Medicaid Drug Rebates

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Medicaid Drug Rebates

- History of Medicaid Drug Rebates and Preferred Drug Lists
- Affordable Care Act
- Setting the Record Straight
- Drug Rebates and Managed Care
- Formulary Management

History - Medicaid Drug Rebates and Preferred Drug Lists

OBRA ’90

- Enacted 1/1/91
- Medicaid – “most-favored” customer status
  - Manufacturers required to sell drugs to Medicaid at BP
  - States required to cover products
  - Explicitly excludes drugs dispensed by MCOs
- Savings projections - $3.5 billion over first five years
  - Savings realized - $19.8 billion in first ten years
  - 2008 - $8.9 billion (37.2% of expenditures)

OBRA '90 Rebate

- Two elements (for single source and innovator multiple source drugs)
  - Basic rebate
    - greater of a) 12.5% of AMP and 2) AMP-BP
  - Additional rebate
    - the amount by which the increase in the AMP from the base period exceeds the increase in the CPI-U
    - Baseline AMP – 7/1/90
- Non-innovator multiple source drugs
  - Basic rebate only = 10% of AMP

Medicaid Drug Rebate - History

- Veteran's Health Care Act of 1992
  - Increased basic rebate for single source drugs to 15.7% of AMP
    - 50% of AMP cap removed
- 1994 = 15.4%
  - Non-innovator = 11%
- 1995 = 15.2%
- 1996 = basic rebate set at 15.1% of AMP

Prescription Drug Spending

- 1997 to 2001 – Medicaid expenditures for prescription drugs grew more than twice rate of total Medicaid spending
- Cost control measures
  - Reduce pharmacy reimbursement
  - Quantity limits
  - Generic substitution
  - Cost sharing
  - Provider education
  - DUR

Florida Medicaid PDL

- Florida law effective 7/1/2001
- Rebate required to have drug included on formulary
  - Minimum rebate – lesser of 10% AMP or total rebate 25%
  - Alternative = "Value Added Programs" – provide disease management and other services that guarantee savings
- Opposition
  - Drug formularies shift costs due to increase hospitalizations, ED/office visits
  - Clinical considerations secondary to rebates
  - Physicians – administrative burden
  - HIV/AIDS and mental health advocacy pushed for exemption
- PhRMA filed suit in August 2001
- HHS approved SPA in September 2001
- Federal court let law stand in January 2002 – did not "prevent access to non-preferred drugs"

Michigan Medicaid PDL

- Michigan PDL - signed into law July 2001
- Reference Pricing
  - Two drugs in each class named “best” based on clinical effectiveness and safety – Preferred
  - Other drugs could offers supplemental rebates to bring cost down to lowest-priced Preferred drug
  - Manufacturer must also provide discount for other non-Medicaid programs
- January 2002 – ruled in favor of PhRMA
- 2002 – PDL implemented
- March 2003 – court upheld law
- April 2004 - PhRMA, et al v. Tommy Thompson, et al. - court ruled in favor of state
  - state can "establish a Medicaid prior authorization program in order to secure rebates on drugs for non-Medicaid populations if a state demonstrates, through appropriate evidence, that the prior authorization program will further the goals and objectives of the Medicaid program.“

Preferred Drug Lists (PDLs)

- Jan-Oct 2002 – 24 states enacted legislation pertaining to Medicaid PDLs, PA, SR, generic drug substitution, co-payments, prescribing/dispensing limitations
- September 2002 – CMS issued SMDL
  - "states may enter separate or supplemental drug rebate agreements"
  - states "may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into" supplemental drug rebate agreements
- 2003 – 21 states had PDLs

Pharmaceutical Bulk Purchasing Pools

- 2003 – National Medicaid Pooling Initiative (NMPI) started with four states
  - 2011 – 12 states
- 2004 – Top Dollar Program (TOP$) started with three states
  - 2011 – 8 states
- 2005 - Sovereign States Drug Consortium (SSDC) started with three states
  - 2011 – 6 states

Medicaid Expenditures and Rebates

Year	Expenditures (in billions)	Federal Rebates (in billions)	Net Expenditures	Federal Rebates as % of Expenditures	*Supplemental Rebates*
2005	$43.2	$11.2	$32.0	26%	*8%*
2006	$22.5	$ 8.6	$13.9	38%	*7%*
2007	$22.6	$ 6.6	$16.0	29%	*6%*
2008	$24.0	$8.0	$16.0	33%	*6%*
2009	$25.6	$9.0	$16.6	35%	*4%*

Affordable Care Act

Affordable Care Act - 2010

- Revised definition of AMP
  - Limitation to “retail community pharmacies” resulting in higher AMPs
- Increased minimum base rebate to 23.1% of AMP for innovator drugs
  - Capped at 100% of AMP
  - 13% for non-innovator multiple source drugs
- Additional rebate redefined for new formulations of oral solid dosage forms (line extensions)
  - Greater of amount computed under existing law or highest additional rebate (as % of AMP) for any strength of the original product
  - Applies to authorized generics

Affordable Care Act

- CMS to offset the increase in Federal Rebates directly related to ACA
  - CMS reports quarterly Unit Rebate Offset Amount (UROA) to states to calculate offset

Affordable Care Act

- FUL calculation changed to no less than 175% of weighted average of most recently reported monthly AMP
  - Applies when >2 equivalent products available for purchase nationwide by retail community pharmacies
  - Previously – 150% of lowest published price
  - DRA (not implemented) – 250% of lowest AMP
- Requires CMS to disclose weighted average of most recently reported monthly AMP for multiple-source drugs

Affordable Care Act

- Draft FULs
  - 40% lower than average SMAC
  - Top 20 drugs in several large FFS programs
    - Nearly ¾ of FULs lower than SMACs
    - Majority of drugs <$0.10 per unit
    - Minimal impact on pharmacy profit
- GAO reports that the new formula adequately reimburses pharmacies for acquisition costs of multiple source drugs

Affordable Care Act

- Impact on Rebates

		Federal Rebates	Supplemental Rebates	Rebate Offset	Total Net Rebate
Pre-ACA	%reimbursement	46%	3%	-	49%
	$/Rx	$31	$2	-	$33
Post-ACA	%reimbursement	53%	3%	5%	51%
	$/Rx	$37	$2	$3	$36

Setting the Record Straight

Lewin Group Report

- "Potential Federal and State-by-State Savings if Meicaid were Optimally Managed" – published December 2010
  - Funded by PCMA
- Medicaid FFS focus on rebates
- Medicare PDPs, MCOs, state employees use PBMs to negotiate pharmacy reimbursement
- Projected 14.8% reduction in prescription costs if Medicaid FFS adopted commercial-like approach
  - DF, ingredient costs, drug utilization, GDR
- Total savings of $30.3 billion over 10 years

Lewin Report

- GDR – Generic Dispensing Rate
  - Stated FFS 68% vs MCOs 80%
  - Actual FFS GDR = 73-74%
    - Range = 64-80%
- Dispensing Fees
  - Stated FFS $4.81 - more than twice commercial
  - Actual = Brands $3.99 ($1.75-7.50)
    - Generics = $4.23 ($1.35-7.35)

“Real World” Analysis

SAVINGS AS % OF 2011 NET EXPENDITURES	AVERAGE	MEDIAN
REDUCTION IN DF	1.6%	1.5%
REDUCTION IN BN ING COST	2.0%	0.0%
INCREASE IN OGER	7.4%	6.1%
INCREASE IN GDR	4.2%	4.1%
DECREASE IN UTILIZATION	2.5%	2.6%
LESS INCREASED ADMIN FEES	(5.8%)	(5.7%)
TOTAL	**12.0%**	**9.7%**

- Over 1/3 of states - <5% savings
- Nearly 1/4 of states - >20% savings
- Reduced pharmacy reimbursement accounts for vast majority of savings
    - Increase OGER most notable

American Enterprise Institute Report

- “Overspending on Multi-Source Drugs in Medicaid” by Alex Brill published March 2011
- Medicaid “wasted” $329 million ($95/Rx) in 2009 by paying for brands of 20 drugs instead of generics
- Estimated Federal Rebate of 15.1%
  - Failed to account for additional rebate

“Real World” Analysis

- Considering additional rebate
  - 100% utilization of generics for the 20 drugs would actually have cost Medicaid $80 million ($23/Rx)
  - Only 9 of 20 generics had lower net cost
    - 100% utilization of generics for these drugs would save $61 million

“Real World” Findings

- Reducing pharmacy reimbursement would reduce Medicaid expenditures
- Significant variation among states
- Generics are not necessarily less costly than brands
  - targeted approach most cost effective
  - take advantage of inflation penalties

Generic Drugs – Targeted Approach

DRUG	1ST GENERIC	FUL	NO SMAC	MODERATE SMAC	AGGRESSIVE SMAC	BN
A	2005	X	$ 54.42	$ 54.42	$ 7.02	$ 19.62
B	2007		$ 210.37	$ 149.96	$ 138.87	$ 269.19
C	2008	X	$ 52.98	$ 18.55	$ 9.06	$ 33.32
D	2008	X	$ 48.55	$ 31.66	$ 24.67	$ 157.02
E	2009		$ 101.56	$ 40.73	$ 35.66	$ 82.98
F	2009	X	$ 111.29	$ 102.35	$ 86.72	$ 32.92
G	2009	X	$ 28.21	$ 7.79	$ 5.54	$ 120.50
H	2009		$ 103.56	$ 19.09	$ 14.61	$ 154.60
I	2009		$ 145.33	$ 74.04	$ 67.98	$ 110.44
J	2010		$ 50.20	$ 10.23	$ 8.09	$ 41.37
K	2010		$ 117.28	$ 42.29	$ 21.02	$ 27.95
L	2011		$ 49.73	$ 8.12	$ 7.48	$ 27.55
M	2011		$ 187.10	$ 187.10	$ 187.10	$ 45.54
N	2011		$ 120.96	$ 9.33	$ 1.82	$ 36.82

OIG Report – August 2011

- "Higher Rebates For Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D"
- Comparison of pharmacy reimbursement, rebates and net costs in Medicaid vs Medicare Part D
- 100 high expenditure brand and 100 high expenditure generic drugs

OIG Report Findings
Pharmacy Reimbursement

- Brands – median Medicaid reimbursement 1% higher than Part D
  - 70% of drugs – less than 2% difference in reimbursement
  - 20% of drugs – Medicaid paid 2-10% more
  - 5% of drugs – Medicaid paid >25% more
- Generics – median Medicaid reimbursement 3% higher than Part D
  - Wide variation between Medicaid and Part D for individual drugs
  - Medicaid paid more for 62% of drugs; Part D paid more for 38% of drugs

OIG Report Findings
Brand Rebates

- Unit rebate amounts
  - Median 3X higher in Medicaid
    - 25% of drugs >5X higher
  - 98% of brands had CPI-U penalty
    - Accounted for 55% of total rebate

OIG Report – Findings
Brand Drugs

- Net Costs
  - Medicaid lower for 93% of brand drugs

	Expenditures	Rebates	Rebates as % of Expenditures
Medicaid	$ 6.4 billion	$2.9 billion	45%
Medicare	$24.0 billion	$4.5 billion	19%

Managed Care and Medicaid Rebates

Medicaid Managed Care

- Argument for carve in
  - Capitated MCO contracts can improve predictability of state budgets
  - Lower pharmacy reimbursement
  - Lower utilization (Rx per beneficiary)
  - Higher GDR
- Evidence of MCO cost savings
  - Mixed results – per person spending, quality of care, utilization patterns

Impact of MCO on Rebates

	PHARMACY REIMBURSEMENT	FEDERAL REBATES	STATE SUPPLEMENTAL REBATES	NET COST TO STATE
FFS FORMULARY	$62.4	$34.8	$2.7	$24.9
MCO FORMULARY	$58.9	$25.1	$0.0	?

All figures in millions

Optimized Formulary

	PHARMACY REIMBURSEMENT	FEDERAL REBATE	STATE SUPPLEMENTAL REBATE	NET COST TO STATE
FFS FORMULARY	$62.4	$34.8	$2.7	$25.0
MCO FORMULARY	$58.9	$25.1	$0.0	?
OPTIMIZED FORMULARY	$59.7	$27.8	$2.1	$29.8

All figures in millions

Optimized formulary can balance the state's rebates with the MCO's reimbursement

Formulary Management

PDL -> Formulary Management

- Rebate Optimization
  - Federal Rebates
  - Supplemental Rebates
- Multisource Drug Pricing/Tracking
- Expansion of PDL to include more classes
- FFS-MCO Coordinated Formulary
- Specialty Pharmaceuticals