Strategies for Containing Drug Costs: Implications for a Medicare Benefit

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As policymakers consider adding a prescription drug benefit to Medicare, cost containment will be an important issue. This article discusses strategies to hold down the prices paid for prescription drugs. Within the private sector these include the use of formularies, the emergence of pharmaceutical benefit management companies, and the expansion of mail order pharmacies. In the Federal Government, costs are contained by the Medicaid drug rebate and the Federal Supply Schedule (FSS) of prices. Since Medicare beneficiaries constitute a large share of the prescription drug market, getting access to FSS prices may not be feasible. A flat rebate is one alternative.

INTRODUCTION

Although Medicare beneficiaries constitute just 13 percent of the U.S. population, they account for approximately 36 percent of total outpatient drug expenditures.[1] Currently, 35 percent of Medicare beneficiaries have no outpatient drug coverage, and an additional 8 percent have coverage only through medigap plans, which do not fully shelter beneficiaries from the risk of high drug expenditures (Davis et al., 1999).[2] Some Medicare beneficiaries are enrolled in health maintenance organizations (HMOs) that offer drug benefits, but those benefits appear to be capped at $2,000 or less in most such plans (Gold et al., 1999). Hence, many Medicare beneficiaries enrolled in HMO risk plans may not have adequate insurance against catastrophic drug expenditures either.

Policymakers are considering the addition of a prescription drug benefit to Medicare. The National Bipartisan Commission on the Future of Medicare has estimated that a modest Medicare drug benefit would cost $10 to $15 billion per year (Pear, 1999).[3] The actual cost of a Medicare drug benefit would be contingent on how the benefit is structured and targeted. Depending on how the deductible, copayments, and other key variables are set and whether the benefit would be extended to all Medicare beneficiaries or more narrowly focused, the costs could fall below or above that range. Clearly, cost control is an important issue. Private health plans and the Federal Government have wrestled with this issue in several ways, including approaches to minimizing payments. The purpose of this article is to review these payment arrangements and what is known about their

[1] Total drug expenditures by Medicare beneficiaries in 1994 was $19 billion according to the Medicare Current Beneficiary Survey, as reported by Westat (1998), and total outpatient drug expenditures in the United States came to $53 billion according to Levit et. al. (1997).

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[2] Only three types of medigap plans offer prescription drug coverage. Those three plans have a $250 deductible, a 50-percent coinsurance rate, and a cap of $1,250 or $3,000.

[3] More recently, the National Academy of Social Insurance found that the cost of a modest Medicare drug benefit would be $443-$609 per Medicare beneficiary in the first year (Gluck, 1999).

effects and it concludes with some implications for a Medicare payment policy under a proposed drug benefit.

The structure of the outpatient pharmaceutical market has changed over the last decade or so, with many more purchasers managing outpatient drug benefits and obtaining lower prices from both manufacturers and pharmacies. Medicare beneficiaries without a drug benefit are left out of that market dynamic and frequently end up paying the highest prices. The increased use of formularies, the emergence of pharmaceutical benefit management companies since 1987, and the growth of mail-order pharmacies have all helped to hold down the costs of outpatient drugs.

This article will also discuss what has and has not worked as the Federal Government has sought lower prices for the drugs it currently purchases. The primary mechanisms examined and explained will be the Medicaid drug rebate and FSS prices. None of the cost-containment mechanisms are perfect. Each has important drawbacks and qualifications.

COST CONTAINMENT: THE PRIVATE SECTOR

Different purchasers pay different prices for brand-name prescription drugs. Limited evidence suggests that cash-paying retail pharmacy customers (without a managed drug benefit) tend to pay the highest prices. Based on average invoice prices, a recent Congressional Budget Office (CBO) study found that retail pharmacies pay more on average than several other types of purchasers for brand-name drugs. Hospitals, long-term care facilities, and clinics paid 5 to 9 percent less on average than retail pharmacies for 100 top-selling outpatient brand-name drugs. HMOs paid 18 to 20 percent less. Federal facilities paid 35 to 42 percent less on average (Cook, 1998). The prices used in the study do not account for manufacturer rebates but, assuming that the excluded rebates are no larger for retail pharmacies than for other types of purchasers, it follows that cash-paying customers of retail pharmacies who lack prescription drug coverage tend to pay the highest prices.[4]

Discounts and Rebates

Purchasers that control the prescription choices of a large patient base through a formulary (a list of preferred drugs that favors generic substitution and substitution of less expensive brand-name drugs) frequently negotiate for discounts and rebates from manufacturers of brand-name drugs. Discounts and rebates are based on volume, and as importantly, on the purchaser's ability to shift its market share between similar drugs. For example, if four similar brand-name drugs use the same therapeutic mechanism to treat a given illness, the formulary may list only two of the four drugs. Formularies are most useful as tools for leveraging discounts when there are several therapeutically similar brand-name drugs on the market, or when generic drugs are available. In the case of breakthrough drugs for which there are no close substitutes yet on the market, manufacturers have little incentive to offer steep discounts.[5]

Discounts and rebates take various forms. The term "discount" is generally used when a lower purchase price is nego-

[4] Health plans that manage their outpatient drug benefit would end up paying lower prices to the extent they are able to negotiate for rebates from manufacturers.

[5] Frequently, a second brand-name drug that is therapeutically similar to the breakthrough drug is approved by the Food and Drug Administration (FDA) within 1-6 years after the original breakthrough drug was introduced (Cook, 1998).

tiated between the final purchaser and the manufacturer.[6] The term "rebate" is generally used when the manufacturer pays the final purchaser an amount based on the volume of drugs purchased over a given period. The size of the rebate may also be tied to a percentage increase in volume, which demonstrates an ability to favor the manufacturer's drugs. For entities that never take possession of the drug, such as a pharmaceutical benefit management company, rebates are the primary mechanism used. The end result is the same, manufacturers sell their prescription drugs for a lower price, usually in exchange for an increase in volume.

Empirical evidence confirms that discounts tend to be higher when a brand-name drug faces competition from several similar brand-name competitors or from a generic copy. Based on an analysis of the largest discounts offered to private sector purchasers, CBO found that those "best price discounts" were 12 to 17 percentage points bigger when a generic drug was available.[7] Interestingly, competition from similar brand-name drugs also significantly affected discounts. The best price discounts on brand-name drugs were 10-14 percentage points bigger in therapeutic classes that had three or more similar brand-name drugs produced by competing manufacturers than in therapeutic classes with only one brand-name drug (Cook, 1998).

[6] Another term used is "charge back" which refers to wholesalers delivering drugs at a discounted price previously negotiated between the manufacturer and the final purchaser. The wholesaler informs the manufacturer of the delivery and is then reimbursed by the manufacturer for the amount of the discount (Cook, 1998).

[7] The best-price discount is equal to the percentage difference between the average price manufacturers charge for brand-name drugs distributed to retail pharmacies and the lowest price charged to any private purchaser. Those prices are reported by manufacturers to HCFA under the Medicaid rebate program.

Pharmaceutical Benefit Management

PCS Health Systems, one of the largest pharmaceutical benefit management companies, first established electronic links with pharmacies that allowed two-way transmission of information and claims data in 1987 (Pittinger, 1996). Since that time the management of pharmaceutical benefits has grown dramatically. In 1998, approximately 64 percent of retail pharmacies' revenues from drug sales came from prescriptions that were handled using an electronic link system facilitating the management of outpatient prescription drug benefits (IMS America, 1998a). Pharmaceutical benefit management companies put downward pressure on the prices paid to both pharmacies and manufacturers. In return for being included in a pharmaceutical benefit management company's network, the pharmacist may agree to charge a lower retail price to the company. And in return for being listed on the formulary, manufacturers may be willing to pay a rebate based on the volume of drugs purchased by the pharmaceutical benefit management company's beneficiaries.

Mail-order pharmacies also have an important role in holding down the cost of outpatient prescription drugs. Many insurance plans now include an option to purchase drugs by mail (and some pharmaceutical benefit management companies also own a mail-order pharmacy). Between 1991 and 1996, the share of prescription drugs distributed through mail-order pharmacies grew from 6-10 percent of manufacturers' total sales revenue (Cook, 1998). And, in 1997, sales through mail-order pharmacies grew by 24 percent, faster than any other distribution channel (IMS America, 1998b). Substituting one brand-

name drug for another requires the doctor's permission. In a mail-order setting, the pharmacist has 2 days to call the doctor and make a switch. In addition, mail-order pharmacies are very effective at promoting generic substitutions (Wagner, 1993). Drugs ordered through a mail-order setting are frequently for chronic conditions where the savings from switching to a lower-cost prescription accumulates over time. The prescriptions used by Medicare beneficiaries frequently fall into this category. Two companies have estimated saving 15-20 percent on employee drug costs by using mail-order (O'Reilly, 1992).

Much of the savings achieved by plans managing outpatient drug benefits come through lower retail pharmacy prices, or lower prices associated with the use of mail-order pharmacies, rather than through manufacturer rebates. The U.S. General Accounting Office (GAO) studied three large health plans participating in the Federal Employees Health Benefits Program that used both pharmaceutical benefit management companies and mail-order pharmacies (U. S. General Accounting Office, 1997a). Mail order phar-macies may receive lower prices either through direct discounts from manufacturers or through rebates. So part of the savings obtained by mail-order pharmacies showed up in lower retail prices (based in part on lower prices paid to the manufacturer) and part of the savings obtained through mail order pharmacies showed up in the form of rebates. The study found that 50-74 percent of the drop in the plans' spending on prescription drugs resulted from lower retail prescription prices (obtained by negotiating lower rates with retail pharmacies or by using a mail-order pharmacy). For two of the plans, 80-90 percent of all manufacturer rebates were returned to them. Manufacturer rebates made up 7 percent of total savings for one of those two plans and 21 percent of total savings for the other. (Part of those manufacturer rebates were paid on sales through mail-order pharmacies.)

Pharmaceutical benefit management companies may be more successful at negotiating rebates when they manage an outpatient drug benefit for an HMO or preferred provider organization (PPO) than for a fee-for-service (FFS) plan. Within an HMO or PPO setting, the formulary can be distributed to the network of doctors within the plan, and the doctors can be given incentives to follow the formulary in their prescribing practices. However, in a FFS setting where there is no network of doctors, promoting formulary compliance is more difficult. Since the value to the manufacturer of being listed on the formulary is not as great, neither is the leverage of the pharmaceutical benefit management company in negotiating for rebates. The pricing data to test this reasoning is not publicly available. Nevertheless, the reasoning implies that policymakers should be cautious in their expectations regarding the ability of pharmaceutical benefit management companies to obtain sizable manufacturer rebates when managing a drug benefit for beneficiaries enrolled in FFS Medicare.

COST CONTAINMENT: THE FEDERAL GOVERNMENT

Medicaid's Rebate and FSS Prices

The purpose of the rebate program, established by the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), is to reduce both Federal and State Govern-ment spending on outpatient prescription drugs for Medicaid beneficiaries. Total Medicaid expenditures on outpatient drugs were $11 billion in 1996. The Medicaid rebate

reduced those expenditures by almost $2 billion, bringing total expenditures net of the rebate to about $9 billion.[8]

Medicaid provides a generous drug benefit to its beneficiaries with very low copayments and no deductible. Purchases by Medicaid beneficiaries account for about 12 percent of total outpatient drug sales through pharmacies and other retail stores. States reimburse pharmacists directly for drugs purchased by Medicaid beneficiaries. The Federal Government, in turn, reimburses States for a portion of those costs. Manufacturers pay a rebate directly to the States based on the quantity of drugs purchased by Medicaid beneficiaries as reported by each State to HCFA (Cook and Harrison, 1996). The savings from the rebate program are then shared with the Federal Government.

The basic rebate on brand-name drugs takes one of two forms. It either equals 15.1 percent of the average price earned by manufacturers on drugs sold through pharmacies (called the average manufacturer price or AMP) or is based on the lowest price the manufacturer charges any private purchaser in the United States (called the best price). If the best price is 20 percent less than the AMP, then the basic rebate is 20 percent (rather than the flat 15.1 percent of the AMP).[9]

If a brand-name drug's price rises faster than the inflation rate, an additional rebate is imposed. The additional rebate is equal to any increase in the AMP above the inflation rate as measured by the Consumer Price Index. The additional rebate makes it unprofitable for manufacturers to offset the basic rebate by raising their prices for drugs already on the market.

All forms of the rebate are based on the AMP paid by wholesalers, inclusive of all discounts and price reductions "for drugs distributed to the retail pharmacy class of trade."[10] Manufacturers are required to report their prices to HCFA on every dosage form of each drug they distribute. The basic rebate is paid on all brand-name (innovator) drugs purchased by Medicaid beneficiaries.[11]

Through Medicaid's rebate system, manufacturers effectively charge Medicaid no more than any other private sector purchaser for brand-name drugs. One question occasionally raised is why not simply require that manufacturers charge a lower price in the first place? Why use a rebate system? A rebate is just one form of obtaining a discount based on the volume of drugs purchased. In the private sector, a rebate system allows manufacturers to charge different prices to different purchasers based on a demonstrated ability to move market share between similar drugs. For example, the rebate may be tied to the purchaser's ability to favor the manufacturer's drug—the higher the increase in the volume of the drug purchased, the higher the rebate percentage. In addition, a rebate system works well for purchasers who do not buy drugs directly from manufacturers. Since State Medicaid programs, like pharmaceutical benefit management companies, do not purchase drugs directly from manufacturers (but instead reimburse pharmacies for the drugs purchased by their enrollees), a rebate system is an effective tool to obtain a lower price from manufacturers.

[8] Based on HCFA-64 form "The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program.

[9] Manufacturers of generic and over-the-counter drugs also pay a flat rebate equal to 11 percent of the AMP.

[10] Section 1927 of the Social Security Act as amended by the OBRA 90 and 1993 and the Veterans Health Care Act of 1992 (42 U.S.C. 1396r-8).

[11] In this article, the term "brand-name drug" and "innovator drug" are used interchangeably. Innovator drugs have been approved by the FDA after extensive clinical testing under a new drug application (NDA). They usually have a patent on their chemical formulation, process of manufacture, or use.

When a manufacturer offers a rebate to a pharmaceutical benefit management company, it does so in exchange for an expected increase in sales. That is, the pharmaceutical benefit management company agrees to favor the manufacturer's drug over a competitor's drug in exchange for a rebate. However, under a mandatory rebate, as in Medicaid's rebate, manufacturers pay the rebate but do not see their drugs favored over a competitor's. They do not get a direct increase in market share as a result of paying a rebate. It is also true that prescription drug sales are higher because of Medicaid's generous prescription drug coverage (than they would be in the absence of such coverage), meaning that manufacturers' sales are somewhat higher because of Medicaid's drug benefit. That higher level of sales could be viewed as partially offsetting the cost to manufacturers of Medicaid's rebate program.

Limitations of Medicaid's Rebate Program

As a result of the best-price provision, some private-sector purchasers are paying higher prices. Since Medicaid constitutes a large share of the outpatient drug market, about 12 percent on average, manufacturers may not find it profitable to offer large discounts to some private purchasers because they are required to give those same discounts on purchases by Medicaid beneficiaries. In 1991, the best-price provision was phased in as there was a cap on the size of the basic rebate set at 25 percent. At that time, nearly one-third of all brand-name drugs still under patent had a best-price discount as high as 50 percent. But by 1994, when there was no longer a cap on the basic rebate, only 9 percent of brand-name drugs still under patent had a best-price discount in that range (Cook and Harrison 1996). That suggests that some private sector purchasers are paying more as a result of the best-price provision of the Medicaid Rebate Program. The best-price provision hampers the ability of some private purchasers to negotiate for steep discounts from manufacturers and, therefore, may undermine price competition in the pharmaceutical market to some extent.[12]

The Federal Government also briefly paid higher prices as a result of the best-price provision. In 1991 and early 1992, FSS prices were counted as a best price, which effectively gave Medicaid access to most FSS prices.[13] The FSS is a catalog of prices available primarily to Federal agencies that includes pharmaceutical prices negotiated by the Department of Veterans Affairs (VA). Since Medicaid constitutes a large share of the outpatient market for prescription drugs, it is not surprising that when Medicaid was given access to FSS prices, those prices rose (U.S. General Accounting Office, 1991). In 1996, Medicaid expenditures on prescription drugs were $9 billion (net of rebates), while the drugs purchased through the FSS amounted to only $1.3 billion (U. S. General Accounting Office, 1997b). The VA and other Federal purchasers complained and Congress exempted FSS prices from the best-price provision in 1992 through the Veterans Health Care Act. Since Medicare beneficiaries constitute an even larger share of the market than Medicaid beneficiaries, that scenario would likely be repeated were manufacturers required to charge FSS prices for all drugs purchased by Medicare beneficiaries.

Another drawback of the rebate program is that manufacturers can charge higher launch prices for new brand-name drugs to

[12] Many theoretical models have also shown that such provisions cause firms to compete less aggressively on prices. Refer to Scott Morton (1997), which also provides an empirical analysis of the impact of the Medicaid rebate program on prices paid by pharmacies and hospitals.

[13] If the FSS was less than 50 percent of the AMP, the basic rebate would have been limited to 50 percent in 1992 because of a cap.

partially offset the rebate. The additional rebate prevents manufacturers from raising their prices to Medicaid faster than inflation after a drug is launched. However, manufacturers still have an incentive to charge a somewhat higher launch price, particularly for drugs they anticipate will have a large Medicaid market share.

Implications: A Medicare Drug Benefit

It may not be feasible for Medicare to get access to FSS prices or to the lowest prices charged to any private sector purchaser. If an attempt is made to link Medicare prices with the FSS or Medicaid's best price, the result is likely to be an increase in those prices since Medicare beneficiaries constitute such a large share of the outpatient market for prescription drugs.

Proposals to extend drug coverage to more low income Medicare beneficiaries have included expanding the number of Medicare beneficiaries that qualify for Medicaid's drug benefit (Long, 1994) or designing a new Federal-State program to offer drug coverage to low income Medicare beneficiaries with a higher federal contribution than Medicaid (Soumerai and Ross-Degnan, 1999). For a more broadly targeted benefit, vouchers could be issued to Medicare beneficiaries toward the purchase of private prescription drug coverage, which the Federal Government could standardize, as was done for medigap plans (Gluck, 1999). To help hold down the costs of such a benefit, health plans would need some freedom to apply a formulary to their patient base enabling them to negotiate for rebates from manufacturers.

More evidence is needed to help determine the rebate levels that pharmaceutical benefit management companies obtain. If skepticism remains about the ability of pharmaceutical benefit management companies to move market share in a FFS setting, then one option for adding a drug benefit to FFS Medicare might be to have a rebate similar to Medicaid's but without the best-price provision. That rebate could be applied to all drug purchases made at retail pharmacies by beneficiaries enrolled in FFS Medicare. If both a flat rebate and an additional rebate were imposed, then manufacturers would not have an incentive to offset the rebate by increasing the prices of drugs already on the market. However, manufacturers would still have an incentive to charge higher launch prices for new drugs to help offset the rebate, particularly those that would be used largely by people 65 years of age or over.

A mail-order option could also be offered with lower copayments and deductibles to encourage its use by beneficiaries. Purchases made through mail-order pharmacies could be exempted from the rebate. Cost savings could be achieved based on the mail-order company's ability to move market share between similar drugs and negotiate for rebates. Since pharmacists have more time to contact the doctor and attempt to switch a prescription between similar drugs in a mail-order setting, and since drugs purchased through mail order tend to be for chronic conditions where the savings from such switches are greater, mail order pharmacies might be more effective than pharmaceutical benefit management companies in negotiating for rebates in a FFS setting.[14] Also, economies of scale and distribution efficiencies may permit mail-order pharmacies to charge lower markups. Medicaid now pays both a wholesaler markup and a retail pharmacy markup. Mail-order pharmacies may be better able to reduce both of those markups and achieve savings without the imposition of a rebate.

[14] Some pharmaceutical benefit management companies own mail-order pharmacies in which case the distinction would be that the leverage to negotiate for rebates may be greater for prescriptions dispensed through the mail-order side of the business.

It should be noted that, although some Medicare beneficiaries without drug coverage may now use mail-order pharmacies, they usually do not get access to deeply discounted drugs by doing so. Since those beneficiaries are not part of a health plan with drug benefits, no one is negotiating for lower prices on their behalf based on an ability to move market share between two similar drugs. So Medicare beneficiaries without drug coverage who use a mail-order pharmacy are probably paying higher prices than would be paid by a health plan using a mail-order pharmacy to help manage its drug benefit.[15]

Finally, adding a prescription drug benefit to Medicare will cause prescription drug sales to rise somewhat. Medicare beneficiaries who are currently without drug coverage are likely to increase their drug purchases once such a benefit is extended to them. Any increase in sales from extending a drug benefit to Medicare beneficiaries would partially offset a rebate or other cost containment option aimed at obtaining lower prices for prescription drugs.

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[15] Beneficiaries with drug coverage through medigap plans also frequently pay higher prices for prescriptions since those plans do not generally negotiate for volume discounts (Gluck, 1999).

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