Getting a Handle on Rx Drug Costs

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Overview (Part One)

- A brief background about PBMs and their conflicts of interest, and what you must do
- Take control of the drugs your Plan covers, and the programs your plan implements
- Address 4 different rebate problems
- Implement cost controls by requiring an entirely different contract
  - Require meaningful price guarantees—not "fish-y" price guarantees
  - Ensure your Plan can control specialty drug pricing

Overview (Part Two)

- Once the contract is in place, what can you do?
- Remain vigilant:
  - Audit your consultant
  - Audit the PBM
  - Audit the pharmacies

I.

A Brief Background About PBMs

PBMs Are at the Center of a Web of Contracts

PBMs execute numerous contracts with different players:

- With rebate aggregators—to obtain "rebates" (and other monies labeled with other names that PBMs retain)
- With drug manufacturers—to purchase drugs
- With wholesalers—to purchase drugs
- With retail pharmacies
- With Plans—like yours

ONLY PBMs know the contents of each of these contracts!

Many of these contracts result in PBMs having conflicts of interest!

What Must Your Plan Do?

- Given PBMs' conflicts of interest, your Plan cannot rely on PBMs to make any decisions!
- Your Plan must "take control" of all key decisions
- You must require your PBM to provide you with core information to enable you to "take control"
- After implementing an entirely different contract, you must monitor, and adjust, your drug coverage on an ongoing basis

II.

Your Plan Must "Take Control" of the Drugs Your Plan Covers, and the Programs Your Plan Implements

Virtually All Plans Allow Their PBMs To Implement PBMs' "Standard" Formularies and Programs

- When your Plan executed a PBM Contract, it had a choice:
  - Let your PBM implement its "standard" Formulary and "standard" Programs OR
  - Contractually require your PBM to implement your Plan's own "customized" Formulary and "customized" Programs
- Almost all Plans are relying on their PBMs' "standard" Formularies and Programs
- But PBMs have conflicts of interest!

Most PBMs' "Standard" Formularies Are Stuffed With Unnecessary High-Cost Drugs

High Cost Drug	Indication	Approx. Cost	Alternative	Approx Cost
Copaxone	MS	$5,700	biosimilar	$1,700
Auvi-Q	allergy treatment	$5,800	epinephrine injector	$313
Absorica	acne	$2,700	isotrenoin	$300
Glumetza	diabetes	$1,000 - $7,000	generic	$30
Fortamet (generic)	diabetes	$200 - $400	generic	$30
Zytiga 500 mg	prostate cancer	$13,000 - $15,000	generic	$500
Qudexy XR (using 200 mg)	epilepsy/Lennox Gastaut	$990	generic	$300
Dexilant	PPI - gastroesophageal reflux	$330	OTC's	$0
Jublia	nail fungus	$650	ciclopirox	$15
Duexis	Combo PPI / ibuprofen	$1,600	OTCs	$0
Picato	actinic keratosis	$1,323	Tolak	$318
Branded antidepressants	depression	$550	generic escitalopram	$15

A Detailed Example Showing the Impact of Unnecessary, High-Cost Drugs

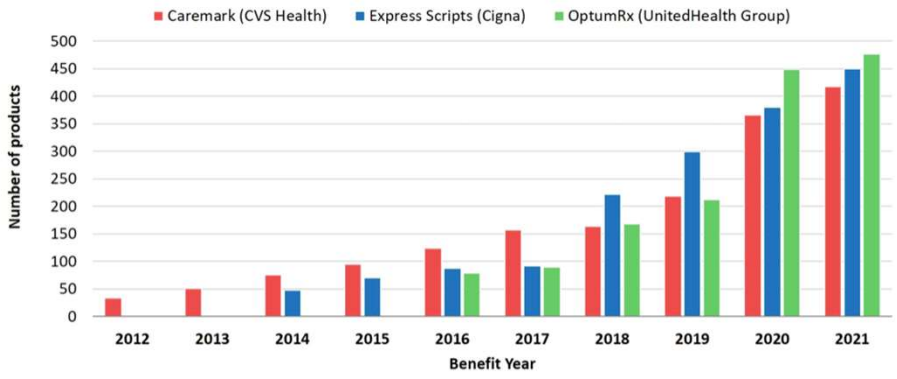
- Tecfidera (a brand MS drug) = $7,400 per 30-day script
  - Let's assume the manufacturer is paying your PBM rebates, and the rebates are large—say, $2,400 a script
  - Your Plan's "net cost" for Tecfidera will still be $5,000 per 30-day script
- Generic Tecfidera = $320 per 30-day script
- Most PBMs still have brand Tecfidera on their "standard" Formularies, and dispense brand Tecfidera
  - Each time they do, your Plan spends an extra $5,000 per script, or $60,000 more, annually, per patient than your Plan should!

Most PBMs' "Standard" Programs Are Contrary to Plans' Interests in Many Ways

- Prior Authorization and Step Therapy Programs:
  - PBMs often favor unnecessary high-cost drugs, rather than lower-cost replacements
- Quantity Limit Programs
  - PBMs often allow 90-day quantities, when 30- (or even 15-) day quantities would make more sense
  - PBMs even dispense 90-day quantities of cancer drugs to new users!

Note: Your PBM Are Excluding 100s of Drugs From Their "Standard" Formularies

Number of Products on PBM Formulary Exclusion Lists, by PBM, 2012 to 2021



Source: Drug Channels Institute analysis of company reports; Xcenda. Note that some data have been restated due to midyear additions to exclusion lists. Express Scripts did not publish exclusion lists before 2014. OptumRx did not publish exclusion lists before to 2016. Note that PBMs may exclude many of the same medications., so certain products may appear on multiple lists.

Published on *Drug Channels* (www.DrugChannels.net) on January 12, 2021.

2021 Formularies:

Express Scripts: 450

Caremark: 417

Optum: 476

What Must Your Plan Do?

- Send out a Contract Termination Notice as soon as your contract allows termination!
- Conduct a PBM RFP to select your next PBM
  - Start by determining the Formulary and Program "customization" you will demand
  - Then draft and bid out your proposed contract that requires each PBM contestant to provide its "Rebate Guarantees" based on your customization
- Then select the PBM that is willing to let you customize, and gives you the best pricing terms and guarantees
- Then customize on an ongoing basis!

But to customize—
you must ensure that your PBM contract requires your PBM to provide drug-by-drug Rebate information

III.

Four Rebate Problems

#1: PBMs Refuse to Provide "Net Cost" Information

For a Plan to know its PBM is favoring higher-cost drugs over lower-cost drugs and then for the Plan to customize its Formulary and Programs, the Plan MUST know the "actual" cost of every drug.

- The "actual cost" = the drug's cost, minus any discount provided, minus the Rebates (and other monies) passed through to the Plan

But almost no PBMs will provide drug-by-drug Rebate Information!

When you draft your next PBM contract, you must contractually require every PBM contestant to provide a quarterly "net cost" report

Some PBMs will provide this information!

#2: PBMs Refuse To Provide Other Necessary Rebate Information

- Many PBM-Manufacturer contracts contain other rebate terms your Plan needs to know
  - A manufacturer may require specific Prior Authorization or Step Therapy or Quantity Limits for a Plan to get rebates
  - A manufacturer may "bundle" the rebates for one of its drugs with requirements related to the manufacturers' other drugs
- Your next PBM contract must require that your PBM provide you with all these types of information so your Plan can effectively customize its Formulary and Programs

#3: PBMs Play A "Rebate Re-Labeling Game": PBMs Execute Two Types of Contracts

PBM contracts with clients:	PBM contracts with manufacturers:
Rebates	Rebates Admin fees Health Mgt Fees Data Sales Fees Etc. Etc. Etc.

What Must Your Plan Do?

- Your next PBM contract must require your PBM to pass-through 100% of Rebates AND 100% of all other monies that your PBM (or its Rebate Aggregator) collects from drug manufacturers
  - Our firm recommends you create a new term: "Financial Benefits"
  - Define "Financial Benefits" to include *all third-party payments and discounts, including but not limited to . . .*
- Then make sure your PBM contract contains explicit language allowing you to audit all relevant contracts, and all invoices from—and payments—to the PBM

#4: Get Rebate Guarantees That Are "Real"

- All PBM-Client contracts contain "Rebate Guarantees"
- But almost all such Guarantees are worthless
  - The guarantees are "per Brand Drug script" guarantees
  - But the definition of the term "Brand Drug" in the contract is ambiguous, allowing your PBM to slip "Brand Drugs" out of the category, and thus owe and pay far less
- You must pin down an "airtight" definition for "Brand Drugs" and obtain guarantees with "real" value

IV.

Implementing Cost Controls— By Requiring Entirely Different Contract Terms To Ensure Meaningful Price Guarantees

Your PBM Contract Likely Has *NO* Actual Value

- The definitions, and other terms, in virtually all PBM-Client contracts make most contracts totally worthless
- As a result, PBMs can charge essentially whatever the PBMs want, for essentially any (and every) drug
- Your Plan must ensure that *every* guarantee in your PBM contract is an "actual" guarantee that will actually control your Plan's costs

A Core Reason Why Virtually ALL PBM-Client Contracts Are Worthless: The Contract Definition Problem

Suppose a grocery had the following "Fish Guarantee":

All Fish* guaranteed to be no more than $7.95 or less per pound

*** Grocery reserves the right to exclude certain fish from Fish Guarantee in grocery's discretion**

- What would the guarantee be worth? (Answer—Nothing)
- As long as the key term, "Fish," is badly defined (allowing the grocery to move fish in and out of the guarantee), the guarantee is worthless!

Conclusion: Every Plan needs to make sure it gets a PBM contract that has pinned down definitions, so the Plan's guarantees are not "fish-y"!

The Problem with PBM Contract "Definitions" and Price Guarantees

- Every PBM Contract contains "Definitions", and Price Guarantees based on those Definitions:
  - Retail "Brand Drug" Guarantees
  - Retail "Generic Drug" Guarantees
  - Retail 90 "Brand Drug" Guarantees
  - Retail 90 "Generic Drug" Guarantees
  - Mail "Brand Drug" Guarantees
  - Mail "Generic Drug" Guarantees
  - A "Specialty Drug" Guarantee (or many "Specialty Drug" Guarantees)
- So, the 3 key terms that all PBM Price Guarantees are based on are: (i) "Brand Drug"; (ii) "Generic Drug"; and (iii) "Specialty Drug"
- **The Problem: Like our grocery store's "Fish*" definition, PBMs write ambiguous contract definitions for each of those 3 core terms, making their Price Guarantees worthless**

Examples of Ambiguous "Brand Drug" and "Generic Drug" Definitions

" Brand Drug means all drugs in First DataBank's National Drug File, or another nationally recognized drug source designated by PBM...."

"PBM uses its own proprietary algorithm to classify Brand Drugs ...."

"Generic Drug" means any single source or multisource drug .... "

"PBM shall use a nationally recognized pricing source (with supplements) for purposes of pricing and classifying drugs (e.g., legend vs over-the-counter, brand vs generic)...."

Example of a Strong "Brand Drug" Definition

Brand Drug(s) - The term "Brand Drug(s)" shall mean the following: The Multisource Code field in Medi-Span contains an "M" (co-branded product), or an "N" (single source brand) , or an "O" (originator brand) (except where the Claim is submitted with a DAW Code of "3","4", "5" or "6", in which case it shall be considered a Generic Drug). Claims with a Multisource Code of "O" and with a DAW Codes of "0", "1", "2", "7", "8" or "9" shall be considered a Brand Drug. The Parties agree that when a drug is identified as a Brand Drug, it shall be considered a Brand Drug for all purposes by PBM, including but not limited to adjudicating the Claim, reimbursing the relevant pharmacy, invoicing CLIENT, determining the Copayment or Coinsurance to be paid by the Plan Beneficiary, calculating the satisfaction of Average Annual Guarantees as further described in Article __ of the Agreement, calculating the satisfaction of Financial Benefit Guarantees as further described in Article __ of the Agreement, and calculating the satisfaction of generic fill rates (if any).

Specialty Drugs

- Virtually all contracts contain a meaningless definition for "Specialty Drugs" too
- Define the term by creating a list of all Specialty Drugs (about 1,400+ drugs) and cross-referencing to the list
- Make sure your definition also allows your Plan to add new-to-market Specialty Drugs, and to obtain the necessary information to make these decisions

Additional Specialty Drug Requirements

- Specialty Drug pricing is continually changing. Therefore, make sure you have a quarterly "right to renegotiate" any Specialty Drug guarantee
- To ensure you have "leverage" when you renegotiate guarantees each quarter, make sure you have a "carve-out right" to have other specialty pharmacies (or retail pharmacies) dispense any Specialty Drug

And Now to Auditing and Monitoring—Remaining Vigilant!

- Auditing your consultant
- Auditing your PBM
  - Auditing for financial performance
  - Auditing for clinical performance
  - Auditing for rebate performance
- Auditing for FWA

Words Worth the Conference Fee

- Here's the bottom line: Most benefit managers are ill-equipped to manage benefits
  - You need a pharmacist, with an understanding of contract law, the programming skills of a data scientist and the ethical training of a philosopher
  - At least, hire a pharmacist for $125,000 a year

New Rules for Consultants

- Consolidated Appropriations Act of 2021
  - Consultants must report to plans, upon plan request, what money they have been paid to place business with a PBM
  - Ask for it!
  - Plan fiduciary must request how much was paid
    - If not received in 90 days, plan fiduciary can report to Secretary of Human Services (DOL), plan may cancel contract

New Rules

- What must be reported:
  - Anything paid to the consultant (direct and indirect compensation over $1,000) for development and implementation of plan design, product selection, recordkeeping, medical management, benefit administration selection on all medical, dental, stop loss, pharmacy programs.
  - Effective date: December 2021, rule making in effect
  - PBMs must report prices to plans and plans must have transparency into prices for drugs

Controversy Over New Rules

- New Pricing transparency rules subject of lawsuit alleging that HHS overstepped its statutory authority
  - *Chamber of Commerce v. U.S. Department of Health and Human Services*—issue is that reporting all this cost information from PBMs is too burdensome
  - Check with your PBM
  - Initially to be started in January 2022 now delayed until July 2022, issue about readable files

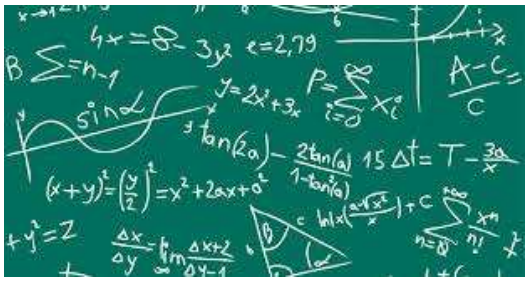
Auditing the PBM—Financial Performance Guarantees

Retail Pricing	
Brand (30 Day Supply)	AWP - 17%
Generic (30 Day Supply)	AWP - 80%
Average Dispensing Fee	$1.33
Brand (90 Day Supply)	AWP - 20%
Generic (90 Day Supply)	AWP - 83%
Average Dispensing Fee	$1.33
Mail Pricing	
Brand	AWP - 24.5%
Generic	AWP - 87%
Dispensing Fee	$0.00
Specialty Pricing	
Brand	AWP - 20%
Generic Retail/Mail	AWP - 82%
Variable Copay™	AWP - 28%
Dispensing Fee	$1.50

Every contract should have a schedule like this one and every contract should NOT have a lot of exceptions. If there is no administration fee, it is a traditional contract with spread pricing.

How an Audit is Conducted

- Claims are aggregated into categories of spend—retail, mail, specialty and brand, generics
- Average of all discounts are derived
- Then, exclusion claims are removed
- And, offsets, if any, are applied
- Were the guarantees met?



Why Definitions Are So Important

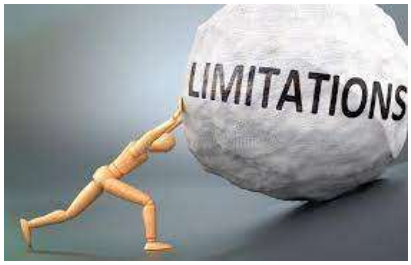
Ten Claims Adjudicated at . . .		The Same Ten Claims Reconciled at . . .	
	AWP Discount		
Brand Claim One	15%	Brand Claim One	15%
Brand Claim Two	15%	Brand Claim Two	15%
Brand Claim Three	15%	Brand Claim Three	15%
Brand Claim Four	15%	Brand Claim Four	15%
Brand Claim Five	15%	Brand Claim Five	15%
Average	15%		
Generic Claim One	25%	Brand Claim Six	25%
Generic Claim Two	25%	Brand Claim Seven	25%
		Average	17.85%
Generic Claim Three	50%	Generic Claim One	50%
Generic Claim Four	75%	Generic Claim Two	75%
Generic Claim Five	99%	Generic Claim Three	99%
Average	54.8%	Average	74.6%

Audit Pitfalls

- What is a brand, generic and specialty drug?
  - Specialty drugs dispensed in retail and mail pharmacies?
- If excluded, how are the drugs priced?
- Are there lots of exclusions (ZBC, LLD, excluded pharmacies)?
- Is U&C "in" and is U&C true and correct?
- How do the offsets work?
  - Offsets should not be allowed when the PBM owns mail and specialty facilities—self dealing.

Watch for Audit Limitations

- "Mutually acceptable auditor" language
- PBM controls the scope of the audit
  - Including the timing (no audits in January??)
- PBM delays data/response to audit findings/payment
- Audit frequency (once a year, for what timeframe?)
  - Performance and clinical guarantees MUST be audited every year—WITHOUT FAIL!
- Maximum liability equal or not equal to something like total annual revenue, total annual administration fees



Clinical Audits

- Are the clinical programs working to your or the PBM's benefit?
- Prior authorization audits
  - A review of a sample of the PAs to determine if sufficient documentation and critical thinking occurred by PBM
  - What happens to the cost of the drug when the PA had NO documentation
- Exclusions/limitations
  - Formulary tier placement, exclusions, quantity limitations
    - Quantity limits set by drug or therapeutic category?

How Big is Fraud, Waste and Abuse?

"Between $70 billion and $234 billion is essentially stolen from the American public through health care fraud schemes annually."

–National Health Care Anti-Fraud Association, June 2009

NHCAA National Health Care Anti-Fraud Association®

Source: https://www.nhcaa.org/docs/nhcaa/PDFs/Member%20Services/Fighting%20Health%20Care%20Fraud_NHCAAJune2009.pdf

Pharmacy Fraud, Waste and Abuse Defined

FRAUD

Schemes that involve illegal behavior like submitting phantom prescriptions, medical identity theft, collusion between prescribers and pharmacists, upcoding pharmacy claims, pharmacists changing prescription orders

WASTE

Pharmacists/technicians not adequately performing duties like not returning claims to stock when not picked up, "over filing" quantities, not questioning clinically inappropriate prescriptions, auto-refills and auto-Fills

ABUSE

Patients, pharmacist or prescribers billing for prescriptions that contribute to addiction, personal financial gain (selling medical identity)

What PBMs Don't Want You to Know

Traditional PBMs bill claims with spread pricing

- The pharmacy is not reimbursed the same amount as the plan is charged

→

Spread pricing is a computer algorithm

- Claims is reimbursed at AWP—18% and billed at AWP—16%

→

Computers do not differentiate between legitimate and fraudulent claims

↓

Therefore, PBMs do not want plans to audit for FWA—imagine a PBM reporting a 10% revenue loss

→

PBMs only audit when contractually required (Medicare, Medicaid)

→

Plans need to carve out pharmacy auditing rights

What is the Magnitude of FWA?

2020 Case Findings–Two Large FWA Clients		
	Case Study 1	Case Study 2
Claims Submitted	12,298,339	19,701,674
Claims Paid	$702,466,000	$1,605,520,559
Claims After Exclusions	4,728,697	19,678,176
Claims Paid After Exclusions	$341,199,000	$1,604,125,339
Claims Audited	54,139	37,797
Claims Paid and Audited	$22,997,936	$115,124,467
Recovered Claims	16,562	19,427
Recovered Amount Paid	$10,616,348	$19,797,096
Percentage recovered/audited claims	30.59%	51.40%
Percentage recovered/audited amount paid	46.16%	17.20%
Percentage recovered/total claims	0.13%	0.10%
Percentage recovered/total paid	1.51%	1.23%

Overall, FWA may not be a disruptive process, but can yield large results without impacting members.
FWA auditing MUST be carved out of your plan.

Fraud? Waste? Abuse?

- Capsule Rx—delivery service medication
- NimbleRx—Uber's prescription drug delivery service
- Roman—Pfizer direct to consumer for ED/men's products
- The Pill Club—Autofills OCs, condoms
- True Pill—Funded by Optum, API connected health care
- RxWiki and RxSpark—Search sites that scrape and sell data to pharmacies, no-traffic pharmacies
- Digital Pharmacist—App and website design for pharmacist to solicit patients with "franchise" pharmacy set ups (Apothecary) dispensing not much other than topical creams

Key Takeaways

- Getting control over your Plan's prescription drug costs requires your Plan to:
  - Draft and implement an entirely different PBM contract that allows your Plan to:
    - Customize its Formulary and Programs
    - Obtain "real" price guarantees
    - Obtain drug-by-drug "net cost" information
    - Ensure your PBM is passing through all Rebates and all other manufacturer payments too
    - Control your Specialty Drug costs
  - Audit every claim and the financial and clinical programs every year
  - Work with a PBM that will not fight you on every contract term and every audit

Your Feedback Is Important to Us

1. Scan the QR code for the session you attended, or

Session 1—
Monday, 9:15-10:30 a.m.

Session 2—
Tuesday, 1:15-2:30 p.m.

2. Go to the IFEBP app, or
3. Visit the evaluation website at http://adfs.ifebp.org/spkreval2101.

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May 10-12, 2022
Boston, Massachusetts
www.**ifebp.org**/health-benefits

Trustees and Administrators Institutes

February 19-23, 2022
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June 25-29, 2022
Seattle, Washington
www.**ifebp.org**/trusteesadministrators

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Self-Funding Health Benefit Plans

John C. Garner, CEBS, 2015.

Item #7563
www.**ifebp.org**/selffunding

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Brief Glossary of Health and Welfare Terms

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association health plan (AHP)—health insurance offered to those in a similar industry or trade group. Members of the association may be self-employed or work for companies such as subcontractors that do not typically offer health insurance to their employees. Associations are also formed by franchise owners who work for a larger corporation. Insurance companies typically use the same underwriting guidelines that apply to individual/family health plans. These plans are not considered group health insurance plans. How these plans are structured, whom they sell to and whether an association is state-based or national determines whether they are subject to state or federal regulation, or both, or are largely exempt from regulations. AHPs may also be referred to as affinity health plans.

average wholesale price (AWP)—term used by the prescription drug industry that refers to the average price at which wholesalers sell a drug to physicians, pharmacies and other customers. Throughout the health care industry, drug payments are typically based on AWP minus some percentage. In reality, what is reported as AWP is a price derived from self-reported manufacturer data collected by commercial publishers. There are no requirements that the AWP reflect the price of any actual sale of drugs by a manufacturer or that it be updated at established intervals. AWP is also criticized for failing to take into account the deep discounts available to various large purchasers such as the federal government and health maintenance organizations.

capitation—process in which a provider contracts to provide services on a per capita basis. The payment is known as a capitation fee; it is fixed without regard to the actual number or nature of services provided to each person in a set period of time. Capitation is commonly used by health maintenance organizations and primary care providers. This approach shifts some risk to the providers, who assume the increased number of patients will level out the risk.

compounded drug—A drug that is tailored to the needs of an individual patient and created through the process of combining, mixing or altering an FDA-approved medication. Compounded drugs are not FDA-approved.

data collection—planning for and obtaining information for analysis. Patient characteristics such as age, gender, race, illness or injury, medical therapies used in treatment, outcome of treatment and cost of treatment are all examples of health care data that are collected. Such information helps providers, insurers, plan sponsors and other stakeholders identify what is working and where improvement is needed.

drug formulary—list of prescription medications that will be covered by a health insurance plan. Criteria for placing a drug on a formulary are often based on what is deemed to be the most effective and economical. Drugs not on the formulary may not be available, may carry a higher cost-share amount or may be accessible only with prior authorization (PA). A formulary can have a single tier, where all drugs have the same cost to patients, or multiple tiers, where cost varies. Many formularies are three-tiered: generic drugs have the lowest copay (tier one), preferred brand name medications have a higher copay (tier two) and non-formulary drugs have the highest copay (tier three) to encourage the use of lower cost drugs.

exclusive provider organization (EPO)—network of health care providers or dental professionals who discount their services to plan participants. EPOs are similar to PPOs in organization; however, they function more like an HMO with a primary care physician acting as a gatekeeper to the network of other providers. There is an authorization system and, if a patient goes outside the network, he or she must pay the full cost of the services received. There are some exceptions for emergency and out-of-area services.

health care fraud—intentional deception or misrepresentation for the purpose of gaining an unauthorized medical benefit or benefit payment. Examples of health care fraud include billing for goods or services never provided, misrepresenting what and when treatment was provided, and performing medically unnecessary services. Health care fraud is almost always criminal, but the specific nature or degree of the criminal acts may vary from state to state.

Medicaid—as implemented by Title XIX of the Social Security Act, a medical benefit program administered by the states and subsidized by the U.S. government that pays certain medical expenses for persons with low income and limited resources.

medical loss ratio (MLR)—insurance company's cost of delivering health care benefits as a percentage of premiums received.

Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)—legislation that requires a group health plan that provides mental health and substance abuse benefits to (1) have financial requirements (e.g., deductibles and copayments) and limitations no more restrictive than those applied to the plan's medical and surgical benefits, and (2) have no separate cost-sharing requirements or limitations applicable only to mental health or substance abuse benefits. The act does not require group health plans to offer mental health and/or substance abuse benefits. This act replaces and expands the Mental Health Parity Act of 1996.

palliative care—Medical care focused on improving the quality of life of patients with serious illnesses, as by treating symptoms and providing emotional support.

PBM—pharmacy benefit manager

pharmacogenetics—study of how genes affect a person's response to drugs, that combines pharmacology and genomics to develop safe and effective medication dosages specific to an individual's DNA.

premium subsidy (subsidy)—a fixed amount of money or a designated percentage of the premium cost that is provided as a tax credit to help low-income individuals buy health coverage through the exchanges.

specialty (biotech) drug—high-cost medication used to treat certain complex and rare medical conditions. Specialty drugs are often self-injected or self-administered. Many grow out of biotech research and may require refrigeration or special handling.

telemedicine—use of video links, email, telephone or another interactive telecommunications system to deliver medical services over a geographical distance.

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