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Pharma Congress:
Compliance in Commercial Operations Update

October 29, 2013

Agenda

- Discount Update: Impact of Omnicare and Novartis Cases; OIG Advisory Opinion 13-07
- Copay Coupons: Litigation Update and Suggested Restrictions
- Reimbursement Support: Challenges in Determining Guardrails

Discount Update

Discounts and Rebates: Legal Background

- Statutory Exception to the Anti-Kickback Statute (AKS)
  - AKS does not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a federal health care program"
- Regulatory Safe Harbor, 42 C.F.R. § 1001.952(h)
  - 3 categories of buyers
    - HMO or other managed Medicare or Medicaid plan
    - Entities that submit cost reports (e.g., hospitals, nursing homes, dialysis facilities)
    - Other (physicians, pharmacies)

Discount Safe Harbor Basics

- Seller or offeror must –
  - Advise buyer of its reporting obligations
    - Cost report buyers must report discount on cost report; HMOs have no reporting obligation beyond CMS or state contract; other buyers must provide complete information to HHS and state agencies upon request
  - Provide information needed to report
  - Not impede buyer reporting
- Discount is reflected on the invoice; the reduced price must be shown
- Rebate is a discount not given at the time of sale; permitted if –
  - Described in writing before sales
  - Invoice reflects existence of rebate program
  - Seller provides end-of-period statement showing calculation and goods to which rebate applies

Discounts Risk Areas: Bundling

- Under safe harbor, the term “discount” does not include
  - 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, as appropriate to the reimbursement methodology
  - In a 2000 proposed rule that was never finalized, OIG “clarified” that same methodology means “the same DRG, prospective payment or per diem payment, but would not include fee schedules”

Other Discount Risk Areas

- "Prebates," meaning up-front discounts/payments/ signing bonuses
- Rebates on *sales* by wholesalers (vs. on wholesaler *purchases*); can look like commission instead of discount
- Discounts that are more than price reductions
  - i.e., conditioned on meeting other requirements, such as actively promoting a product

Enforcement Against “Improper” Discounts

- Historically, cases involved situations in which companies did not want to discount because of price reporting implications
  - So, allegation was manufacturer disguised the discount by entering into data purchase agreements or by providing grants instead (e.g., Schering-Plough 2004)
- Omnicare case (*U.S. ex rel . Lisitza v. Johnson & Johnson*) takes a different tack

Omnicare Allegations

- J&J unlawfully induced Omnicare to promote J&J's branded drugs over less costly alternatives in violation of AKS, False Claims Act (FCA) and state consumer protection laws by means of market share rebates, data and sponsorship fees and grants
- Omnicare earned rebates by satisfying 2 criteria –
  - Meeting market share thresholds "at the expense of competitors"
  - Successfully implementing "Active Intervention" programs
    - Including disease management initiatives, correspondence to providers, nursing home staff education and intervention recommendations to prescribers

The Government's Position in Omnicare

- "[T]he law clearly does not permit a pharmaceutical manufacturer to make any payments – no matter how they are labelled [sic] – that are conditional on the recipient taking specific steps to promote the ordering or use of that manufacturer's drugs by others."
- "The 'Active Intervention' requirements in J&J's contracts with Omnicare transformed the 'rebates' into illegal kickbacks . . . Because J&J's contractual payments unlike normal rebates, were not mere reductions in the price of J&J drugs, those payments do not fall within the anti-kickback statute's exception for discounts or other reductions in price."

Other Factors in the Case Against J&J

- J&J's agreement was not with a health plan, which openly engages in formulary management and where beneficiaries agree to be subject to formulary choices
- Pharmacy drug switching activities were not transparent to the plans or beneficiaries, and may have undermined plan formulary decisions
- Congress mandated consultant pharmacists for nursing homes to ensure "independent" review of drug utilization
  - i.e., a check against "chemical restraints"

J&J's Motion to Dismiss Denied (February 2011)

- "J&J argues that its data acquisition fees, grant awards, sponsorship fees, and other payments all fell within the safe harbor provision of the statutory discount exception of the AKS."
- "The court disagrees. While the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not."
- Case stayed; presumably included in pending global J&J settlement

Open Questions After Omnicare

- Are performance-based rebates always suspect?
- How much was this a unique case about the special influence of nursing home pharmacies?
- Are all “active interventions” equally problematic?
  - e.g., disease management communications vs. refill reminders vs. “switching” initiatives?
- Do the same considerations apply to PBM or health plan rebates?
- Has the safe harbor been rendered meaningless, so that all discounts have to be evaluated on their merits?

Complaint-in-Intervention v. Novartis (April 2013)

- Government alleges “Novartis paid kickbacks to pharmacies in exchange for switching transplant patients to the Novartis drug Myfortic…instead of cheaper, generic competitor drugs”
- Novartis “disguised these kickbacks as ‘performance’ rebates or discounts”

Government Alleges “5 Step” Kickback Scheme Orchestrated by Novartis

1. Novartis ascertained pharmacy had sufficient influence to “drive the Myfortic business” (thus, the alleged scheme involves only 20-some pharmacies)
2. Novartis sought an “explicit agreement” as to how the pharmacy would convert transplant patients to Myfortic
3. Parties signed a rebate agreement that “only memorialized one side of the bargain” – promises to convert “extracted from the pharmacies…invariably were left out of the contracts”
4. “Pharmacies carried out their end of the bargain”
5. “Novartis and the pharmacies earned hefty profits”

Common Elements in Omnicare and Novartis Allegations Suggest Discount Risk Factors

- Performance-based (e.g., market share) discounts offered to pharmacies (vs. plans or PBMs)
- Not just any pharmacies, but specialty pharmacies with significant influence over product choice
- Advance commitments to “active intervention” or “conversion” (vs. more traditional formulary activity)
  - n.b., open question whether such commitments actually were made by Novartis
- Presence of less costly generic or therapeutic alternatives

Framework for Analyzing Discount Risk

- Level of scrutiny varies based on –
  - Nature of discount: Volume vs. performance-based
  - Who the purchaser is: Pharmacy or provider (e.g., hospital or physician) vs. plan or PBM

- Lowest Scrutiny
  - Straight volume discounts/rebates to any purchaser
  - Market share rebates to plans or PBMs for traditional formulary activity
    - No disadvantaging (including no less favorable treatment than others in same therapeutic class and no counter-detailing)
    - Maintaining formulary position
    - Limit on number of products in tier
    - Notice to providers of formulary status

Discounts Requiring Enhanced Scrutiny

- Intermediate Scrutiny
  - Market share rebates to plans or PBMs for intervention activities
    - Disease management initiatives
    - Provider education
    - Correspondence to providers
    - Intervention by pharmacists (i.e., contacting prescribers)

- Strict Scrutiny
  - Market share or other performance-based rebates to pharmacies or providers
    - Carefully consider issues of cost, transparency and proper role of pharmacist or other provider/conflicts of interest
    - If appropriate/*bona fide*, consider restructuring intervention activities as fixed, fair market value service fees

Tiered Discounts and OIG Advisory Opinion 13-07

- Involved a tiered discount program for various surgical devices and supplies based on total purchases in a calendar year
  - Purchase $X of products, receive 5% rebate
  - Purchase $2X of products, receive 10% rebate
  - Purchase $4X of products, receive 20% rebate
- Although the products were not necessarily reimbursed under the same methodology, OIG concludes the program is not a “bundle” and qualifies for the safe harbor
  - Discount on one product not contingent on the purchase of another
  - Discount readily attributable to each item purchased

Copay Coupons

Basic Features of Copay Coupon Programs

- Manufacturer reimburses pharmacy for some or all of patient's co-pay obligation
  - Often administered through third party vendor (e.g., McKesson)
  - Coupon or re-usable card
  - Presentation of coupon or enrollment in card program
- Payment
  - Up to $x off
  - Reduce co-pay to $x
- Annual or lifetime limits
- Prescription drug coverage
  - Commercial insurance
  - Federal health care program (FHCP) patients ineligible
  - Uninsured patients often excluded
- Other potential limits
  - New prescription
  - Financial need
  - Particular indication(s)
  - Participation in other manufacturer patient support activities

Legal Considerations

- Federal Law
  - AKS
  - HIPAA Fraud
  - RICO
  - Robinson-Patman
  - Medicaid rebate/ASP price reporting
- State Laws
  - "All payer" anti-kickback statutes
  - Co-pay waiver statutes
  - Health insurance or common law fraud
  - Tortious interference

Private Class Actions

- Filed in March 2012 by four health and welfare funds in four different federal courts against nine drug manufacturers
  - S.D.N.Y., N.D. Ill., E.D. Pa., D.N.J.
  - Abbott, Amgen, AstraZeneca, BMS, GSK, Merck, Novartis, Otsuka America and Pfizer
- Legal Claims
  - Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 *et seq.*
  - Robinson-Patman Act, 15 U.S.C. § 13(c)
- Cases in early stages: motions to dismiss and discovery

Racketeer Influenced and Corrupt Organization Act (RICO)

- Scheme to interfere with formulary causing payer to pay for drugs that they would not ordinarily pay for and at higher amounts
  - Third party program administrators (e.g., McKesson) alleged as co-conspirators
- Allegations based on 2 predicate acts (mail fraud and wire fraud) and 3 fraud theories –
  - *Misrepresentation Theory*: Caused pharmacists to misrepresent true charges by not accounting for copay subsidies
  - *Waiver Theory*: Routine and undisclosed copay waivers a scheme to defraud
  - *Benchmark Theory*: Manufacturers reported fraudulent benchmark prices (WAC and AWP) to reporting services that did not account for copay subsidies

Section 2(a) of Robinson-Patman

- Claim is copay assistance is commercial bribery because it is –
  - Paying the patient to purchase the manufacturers' drugs,
  - But where the purchase itself is being paid for by the insurer

Favorable Ruling on BMS's Motion to Dismiss

- Earlier this month, District Court (SDNY) dismissed almost all of plaintiffs' allegations *with prejudice* –
  - Found the BMS program "open and notorious"
  - "[T]he mere existence of the BMS copay subsidy program is not a fraud on anyone because it involves no element of deception"
- On the Benchmark Theory only, granted leave to amend to add the requisite particularity (i.e., the "when, where and how" of the alleged scheme)

BMS Court: Plaintiff's Theories Fail as Matter of Law

- On the Misrepresentation Theory
  - No false statements that "an insured paid the co-pay unaided by a co-pay subsidy program"
  - Statements that patients satisfied copay no more deceptive than if patient got the money from "his rich uncle or a stranger on the street"
  - Failure to disclose subsidies cannot be fraud by omission absent a contractual duty to disclose
- On the Waiver Theory
  - Court found there "is not *actually* any waiver" because full copay collected every time, from either patient or BMS
- On the Robinson-Patman/Commercial Bribery Claim
  - No allegations of contractual or other duty owed by patients to insurers, rejecting claim that insured patients are agents of their insurer

HIPAA Health Care Fraud

- Federal criminal law, but cited by plaintiff's in support of their RICO claims
  - Theory is use of copay coupon and failure to collect entire copay from the insured constitutes a scheme to –
    - Defraud,
    - Obtain payment under false pretenses, or
    - Make a false claim for benefits under the plan (n.b., law extends to private plans)
- BMS court noted there are no cases finding use of copay cards to state a claim under the HIPAA fraud statute

State All Payer Anti-Kickback Laws

- Michigan, Minnesota and Rhode Island all payer statutes specifically permit copay coupons as an exception to their general kickback prohibitions
- The Massachusetts law historically did not, but was amended effective July 1, 2012 to permit certain discounts, rebates, vouchers or other cost reductions, provided certain conditions are met –
  - No excluding or favoring any pharmacies in redemption of the coupon
  - No AB rated generic alternative
    - MA exception expires July 1, 2015 unless extended following state impact study

Application of State Copay Waiver Laws

- In general, prohibit providers from waiving co-payments (except based on financial need)
  - In some states, the prohibition extends to "distorting" copays
- Such waivers are characterized as "insurance fraud"
- Language of statutes differ regarding advertising the waiver as a key element
- Directed primarily at providers, including pharmacies, but some state laws have aiding and abetting language

Tortious Interference With Contracts

- Elements of case for tortious interference
  - The existence of a valid contract between the plaintiff and a third party
  - The defendant's knowledge of that contract
  - The defendant's intentional acts designed to induce a breach or disruption of the contractual relationship
  - Actual breach or disruption of the contractual relationship
  - Resulting damage
- Growing self-help by insurers to prohibit use of coupons by contracts or other means
  - e.g., United bars copay coupons for 6 specialty drugs

Exclusion of FHCP Beneficiaries

- OIG has made clear that manufacturer copay assistance to FHCP beneficiaries is impermissible under the AKS
  - FHCP definition (42 U.S.C. § 1320a-7b(f)) includes Medicare, Medicaid, TRICARE, VA and Indian Health Service programs, *but not Federal Employees*
  - Arguably will include patients who receive federal subsidies to purchase insurance through the ACA exchanges
- Recent study released by National Coalition on Health Care "Senior Awareness and Use of Prescription Co-pay Coupons in Medicare" found 6% of seniors polled have used a copay coupon
- Coupon lawsuits allege Medicare Part D and and managed Medicaid beneficiaries mistakenly report themselves eligible, and manufacturers don't enforce limitation

Increased Due Diligence to Assure FHCP Eligibility Restrictions

- Print the eligibility criteria on the coupon (in a prominent and legible way) or include in the on-line activation process
  - Include a series of questions that make restriction clear vs. conclusory
- Require patients to actively certify that they meet the criteria
- Provide instructions to the pharmacy/physician to confirm eligibility before accepting the coupon
- Instruct the pharmacies/physicians that by submitting the coupon for redemption, they are certifying that the patient is not enrolled in a FHCP, or require affirmative check off by pharmacy/physician
- Obligate vendor to implement effective compliance measures

Special Considerations with Coupons for Physician-Administered Drugs

- Potential for "spillover" effects even if FHCP beneficiaries excluded
  - In several Advisory Opinions, OIG has expressed concern over "disguised remuneration for federal referrals through the payment of amounts purportedly related to non-federal business"
- Potential inducement to physician to prescribe and administer product
  - Coupon provides assurance that part or all of patient copay *to the physician* will be paid in a timely manner

Factors Impacting Level of Legal Concern

- Length of individual eligibility for program (e.g., is it a one-time coupon or 12 months worth of coupons)
- Richness of benefit
- Coupon is for a variable amount (e.g. patient pays $50 and manufacturer pays the remainder vs. coupon pays $50 or co-payment, whichever is less)
- Product class and competition (especially generic alternatives)
- Coupon is for a product new to the market
- Coupon is only available to new users of the product
- Coupon availability limited to individuals with insurance
- Coupon is for a chronic use product
- Patient ability to switch from coupon drug is limited
- Method of distribution of coupon

Suggestions for Mitigating Legal Risks

- Adopt a process for pharmacies/physicians/vendor to verify that coupon users meet the eligibility requirements
- Put insurers directly on notice of the copay program
  - Manufacturer notices to insurers
  - Pharmacy/physician notices on claims submittal
- Obtain reps and warranties from pharmacies/physicians that (a) their participation is consistent with their insurer contracts, and (b) they will report coupon use to insurers or, alternatively, will report such use if required to do so
- Adopt a process for patients to certify that (a) acceptance of manufacturer support is consistent with their subscriber certification, and (b) they will make any required reports to the insurer

Other Suggested Restrictions

- Coupon is made generally available (e.g. website, advertisements, physicians) and not targeted at specific insurer(s)
- Coupon availability for physicians is not provided as a reward for prescribing
- Coupons should not be designed, and should not be discussed with physicians, as a way of overcoming formulary placement

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Reimbursement Support

Challenges in Determining Guardrails

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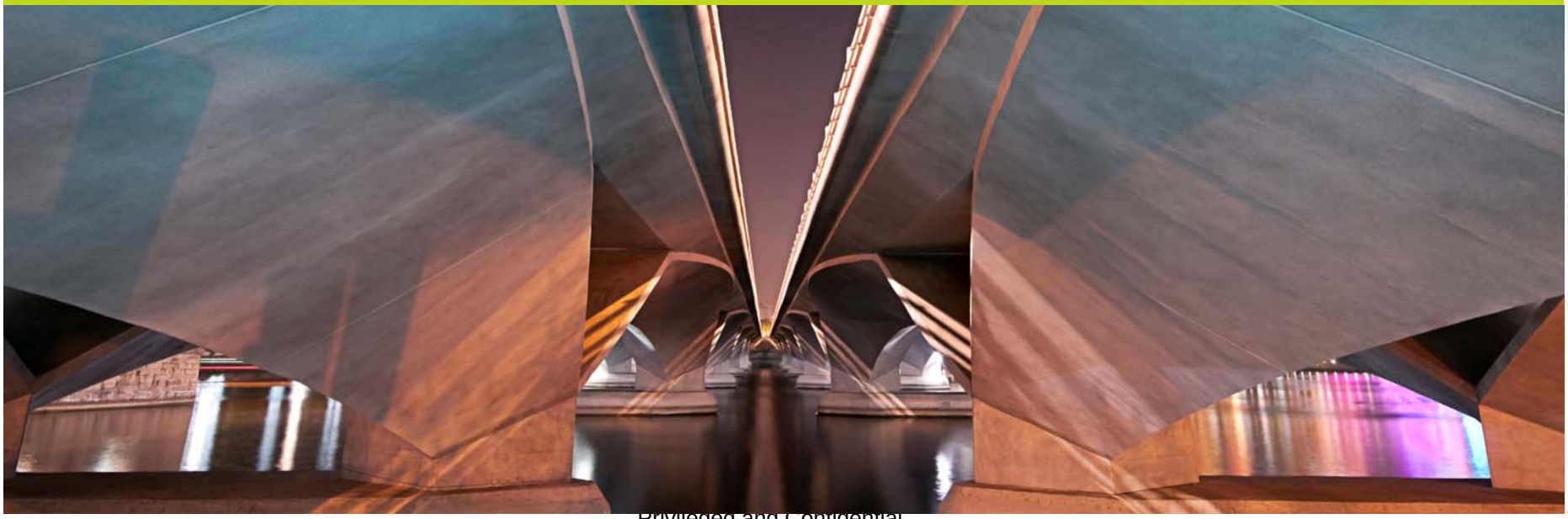

Reimbursement Support for Unapproved Uses

- FDA statements in 1999 recognize that information may be provided in certain circumstances
  - These formed the basis for certain program elements
- Two cases point to the provision of reimbursement support as evidence of intent to promote off-label
  - *Allergan* in 2010
  - *Scios* in 2011
- The changing landscape raises important questions that should be thoroughly evaluated

FDA Statements

- In 1999, FDA affirmatively stated that information may be provided in response to a request for assistance in seeking reimbursement
  - e.g. reprints supporting the proposed use
- 2011 guidance did not directly address information provided for reimbursement purposes
  - Were OPDP to evaluate the practice, it may focus on how broadly these programs are advertized
- DOJ has drawn a clearer line -- actions to encourage inappropriate use of the drug through reimbursement support will be subject to penalties
- A potential middle ground is to provide information, but not services
  - its not clear where the government may draw the line in the future
  - will likely depend on the facts of a case

Allergan: Allegations

- Exploited on-label cervical dystonia (CD) indication to grow off-label pain and headache (HA) sales
  - In 2003, Allergan developed the “CD/HA Initiative” as a “rescue strategy” in the event of negative results from its clinical trials to assure continued expansion into the pain and headache markets
  - claimed CD was “underdiagnosed” and that doctors could diagnose CD based on headache and pain symptoms, even when the doctor “doesn’t see any CD”
- Used reimbursement support programs to promote off-label uses
  - Doubled size of reimbursement team to assist doctors in obtaining payment for off-label Botox® injections
  - Embedded reimbursement support as part of the sales team
  - Conducted detailed audits of doctors’ billing records to demonstrate how they could make money by injecting Botox
  - Held workshops to teach doctors and their office staffs how to bill for off-label uses
  - Operated Botox Reimbursement Hotline, providing free on-demand services to doctors for off-label uses
- Lobbied government health care programs to expand coverage for off-label uses
- Created purportedly independent online neurotoxin education organization to stimulate increased use of Botox for off-label indications

J&J and Scios

- Government unsealed its civil complaint at the time of the plea agreement
- Government alleges that, among other things, J&J and Scios used their reimbursement support services to promote off-label uses of Natrecor for serial, scheduled outpatient infusions (a use not FDA-approved, and not covered by federal health care programs). Specifically:
  - Outpatient reimbursement was listed under "Outpatient Marketing Overview" at a July 2002 Scios advisory board meeting
  - Defendants established a reimbursement team to handle reimbursement issues and the Medicare Contractor's local coverage determinations regarding Natrecor
  - Used a consultant, the Lash Group, to develop reimbursement guides that instructed health care professionals, in great detail, how to bill Medicare for outpatient infusions of Natrecor (the guide provided limited information on billing for inpatient infusions)
  - Provided a hotline number (staffed by the Lash Group) for health care professionals to call with Natrecor reimbursement questions
  - At Scios's expense, the Lash Group also assisted providers through the Medicare appeal process for denied claims for payment

Information vs. Services?

- We have no clear guidance on the specific elements of the most common programs
  - Benefit investigation
  - Prior Authorization
  - Appeals
- One approach is to provide information but stop short of providing services
  - Not clear that DOJ and FDA will adopt this
  - First Amendment might support this approach

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