allegation → Nursing home chain's in-house DME supplier "dangled" the prospect of McKesson receiving general medical supply contract in order to get the contract billing services below FMV, below actual costs, or at a discounted price.
Jamison (Cont.)

- Motion for Summary Judgment – 2003 Transaction
  - Defendants argued that McKesson's bid was FMV because the competitive bidding of RFP process ensured that the pricing was FMV.
  - Government argued that the bid was below FMV because bringing enteral billing in-house would be cost-prohibitive to the nursing home and McKesson either lost money or broke even on these contracts.
  - The court found genuine issues of material fact as to whether:
    - There was any remuneration; and
    - McKesson offered, and the nursing home chain knowingly and willingly received, remuneration in return for referrals of Medicare business.

Jamison (Cont.)

- 2006 Transaction Allegation → Nursing home chain's in-house DME supplier "carved out" enteral supply distribution from its general medical supply contract in order to induce McKesson to provide below FMV, below actual cost, or discounted prices on its contract billing services.

- Motion for Summary Judgment – 2006 Transaction
  - Defendants argued that regardless of whether the price charged was FMV, the arrangement was protected by the statutory discount exception and/or regulatory discount safe harbor.
Jamison (Cont.)

- Motion for Summary Judgment – 2006 Transaction (Cont.):
  - Government argued that the statutory discount exception did not apply.
  - Court agreed with the government and denied the motion for summary judgment.
    - The statutory exception did not apply because the parties were not required to, and did not, report the "discounts" to the government.
    - The discount safe harbor did not apply because no federal health care programs received the benefit of the reduction in price.

Jamison (Cont.)

- Final Judgment
  - Judgment in favor of the defendants for both the 2003 and 2006 transactions
  - Fundamental failure of proof by the government
  - Court looked at reasonableness of business transactions and common-sense rulings about FMV
  - Factual failure of proof regarding swapping allegation (nursing home had already taken the enteral contract off the table)
  - Government failed to prove that McKesson offered its services below FMV, below actual costs, or at discount (i.e., there was no inducement or remuneration)
Relators brought two separate claims alleging that Omnicare paid kickbacks in the form of below-cost discounts offered to SNFs as an inducement to select Omnicare as their pharmacy provider.

Allegations:
- Relators alleged a "swapping" kickback scheme in which Omnicare traded heavy discounts on prescription drugs covered under Medicare Part A in exchange for the right to service the nursing home's residents whose drugs were covered under Medicaid and Medicare Part D.

Ruling on Motion to dismiss:
- Court found that Omnicare had raised sufficient evidence to create a triable issue of material fact as to whether the price reductions would qualify as remuneration under the AKS.

On June 25, 2014 Omnicare settled the Gale and Silver qui tam matters for $124 million.
Another relator brought a claim against Omnicare alleging that Omnicare engaged in a series of schemes to offer and pay illegal inducements (including credits, rebates, payments, free services and discounted products and services) to induce SNFs to purchase or continue purchasing products from Omnicare.

Allegations:

- Omnicare forgave payment of bills for many of its customers in exchange for the SNFs to continue purchasing expensive prescription drugs from Omnicare.

Allegations (Cont.):

- Omnicare contacted customers that were threatening to terminate their relationships with Omnicare and offered these customers a "credit" on amounts "overcharged" to these customers when there was no actual overpayment.

- Omnicare offered discounts and payments to SNFs in exchange for entering into long-term agreements with Omnicare for the provision of pharmaceutical products and services.

- Omnicare provided free consulting and other administrative services to SNFs in exchange for continuing to purchase products and services from Omnicare.
**Litwiller (Cont.)**

- On Motion to Dismiss, Court dismissed claims related to most of the allegations under the first-to-file and public disclosure rules.
  - However, the court allowed the allegations related to the provision of free and discounted services to stand.


- Relator brought an action against Symphony Diagnostic Services ("Mobilex"), a national provider of mobile x-ray services, alleging an illegal "swapping arrangement."

- Allegations:
  - Mobilex entered contracts with SNFs to provide services payable under Medicare Part A and/or B.
  - Mobilex offered substantial discounts (or sometimes did not charge) for Part A services to SNFs (billed directly to SNFs, which receive Medicare payment).
  - In exchange for discounts on Part A services, Mobilex allegedly received referrals of patients for whom it could submit claims to Medicare for Part B services.
McDonough (Cont.)

- On motion for summary judgment, the court ruled in favor of Mobilex.
  - Court flatly rejected the notion that fully loaded or total costs is the only appropriate measure for setting rates in this context.
  - Relator lacked any direct evidence of Symphony's intent to violate the AKS.
  - Mobilex made efforts to offer competitive prices that reflected the market, tracked costs as well as its profits and losses, and reviewed contracts when prices fell below a certain threshold, in an effort to ensure AKS compliance.

MARKET SHARE REBATES
MARKET SHARE REBATE QUESTIONS

➢ How does a lawful discount (remuneration is price discount or rebate, fully disclosed, etc.) become illegal based on –
  ▪ Additional contractual terms?
  ▪ Common, commercially reasonable promotional activities?
  ▪ Improving formulary placement status?

➢ What is the government’s legal theory?


➢ Relators filed a *qui tam* action claiming defendants unlawfully induced Omnicare to promote J&J’s branded drugs over less costly alternatives.

➢ Allegations:
  ▪ J&J funneled kickbacks in the form of payments for "physician data," grants, and sponsorship fees through Omnicare to its consultant pharmacists to induce them to recommend J&J drugs over competitor drugs.
Allegations (Cont.):

- Omnicare received rebates on the price of certain J&J specialty drugs if it met a threshold share of the market based on a comparison to its purchases of similar drugs from J&J's competitors, and if Omnicare successfully implemented "Active Intervention" and "Appropriate Use" programs, which were designed to shift market share to J&J products.

Motion to Dismiss:

- J&J argued that the rebates, data acquisition fees, grant awards, sponsorship fees, and other payments were not unlawful because the "discount[s] or other reductions in price" were "properly disclosed and appropriately reflected in the costs claimed or charges made" and thus all payments fell within the discount safe harbor to the AKS.

- Court disagreed and found that "[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not."
**Lisitza (Cont.)**

- In November 2013, the J&J parties settled the case with the defendants collectively paying $149 million dollars and J&J entered into a CIA with the government.

- (Omnicare settled this matter in a 2009 global settlement, including several other *qui tam* cases for $98 million.)

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- Relators filed an action against Organon, other pharma companies, PharMerica and Omnicare.

- Allegations:
  - Organon paid "conversion rebates" to LTCPs (Omnicare and PharMerica) in exchange for switching prescriptions to Remeron SolTab.
  - Organon also paid the LTCPs a "therapeutic interchange bonus" for making Remeron a "preferred drug" and instituting a therapeutic interchange program that encouraged prescribing Remeron over competitor products.
**Banigan (Cont.)**

- **Motion to Dismiss**
  - Omnicare argued that discount kickback allegations must fail because all discounts and rebates were disclosed in accordance with the discount safe harbor.
  - Relators argued that rebate amounts and discounts were not properly disclosed because contracts did not disclose complete terms and conditions.

- **Court denied the motion to dismiss:**
  - Discount safe harbor not available because discount not passed on to Medicaid.
  - Cites to *Lisitza*.

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- Relator filed an action claiming Novartis paid kickbacks to induce specialty pharmacies to recommend that patients order certain Novartis specialty drugs.

- **Allegations:**
  - Pharmacies were rewarded with performance, market share, and "bonus" rebates for switching patients to a Novartis drug or for performing clinical outreach that resulted in increase usage of Novartis' drugs. Rebates were tied to refill rates or refill shipments.
Kester (Cont.)

- Allegations (Cont.):
  - Novartis controlled pharmacy behavior by operating hubs that directed prescriptions, which enabled them to directly tie how many prescriptions a pharmacy would get with how it was performing in driving up Novartis market share.
  - Novartis used a scorecard system to benchmark pharmacies against the others, so Novartis could see who was outperforming their peers and drive behavior that would result in higher scores.

- Allegations (Cont.):
  - Pharmacists presented their recommendations as unbiased professional opinion and used their influence to switch patients to the Novartis drug – in spite of generic alternative and dangerous patient side effects.
  - Performance rebates did not account for patients stopping use of a drug because of side effects or physician direction. Pharmacies did not adequately disclose or discuss potential side effects with patients.
  - The parties withheld key dimensions of the kickback scheme from the written agreement that purported to reflect all material aspects of the relationship.
Kester (Cont.)

- **Motion to Dismiss:**
  - Novartis argued that for the allegations to remain, the pharmacy receiving the kickback must have caused a particular doctor to prescribe the specialty drugs to particular patients.
  - The court disagreed and ruled that the government had adequately pled that many of the claims submitted to Medicare Part A and Part D were false, but the court did throw out claims involving state Medicaid programs under the AKS.

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**REDUCE CHARGES?**
Does Medicare/ Medicaid Need To Benefit From The Discount?

- 1991 Safe Harbor -- charge-based/fee schedule providers need not reduce prices
- 1999 Safe Harbor -- changes to reporting requirements
- Currently virtually no reporting/disclosure obligations on charge-based/fee schedule

Benefit To The Government

  - Take aways from these decisions: one essential component of the exception is that Medicare and Medicaid must share in and benefit from the reduced cost of the services or goods that are being provided at a discount, and that can only happen if the government is “made aware” of the lowered cost so that it can commensurately lower the reimbursement it provides.
Discount Exception
20 We had evidence, for example, of the offer of
21 discounts by TAP. I instruct you as a matter of law that
22 because TAP, as a seller, is conceded by the government to have
23 properly disclosed its discount within the meaning of the
24 discount safe harbor by providing the purchaser with an invoice
25 that reflected the actual price paid by the buyer, TAP’s
1 discounts were brought within the discount safe harbor.
2 . . . [T]he physicians had no duty
3 to reduce their charges to the government as a result of those
4 discounts, and TAP had no duty to instruct them to do so.

Source: July 9, 2004 Transcript

To Bill Or Not To Bill For A Free Good?

- Government position: Cannot bill for something obtained for free (see MacKenzie)
- But: No law prohibits billing for free goods
- Same issue as requirement to reduce charges by the amount of discount
To Bill Or Not To Bill For A Free Good?

(Cont.)

But:

“On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered “no cost items.” Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act.” CMS Pub. 100-04, The Medicare Claims Processing Manual, chapter 32, section 67.

 “In some instances, providers do not have to report the usage of a no cost device. However, in most cases, providers are required to bill a no cost item due to system edits that will ensure that an item (received at no cost or not) is billed along with an associated service (e.g., a device/drug must be reported along with an implantation/administration). To report a no cost item, institutional providers must place a token charge in the ‘Non-Covered’ charge field for the no cost item.” Id. at section 67.2.

 $0.01 charge.

 See also incident to billing rules. CMS Pub. 100-02, Medicare Benefit Policy Manual, ch. 15, section 60.1 (supplies must represent a cost to the practice)
Operation Headwaters

- A government sting operation in the mid-to-late 90s, known as Operation Headwaters, was based on evidence of bundled discount arrangements whereby DME infusion pumps were provided for free or at a discount in return for the purchase of enteral nutrition therapy products and related supplies, including the enteral nutrient solutions and disposable tubing (known as pump sets).

- **Key fact** -- free/discounted pumps paid on same reimbursement methodology as enteral nutrition products and supplies

- Cases without any harm to the government

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Operation Headwaters (Cont.)

- Federal agents created a fictitious medical supplier known as Southern Medical Distributors.

- During its operation, gov’t alleged that various manufacturers, offered kickbacks to undercover agents to purchase the manufacturers’ products and then advised them how to fraudulently bill the government for those items.
**Operation Headwaters (Cont.)**

- As a result of Operation Headwaters --
- Approximately 12 criminal convictions overall and, from these three cases alone, approximately $670 million in criminal and civil fines.
- Subsidiaries of Novartis Corporation, Abbott Laboratories, and McKesson Corporation, among other companies, entered into settlement agreements involving criminal plea agreements, civil fines and CIAs.

**Operation Headwaters - Carroll**

- “Defendants apparently believed, whether correctly or incorrectly, that SMD would need to incur some cost for the pumps if it was to be reimbursed under Medicare Part B. So, rather than simply providing SMD with the pump for free, Defendants charged SMD an arbitrary rental fee that would be offset by an equal reduction in the price of the tubes and food.” At 752
- SMD paid this rental fee.
- Court in ruling on motion to dismiss ruled that in light of the arrangement to create a rental fee for pumps, defendants did not satisfy safe harbor discount.
Operation Headwaters - Settlements

➢ The CIAs expressly permitted bundled arrangements

➢ Three relevant provisions:

- (1) Companies were required to adopt policies prohibiting conditioning the purchase of one product on the purchase of a different product.

Operation Headwaters - Settlements (Cont.)

- (2) The companies agreed to establish compliance policies and procedures, including the requirement that enteral nutrition pumps and pump sets “shall be billed to customers in such a manner that the line item price for each product (including, if applicable, when the product is provided free of charge) may be separately and readily identified by each party to the transaction (e.g., on the invoice, rebate form or other document).”

  -- Expressly permitted provision of free goods.

- (3) Discounts could be set forth in the invoices “or other documents.”

  -- Invoice would need to disclose the existence of a discount arrangement to qualify for the safe harbor, but the terms could be in another document.
Operation Headwaters - Settlements
(Cont.)

- Compliance lessons are applicable to buyer-providers
  - Bundling aggregate purchases is acceptable
  - Think through reasons for linkage requirements where
discount on A is only available with purchases on B
    → Many lawful reasons for such linkage
  - $0.00 bill
  - Discount terms can be in the purchase agreement

**U.S. ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc., N.D. GA**
(Sept. 17, 2013)

- Relator brought an action alleging that Fresenius fraudulently billed Medicare for free drug overfill in violation of the Medicare Act.
  - Overfill is the term used to describe the FDA mandated extra product found in vials of drugs.
  - The Medicare Act restricts reimbursement to “expenses incurred,” or what the company actually paid for, in providing health care to eligible recipients.
Saldivar (Cont.)

Motion for Summary Judgment:

- Relator argued that billing for overfill is prohibited by the Medicare Act. Additionally, because overfill is not included in Congressionally mandated calculations of the Average Sales Price (ASP) to which Medicare reimbursement for end stage renal disease (ESRD) drugs has been pegged since 2006, Medicare cannot pay providers for overfill.
- Fresenius argued that because there was nothing in the law that specifically prohibited billing for overfill, the billings were legal.

The court ruled in favor of the Relator stating that "based on the facts here presented... Fresenius’s practice of billing Medicare for overfill of Epogen and Zemplar [the two drugs in question] provided to patients constitutes a false claim because, as a matter of law, it represents billing for an expense the provider did not incur."

- Snippets of statutory citation to general Medicare principles.
- Reasoning specific to overfill issue.
- Issue of intent not decided.
Allocation Issues

- To allocate the discount or not?
- In many respects this is a buyer's or drug manufacturer's issue
- Government gives no consistent answer
- If discounted item is not covered or included within fixed payment, e.g., PPS, allocating the discount removes any harm to the program
- Seller's obligation is to give buyer transparent information sufficient to properly report -- allocate? -- the discount
- Carroll case shows problem of allocation when that involves creation of false documents
Medicaid Drug Rebate Statute

- MDRS presents an unusual allocation situation for a seller because manufacturer’s must calculate and report Average Manufacturer’s Price (AMP) and Best Price (BP).

- In responding to criticism that the July 17, 2007 regulation was changing the definition of a bundled sale from that found in the Rebate Agreement, CMS stated:

  “It has always been our policy that AMP and best price must be adjusted to reflect discounts offered in bundled sale arrangements to those entities included in the determination of AMP and best price.” 72 Fed. Reg. 39158-59.

Medicaid Drug Rebate Statute (Cont.)

- “AMP should be adjusted for bundled sales (as defined above) by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations. The aggregate discount is allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement.

- “Where discounts are offered on multiple products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.”

  72 Fed. Reg. 39145 (July 17, 2007)
**Medicaid Drug Rebate Statute (Cont.)**

- **Bundled Sale Example**

  “Products A and B are sold under a bundled arrangement and have a combined bundled discount equal to $200,000 on total undiscounted sales of $1 million. If Product A has undiscounted sales of $600,000 and product B has undiscounted sales of $400,000, the manufacturer would allocate 60 percent of the combined bundled discount to Product A when calculating AMP. Forty percent of the combined bundled discount would be allocated to Drug B. The effective unit price of each product would be calculated by subtracting the discount allocated to each drug product ($600,000 ¥ $120,000 = $480,000 for Product A; $400,000 ¥ $80,000 = $320,000 for Product B) and dividing the result by the number of units for each drug product in the bundled sale.” 72 Fed. Reg. 39158.
OIG Position On Prebates

➢ While the regulatory language does not require that a rebate be paid only subsequent to the sale of a drug, in 2000, the OIG, took the position that prebates cannot qualify for protection under the safe harbor because the monies are paid before any purchase and are not tied to the purchase of drug products.

OIG Position On Prebates (Cont.)

▪ “The payments would not be covered by the discount safe harbor, which applies to certain discounts and rebates (42 C.F.R. §1001.952(h)), because they are made prior to any purchase and are not attributable to identifiable purchases of items or services. Simply put, discounts are price reductions at the time of sale of goods, and rebates are discounts subsequent to the sale.”

OIG Position On Prebates (Cont.)

- In 2003, the OIG opined that a “prebate” is one form of remuneration that implicates the Anti-Kickback Statute:
  - “[A]ny remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of remuneration in connection with a sale include, but are not limited to, ‘prebates’ and ‘upfront payments,’ other free or reduced-price goods or services, and payments to cover the costs of ‘converting’ from a competitor’s product.”

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