Morgan Lewis

THIRD PARTY REIMBURSEMENT OF COVERED ENTITIES: MANUFACTURERS' PERSPECTIVE

Donna Lee Yesner
Morgan Lewis and Bockius
Phone : 202.739.5887
Email: dyesner@morganlewis.com

BACKGROUND

- In the beginning
  - Congress was concerned with increases in cost of drugs purchased by community health centers and outpatient clinics that treated a large number of indigent and uninsured patients where federal funds were used to support these safety net providers and the cost of drugs had to be absorbed
  - The 340B program is intended to reduce this cost in order to stretch federal resources needed to purchase drugs to treat patients

BACKGROUND

- Relationship to Medicaid
  - Medicaid reimburses covered entities as a third party payer, just as it does other providers.
  - Medicaid derives no benefit from the 340B program if it reimburses covered entities the same as non-covered entities and obtains a manufacturer rebate
  - 340B statute prohibits covered entities from billing Medicaid for a drug purchased under the 340B program if it is subject to a Medicaid rebate
  - CMS requires the 340B price to be passed through to Medicaid for the purchase to be under the program

BACKGROUND

- Disparity Between Acquisition Cost and Resale Price
  - Drug manufacturers enter into agreements in which they promise to sell drugs to covered entities at a price derived from the rebate percentage provided to Medicaid
  - This price is substantially below market
  - When a patient is treated by a non-covered entity, the dispensed drugs are purchased from manufacturers at a market price. However, prices providers charge insured patients for drugs are driven by the third party payers, and historically the price they paid for drugs was the same for covered entities and non-covered entities

BALANCING INTERESTS

- Limiting the Program Scope
  - Drugs purchased under the 340B program may only be resold to patients of covered entities
  - Manufacturers' expectation was that savings on drug purchases would be used to reduce treatment cost, which covered entities bore, not to finance a retail pharmacy business
  - The statute protects manufacturers from providing the 340B discount to covered entities and the same discount on the same units to Medicaid when it reimburses them, but does not protect against other similar double discounts

PROGRAM CHANGES SINCE 1992

- There are many more covered entities purchasing at the 340B price
- In 1992, there was no Medicare Part D program and no Tricare rebate program, and commercial drug benefit plans and pharmacy benefit managers did not influence the sale of drugs to the extent they do today.
- In 1992, there was no contract pharmacy program. Now HRSA allows covered entities to provide drugs through retail pharmacies without having to actually finance the purchase of the drugs – the concern that led to the creation of the 340B program in the first place
- 340B drugs are resold to one-time patients whose only encounter with the covered entity is to obtain a prescription

MANAGED CARE INFLUENCE

- Commercial Model - Formulary Controls
  - Managed Care Organizations and their PBMs control prescription reimbursement costs through drug benefit plans that leverage access and competition to obtain price concessions. They create formularies of drugs they will cover and the rules for coverage.
  - Providers, including covered entities must accept these rules if they want to be paid by their patients' plans
  - Formularies typically consist of multiple tiers and incentives for plan beneficiaries to choose drugs in the lower tiers

MANAGED CARE INFLUENCE

- Commercial Model (cont.)
  - Prescribers generally do not care which therapeutically equivalent drug is dispensed
  - Pharmacy drug benefit plans typically require generic substitution for more expensive brand drugs and include a preferred drug tier. The co-payment is lower for brand drugs in this tier, which improves market share
  - Where there are multiple therapeutic equivalents, plans will usually put the drug that yields the lowest net cost in this tier. Net cost is derived from the pharmacy reimbursement amount less manufacturer rebates on the dispensed units

MANUFACTURER REBATES

- Commercial Rebates
  - Today, the overwhelming majority of Americans receive pharmacy benefits through managed care plans, and manufacturers cannot realistically sell drugs to pharmacies if the drugs are not covered by the pharmacy customers' plans. Although rebates to plans are purely voluntary, competition for formulary position necessitates manufacturers negotiate contracts to pay them
  - Commercial plans obtain rebates the same way Medicaid does – by capturing prescription utilization data from pharmacy claims and submitting it to manufacturers for payment

MANUFACTURER REBATES

- Commercial Rebates
  - There is no protection under the 340B statute against the provision of discounts to both the covered entity and a plan paying the provider on behalf of the entity's patient except for Medicaid.
  - To prevent significant loss in revenue from drugs dispensed to patients of covered entities, including retail pharmacies that dispense the drugs on behalf of the entities, manufacturers must exclude this utilization from their commercial rebate agreements

TRICARE RETAIL PHARMACY PROGRAM

- Exclusion from Rebates
  - In order to prevent subjecting manufacturers to two discounts on the same prescription, the Tricare retail pharmacy program excludes utilization from covered entities from the obligation to pay prescription rebates
  - Tricare's PBM pays covered entities pursuant to its commercial network agreement
  - If the PBM creates a two-tier reimbursement system for its network providers, presumably it will apply to Tricare-covered prescriptions and Tricare will recoup some of the loss

CONTRACT PHARMACIES

- Contract Pharmacy Problem
  - Prescription data received by PBMs and provided to manufacturers indicates whether a script has been filled by a covered entity or a contract pharmacy, but does not indicate whether a retail pharmacy that services patients of 340B entities filled the patient's script with drugs purchased at the 340B price
  - Manufacturers must choose between disputing rebates on these prescriptions or risk paying a double discount on them

MEDICARE PART D

- Part D Plans
  - Congress contemplated PDPs would negotiate rebates with drug manufacturers in exchange for formulary position to reduce the cost of prescription drugs to the plans and their insured and to the Medicare program which pays a significant portion of the prescription cost
  - PDPs follow a commercial model and negotiate rebates units dispensed to their members even on zero pay claims
  - Congress did not address the double discount problem for manufacturers if the scripts paid by PDPs are provided by covered entities. Manufacturers must exclude utilization as with other commercial type plans

IMPACT OF DOUBLE DISCOUNTS

- Example
  - Manufacturer sells to retail pharmacies at WAC of $100, and pays a plan a $30 rebate on Part D utilization If plan pays its pharmacies $120, and co-pay is $20, plan would pay $70 and manufacturer would realize $70 on a script dispensed to the plan's beneficiary
  - If manufacturer's 340B price is $60, and it pays a $30 rebate on the same script dispensed by a covered entity or contract pharmacy, its realization is reduced to $30, while the covered entity nets $60 on a $60 purchase
  - If the plan receives no rebate on this sale, it pays $100 (net co-pay) and the manufacturer realizes $60

MEDICARE PART D DONUT HOLE

- Medicare Part D Coverage Gap Discount Agreements
  - Medicare will not cover a manufacturer's drugs unless the manufacturer agrees to pay 50% of the net price of a prescription while the patient is in the coverage gap (PDPs are not responsible for paying the pharmacies)
  - Net price is the retail price agreed to between a PDP and its network pharmacies less any discounts to the consumer
  - Manufacturers are third party payers under this program – the PDPs advance their share and are reimbursed

STACKED DISCOUNTS IN DONUT HOLE

- Three Discounts Applicable to Same Unit Sold
  - CMS refused to exclude prescriptions filled with 340B drugs so manufacturers with PDP rebate agreements must pay covered entities (and their contract pharmacies) 50% of the marked up retail price on drugs sold to those entities at a deep discount
  - In addition, the PDPs want to be paid rebates on the same prescriptions for which the manufacturer shares payment responsibility with the beneficiary
  - As a result, provision of these three discounts on the same unit can easily result in a negative realization

AUTHORIZED GENERICS

- Authorized Generics are subject to the Coverage Gap Discount
  - Although manufacturers do not typically pay rebates to commercial plans or Part D Plans on generic drugs, Authorized Generics are subject to the coverage gap discount
  - Like other generics, AGs are heavily discounted and have low AMPs and correspondingly low 340B prices – well below market
  - When the manufacturer must pay the entity 50% of the marked up retail price, it can yield a negative realization

IMPACT OF COVERAGE GAP (TRIPLE DISCOUNTS)

- Example 1: Brand
  - Manufacturer ‘s retail AMP is $100, rebate percentage is 40%, and 340B price is $60.
  - PDP negotiated pharmacy price is $120 and negotiated manufacturer rebate is $30
  - If a covered entity dispenses the drug it purchased at $60 to a Medicare covered patient in the donut hole, the manufacturer pays the covered entity $60 of the $120 negotiated price and then rebates $30 to the plan
  - The covered entity nets 100% profit and the manufacturer’s net on the dispensed unit is (- $30)

IMPACT OF COVERAGE GAP

- Example 2: Authorized Generic
  - Manufacturer acquires a unit of an AG from the innovator at $7.00 and has a retail AMP of $10
  - PDP pays pharmacies $15
  - Manufacturer sells to covered entity at $7.70 ($.70 above cost)
  - Manufacturer must pay covered entity $7.50 for same drug sold at $7.70 (beneficiary pays remaining $7.50)
  - Covered entity nets $7.30; manufacturer ‘s net is (-$6.80)

POLICY ISSUE

- What is Fair for Manufacturers?
  - Manufacturers are paid the 340B price regardless of how much margin the covered entities make on resale to their patients, but net far less if they provide double or triple discounts
  - Expansion of the program has exacerbated problem for manufacturers confronted with need to provide managed care rebates on drugs sold at a deep discount
  - If third party payers do not receive manufacturer rebates on prescriptions filled with discounted drugs, they have no choice but to reduce the price they are willing to pay providers commensurate with their true cost.

POLICY ISSUE

- Who should benefit from 340B price?
  - Covered entities are supposed to benefit from the 340B program in order to care for the uninsured and underinsured
  - Goal of health care reform is to maximize percent of insured population through subsidized plans and reduce cost to plans that pay providers on behalf of their insured, but 340B program doesn't generate tax savings for Medicare or reduce costs to private plans and consumers
  - Covered entities should need less taxpayer subsidization as they treat more insured patients and fewer uninsured patients. Shouldn't they share 340B savings with payers?

QUESTION

- Are manufacturers of covered drugs required to pay rebates on drugs dispensed by covered entities or their contract pharmacies and reimbursed by commercial plans?

ANSWER

NO

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