

Issues and Compliance Strategies Related to Government Pricing

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Introduction

OLG Draft Compliance Guidance identifies government price reporting as a risk area

1. Information used to set reimbursement rates
2. Medicaid rebates and related price regulation programs

Overview of price reporting issues and compliance strategies

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The Medicaid Rebate Program: Overview

Manufacturers of “covered outpatient drugs” must enter into three pricing agreements as a condition to federal Medicaid matching funds for those products

1. Medicaid rebate agreement
2. PHS covered entity discount agreement
3. VA Master Agreement

States generally must cover products of manufacturers with pricing agreements, but may subject drugs to prior authorization

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Medicaid Rebate: Manufacturer Reporting Obligations

Manufacturers must report product information and pricing data for all package sizes

Unit rebate amount is based on “average manufacturer price” and “best price” reported quarterly

Penalties for false/late reporting

1. \$100,000 for knowingly false reporting
2. \$10,000 per day for late reporting

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Rebate Calculation Formula: Single Source and Innovator Multiple Source Drugs

Basic rebate: GREATER of:

1. Average Manufacturer Price (AMP) x 15.1%
2. AMP - Best Price (BP)

Additional rebate

1. Current AMP - (Base Period AMP adjusted by CPI)
2. Base Period
 - Existing products: 3Q1990
 - New products: First full calendar quarter after date first marketed

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Rebate Calculation Formula: Noninnovator Drugs

AMP x 11%

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AMP Calculation

Basic definition: Average price paid by wholesalers for drugs distributed to the retail pharmacy class of trade

“Retail pharmacy class of trade”

Must take into account price concessions

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AMP: Classes of Trade

Included classes of trade

1. Retail pharmacies
2. Chain pharmacies
3. Long term care
4. Home health

Excluded classes of trade

1. Hospitals
2. HMOs

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BP: General

Definition: Lowest price available to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity in any pricing structure, except for otherwise excluded sales

Must take into account all price concessions associated with relevant purchases of any package size

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BP: Excluded sales

DOD/VA/PHS/State veterans homes

Federal Supply Schedule purchases

Participating 340B “covered entities”

State supplemental Medicaid rebates

State pharmaceutical assistance programs

Nominally priced sales (<10% of AMP)

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Price Calculation Issues

Volume discounts

Variable discounts

Cumulative discounts

Bundled sales

Free goods

Sales to relabelers/repackagers

Grants and service fees

Administrative fees

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Medicaid Rebate Program: Developments and Issues

Pfizer settlement

State rebate programs

Coupons and other patient-focused programs

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Pfizer Settlement

\$49 MM settlement based on Medicaid rebate program

Alleged failure to take into account in BP determination \$250K grant to health plan in exchange for favorable formulary status for Lipitor

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State Programs

Medicaid expansion demonstrations

Supplemental rebate programs

State pharmaceutical assistance programs

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Medicaid Expansion Demonstrations

Seek to provide Medicaid drug coverage to higher income populations

Require federal waiver

Medicaid rebates due on expanded populations

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Supplemental Rebate Programs

Seek greater than mandated rebates on Medicaid utilization to avoid prior authorization

Increasingly used to implement Medicaid formularies

Must be approved by CMS and rebates shared with federal government

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State Pharmaceutical Assistance Programs

Medicaid coverage may not be conditioned on participation

State only funding

Indigent assistance, and not “mere” procurement

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Coupons and Other Patient-Focused Programs - I

6/02 Scully-Holmer Letter

1. Where concessions under manufacturer-sponsored cards affect the price paid by retail pharmacies, they affect BP
2. Coupons administered through point of sale mechanisms at pharmacies affect BP, while coupons redeemed directly by patient to manufacturer do not

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Coupons and Other Patient-Focused Programs - II

10/02 Scully Clarification

1. Together Rx card does not affect BP
2. Manufacturer establishes discount, pharmacy does not realize benefit, no third party negotiation

CMS Medicare Endorsed Drug Card

1. Proposed Rule indicates rebates will affect BP

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Other Federal Programs

PHS Covered Entity Discounts

VA Master Agreement

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PHS Covered Entity Discounts

Manufacturer price to “covered entities” may not exceed ceiling price

Ceiling price calculated using Medicaid AMP and BP

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PHS Covered Entity Classes

Hemophilia treatment centers

Native Hawaiian health centers

Urban Indian organization

HIV health services programs

STD/TB clinics

Certain disproportionate share hospitals

Federally qualified health centers

Health centers in public housing

Family planning projects

Early HIV intervention grantees (Ryan White)

State ADAP programs

Black lunch clinics

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Covered Entity Requirements

No diversion

1. Nonpatients
2. Outpatient use only

No double discounting

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PHS Ceiling Price

AMP - Average total Medicaid rebate

OTC: AMP - 11%

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VHCA Master Agreement Obligations

Offer all S/I products on FSS

Price to state veterans homes based on FSS

Prices to “big three” agencies cannot exceed “federal ceiling price”

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Federal Ceiling Price Calculation

76% of Non-Federal Average Manufacturer Price, less “additional discount”

Non-FAMP Definition

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Average Wholesale Price

No affirmative reporting obligations

Government and private actions

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Average Wholesale Price: Government Concerns

*“False” AWP*s lead to *“excessive”*
reimbursement

“Manipulating” AWP

“Marketing the Spread”

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AWP: Compliance Strategies

Scope of price information reported

Appropriate disclaimers in price reporting

Document appropriate bases for price changes

Avoid marketing the spread

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Conclusions/Questions and Answers

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