



Preconference Workshop: Managed Markets 101

*Overview of the U.S. Payment System for
Pharmaceuticals*

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Agenda

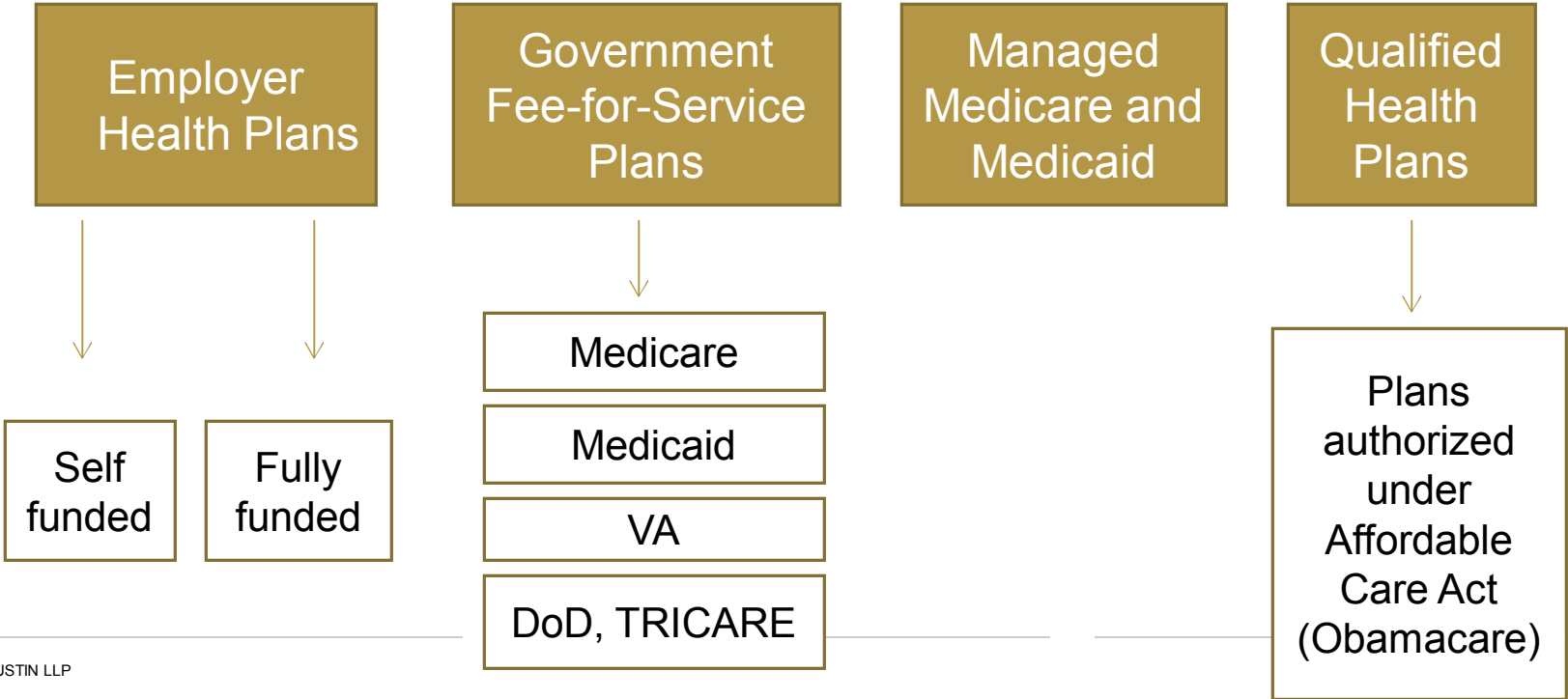
- **Private and Employer-sponsored Payer System Basics**
 - Key Insurance Players
 - Other Key Players (Wholesalers, PBMs, and GPOs)
 - Drug Formularies
- **Relevant Federal Healthcare Laws**
- **Market Access Activities and Communications**
 - Patient Access Programs
 - Current Options for Communicating Health Economic Information

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Key Questions

- How do patients gain access to prescribed medications?
- What is the flow of money?

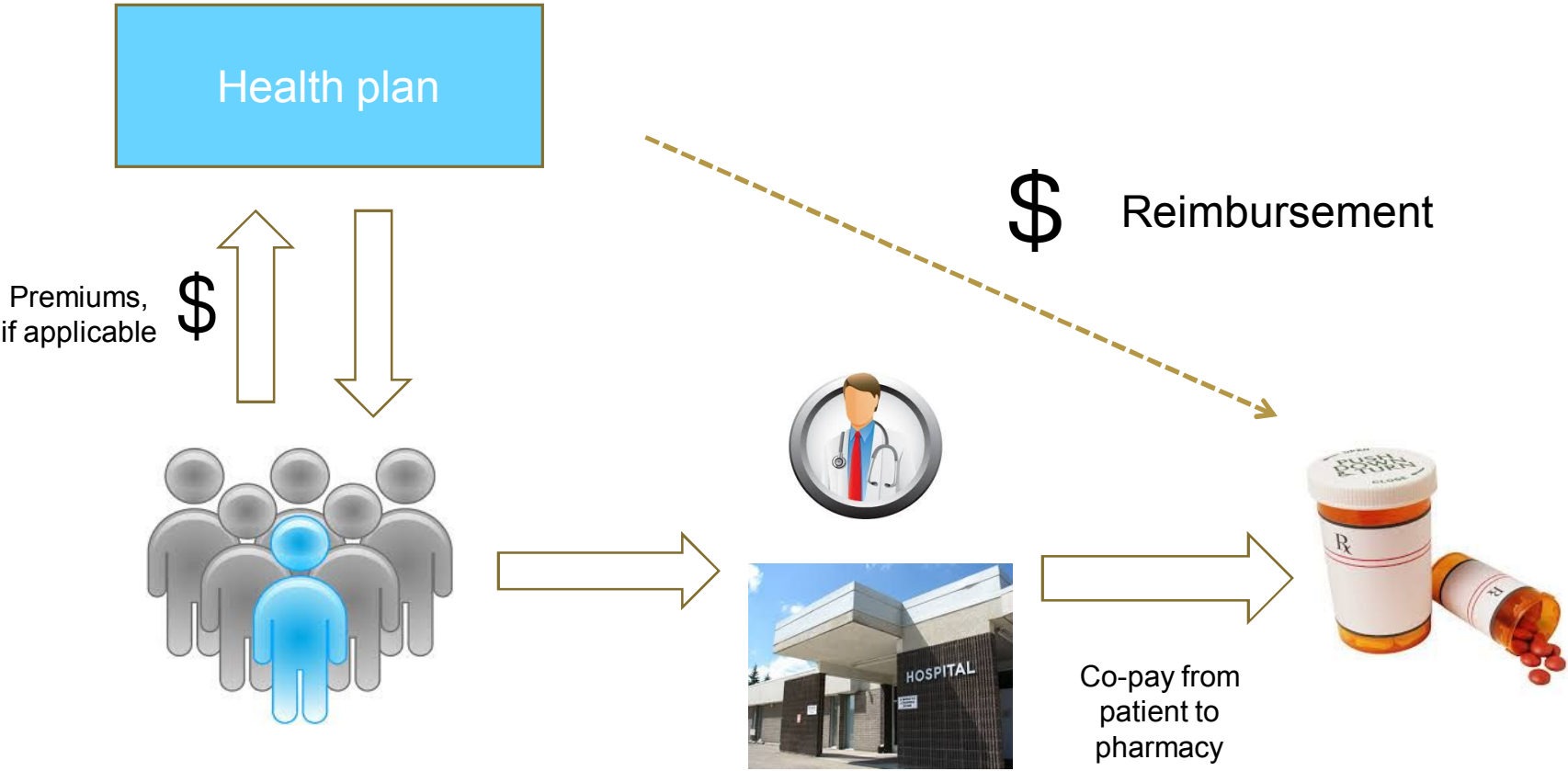
Basic health insurance options in the U.S.



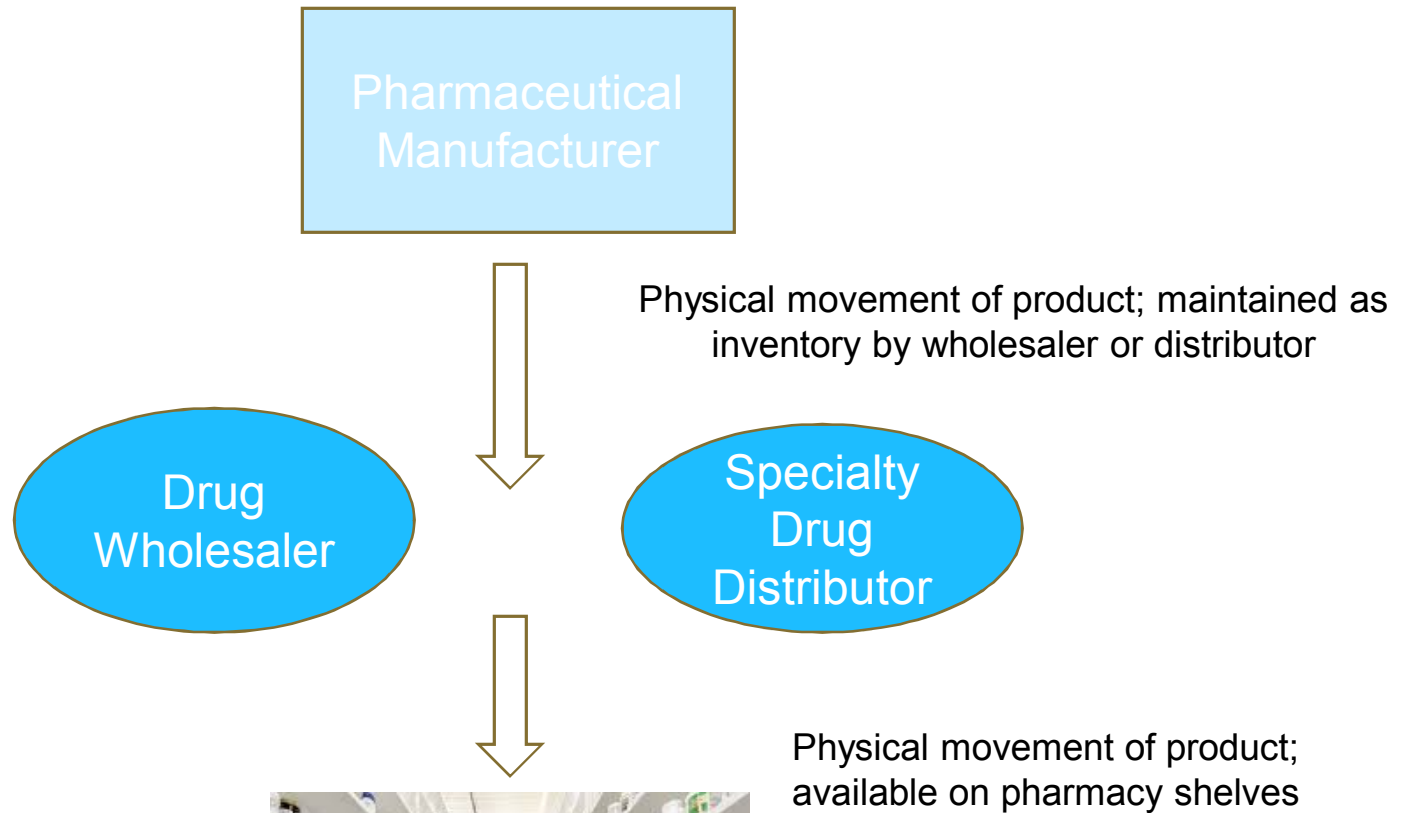
Types of health plan benefits

- There are various types of health plan benefits:
 - Medical (physician office and hospital inpatient)
 - Prescription drug (typically outpatient)
 - Dental
 - Vision
- Reimbursement varies depending on type of benefit and the item or service being reimbursed
- Prescription drug benefit → commonly separate reimbursement to pharmacy
- Medical benefit → often bundled (global composite) payment, but sometimes separately reimbursed

How do patients gain access to prescribed medications?

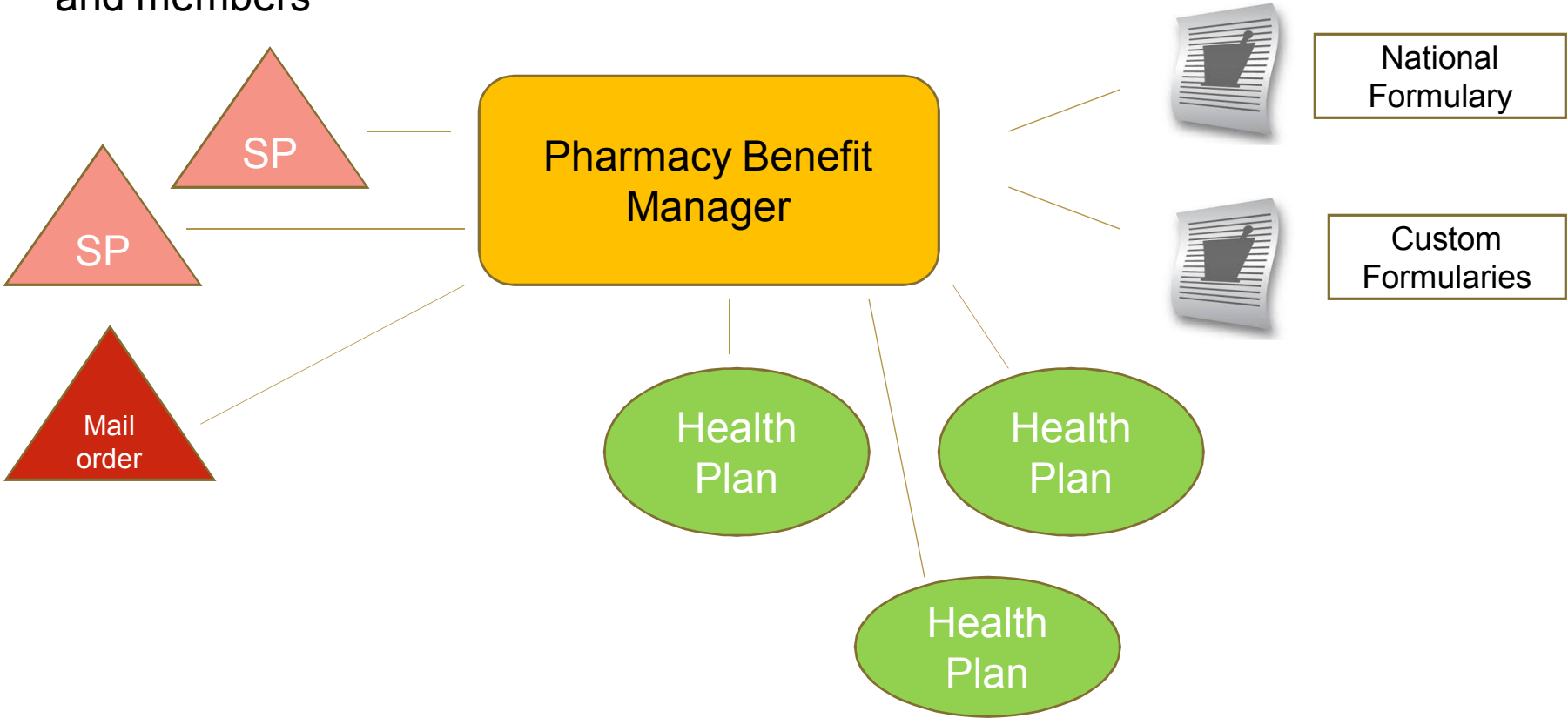


How are drugs distributed to pharmacies and providers?



Other key players: pharmacy benefit managers

- Organizations that provide programs and services designed to help maximize drug effectiveness and contain drug expenditures through financial and utilization management techniques that influence the behaviors of physicians, pharmacists, and members



Other key players: health maintenance organizations (HMOs)

HealthCare.gov

Health Maintenance Organization (HMO)

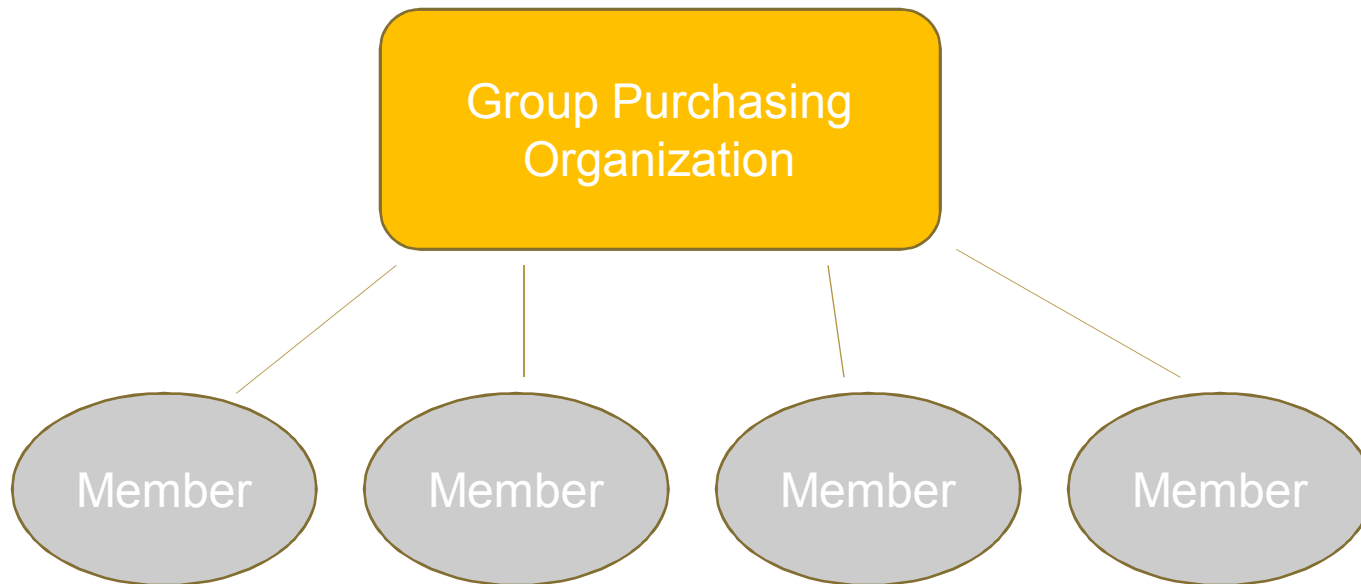
A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO. It generally won't cover out-of-network care except in an emergency. An HMO may require you to live or work in its service area to be eligible for coverage. HMOs often provide integrated care and focus on prevention and wellness.

Other key players: group purchasing organizations



What is a group purchasing organization?

A group purchasing organization (GPO) is an entity that helps healthcare providers-such as hospitals, nursing homes and home health agencies-realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors and other vendors.



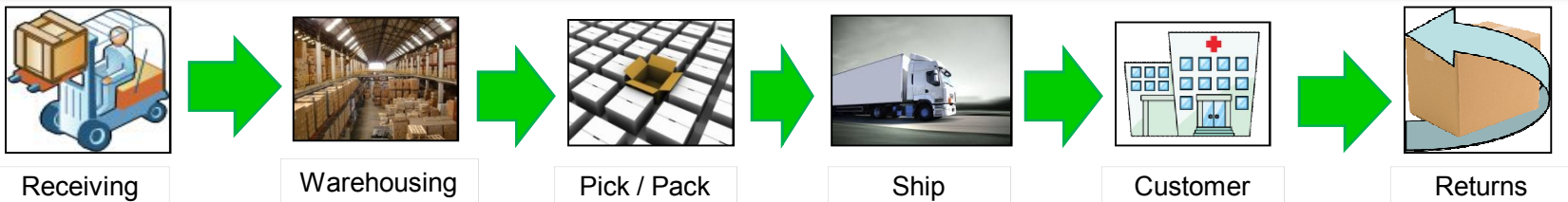
Trade and Distribution

Third Party Logistics Overview

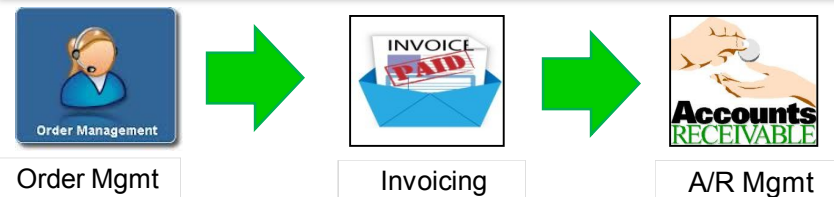
Third Party Logistics Services

A third party logistics provider (3PL) contracts with a drug or device manufacturer to provide warehousing, distribution and order-to-cash services on behalf of a manufacturer, but typically does not take title to the product(s) or have responsibility to direct the sale or disposition of the product(s). The 3PL is reimbursed for services by activity performed on behalf of the manufacturer.

Distribution Services



Order-to-Cash Services



- Order Management
- Credit Check
- License Management
- Inventory/Assignment
- Customer Set-up

- Chargebacks
- Gov't Reporting
- Contract Management
- Credit Processing

Trade and Distribution

Wholesaler Overview

Wholesaler Services

Wholesalers are equipped to handle pharmaceuticals with low drug cost, high product volumes, extended shelf life, and ambient temperature and handling. Wholesalers charge a fee for service, generally a percentage of the drug cost. Additionally, Wholesalers may sell a product for less than the manufacturer's list price, extending a cost-minus discount to customers.

Distribution Services



Receiving



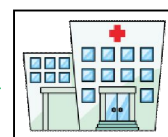
Warehousing



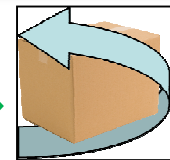
Pick / Pack



Ship



Customer

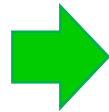


Returns

Sales Support Services



Order Mgmt



Invoicing



A/R Mgmt

- Order Management
- Credit Check
- License Management
- Inventory/Assignment
- Customer Set-up

- Chargebacks
- Contract Management
- Credit Processing

Manufacturer Services



Product Support



Data Services

- Inside Sales
- Sales Coordination
- Coordinated Credit Thresholds
- Credit Cards

- 852/867 sales data
- ADM data
- Customer Service Data

Other key players: specialty pharmacies

- “Specialty pharmacy” are pharmacies that focus on specialty products
 - URAC & UCHC Accreditation
- Common Attributes:
 - Cost of Therapy
 - Complex Administration
 - Special Handling/Storage
 - Small Patient Population/Rare Disease
 - Special Monitoring
- Ownership:
 - Payer/PBM
 - Distributor
 - Chain Retail Pharmacy
 - Independent



The rise of the specialty pharmacy model

- Manufacturers are increasingly contracting with specialty pharmacies
 - Patient access
 - Retail pharmacies will not stock expensive or special handling products
 - Reach to patients in rural or remote locations
 - Access to unique, de-identified data otherwise not available
 - REMS compliance
 - Integration with reimbursement hub (more on this later) to identify insurance coverage or forms of legitimate patient assistance
 - Pharmacy counseling for product administration, safety, risk information
- Concept of specialty pharmacy networks

What are drug formularies?

- Health plans, pharmacy benefit managers, and hospitals maintain written drug formularies (also called preferred drug lists)
- Formularies and PDLs drive utilization towards certain products within each therapeutic class
- Formularies and PDLs are designed by Pharmacy & Therapeutics Committees (or equivalent bodies)
 - Comprised of physicians, pharmacists, nurses, administrators, quality improvement managers, and other staff
 - Evaluate medications for formularies
 - Develop and implement strategies to manage medication use
 - P&T Committee recommendations are often subject to approval by medical staff



Rules governing drug formularies and PDLs

- Product minimums
 - Government plans require that plans include a minimum number of products per therapeutic class or category
 - Exchange plans require one product per United States Pharmacopeia (USP) therapeutic class or category
- US Pharmacopeia Medicare Model Guidelines

MODEL GUIDELINES—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.

- Review cycle: 3 years; comment period (September – October 2016)
- Impact on products new to market
- Impact on products creating new therapeutic classes or categories

The role of co-pays and utilization management

- Formularies and PDLs have tiers
 - These tiers are what drive utilization and deter unnecessary prescriptions
 - Tier 1: typically for generic products; lowest co-payment
 - Tier 2: preferred, branded product; moderate co-payment
 - Tier 3: non-preferred, branded product; high co-payment
 - Specialty Tier: very expensive branded products; very high (e.g., 25%) co-payment
- Plans also employ utilization management techniques
 - Prior authorization
 - Step through requirements
 - Drug utilization review
 - Disease management
 - Care coordination / case management

Why do drug formularies matter?

- Estimated \$50 billion in rebates paid annually by pharmaceutical companies to insurers, pharmacy benefit managers, and group purchasing organizations for formulary or price list placement. [Source: ZS Associates]
- Pharmaceutical industry offers discounts on its products to various customers
 - Rebates are a particular type of discount provided by pharmaceutical manufacturers to health plans, pharmacy benefit managers, and physician practices
 - Upfront discounts are another type of discount provided, commonly to customers like hospitals, group purchasing organizations, and physician practices
- Discounts and rebates can be tied to conditions such as:
 - Placement on formulary tiers
 - Minimum or tiered volume
 - Market share
 - Inclusion of multiple products
 - Value-based arrangements

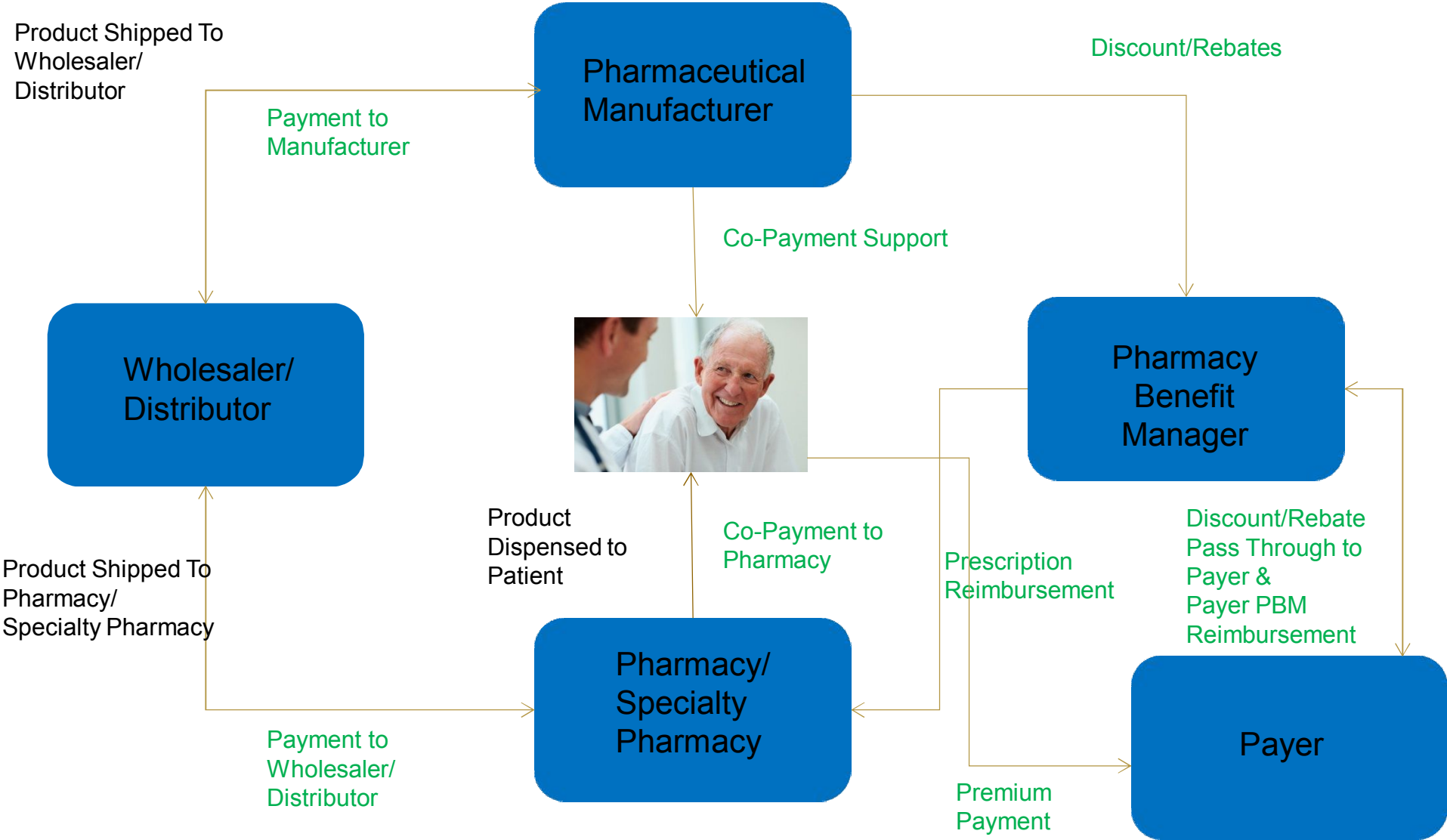
A word about drug compendia

- Drug compendia are compilations of drug information used by FHCPs and private insurers to determine coverage
- Examples of compendia relevant to government reimbursement include:
 - American Hospital Formulary Service Drug Information
 - United States Pharmacopeia-Drug Information (or its successor publications)
 - DRUGDEX Information System
- Interactions with compendia personnel may implicate the AKS, FCA, and the Federal Food, Drug and Cosmetic Act
- Compendia can drive the breadth of coverage a health plan provides for a drug

What kind of discounting contracts are there?

- Rebate contracts
 - Rebate contracts govern the provision of rebates to insurers in exchange for formulary or PDL placement
 - Common contracting parties:
 - Individual health plans
 - PBMs
 - Health maintenance organizations (HMOs)
 - Specialty GPOs
- Upfront discount contracts
 - Discounted pricing to group purchasing entities or individual institutions, often in exchange for minimum commitments or preferred product status
 - Common contracting parties
 - GPOs
 - Hospitals
 - Physician groups
 - Specialty pharmacies

Product and Financial Flow



Agenda

- **Private and Employer-sponsored Payer System Basics**
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Government enforcement key principles

- Decisions that increase Federal health care program costs are inherently suspect
- Government tends to infer intent from structure, including “secretive” arrangements
- Government is focused on actual and perceived conflicts in evaluating what constitutes fraud and abuse
- Activities that threaten health of Federal health care program beneficiaries will be aggressively pursued
- Government’s leverage gives it power to reject “legal defenses”

Legal Background: Federal Anti-Kickback Statute

- Prohibits
 - Any person from
 - Knowingly and willfully
 - Soliciting, offering, paying, or receiving
 - Directly or indirectly
 - Overtly or covertly
 - In cash or in kind
 - Any remuneration (including any kickback, bribe, or rebate)
 - In return for making referrals or otherwise generating business
 - Or to induce the purchase, lease, order of any item or service
 - For which payment *may* be made under Federal or state health care programs

Legal Background: Purpose of the AKS

- Intended to prevent financial considerations from:
 - Interfering with decisions regarding quantity, type and quality of medical care; and
 - Interfering with decisions regarding who provides care, and which items or services are provided
- Intended to prevent increased costs to the federal health programs (overutilization)
- Intended to prevent patient harm

Legal Background: Persons to Whom AKS Applies

- “Whoever” gives, receives, offers, solicits
- Both sides of the transaction and anyone in between, *e.g.*,
 - Physicians and other providers (including their office staff)
 - Sales and marketing representatives
 - Industry representatives and vendors
 - Hospital administrators

Legal Background: Remuneration

- Direct or Indirect
- Remuneration is defined broadly to include ***anything of value***
 - *E.g.*,
 - cash or cash equivalents
 - gifts, discounts, or free items or services
 - salaries, business opportunities, or loan guarantees
 - payment for non-*bona fide* or unnecessary services
 - “value-added” services
 - No de minimis exception or safe harbor

Legal Background: An Intent-Based Statute

- Significance of Intent
 - Intent-based prohibition
 - “One purpose” test
 - “To induce” is an important concept
- 2010 Health Care Reform Law Changes to Intent
 - Effectively overrules prior court decisions that require that a person have actual knowledge of and specific intent to violate the AKS
 - Twenty years ago, enforcement actions based on this theory seemed far-fetched
 - The new subsection reads: “With respect to violations of **this section, a person need not have actual knowledge of this section or specific intent to commit** a violation of this section.”
 - In plain terms, this means it is easier for prosecutors to bring and win AKS cases

Legal Background: AKS Penalties

- Felony
 - Up to 5 years in prison + up to \$250,000 fine for each violation for individuals, \$500,000 for corporations
 - Mandatory exclusion
- Violation may also trigger civil monetary penalties
 - Up to \$50,000 fine for each violation
 - Permissive exclusion from participation in federal healthcare programs
- False Claims Act (“FCA”) liability (per health care reform amendment)
 - “In addition to the penalties provided for [under the AKS], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim [under the FCA]”
 - FCA violations may result in civil penalties up to \$11,000 per claim, plus up to three times the actual damages sustained by the government as a result of the violation

Legal Background: Exceptions and Safe Harbors

- Exceptions and safe harbors designed to protect common business relationships
 - Discounts
 - Personal Services
 - Employees
 - Warranties
 - Managed care arrangements
 - Many others
- These exceptions and safe harbors only provide protection when the parties fully and completely comply with ALL of the requirements of the applicable exception or safe harbor
- Remuneration outside a safe harbor does not necessarily mean that the statute has been violated
- If intent is nefarious, or significant clinical, safety, and/or overutilization issues are present, will government care if a safe harbor is technically met?

Federal False Claims Act

- The FCA imposes liability on any person who, among other things, “knowingly presents, or causes to be presented” “a false or fraudulent claim for payment or approval”
 - Most FCA actions are filed as qui tam (whistleblower) actions
- Liability under the FCA can give rise to various penalties, including:
 - Civil penalties: up to \$11,000 per false claim and treble damages
 - Exclusion: individual or corporate
 - Criminal penalties: up to 5 years’ imprisonment and a \$250,000 fine for an individual, or a \$500,000 corporate fine and up to 2 times corporate gain under Alternative fines provision
 - Criminal liability is imposed under separate statutory provisions that criminalize false claims to the government generally and false health care claims specifically

Early Enforcement Examples – Pharmaceutical Contracts

Company and year of settlement	Allegations	Settlement amount
Pfizer (2002)	Pfizer subsidiaries allegedly overstated Lipitor's Best Price in the first and second quarters of 1999 by concealing \$250,000 of cash discounts that were given to a key managed care customer in Louisiana in exchange for favorable status on the managed care organization's drug formulary	\$49M (civil)
Schering-Plough (2004)	Schering Sales offered to make up the difference between the price of Claritin and Allegra by offering the HMO a \$10 million package of added value, in lieu of an actual price reduction on Claritin	\$345.5 million (civil and criminal)

More Recent Enforcement - GlaxoSmithKline (2012)

- In July 2012, GlaxoSmithKline (“GSK”) agreed to plead guilty and pay \$3 billion to resolve its criminal and civil liability.
 - Civil allegations: Pricing fraud, FCA violations.
 - \$2 billion civil settlement.
 - Criminal allegations: Introducing misbranded drugs into interstate commerce, failing to report safety data to the U.S. Food and Drug Administration (“FDA”).
 - Guilty plea to a three-count criminal information.
 - \$1 billion criminal plea agreement.
 - Five-year CIA (requiring, among other things, implementation of policies/procedures governing interaction with payors related to formulary placement, supplemental rebates, and other types of rebate agreements).
- Allegations. GSK allegedly “paid certain supplemental rebates on its products only if Medicaid agreed not to place restrictions on its products.”
 - “[H]owever, the proposed restrictions would have only brought recommended usage in line with the FDA-approved indication and NIH Guidelines.”

More Recent Enforcement - AstraZeneca Pharmaceuticals (2013)

- In 2003, a relator filed a *qui tam* action against AstraZeneca in E.D. Pa., alleging that “special deals” given to a pharmacy benefits manager (“PBM”) amounted to kickbacks, resulting in FCA violations and Best Price fraud.
 - In January 2013, the court dismissed the matter with prejudice for failure to satisfy the FCA’s “original source” requirement. However, the underlying allegations still illustrate the ways in which rebate arrangements may be scrutinized.
- Allegations. AstraZeneca allegedly issued “special deals” to Medco with the goal of getting AstraZeneca products added to “trophy account” payors’ formularies.
 - Examples of “special deals” included: funding of sham Medco programs if AstraZeneca remained preferred on payor formularies or competitor products were not added to such formularies, funding formulary mailings for Medco to promote sales of AstraZeneca product, issuing undisclosed discounts to Medco.

More Recent Enforcement - Johnson & Johnson (2013)

- In November 2013, Johnson & Johnson (“J&J”) entered into a \$2.2 billion settlement, which included \$149 million to settle civil claims for an FCA action premised on alleged AKS violations.
 - J&J also executed a five-year CIA.
- Allegations. The government alleged that J&J paid kickbacks to Omnicare, a long-term care PBM, to induce purchases of J&J products.
 - The government alleged that J&J paid quarterly market share rebates to Omnicare to switch patients to J&J drugs.
 - The government also alleged that J&J paid quarterly rebates to Omnicare in advance in many instances, “effectively providing Omnicare with interest-free loans of millions of dollars.”
 - J&J and Omnicare also reportedly entered into an agreement conditioning rebates upon providing favored formulary positions on two J&J products, Levaquin and Risperdal.

More Recent Enforcement - Novartis (2015)

- In 2011, relator filed a FCA *qui tam* suit against Novartis, Bioscrip, and CVS. The United States intervened only with respect to Novartis and Bioscrip, with regard to two drugs (Myfortic and Exjade).
 - In November 2015, Novartis agreed to pay \$390M to settle kickback theories of liability (largest recovery ever under the FCA for a kickback theory of liability)
- Allegations. Among other allegations, the government alleged that Novartis issued kickbacks to a particular pharmacy because the pharmacy owner was a member of the formulary committee for a large managed care organization.
 - Specifically, Novartis allegedly offered this pharmacy “the opportunity to earn up to 15% of its Myfortic sales in rebates and discounts if the pharmacy would ‘move patients from CellCept to Myfortic.’”
 - “[T]he written contracts . . . were silent on what the pharmacy would do for Novartis in exchange for the financial benefits it stood to earn. Instead, those agreements simply state the amount of the upfront discount and the amount of a ‘performance’ rebate tied to [the pharmacy] achieving a series of specific market share hurdles.”

More Recent Enforcement - Wyeth (2016)

- In 2009, U.S. Department of Justice (“DOJ”) (both Main Justice and the U.S. Attorney’s Office for D. Mass.) and various states joined two FCA *qui tam* actions against Wyeth.
 - This case settled in April 2016 for \$785M
- Allegations. The government’s complaint alleged that Wyeth offered massive discounts on its acid suppressant drugs, Protonix Oral and Protonix IV, through the use of bundled price arrangements offered to hospitals that required the hospitals to purchase the two products together in order to realize the discount.
 - Specifically, the government alleged that Wyeth set a high price for Protonix IV, which did not have significant competitors in the marketplace, and offered a bundled discount on both the IV and oral formulations to hospitals that agreed to purchase both to drive sales of the oral formulation.
- Whistleblowers: Former AstraZeneca sales rep and a practicing physician

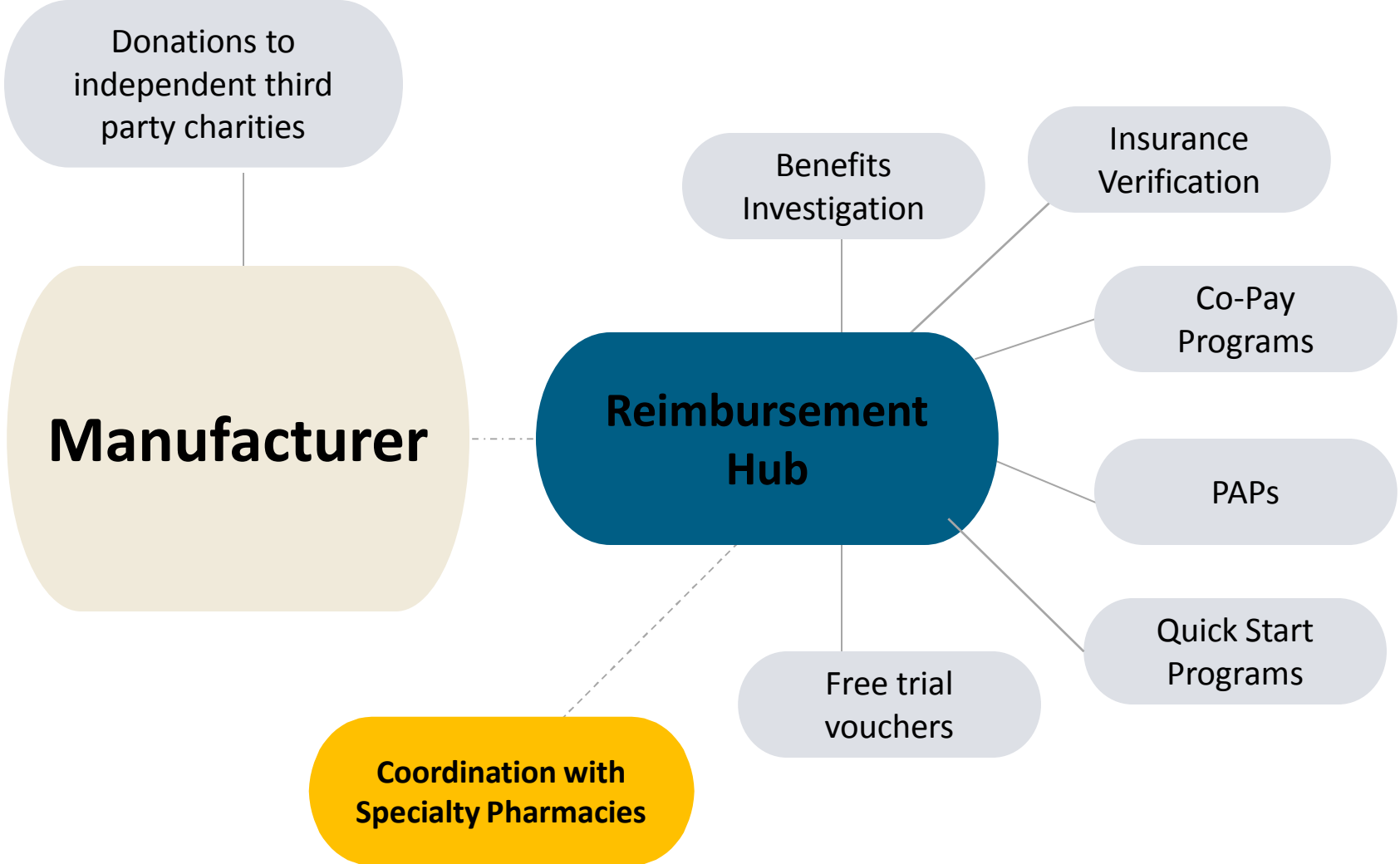
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- **Relevant Federal Healthcare Laws**
- **Private and Employer-sponsored Payer System Basics**
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Government Guidance on Patient Support Programs

- **OIG Compliance Program Guidance for Pharmaceutical Manufacturers –**
 - Permits support services in connection with the sale products including billing assistance to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product if not coupled with service conferring independent value to the referring HCP.
- **OIG-00-10 – Acknowledged (& permitted) providing certain billing, coding, reimbursement support has no independent value and properly considered part of products' price. Further permitted pre-qualification services, extended payment terms, & invoice Credit**
- **OIG- 06-16- Finding extensive reimbursement support services when combined with subsidized advertising and call center that would relieve targeted DME Supplier of costs would raise substantial risk of disguised kickback scheme.**
- **OIG 10-04 – Permitted Imaging Centers to Transparently As to Payors Provide Prior Authorization Support Equally to All Referring HCPs and Patients.**
- **OIG 15-11 – Permitted Bridging Program for Patients During Pendency of Insurance Coverage Determination**

Manufacturer-sponsored patient support programs



Examples Various Patient Support Programs

The following are examples of support programs to help patients to start and adhere to their prescribed therapies

Benefit Investigation/Claims Support	<ul style="list-style-type: none"> Assist patients to determine the extent of their insurance coverage and obtaining payers approval for prescribed medications
Billing/Coding Education	<ul style="list-style-type: none"> Provide information to billing managers on correct filing of reimbursement claims
Bridging Programs	<ul style="list-style-type: none"> Temporary free medication to patients during pendency of coverage determination
Co-Pay Assistance	<ul style="list-style-type: none"> Assist Patients on Cost Sharing Obligations
Indigent Patient Assistance	<ul style="list-style-type: none"> Free products to patients based on needs
Injection Training	<ul style="list-style-type: none"> Patient education on administration
Patient Education and Reminders	<ul style="list-style-type: none"> Patient education on disease state, prescribed medication and refill reminders

Access is a critical issue for various types of medications

- Specialty medications are typically subject to higher cost sharing
- Many drugs have no lower cost alternative
- There is a need for various channels and types of patient assistance
- The government has recognized this need in various context, but also expressed skepticism and suspicion in some cases
- Common types of assistance
 - Free drug assistance
 - Co-pay assistance
 - Insurance coverage delay assistance
- There are also important market access tools that assist patients in affording their medication and giving new medications a fair trial:
 - Co-pay coupons
 - Free trial vouchers

Patient Assistance Allegations in Recent Cases - Cephalon

U.S. ex rel. Cestra

“[R]elator alleges that Cephalon used its CORE Program to ensure that off-label prescriptions would be reimbursed by government programs. Id. at ¶¶ 219-37. Relator asserts that Cephalon spent over three million dollars per year to provide reimbursement support to doctors and office managers submitting claims to government programs.”

“Relator also alleges specific facts suggesting Cephalon understood the CORE Program was being used to overturn coverage denials of off-label prescriptions of Treanda.”

U.S. ex rel. Boise

“[R]elators contend that Cephalon provided physicians with front office ‘personnel in the form of Cephalon sales representatives who were instructed to provide free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work.’”

Relators contend that Cephalon was faced with payer ‘resistance to reimbursing for many of its drugs for off-label uses’ and so it ‘paid doctors to facilitate falsified prior authorization requests in order to obtain reimbursement.’ Id. at ¶ 225. Those payments were allegedly made in the form of free reimbursement services provided by Cephalon, where ‘at the instruction of their managers, sales representatives [] (1) induced physicians and staff to complete prior authorization requests; (2) coached physicians and staff on language, often false, to include in prior authorization requests; and (3) themselves completed and submitted prior authorization requests, including by reviewing patient files.’”

Court's Rulings and Their Limitations

U.S. ex rel. Cestra

“Coupled with the allegations that Cephalon’s CORE program aimed at ensuring these increased sales resulted in reimbursement for off-label prescriptions from the government, a program that relator alleges in itself constitutes a kickback, these allegations are sufficient to inform Cephalon of the precise misconduct against it and indicate the action was not commenced in bad faith.”

U.S. ex rel. Boise

“Yet, this alleged kickback is unique in that the form of the kickback, free reimbursement services, is oriented towards ensuring the actual submission of claims tainted by that kickback. Thus, the form of the alleged kickback itself provides a strong inference that claims were actually submitted as a result of the kickback being provided to physicians.”

- In both cases, Judge O’Neill in the E.D. Pennsylvania ruled that for purposes of Rule 12(b)(6), allegations of free prior authorization services combined with allegations of off label promotion were sufficient to overcome a motion to dismiss.
 - These rulings represent one judge’s view at the motion to dismiss stage. Litigation remains ongoing.
- The rulings did not involve patient support programs in isolation. Rather, both relators alleged that the patient support programs were just one component of an allegedly broad scheme to promote products off-label.

Patient Assistance Allegations in Recent Cases – Warner Chilcott

- 2015 – Guilty Plea and Civil Settlement of \$125 Million
- Criminal Prosecution Against Former President and District Manager
- Allegations of Broad and Pervasive Scheme to Promote Off-Label, Provide Kickbacks, and Submit False Claims Encouraged by Senior Management

153. ...Indeed, management has instructed sales representatives to actively manipulate the prior authorization process to increase sales of the Company's drugs. At the instruction of their managers, sales representatives have (1) induced physicians and staff to complete prior authorization requests; (2) coached physicians and staff on language, often false, to include in prior authorization requests; and (3) themselves completed and submitted prior authorization requests, including by reviewing patient files.

165. Warner Chilcott's falsification of prior authorization requests has not only violated the False Claims Act and its own Code of Ethics, see ¶ 204, *infra*, but also HIPAA. HIPAA guards patients' "protected health information" ("PHI"), ranging from personally identifying information to medical history and records, from disclosure outside of a limited group of people including treating health care professionals, without patients' express permission.

OLG Special Advisory Bulletin: Patient Assistance Programs for Part D Enrollees (2005)

- Medicare Part D was a watershed event for PAP fraud and abuse guidance
 - Medicare Part D brought federal healthcare program funds into play for prescriptions filled for Medicare beneficiaries. This necessarily entailed AKS considerations.
 - PAPs still needed for patients in the coverage gap.
 - Concern with how PAPs are used to meet TrOOP requirements (“speed through” the coverage gap).
 - Health care reform could well alter the analysis
- Special Advisory Bulletin (SAB) November 2005
 - 70 Fed. Reg. 70623 (Nov. 22, 2005)
 - Addresses how PAPs can assist Medicare beneficiaries
 - Does not apply to PAPs assisting the uninsured

OIG Special Advisory Bulletin: Independent Charity Patient Assistance Programs (May 2014)

- “Reiterates and amplifies” guidance provided in the 2005 SAB
- Focuses on three areas of concern:
 - **(1) Disease funds that too narrowly define eligible disease states.**
 - Includes disease funds that are too narrowly defined, such as those defined by stages of a particular disease, type of drug treatment, and other ways of narrowing the definition of widely-recognized disease states.
 - May include disease funds that previously obtained favorable advisory opinions.
 - Includes disease funds that limit assistance to a subset of available products, such as by covering copayments for expensive or specialty drugs only.
 - **(2) PAP eligibility defined with respect to drug cost.**
 - OIG emphasized that the cost of a particular drug is not an appropriate stand-alone factor for determining individual financial need for PAP eligibility.
 - Generous need criteria may also evidence intent to fund particular drugs, especially where a fund is limited to a subset of drugs or drugs of a major donor.
 - **(3) Donors correlating PAP contributions with support for own products.**
 - Actions by donors to correlate their PAP funding with support for their own products may implicate the AKS by indicating a donor’s intent to channel financial support to copayments for its own products.

OIG Special Advisory Bulletin: Pharmaceutical Manufacturer Copay Coupons (Sept. 2014)

- Issued concurrently with Office of Evaluation and Inspections (OEI) report analyzing manufacturer measures to prevent coupon programs from inducing Part D drug purchases.
- Findings of OEI report:
 - Not all coupon formats bear notice that excludes FHCP beneficiaries
 - Not all claims edits reliably identify all claims submitted in connection with Part D drugs.
 - Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers.
 - CMS should cooperate with stakeholders to improve reliability of mechanisms to determine when coupons are used in connection with Part D drugs, including making coupons universally identifiable.
- Additional OIG conclusions:
 - “[M]anufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including [Part D drugs].”
 - “Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the [AKS].”

OIG Podcast on Copayment Coupon Report

“So, what can be done to solve this problem?”

“We think the manufacturers will need to find a technical solution.”

“Is it only up to the manufacturers to solve this problem?”

“In our report, we recommended that...CMS cooperate with industry efforts to create reliable safeguards.”

Interview of Melissa Baker, team leader in the Chicago Office of Evaluation and Inspections, by Laura Kordish, Deputy Regional Inspector General for Office of Evaluation and Inspections

U.S. ex rel. Yarberry v. Sears Holding Corp.

- Relator, a Kmart pharmacist, brought a *qui tam* suit alleging that Kmart violated the AKS through its retail rewards program.
 - Kmart’s policies expressly prohibited the provision of coupons and gift cards to FHCP beneficiaries and prohibited coupons from being used to pay for any prescriptions covered by FHCPs.
 - In six years, Kmart issued over 76,000 gift cards in the same transaction as a purchase of a prescription drug by a FHCP beneficiary.
- Kmart contended that it did not “knowingly” violate the AKS.
 - In 2009, Kmart developed an automatic flag system, which allowed pharmacists to identify a FHCP beneficiaries.
 - Prior to this system, Kmart asserts that it implemented several mechanisms for pharmacists to identify FHCP beneficiaries.
 - Relator alleged, and some employee pharmacists testified, that they had no way to reliably identify FHCP beneficiaries.
- The court held, “If it is found that Defendants did not take sufficient precautions to detect [FHCP] beneficiaries until...the flag program was implemented, a reasonable fact finder could conclude” that defendants acted” recklessly or in deliberate ignorance.”

Private Payor Coupon Litigation

- In March 2012, seven complaints were filed against nine pharmaceutical manufacturers in federal class action lawsuits.
 - The lawsuits alleged violations of federal racketeering and antitrust laws in connection with the manufacturers' copayment coupon programs.
 - Manufacturers allegedly conspired to offer programs that bribed privately-insured individuals to select brand name drugs over less expensive therapeutic alternatives by subsidizing copayments in a manner that undermined health plans' cost-sharing and formulary structures.
 - Aggregating factors included: (1) products were non-preferred on payors' formularies; (2) cost of product was expensive for the payor; and (3) product had high utilization.
- Future implications.
 - The claims have been dismissed, but several entities continue to assert the plaintiffs' perspectives.
 - OEI's September 2014 report is reminiscent of positions and claims asserted by the plaintiffs, suggesting that similar issues may also continue to be asserted by the government.

Market Access Communications: Health Care Economic Information

- Health Care Economic Information
 - Definition: “[A]ny analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention” FDCA § 502(a), 21 U.S.C. § 352(a).
 - Permissible audiences: “a formulary committee, or other similar entity, in the course of . . . carrying out its responsibilities for the selection of drugs for managed care or other similar organizations” *Id.*
 - Limitations
 - Must “directly relate[]” to an “approved” indication
 - Must be “based on competent and reliable scientific evidence”
 - Information relevant to “the substantiation . . . shall be made available” to FDA on request
 - Consequences
 - Not false or misleading under section 502(a)
 - Not subject to section 505(a) or analogous PHSA provision

Data Purchases

- Examples include purchasing prescription utilization information from specialty pharmacies, hospitals, GPOs, and PBMs
- Key fraud and abuse risks from the government’s perspective include:
 - Payment for data could be construed as disguised rebates includable in government pricing metrics, e.g., Best Price, AMP, and ASP, as applicable
 - To the extent the same data has historically been provided at no cost, it will present challenges from a FMV perspective
 - There have been several FCA actions alleging “sham data purchase agreements” (e.g., J&J, AdvancePCS, AstraZeneca, and Schering-Plough)
- Consider key safe harbor factors such as legitimacy of purchase, need for data, and determination of fair market value, among other factors

Ancillary services

- Administrative services can give rise to a number of AKS, government pricing, and patient privacy issues
- Examples include:
 - Services compensated through discounts
 - Medication adherence messaging

Services for Discounts or Percentage Fees

- Hypothetical examples:
 - 5% rebate for active intervention program
 - 2% prompt pay discount, including for certain additional de-identified data
- Fraud and abuse risks from the government's perspective include:
 - Government might interpret a rebate or discount as outside the discount safe harbor, if contingent on the performance of services
 - Service fee based on percent of revenue may not reflect FMV
 - Rebates/discounts are included in government price reporting metrics if to an included customer; *bona fide* service fees are not

Services for Discounts or Percentage Fees Enforcement Examples

- Amgen Complaint (6/14/2011)

**UNITED STATES DISTRICT COURT
DISTRICT SOUTH CAROLINA**

UNITED STATES OF AMERICA, and the States of CALIFORNIA, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA and the CITY OF CHICAGO. Plaintiff Ex parte FRANK KURNIK Plaintiff v. AMGEN, Inc., OMNICARE, PHARMERICA CORP and HEALTHCARE, INC. Defendant	<p style="text-align: center;">2. Accordingly, on behalf of the United States of America and the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Montana, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, the District of Columbia and the City of Chicago, Plaintiff and “Relator” Frank Kurnik, under this <i>qui tam</i> Complaint and alleges:</p> <p style="text-align: center;">3. In violation of the Federal False Claims Act, 31 U.S.C. § 3729 <i>et seq.</i> and similar state and municipal law provisions, Defendant Amgen knowingly presented or caused to be presented false or fraudulent claims to be submitted in violation of the law for payment or approval by federal and state agencies and/or programs by:</p> <ul style="list-style-type: none"> • providing rebates and other financial incentives to long term care pharmacies, including Defendants Omnicare, PharMerica and Kindred, to induce doctors to switch patients from Procrit to Aranesp in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b);
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“In violation of the Federal False Claims Act . . . and similar state and municipal law provisions, Defendant Amgen knowingly presented or caused to be presented false or fraudulent claims to be submitted in violation of the law for payment or approval by federal and state agencies and/or programs by:

- Providing rebates and other financial incentives to long term care pharmacies, including Defendants Omnicare, PharMerica and Kindred, to induce doctors to switch patients from Procrit to Aranesp in violation of the Anti-Kickback Statute[.]”

Refill Reminder and Adherence Programs

- Examples of manufacturer-sponsored programs:
 - “It’s time to refill your prescription”
 - “Have you been taking your medication?”
 - In both cases, the communication is about a drug or biologic currently prescribed to the individual
- Fraud and abuse risks from the government’s perspective include:
 - “White coat” marketing (pharmacist as extension of manufacturer sales force)
 - Interference with professional judgment
 - Implicit “switch back” messaging if the patient has switched to another product
 - Compensation for services in the form of discounts and/or fees in excess of FMV
 - Refill reminder exception under HITECH marketing guidance limits payments to covered entities to reasonable and direct costs unless HIPAA patient authorization is obtained

Refill Reminder and Adherence Programs Enforcement Examples

- Second Amended Complaint (1/30/2014), Novartis, BioScrip, Accredo, Curascript, CVS Caremark

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

DAVID M. KESTER, et al.
Plaintiffs

vs.

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIPT CORPORATION, CURASCRIPT, INC., AND CVS CAREMARK CORPORATION
Defendants

SECOND AMENDED COMPLAINT
(False Claims Act)

SUMMARY STATEMENT

1. This lawsuit involves a scheme by Defendant Novartis Pharmaceuticals Corporation ("Novartis"), one of the largest manufacturers of pharmaceutical products in the world, to pay kickbacks to owners of specialty pharmacies, including, but not limited to Defendant Corporation BioScrip Corporation ("Bioscrip") (a Defendant only to the related claims on behalf of the state plaintiffs), as well as the other Defendant Corporations in the present complaint: Accredo Health Group, Inc. ("Accredo"), Curascript, Inc. ("Curascript"), CVS Caremark Corporation ("Caremark"). Novartis paid kickbacks to induce these pharmacies to recommend that patients order Novartis specialty medications reimbursed by federal and state health care programs, including, but not limited to, the iron chelating drug Exjade, the myelosuppressant drug Zosyn, the leukemia drug Gleevec, the oral cancer drug Tasigna, the cystic fibrosis drug Tobramycin Inhalation Solution ("TOBI"), and the organ transplant drug Myfortic.

"This lawsuit involves a scheme by Defendant Novartis Pharmaceuticals ("Novartis"), one of the largest manufacturers of pharmaceutical products in the world, to pay kickbacks to owners of specialty pharmaceuticals . . ."

Questions?