Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates
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AGENDA

- Coupon/Accumulator/Maximizer Issues
- Mechanics of copay cards, accumulators, and alternate funding programs
- Implications for government price reporting
- Lawfulness under the Anti-Kickback Statute

MECHANICS OF COPAY CARDS AND ACCUMULATORS

Defining and Exploring Coupons, Accumulators, and Maximizers

Term	Description
Coupons	Copayment offset tools, which cover all or a portion of a beneficiary's out-of-pocket costs, generally, for a brand-name drug or biologic
Accumulators	Tools health plans, or their PBMs, use to identify beneficiary use of coupons in order to delay a beneficiary's satisfaction of his/her annual deductible and/or out-of-pocket maximum
Maximizers	Tools health plans, or their PBMs, use on identified specialty drugs or biologics to ensure the maximum value of manufacturer coupon programs is applied evenly throughout the plan year

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Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

- These programs can take one of several forms:
  - The health plan excludes coverage of drugs that have copay cards until the copay card is exhausted, at which time the patient requalifies under an exceptions process
  - The health plan coordinates with pharmacies to determine if a copay card was used and, if so, excludes the copay assistance from out-of-pocket (OOP)
  - The health plan has the pharmacy call the manufacturer to find out how much benefit is left, and provides no coverage until there is no more coverage
  - The health plan excludes coverage for certain specialty drugs and redirects “uninsured patients” to PAP

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

- The situation as explained by CMS in the 2020 MDRP Final Rule:

Example:

Assume: $2,500 Drug cost
$2,500 Patient Deductible
$10,000 Copayment Assistance Program Maximum

TABLE 1—COPAY ASSISTANCE PROGRAM WITH NO PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$2,000	$2,000	$2,000	$2,000	$2,000
Patient Pays	25	$25	25	25	25	25
Manufacturer Pays	2,475	$475 deductible reached. Manufacturer only pays $475.	475	475	475	475

TABLE 2—COPAY ASSISTANCE PROGRAM WITH PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$0	$0	$0	$0	$2,000
Patient Pays	25	25	25	25	$2,400	500
Manufacturer Pays	2,475	2,475	2,475	2,475	100 manufacturer copay benefit max. reached	0

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

- If the plan gets it wrong, the beneficiary could have tremendous liability in the middle of the year, possibly resulting in script abandonment
- There is some momentum in Congress to render these programs unlawful (*see* S.1375 introduced on April 27, 2023 as the "HELP Copays Act") by requiring that regulated plans count copay cards to OOP
- Many states have adopted laws restricting the use of accumulators by PBMs and payors

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

- Alongside coupons, accumulators, and maximizers, there are now alternate funding programs ("AFPs")
- These programs remove coverage for specialty drugs and require patients to enter into manufacturer PAP programs, typically with the assistance of a vendor under contract with the health plan
- If the patient receives a PAP denial letter, then the health plan will on an exceptions basis approve the product
- Some manufacturers are changing their rules, such that they deny PAP for any patient who is on an AFP, but this sometimes easier said than done

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

- For non-grandfathered plans, and eventually for grandfathered plans, these programs based on carve outs will get harder because of agency rulemaking
- To carve out a drug, it must be deemed not to be an essential health benefit
- CMS in April stated that all drugs that are covered, including those that go beyond the minimum, must be viewed as EHBs
- Plans must cover at least one drug for each class or category in the USP, or, if more, they must cover what is required in the State's benchmark plan
- For some drugs, there may be only one or only a couple of drugs in their class or category, making that drug harder to subject to these strategies

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

Accumulators on Exchanges

- In a 2020 NBPP rulemaking, HHS established a policy for most individual and group health insurance plans that granted health insurers the flexibility to count – **or not to account** – copay assistance toward an individuals annual limitation on cost-sharing
- In August 2022, the HIV and Hepatitis Policy Institute and other patient groups filed suit challenging the NBPP Final Rule. The plaintiffs argued that the CY 2021 NBPP Final Rule conflicts with the definition of cost sharing under both the ACA itself and the ACA's implementing regulations at 45 CFR 155.20.
- On September 29, 2023, the US District Court for the District of Columbia struck down the rule, finding it was *arbitrary and capricious* to interpret "the same statutory and regulatory provisions as having two different meanings, to be chosen at the discretion of regulated parties."
- CMS, a year later, still has only undertaken to publish a rule implementing the court's decision, but has not yet done so.

Defining and Exploring Coupons, Accumulators, and Maximizers (cont.)

Implications of Changes to Part D Benefit (to PAP)

- In 2025, maximum out of pocket in Part D is $2000, and there is no donut hole
- Can also qualify in some instances for a payment plan with even payments over the course of a year
- Some manufacturers, like Pfizer, will require enrollment in a payment plan as a prerequisite before consideration of PAP qualification

IMPLICATIONS FOR GOVERNMENT PRICE REPORTING

Regulations and Guidance on Coupons from 2007 and 2016 MDRP Final Rules

- Manufacturer coupons meeting the terms set out in the MDRP regulations are explicitly excluded from Best Price, traditional AMP, and 5i AMP and by extension 340B Ceiling Price and Average Sales Price

- **2007 and 2016 MDRP Final Rules**

  Regulation text

  "Best price excludes . . . [m]anufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession." 42 C.F.R. § § 447.505(c)(9)

Regulations and Guidance on Coupons from 2007 and 2016 MDRP Final Rules (cont.)

- **Boiling it down (the focus at the time):**

1. Is the coupon not contingent on a purchase requirement?
2. Is the value of the coupon not negotiated with a PBM or payor?
3. Will a third-party not take a portion of the coupon for its own benefit, beyond a bona fide service fee?

Regulations and Guidance on Coupons and Accumulators from 2020 MDRP Final Rule

- **2020 MDRP Final Rule, effective January 1, 2023**

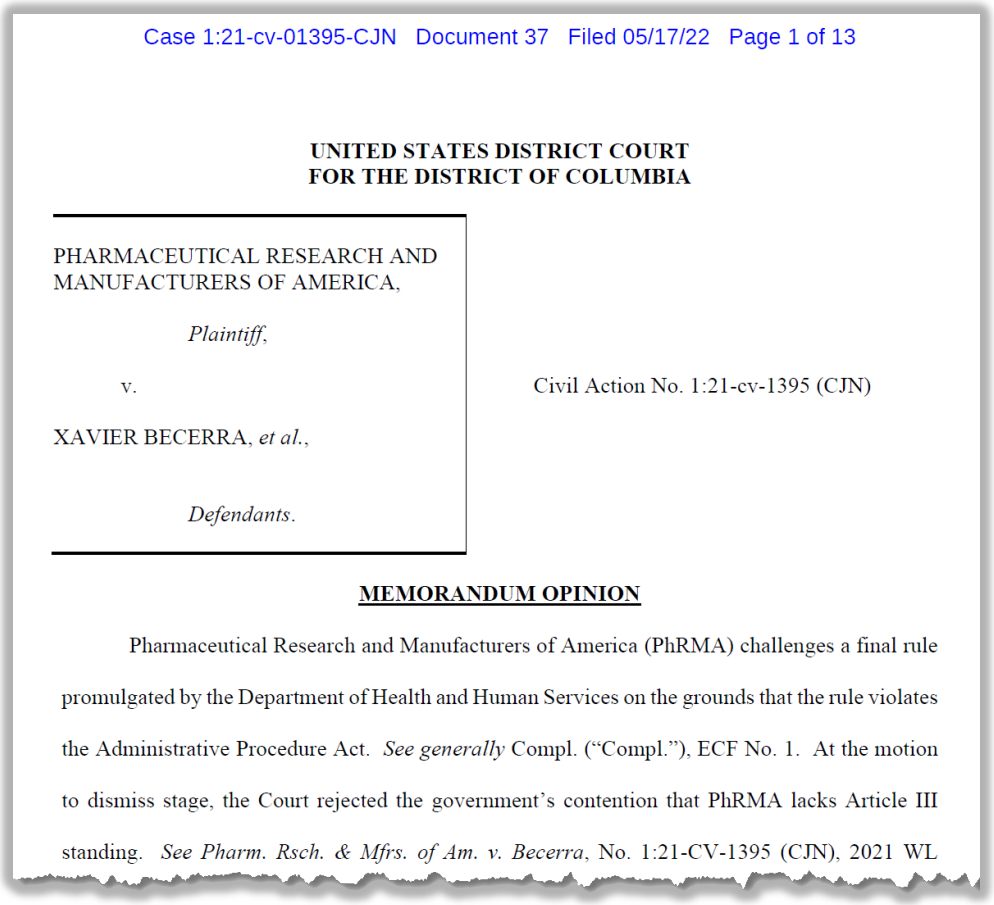
Regulation text

"Best price excludes . . . [m]anufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent ***the manufacturer ensures*** *that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession." 42 C.F.R. § § 447.505(c)(9)*

Preamble text

"By not applying the manufacturer assistance to a patient's deductible or other cost sharing obligations to obtain the drug, the assistance becomes a price concession to the health plan by delaying the point at which the health plan's contribution toward the patient's cost sharing begins, or reducing the value of the assistance to the patient, and thus should be counted in best price and, in certain cases, the calculation of the AMP."

Court Set Aside Accumulator Adjustment Rule



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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 1:21-cv-1395 (CJN)

MEMORANDUM OPINION

Pharmaceutical Research and Manufacturers of America (PhRMA) challenges a final rule promulgated by the Department of Health and Human Services on the grounds that the rule violates the Administrative Procedure Act. *See generally* Compl. ("Compl."), ECF No. 1. At the motion to dismiss stage, the Court rejected the government's contention that PhRMA lacks Article III standing. *See Pharm. Rsch. & Mfrs. of Am. v. Becerra*, No. 1:21-CV-1395 (CJN), 2021 WL

- On May 17, 2022, in an opinion granting PhRMA's motion for summary judgment, the U.S. District Court for the District of Columbia (D.D.C.) ruled in favor of PhRMA and vacated the Accumulator Adjustment Rule.
- The court held that the Accumulator Adjustment Rule fails Chevron Step One because CMS lacked the authority to issue the regulation under the text of the MDRP statute.

CMS' 2023 Proposed MDRP Rulemaking

- On September 20, 2024, CMS finalized a rule that removed the requirement to "ensure" that the patient retain all of the benefit.
- Still need to make sure that not giving any sort of price concession to a pharmacy

LAWFULNESS UNDER THE ANTI-KICKBACK STATUTE

Anti-Kickback Statute

- Criminal liability
- Includes offering or giving anything of value in exchange for Federal healthcare program business
- Requires knowing and willful conduct
- There are certain “safe harbors” that protect some types of behavior, but none apply to the issuance of copay cards
- An AKS violation can also lead to False Claims Act liability
  - Treble damages plus per claim liability over $20K

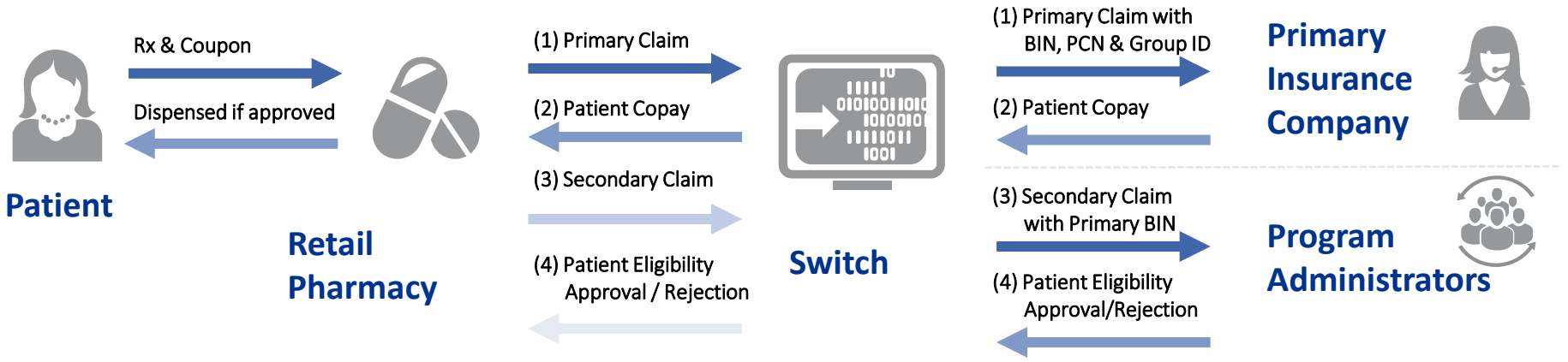
Co-Pay Card AKS Risks

- In 2014, the Department of Health and Human Services Office of Inspector General (OIG) did a review of copay cards
- OIG determined that 6 to 7% of Medicare beneficiaries were using copay cards, even though its stated policy is that they violate the AKS when offered to Federal healthcare program beneficiaries
- OIG determined that notices on copay cards, websites, etc., to patients and/or pharmacists were not very effective
- OIG also noted that using information about the primary payer was not always effective
- OIG stated that manufacturers bear the risk of how effective their screening techniques are

Copay Card Available Safeguards

- Can do due diligence on website portal
  - *Instead of asking, "Are you a Federal healthcare program beneficiary?" consider asking discrete questions, such as "Are you and your spouse retirees over the age of 65?"*
- Can put notice language on card and website, with a box-check approval
- Can do a full Benefits Investigation (generally only for specialty pharma)
- Can hire a 3PL to administer the copay card program

Claim Adjudication Process



Pharmacy Claim Adjudication Process:	
1	Pharmacy submits primary claim with patient's primary insurance to switch. Switch routes claims to primary insurance for approval or rejection.
2	Primary insurance company determines patient out of pocket copay remaining to switch to send to pharmacy.
3	Pharmacy submits secondary claim with PSP information to switch. Switch routes to appropriate program administrator.
4	Program administrator determines patient eligibility (e.g., GPE process), patient out of pocket copay remaining and sends to switch to send to pharmacy.

Types of 3PL Programs

- Some use data about the primary payer received over the switch
  - Only helpful if pharmacy is using the switch synched with the card
- Some use the Benefit State Qualifier field
- Some use other algorithms linked to coinsurance amount
- Some have a dedicated pharmacy that submits ghost claims

Doing Due Diligence

- The AKS has an intent requirement – make sure you ask questions of your vendor
- How do you screen out Federal program beneficiaries?
- Are you able to screen out Medicaid, as well as Medicare?
- Have you ever audited how successful your approach is? Please describe methodology.
- Does your technique require that the pharmacy use a specific switch?

Advisory Opinion Route

- Manufacturers can also develop a program that does not carve out Federal program beneficiaries and seek an advisory opinion
- Pfizer sought an advisory opinion regarding a copay card program for its drug tafamidis
- OIG issued AO 20-05 concluding that Pfizer's making its copay card program accessible to Part D beneficiaries posed more than a minimal risk of fraud and abuse
- Pfizer sued in Federal court, claiming that the AKS requires evidence of a "corrupt intent" purportedly not present here
- The district and appellate court, however, determined that the statute had no such requirement

Advisory Opinion Route (cont.)

- The “Pharmaceutical Coalition for Patient Access” has recently tried to change OIG’s view on copay assistance for Medicare beneficiaries
- In Advisory Opinion 22-19 (issued 10/5/22), OIG finally examined a potential use of the “coalition model” that it had first offered in 2005 as a potential pathway forward
- However, OIG could not accept the proposed model here, primarily because the manufacturers would only be responsible for subsidizing the costs of their own drugs
- OIG found that the arrangement would circumvent the incentives that Congress intended to put in place to increase patient sensitivity to the costs of their drugs
- The Coalition subsequently sued OIG in EDVA, but lost on similar grounds as the Pfizer suit

Permissibility of Bridge Programs

- Free drug on a trial basis (distributed by manufacturer, and not samples)
  - OIG has found certain factors helpful for establishing the acceptability of these arrangements, such as:
    - The drug is used only for its labeled indication
    - The free drug is for a very narrowly circumscribed time period
    - The free drug is only available if a prompt payer coverage decision is not forthcoming
    - There are no clinical limitations that preclude converting from the drug to a competitor product

OIG Advisory Opinions 15-11 and 08-04

Permissibility of Self-Pay Drugs

- Cash-paying patients foregoing Part D and receiving a discount
  - OIG has said that these arrangements are acceptable so long as:
    - Neither the pharmacy nor the patient submits any claims to the payer, and the payment does not count towards TrOOP
    - Neither the manufacturer or pharmacy uses the program as a vehicle for marketing other goods or services
    - The product has a generic equivalent on the market, meaning that most plans do not include the product on formulary
    - Fees to the pharmacy are at FMV

Permissibility of PAP Foundation Donations

- In Advisory Opinion 24-02, OIG deemed acceptable a PAP foundation's structure, which had disease funds dedicated to rare disorders, each of which was funded by a single manufacturer
- OIG looked favorably at the fact that the IRA meant that demand for these funds would now be more limited
- It also viewed favorably that the foundation reimbursed for more than drugs
- OIG time limited the opinion for two years, as it wanted to consider further the incentives created by the IRA

Buy and Bill Drugs

- **Generally these are arrangements where the manufacturer allows physicians to process coinsurance support at the physician's office when administering a drug**
  - Generally covered under patient's medical benefit, not pharmacy benefit
  - Typically involves a 3PL making direct contact with the payer, meaning that there are generally no Federal healthcare program beneficiaries receiving the support
  - But . . . there is a concern with providing an item of value to physicians that "pulls through" the Federal healthcare program business

Buy and Bill Drugs (cont.)

- **Safeguards to consider:**
  - Provide a card to the beneficiary, who has to affirmatively present it to the physician
  - Only pay the beneficiary upon proof of payment to the physician, and not the physician directly
  - Obtain info on the patient's income status
  - Carefully look at the scope of what the coinsurance support applies to

Other Laws

- Off-label promotion (?)
- State laws
- HIPAA

HAVE A QUESTION?

Please submit your questions on the Session Chat box on the right.