



Free Drug Programs – Regulatory Guidance and Enforcement



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Manufacturer Assistance Programs



Government Guidance and Enforcement



Accumulators, Maximizers, and Federal & State Legislation

The background of the slide is a blurred image of an industrial facility, possibly a refinery or chemical plant, with various structures and pipes. Overlaid on this are several teal-colored geometric lines, including a large 'X' shape and several parallel diagonal lines, creating a modern, technical aesthetic.

Manufacturer Assistance Programs

Manufacturer Assistance Programs

Types of Manufacturer Assistance



Copayment Assistance

- Offered directly from manufacturers to commercial patients
- Used at the pharmacy counter to reduce or eliminate patient's copayment obligation
- Widely available on direct-to-consumer basis



Charitable Foundations

- Patient assistance programs offered by independent charities
- Help eligible patients pay for the cost of prescription drugs
- May receive funding from pharmaceutical manufacturers



Manufacturer Support

- Cost support offered directly from manufacturers to commercial and sometimes federal patients
- Take a variety of forms (e.g. bridge program, direct subsidy)
- Eligibility requirements vary

Product and Reimbursement Support Programs

- Manufacturer programs that provide product and reimbursement support to physicians and patients
- Assist patients with cost and access issues – e.g., specialty drugs
- Services and support include:
 - Benefits investigation and verification
 - Prior authorization assistance
 - Copayment support
 - Financial assistance
 - Patient education
 - Drug delivery and prescription coordination



**Source: Pharmacy Today*

Industry Dynamics Contributing to Growth of Manufacturer Assistance Programs

- **High Drug Prices:** Continued controversy over high drug prices and manufacturer price increases
- **Specialty Drugs:** Increased utilization of expensive specialty medications that require high touch patient support
- **Restrictive Benefit Designs:** Plan adoption of benefit designs that require patients to bear full cost of drug (e.g., HDHP)
- **Aggressive Utilization Management:** Implementation of utilization management policies (e.g. prior authorizations) that are perceived to restrict patient access to prescribed medications
- **Formulary Exclusions:** Increase in PBM formulary exclusions and competition for favorable formulary placement

HEALTH CARE

House Democrats probe finds drugmakers drove U.S. price hikes



How Copayment, Coinsurance Impact Member Healthcare Spending

As employers search for new ways to control and reduce healthcare spending, copayments and coinsurance may be useful tools for particular healthcare services.

8 in 10 employers ranked specialty prescription drugs among the top 3 factors in rising health care costs.*



*According to National Business Group on Health, 2017 Press Release

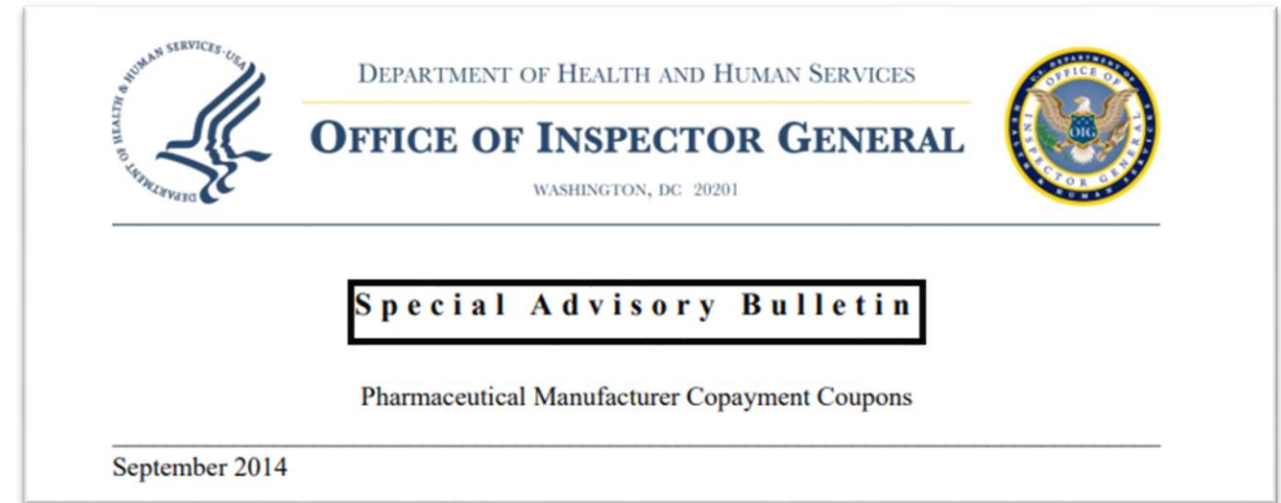
PBM Exclusion Lists: Useful For Leverage But Do They Benefit The Patient?



Government Guidance and Enforcement

Copayment Assistance – OIG Special Advisory Bulletin

- OIG takes position that copay coupons constitute remuneration offered to consumers to induce the purchase of specific drugs in violation of the federal anti-kickback statute (AKS)
- Copayment coupons create risk of excessive costs to government programs: (i) physicians or patients may choose expensive brand drug over cheaper generic, and (ii) manufacturers relieved of market constraints on drug prices
- Manufacturers must have measures in place to prevent use of copay coupons by federal program beneficiaries (e.g., screening, claims edits)
- Some state laws restrict the use of copay cards (e.g., CA, MA)



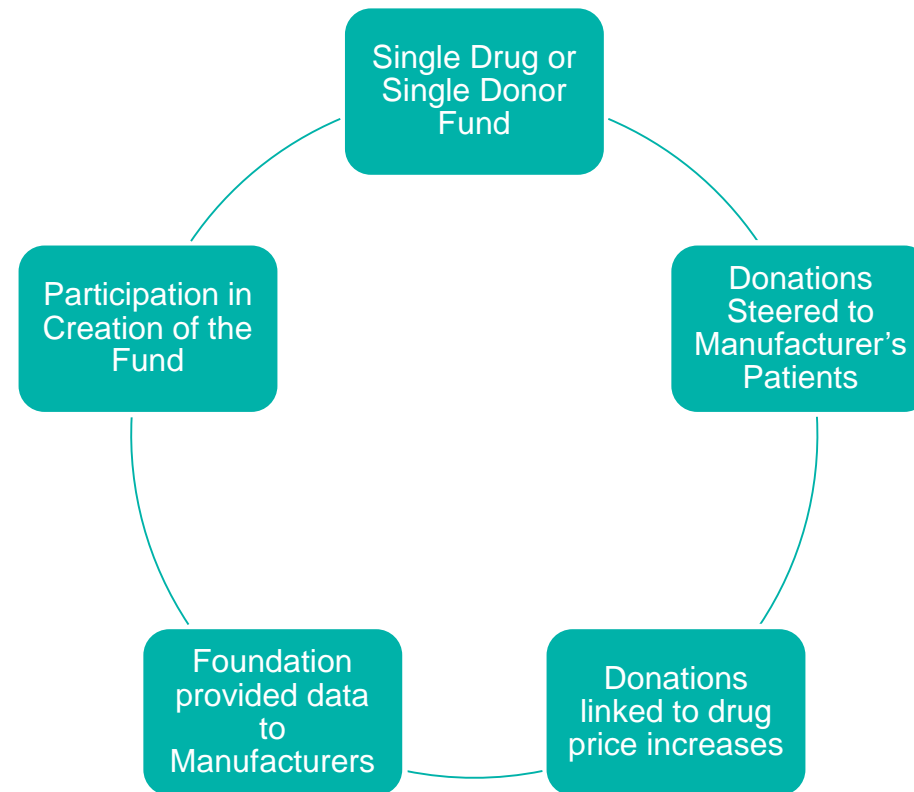
Patient Assistance Programs – Independent Charities

- Charitable patient assistance programs (PAPs) provide financial assistance to help uninsured or underinsured patients access their prescription drugs for little or no cost
- Eligibility requirements vary by program, but typically include:
 - U.S. resident
 - Uninsured or insurance does not cover your medication
 - Meet certain income eligibility requirements
- Receive contributions and donations from pharmaceutical manufacturers
- Medicare Part D requirements



Patient Assistance Programs – DOJ Enforcement

- DOJ enforcement sweep from 2017-2020 against manufacturers and charities based on PAP donations
- Theory of Liability – PAPs operated as a conduit for manufacturers to offer copayment assistance indirectly to federal health care program beneficiaries in violation of AKS and OIG prohibition on offer of copayment assistance to federal health care program beneficiaries



JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 23, 2020

Gilead Agrees To Pay \$97 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks

Pharmaceutical company Gilead Sciences, Inc. (Gilead), based in Foster City, California, has agreed to pay \$97 million to resolve claims that it violated the False Claims Act by illegally using a foundation as a conduit to pay the copays of thousands of Medicare patients taking Gilead's pulmonary arterial hypertension drug, Letairis, the Justice Department announced today.

Amgen and Astellas pay \$125.75 Million to Settle Allegations of Providing Illegal Kickbacks Through Patient Assistance Programs

PHARMA

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J&J joins Pfizer, Celgene, Biogen and more in DOJ's patient-assistance dragnet

By Tracy Staton • Feb 28, 2017 09:07am

Disclosure Investigation patient assistance programs subpoena

Direct Manufacturer Assistance

- **2018 OIG Letter – “Drug Companies that Provide Free Drugs to Federal Health Care Beneficiaries”**
 - “OIG will not pursue administrative sanctions against any Drug Company for providing free drugs during 2018 to Federal health care programs beneficiaries who were receiving cost sharing support for those drugs from [Caring Voice Coalition] as of November 28, 2017, as long as the Drug Company complies with the safeguards described in this letter.”
- **Safeguards for the Offer of Free Drugs:**
 - Provided in uniform and consistent manner to federal program beneficiaries
 - Provided without regard to beneficiary’s choice of provider, practitioner, supplier, or health plan
 - Not billed to any federal health care program, counted toward TrOOP, resold, or otherwise billed to a payor
 - Not contingent on any future purchases or orders of the drugs
 - Maintain accurate records of free drugs provided



See also OIG Advisory Opinions:

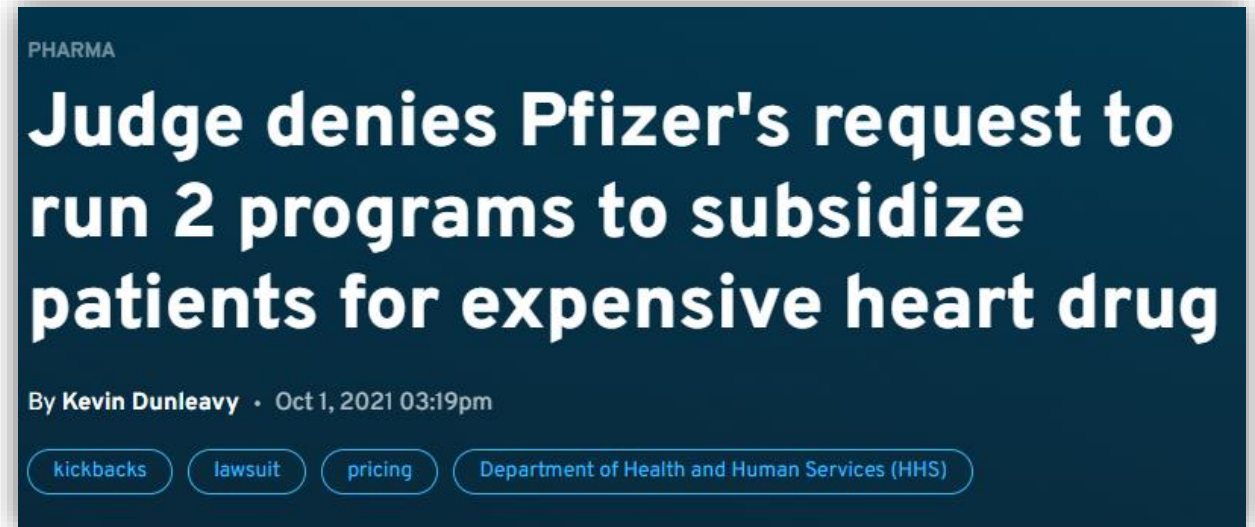
- No. 06-03 (Apr. 18, 2006)
- No. 08-04 (Feb. 5, 2008)
- No. 14-05 (July 21, 2014)
- No. 15-11 (Aug. 5, 2015)
- No. 16-07 (June 20, 2016)
- No. 18-14 (Nov. 16, 2018)
- No. 20-05 (Sept. 18, 2020)
- No. 21-01 (Mar. 18, 2021)

Manufacturer Litigation

- In 2020, Pfizer sued HHS over OIG's AKS prohibition on Pfizer's (i) offer of direct copay support to Medicare patients on Pfizer's tafamidis medications – Vyndaqel and Vyndamax – which costs \$225,000/year, and (ii) request to fund an independent charity to help with copays

“While there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the court”

- Judge Mary Kay Vyskocil



Source: Fierce Pharma

Patient and Provider Support Programs

- OIG has acknowledged that manufacturers sometimes offer purchasers/prescribers support services in connection with the sale of their products, such as billing assistance and reimbursement consultations
 - If such services have no substantial independent value to the purchaser they may not implicate the AKS
 - If the services have independent value or are coupled with another service or program that confers benefit, the AKS is implicated

Government enforcement actions and FCA relator claims have attempted to scale back the extent to which pharmaceutical manufacturer product support services may be permissible under the AKS

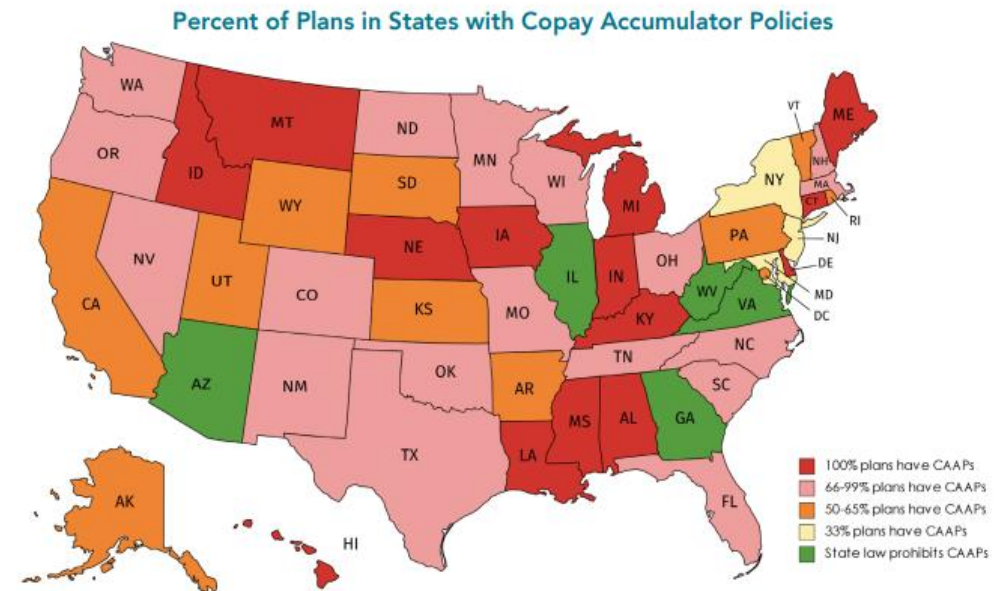
- Government settlements with Insys, Allergan, Celgene, Warner Chilcott, Shire
 - Assistance with billing and coding
 - Sales rep completion of prior authorizations
- In a recent settlement between the California Department of Insurance and Abbvie, the State of California claimed that nursing and reimbursement support services provided by Abbvie to physicians prescribing Humira amounted to kickbacks to induce Humira prescriptions
- Investigations also focus on prior authorization support programs that allegedly result in overutilization through obviating or weakening the role that prior authorizations play in reducing inappropriate or unnecessary utilization.



Accumulators, Maximizers, and Federal & State Legislation

Accumulator and Maximizer Programs

- Strategies to leverage manufacturer copay assistance and limit plan sponsor exposure to specialty drug costs
- **Accumulator:**
 - Manufacturer assistance does not count toward patient's deductible and OOP maximum
 - Manufacturer funds prescription until the maximum value of the copayment assistance is reached
- **Maximizer:**
 - Manufacturer's payments do not count toward patient's deductible or OOP maximum
 - Maximum value of the copayment assistance is split evenly across the benefit year
- **Increasing Adoption:**
 - 83% of commercial enrollees in plans with accumulator program



HHS Rulemaking – Notice of Benefit and Payment Parameters (NBPP)

- **2020 Rulemaking**

- HHS allowed commercial payors to implement copay adjustment programs for brand drugs with generic equivalents

- **2021 Rulemaking**

- HHS backtracks and allows commercial payors to implement copay adjustment programs for all drugs



CMS Rulemaking – Medicaid Best Price and Average Manufacturer Price (AMP)

- **December 2020 Rulemaking:**

- Revised the calculation methodology for AMP and best price as part of the Medicaid value-based purchasing rule
- Historically, co-payment assistance not included in the calculation of best price because the assistance goes directly to the patient
- Effective January 1, 2023, manufacturers must “ensure” the full value of copay assistance is passed on to the patient or the value will count toward and lower the manufacturer’s AMP and best price calculation of the drug
- Under accumulator programs price concession lowers the health plan’s cost for the drug



AMP Rule Impact on Copayment Assistance

- **CMS Rulemaking Creates Challenges for Manufacturers:**
 - Unclear how manufacturers can ensure that patients receive the full value
 - Lack of visibility - Information on plan accumulator and maximizer programs is often difficult to locate
 - Lack of control – Plans may account for benefits after claims adjudication in varying ways
 - In May 2021, PhRMA filed suit against the new policy
 - Manufacturers will need to consider operational changes in anticipation of 2023

Manufacturer Options

- Reduce copayment assistance to an amount that avoids best price impact
 - Lower patient benefits
- Offer direct-to-patient rebates – patient pays copay out-of-pocket and submits to manufacturer for reimbursement
 - Potential for increased regulatory risk





Questions?