Impact of Pharmacy Landscape Changes on PDL Strategies to Manage Drug Costs

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Discussion objectives

1. Historical perspective and background
2. Impact of pharmacy landscape changes on PDL strategies and "Why PDL"
3. Modeling considerations when evaluating PDL changes

Pop quiz

What year was the following quote stated?

"Rising drug prices, particularly the high prices of new drugs, are driving State Medicaid program costs and projected Medicare drug benefit expenditures to unsustainable levels, causing the Congress to consider reducing benefits to the elderly and poor, and forcing State legislatures to choose between funding drug benefits or other health care needs of the elderly and poor…"

1989 | 2006 | 2014

Hint #1 *"Spending for prescription drugs in the United States now accounts for about 7 cents of every health care dollar."*

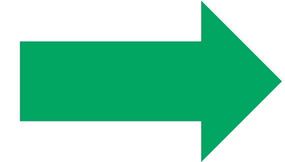
Hint #2 "While the public is using about the same amount of drugs today as in 1980, price increases for prescription drugs have increased by 88% from 1981-1988, a period during which the Consumer Price Index increased only 28%"

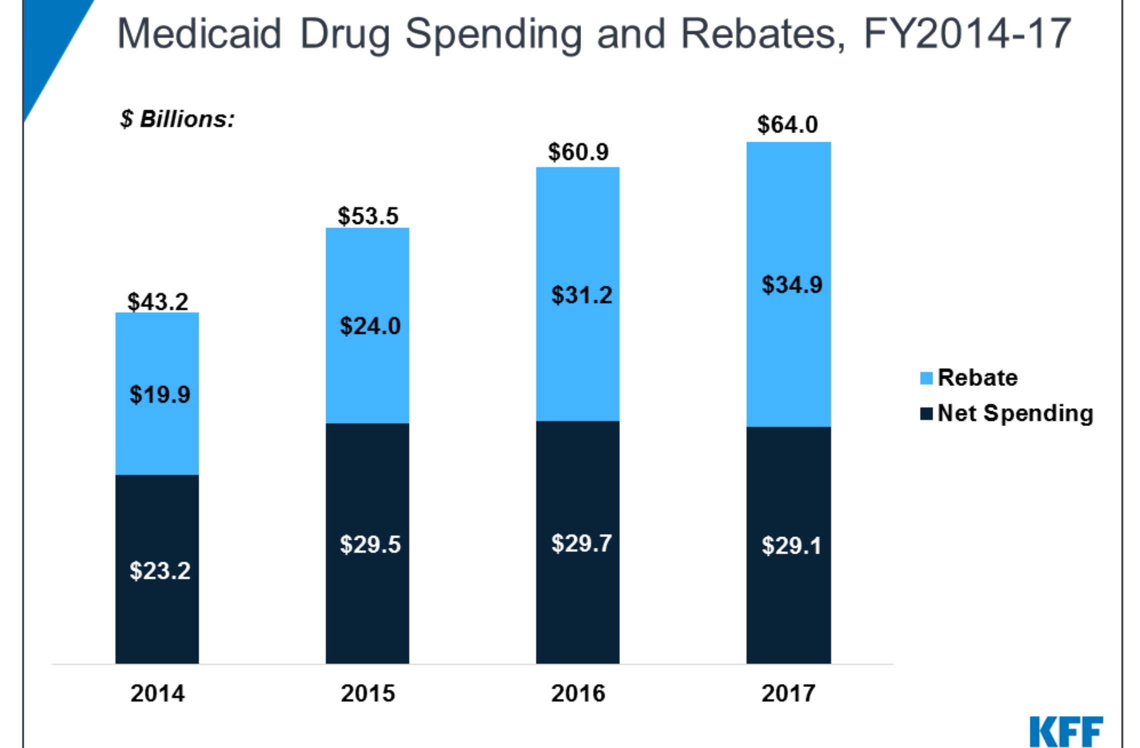
Gross-to-net spending

2005 GAO report:

*"FY 2003 - Medicaid Drug Expenditures were **$33.8B** and manufacturers paid rebates to states of about **$6.5B**…"*

which equates to rebates are approximately **19%** of program costs





Source: https://www.gao.gov/assets/120/111819.pdf accessed June 26, 2019.

Impact of the Affordable Care Act (ACA)

The ACA established new rebate formula for drugs, increasing overall rebates

Pre-ACA

- Single Source Brands
  - 12.5% (original)
  - 15.7% 1993
  - 15.1% 1996
- Maximum rebates
  - 25% of AMP (original)
  - 50% 1992
- **Prior to ACA:** Rebates only applied to Medicaid recipients under the FFS program

Post-ACA

Single Source Drugs and Multiple Source Innovator Drugs

- 23.1% of AMP or AMP minus best price
- Plus inflationary component
- Rebate capped at 100% of AMP

Clotting Factors and Drugs Approved Exclusively for Pediatric Indications

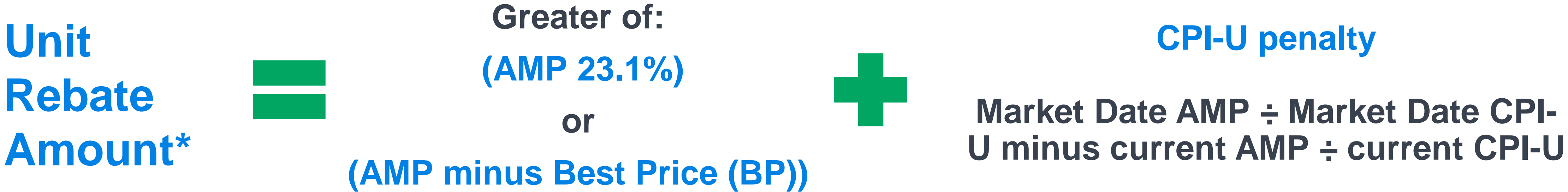
- 17.1% of AMP or AMP minus best price
- Plus inflationary component

Non-Innovator Multiple Source Generic Drugs

- 13% of AMP
- Plus inflationary component as of 1/1/2018

AMP = Average Manufacturer Price

Unit rebate amount considerations



SSB medications often required to offer 100% AMP rebates due to combination of BP + CPI-U penalty

*URA is currently capped at 100% of AMP
AMP = Average Manufacturer Price
CPI-U = Consumer Price Index for All Urban Consumers
SSB = Single-Source Brand

Most states have PDL strategies

	PDL	Supplemental Rebates	Script Limits
SFY 2008	43	41	19
SFY 2009	45	44	16
SFY 2010	44	44	16
SFY 2011	46	46	16
SFY 2012	46	46	16
SFY 2013	46	46	17
SFY 2014	46	45	16
SFY 2015	45	45	14

SOURCE: KCMU surveys of Medicaid officials in 50 states and DC conducted by Health Management Associates, 2007-2015.

Impact of pharmacy landscape changes on PDL strategies and "Why PDL"

Changes to the pharmacy landscape

PCSK9s decrease list price by 60%

Repatha (evolocumab) injection 140 mg/mL

Praluent (alirocumab) Injection

List price decreases

Authorized Generics

Removal of anti-kickback statute

Implications for best price

Evaluation of PDL Strategy

Many manufacturers have launched authorized generics

PCSK9 = proprotein convertase subtilisin-kexin type 9; a biologic treatment for high cholesterol

Why is it important to consider control of PDL?

Recently launched generic medication example

State Financial Incentives

Brand Insulin with **100%** rebate

$400 payment to MCO

$400 rebate from manufacturer

$0 net cost to state

$400 payment

Included in capitation rate

MCO Financial Incentives

Brand Insulin with **100%** rebate

$400 payment to pharmacy

$400 payment from State

$0 net cost

Why is it important to consider control of PDL?

Recently launched generic medication example

State Financial Incentives

Generic Insulin with **23.1%** rebate

$400 payment to MCO

$46 rebate from manufacturer

$354 net cost to state

$400 payment

Included in capitation rate

MCO Financial Incentives

Generic Insulin with **23.1%** rebate

$200 payment to pharmacy

$400 payment from State

$200 net profit

PDL management techniques

- No national drug code (NDC) block allowed as long as manufacturer is enrolled in Medicaid Drug Rebate Program
- Carve-In / Carve-Out
  - Therapeutic classes may be carved out of MCO capitation
    - Behavioral Health, HIV, Hepatitis C
- State or managed care organization (MCO) may control PDL creation
  - Entity which creates PDL generally receives Supplemental Rebates
  - Supplemental rebates are typically negotiated for “Preferred” Access
- State may control all or a portion of the PDL
- Primarily managed through a series of Utilization Management criteria
  - Prior authorization (PA) / step therapy (ST) / quantity limit (QL)

Modeling considerations when evaluating PDL changes

Considerations of modeling PDL strategy

Starting base data	Formulary	Other factors	Sensitivity testing	Output
▪ Most recent quarter of data ▪ Formulary status of proposed PDL ▪ Group data by therapeutic class ▪ Market Share shifting algorithm	▪ PA / ST / QL ▪ Utilization management ▪ Rebates ▪ Formulary compliance rates	▪ Sub-population characteristics ▪ Policy changes – Change in PBM pricing – Change in UM requirement ▪ Traditional vs. specialty drugs ▪ 340B program	▪ Sensitivity of inputs ▪ Range of outcomes	▪ Gross cost ▪ Impact to MCOs ▪ Net costs ▪ Impact to state

Starting base data

Example: Modeling MCO PDL to State PDL

- Start with most recent quarter of data available
- Group data by Therapeutic Class (i.e., market baskets)
- Need formulary position of all drugs managed by PDL (Preferred vs. non-Preferred)
- Easier to model shift from MCO PDL to State mandated PDL than reverse
  - Typically have data available that reflects how the State PDL performs
- Need MCO PDL if shifting from State PDL to MCO PDL

MCO base data
Most recent quarter
MCO PDL market shares

PDL Shift

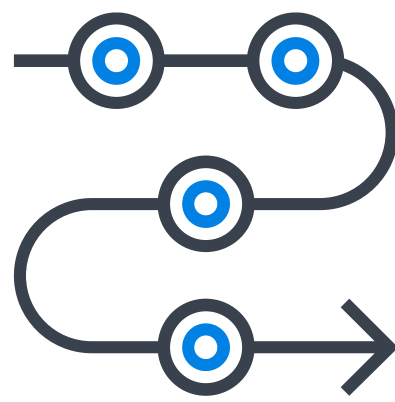
→

Cost difference between MCO PDL and State PDL

MCO base data
Most recent quarter
State PDL market shares

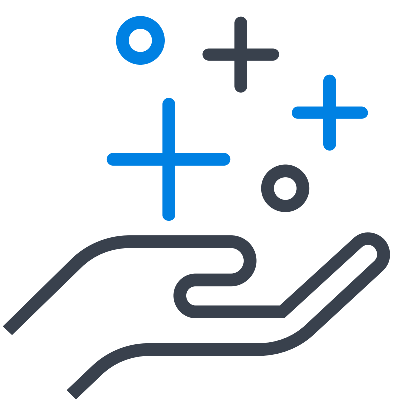
Formulary

- Utilization Management (PA / ST / QL)
  - Level of management
- Formulary compliance (non-preferred > preferred)
- Therapeutic class market baskets
- Rebates (including URA and supplemental rebates)
- Shift assumptions
  - Differing between small molecule and specialty drugs



Other factors

- Sub-population considerations
  - Adults vs. children
- Differences among various MCOs
- 340B contracting changes
- Policy changes
  - Changes in prescription benefit manager (PBM) payment types (pass-through vs. spread)
  - Changes in UM requirements
- Seasonality
- Phasing in the adoption of the PDL over time (i.e., 90 days)
- Addressing brand to generic launches
- How to integrate results into the rate settings
  - PDL factor should be a separate adjustment
  - Does not include cost/util trend or new-to-market pipeline drugs



Sensitivity testing / Reviewing results

Sensitivity testing

- Evaluate range of results due to high variability in shift assumptions
- What if MCOs move fewer products to preferred status?
- What if MCOs move more products to preferred status?

Reviewing results

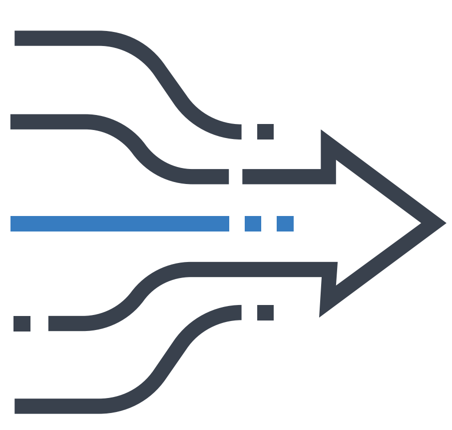
- Need to review results in many layers
- Review aggregate results using average metrics
  - Avg cost/script (pre- and post shift)
    - Preferred vs. non-preferred
  - GDR changes
  - **Preferred:** non-preferred ratio pre- and post shift
- Also need to review at a therapeutic class level checking for outliers

Output

- Wide range of outputs to be considered:
  - Gross cost impact to MCOs
  - Net cost impact to State
  - Change in rebates (URA) to state
  - Change in supplemental rebates
- What are the top therapeutic classes driving the results?
- How to incorporate the PDL cost factor into the capitation rate payments?

Illustrative output

Program	MCO Gross Cost Change	State Rebate Change Federal	State Supplemental Rebate Change	MCO Loss of Supplemental Rebates	Net Cost Change
Eligibility Group 1	-1.5%	1.5%	1.0%	3.4%	0.7%
Eligibility Group 2	-1.1%	1.6%	6.7%	4.4%	-5.1%
Eligibility Group 3	-1.0%	1.0%	0.5%	3.3%	-0.8%
Eligibility Group 4	1.5%	1.3%	0.5%	2.7%	-1.2%
Eligibility Group 5	-2.6%	1.5%	4.2%	3.1%	-5.1%
Eligibility Group 6	-0.5%	2.0%	2.0%	2.6%	-2.4%
Program Total % Change	**-2.4%**	**1.4%**	**3.6%**	**3.4%**	**-2.9%**



Summary

- The ACA has put into motion several catalyst that have significantly increased rebates in Medicaid
- In addition to the ACA, significant changes in the pharmacy landscape have intensified or changed PDL strategies
- MCOs have different (and at times – opposing) financial incentives when compared to the State in preferred drug selection
- It is important to consider if MCOs are managing PDL preferred drugs to the lowest net cost to the Medicaid program

Thank you

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