

The Medicare Prescription Drug Benefit: How Will The Game Be Played?

A nuts-and-bolts proposal for using competition and pharmacy benefit managers to contain drug costs and promote quality.

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PROLOGUE: Thirty-five years ago, when Congress created Medicare, it decided that private health insurers, under contract to the federal government, should serve as the program's paymasters. These agents were seen as a buffer between a government perceived as all-powerful and providers who were seriously concerned about the newly prominent federal role in the health care system. Today, a generation later, Congress is moving toward serious consideration of expanding Medicare benefits to include coverage of outpatient prescription drugs. No one disputes that leaving outpatient drugs uncovered is a serious shortcoming of Medicare, but how to pay for and administer the benefit are among the tall questions facing Congress. A number of different proposals have been advanced, but one of their common threads is reliance on pharmacy benefit managers (PBMs) as the administering agents. However, these proposals contain few details on how PBMs would operate, particularly as an agent of the government, rather than private employers.

In this important paper Haiden Huskamp and three of her colleagues at Harvard University begin to flesh out these details. Huskamp is an assistant professor in the Medical School's Department of Health Care Policy. Meredith Rosenthal is an assistant professor in the Department of Health Policy and Management, School of Public Health. Richard Frank is the Margaret T. Morris Professor of Health Economics at Harvard, and Joe Newhouse is the John D. MacArthur Professor of Health Policy and Management there.

ABSTRACT: Most recent proposals to add a prescription drug benefit to the Medicare program suggest using pharmacy benefit managers (PBMs) to control costs and promote quality. However, the proposals give little detail on the institutional arrangements that would govern PBM operations and drug procurement. The recent Congressional Budget Office cost estimate of the Clinton administration's proposal reflects this lack of detail on how PBMs would function. We sketch an approach for structuring PBM operations that focuses on competition among PBMs, manufacturers, and distributors; incentive pricing; and risk sharing with PBMs.

When the One Great Scorer
comes to write against your name
He marks—not that you won or lost—
but how you played the game.

Grantland Rice

CONGRESS IS ENTERTAINING A FLURRY of new proposals to extend insurance protection to outpatient prescription drugs under Medicare. Most of the attention has centered on the variation in benefits and eligibility among the proposals. For example, some propose targeted insurance and subsidy schemes aimed at low-income elderly and disabled persons (H. 2925). Others would cover low levels of drug spending under a universal benefit (the Clinton administration's proposal), and a third set of plans would offer universal catastrophic coverage, some with front-end coverage as well (S. 841).¹

Although most of these proposals suggest the use of pharmacy benefit managers (PBMs) to limit cost and enhance quality, they contain little discussion about how PBMs might function as part of Medicare. Yet there is wide variation in how existing PBMs manage care, use financial incentives, structure formularies, and gain bargaining power with manufacturers. Moreover, evidence of their effects is mostly anecdotal, which leads to uncertainty about the cost of implementing the various proposals. For example, the U.S. General Accounting Office conducted a qualitative study of three PBMs used by three health plans in the Federal Employees Health Benefits Program (FEHBP).² The three plans reported estimated savings in drug spending from a PBM of 20–27 percent, with no perceived loss in quality or patient satisfaction. Using a combination of industry reports and interviews with the five leading PBMs in the market, Henry Grabowski and Daniel Mullins estimated cost savings in drug spending from using a PBM of 14–31 percent.³

The dearth of evidence is reflected in how the Congressional Budget Office (CBO), the federal government's "great scorer," estimated the cost of the administration's proposal, as well as in the unofficial cost estimates that accompany many of the other propos-

als.⁴ The CBO's scoring of the administration's proposal estimated much lower savings (12.5 percent) from PBMs than did the studies just cited. The CBO argued that the PBMs' role under the administration's proposal was likely to limit their ability to use some cost-saving techniques common in private-sector contracts, but the CBO qualified its scoring as possibly changing "as details of the proposal's design emerge." This qualification highlights the importance of clarifying how PBMs can affect prices and use of drugs. These specifics will ultimately determine the degree to which PBMs can serve the role envisioned for them in the various legislative initiatives.

Consequently, we focus on the institutional framework within which the PBMs will function—or how the "game" will be played. We do, however, have a point of view about the appropriate framework. Because we are all economists, our view not surprisingly emphasizes the use of competition among PBMs, drug manufacturers, and pharmacy distributors to promote efficiency. We also consider the structure of formularies, the role of government, and the use of financial incentives. Many other issues related to benefit design and financing, such as the potential shift of monies now paid by employers and states to the federal budget ("crowding out"), must be addressed in designing a sustainable Medicare prescription drug benefit, but we do not address them here.⁵

PBMs And Supporting Institutions

PBMs provide pharmacy benefits to about half the insured population in the United States.⁶ To implement a Medicare drug benefit using PBMs, one must make several key decisions, including structuring competition among PBMs, defining rules for specifying formularies, and determining the degree of risk PBMs face and the terms under which networks of retail and mail-order pharmacies will be constructed.

■ **Structuring competition among PBMs.** *Enrollees or contracts?* Medicare can structure competition among managed pharmacy benefit plans as either competition for enrollees or competition for contracts.⁷ If plans compete for enrollees, beneficiaries enrolled in traditional Medicare would choose among multiple drug plans competing within a defined geographic market. Unfortunately, this approach almost certainly would result in adverse selection, as those who expect to spend more on prescription drugs seek out more generous plans. For example, individual Medigap Plans H, I, and J, which cover drugs, have high premiums not only because of the more generous benefit package but also because enrollees with high use of drugs disproportionately enroll in them. Thus, the premium for drug benefits in the most generous supplementary plan (Plan J)

is more than twice as high as it would be with a representative sample of enrollees, 57 percent higher in Plan H, and 39 percent higher in Plan I.⁸ Competition to avoid the sick may result in a number of undesirable outcomes, including overly restrictive access to drugs and instability in the market for PBMs.⁹

If plans compete for contracts rather than enrollees, they periodically bid to secure an exclusive contract for a particular geographic area (a monopoly franchise). Employers sometimes use such an approach for their prescription drug benefit (for example, the State of Maryland employees' plan).¹⁰ In theory, competition for contracts yields many of the benefits from competition in terms of lower price and higher quality but avoids adverse selection by eliminating enrollees' choice of plans.

Because adverse selection poses a serious threat to the efficient functioning of markets, we favor competition for contracts rather than for enrollees, which means awarding a single contract to manage the pharmacy benefit for traditional Medicare in each local market. For this model to succeed, however, there must be effective competition for the contract, both initially and over time. Maintaining competition can be aided by defining markets appropriately.

Defining markets. For either type of competition (enrollees or contracts), it is necessary to define markets for which PBMs could compete. Using regional rather than national markets allows geographic variation in treatment patterns and population characteristics to influence contracting and potentially avoids the need for the Health Care Financing Administration (HCFA) to define a geographic price index analogous to the hospital wage index. In a competition-for-contracts world it also permits a national PBM market to be sustained, because one can avoid the winner-take-all situation inherent in a single national contract.¹¹ Although awarding contracts in several local markets increases the administrative burden, we believe that the benefit from maintaining competition in the PBM market greatly outweighs the additional administrative costs.

We suggest defining markets so that they have roughly equal numbers of Medicare enrollees, so that PBM contractors in each region would have comparable bargaining power with manufacturers. We propose using about sixty approximately equal-size regions, the number set out for Medicare intermediaries, as the regional units for procurement.¹² There could, of course, be fewer, depending upon administrative costs and economies of scale.¹³ Moreover, to maintain competition over the long run in the PBM market, we suggest a limit, such as 20 percent (twelve regions), on the proportion of the national market that any single PBM could control. The exact numbers are not critical; what is important is that

“Implementing a closed formulary for Medicare would put the government in the position of influencing drugs’ market share.”

there be a sufficient number of contracts and potential bidders to ensure competition when contracts are rebid. PBMs would be required to offer services to all beneficiaries in a region, another protection against selection-based inefficiencies.

Competitive procurement. Medicare could use the procurement process used by some private employers’ and state employees’ health benefits programs as a model. Initially, a request for proposals (RFP) is issued. Eligible organizations submit a detailed bid for the contract describing key features of their proposed management approach and the characteristics of their organization. Bids are evaluated according to specified criteria, including both cost and technical aspects of the proposed approach. The primary factors upon which PBMs compete in addition to cost are the composition of their proposed distribution networks (that is, which pharmacies and/or mail-order firms may be used by enrollees at the lowest cost); the adequacy of any drug utilization review (DUR) or disease management programs; and management information systems.

As of 1998 seventy-six PBMs were doing business in the United States, although the industry is dominated by five large firms.¹⁴ To encourage competition, other types of managed care entities besides PBMs could be eligible to become contractors for the program if they have the capability to manage drug utilization and negotiate with manufacturers and distributors.¹⁵ Qualified bidders would be permitted to submit bids for managing the Medicare pharmacy benefit in any of the defined markets.

The duration of PBM contracts should balance the administrative costs and any possible disruption in the enrollee’s pharmacy benefit that are associated with each round of procurement with any potential increase in the level of performance that might result from more frequent procurement. Two- and three-year durations are common in private PBM contracts.¹⁶ As already noted, a key issue when procuring multiyear exclusive contracts is how to stimulate competition and thus performance after the initial round of procurement, given that a monopoly franchise has been awarded. If the threat of switching contractors in the second and subsequent rounds is not perceived as real by potential bidders, some may choose not to bid, and the gains from competition are likely to be lost.¹⁷

■ **Formularies and drug pricing.** Drug formularies (lists of drugs covered by a plan) are a primary tool of pharmacy benefit

management. Formularies, which are tied to reimbursement rules, may be more or less restrictive, with “open” formularies placing no restrictions on drugs for which an enrollee can receive coverage and “closed” formularies providing coverage only for those drugs on the formulary list. A closed formulary gives the PBM the greatest leverage with manufacturers in negotiating price discounts because the PBM is able to shift the maximal patient volume to the manufacturer offering the most advantageous prices. Implementing a national closed formulary for Medicare, however, would put the government in the position of strongly influencing the market shares of various drugs and would severely limit choice. Instead of using a closed national formulary, we propose that each PBM bid an open formulary and use incentive pricing to encourage price competition between manufacturers and efficient choices by consumers.

Incentive pricing. Incentive pricing is a method of introducing price competition for pharmaceuticals while making consumers and physicians (as agents of consumers) sensitive to the relative prices of drugs used to treat a particular illness.¹⁸ Under an incentive-price system, a “reference drug” is selected for each drug class. In general, this would be the lowest-price drug in the class. The price of that drug is fully covered except for any copayment that may be specified by the benefit design for all prescription drugs.¹⁹ If the patient fills a prescription for a drug that is not the reference drug for a particular class, the patient pays the difference in prices. Incentive pricing creates competition among manufacturers to offer low prices to PBMs so that their product will be selected as the reference drug in a particular class.

The use of incentive pricing would differ among three types of drug classes: (1) those that include a generic equivalent; (2) those that include more than one brand-name drug but no generic equivalent; and (3) those that include a single brand-name drug (typically new drugs, which have not yet attracted so-called me-too drugs). An incentive-price system can be used for the first two classes but is not feasible for the third.

A key aspect of incentive pricing is how drugs are grouped into classes for the purpose of pricing.²⁰ For example, should a therapeutic class include all antidepressants (which would include older tricyclic antidepressants [TCAs], newer selective serotonin reuptake inhibitors [SSRIs] such as Prozac, and atypical antidepressants), or should TCAs and SSRIs be separate classes? This issue is particularly complicated when a drug has a different side-effect profile than other drugs that treat the same condition.

Ideally, a class should comprise drugs that are close substitutes in treating a given condition. Clearly, generics and brand-name prod-

ucts with the same active ingredient would be in the same class. The difficult judgment call involves deciding when brand-name drugs that are similar but have different active ingredients are similar enough to be considered in the same class.

How therapeutic classes are defined has important implications for the level of price competition that can be achieved and for the quality of clinical care. There are two steps involved. The first, which has a high technical content, is simply describing the similarities and differences among drugs. An example might be which drugs should be considered TCAs and which SSRIs. The second, which has policy relevance, addresses which drugs beneficiaries should pay additional money to receive. An example might be whether TCAs and SSRIs should be considered one class or two.

The first type of decision could presumably be made within the U.S. Food and Drug Administration (FDA), but the second type will require a different apparatus. One option is to leave the second decision within the executive branch, subject to review from an outside panel of clinical and policy experts. This would be analogous to the current policy of allowing HCFA to modify the definitions of diagnosis-related groups (DRGs), subject to review by the Medicare Payment Advisory Commission (MedPAC).

The incentive price for a given therapeutic class would be based on a defined daily dose and a thirty-day supply (the standard supply for most prescription drugs), with the exception of certain short-term medications such as antibiotics. In general, the patient would pay any difference in price resulting from the convenience associated with the number of or ease of administration for particular forms of a given drug. For example, if a drug comes in a multiple-dose-per-day form and in a more expensive single-dose-per-day form, the incentive price would be based on the lower-price multiple-dose form.

Appeals to the policy-setting board could be made in cases where there would be better compliance, improved patient response, and/or lower total Medicare costs from one form versus another. In such cases, the panel could waive the differential cost of the non-reference drug. As a further precaution, drugs for which allowing therapeutic interchange would raise serious quality concerns could form a separate class. This is particularly attractive if the drugs in question account for only a small amount of spending.

As new competitors appear in the marketplace and company pricing policy changes, PBMs must have the ability to change the reference drug. Frequent changes, however, could confuse physicians, pharmacists, and beneficiaries. We suggest that PBMs should only be able to change the reference drug no less than annually.

For the third class of drugs, those with no close substitutes, some kind of reimbursement rule is essential; Medicare should not have to pay any price a manufacturer names for its product.²¹ At the same time, any reimbursement rule must preserve incentives for innovation. Some countries make reimbursement a function of prices for the same drug in other developed countries. Such a rule is problematic for Medicare because the price, which would reflect the price-regulation systems of other countries, might not cover U.S. research and development (R&D) costs.

Instead, we propose a two-prong strategy. For drugs with relatively small Medicare shares, Medicare would pay the lowest transaction price (less rebates and discounts) that private managed care plans pay for the drug. Such prices reflect a market price in the private sector and so avoid the potential chilling effect that government price setting could have on drug development. Because this rule would distort private market prices upward, and because the distortion would rise with the Medicare market share, it cannot be used for drugs with a sufficiently high Medicare share.²² For those drugs we see no alternative to HCFA negotiating or Congress specifying a price, as is the case now for erythropoietin for renal patients.²³ The Medicare share at which the private market price should no longer be used for reimbursement is a difficult question, and we leave it for future work should our general approach prove attractive.

Unlike a closed formulary, which offers no coverage for nonformulary drugs, an incentive-price system allows for heterogeneity in individual clinical needs, preferences, and responses to specific medications. Differences in individual valuations of treatment benefits and side effects are recognized by allowing coverage up to the incentive price for all drugs in a given class and allowing people to pay more if extra benefits exist for them. If substantial numbers of beneficiaries did pay for a nonreference drug, consideration then should be given to establishing a separate class.

There will undoubtedly be cases in which the reference drug is not clinically appropriate for a patient. An exceptions policy could be established so that the patient is not charged the difference in price from the reference drug. For example, under the Department of Veterans Affairs (VA) national formulary, nonformulary drugs are covered if (1) there is a contraindication or adverse reaction to a formulary drug or a therapeutic failure of all formulary drugs; (2) no formulary alternative exists; or (3) the patient has previously responded well to a nonformulary drug and changing drugs is risky.²⁴

Unlike traditional Medicare, however, this policy is administered in the context of a fixed budget for the VA system as a whole. In

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Medicare the budget constraint would be more remote, and the administrative burden of an exceptions policy could be unmanageable. Each region could be administering care for 400,000 people or more. If the administrative burden became unmanageable, there could be a threshold for the exceptions process; for example, the beneficiary would have to incur additional charges of more than \$100 per year for the nonreference drug before asking for a clinical exemption from additional charges.²⁵ Even without a threshold, each PBM would have an internal appeals process, outlined in its bid, whereby consumers could appeal and seek full coverage of a nonreference drug. If a patient was then dissatisfied with the appeal outcome, the patient could follow standard Medicare appeals procedures. Also, grievances should be monitored by Medicare and used as a selection criterion in future procurements.

Competition and the distribution network. Because the cost of distributing drugs represents about 20 percent of drug spending, it is important to establish incentives for efficient distribution as well as efficient procurement. We therefore propose subjecting distribution costs to market forces by encouraging competition among retail pharmacies. Private-sector PBMs sometimes set up exclusive networks of pharmacies. The ability to exclude some pharmacies from the network creates price competition among the various outlets, and PBMs can search for the minimum price outlet. The danger in simply adapting this process for Medicare is that access to pharmacies might be too limited. Consequently, Medicare should set minimum criteria. For example, the government could specify in the RFP that 90 percent of the population in the region has to be within a fifteen-minute travel distance of a participating network (“reference”) pharmacy, a criterion common in private RFPs. These figures could vary between rural and urban areas.

The negotiated dispensing fee would be added to the manufacturer’s price for the reference drug to obtain the price Medicare would reimburse, along with a notice to beneficiaries about which outlets charge at that level. Consumers then would be obliged to pay for any difference in either dispensing fees or drug prices if they use a different outlet. For drugs used to treat chronic illnesses (when frequent monitoring of the patient’s response to the medication is unnecessary), mail-order firms could be part of the network, and their price could conceivably be the base price.²⁶

Although the monopoly PBM in a region would have substantial market power in negotiating with local pharmacies, four factors would mitigate that power: (1) Beneficiaries can pay an additional amount and use any pharmacy; (2) Medicare beneficiaries account for only about 40 percent of outpatient drug sales; (3) national-chain drugstores are unlikely to be shut out in all regions because they would negotiate with many PBMs; and (4) the minimum access requirement would serve to reduce the PBM's market power.²⁷

■ **Payment arrangements and risk sharing.** Private-sector PBMs are rarely placed at great financial risk for prescription drug costs and are typically paid a management fee for their services. This arrangement reflects the limits of their influence over physicians' prescribing decisions and thus over prescription drug use. PBMs do, however, have a number of levers for influencing pharmacy spending, including negotiation of discounts with pharmaceutical manufacturers, retailers, and mail-order firms; management of administrative costs; and use of generic-substitution policies.

As a result, we believe that a modest level of risk sharing with PBMs is appropriate to create a meaningful incentive for PBMs to use available tools to contain pharmacy costs. Risk sharing seems especially appropriate if the prices of reference drugs change more frequently than PBM contracts are negotiated (for example, PBMs obtain annual bids from manufacturers but have three-year contracts). PBMs bidding for a local contract would propose both a pharmacy claims target and an administrative fee. PBMs could be placed at limited financial risk within a "corridor" around the claims target.²⁸ For example, PBMs might assume 50 percent of the risk for savings or losses within 10 percent of the target; thus, the total dollars at risk would be 5 percent of the target. Obviously, the corridor size and risk-sharing percentages are choices to be made. PBM contracts also would include financial incentives for meeting performance standards such as access to pharmacies, speed in processing and paying claims, enrollee satisfaction, speed in addressing enrollees' and network pharmacies' concerns, and appropriateness of prescribing. Although the level of the PBM fee and the pharmacy claims target might differ across regions, the risk-sharing parameters and the performance incentives would be uniform. This type of risk-sharing arrangement would create stronger incentives for PBMs to control pharmacy benefit costs than are typical in most markets today.

Implications For Drug Spending

The institutional features we have discussed for strengthening PBMs' ability to control spending focus on creating competition for

PBM contracts, using PBM formularies and incentive pricing, and sharing financial risk with PBMs. What is the evidence that these mechanisms might control the costs of a Medicare drug benefit?

■ **Prices.** Incentive pricing is central to achieving lower prices. It has not been much used in the United States but has been used in several other countries, including Germany, the Netherlands, and New Zealand. It is, however, quite common for U.S. PBM formularies to require enrollees to pay at least some of the difference between generic and brand-name prices for the same chemical. A recent review of incentive pricing suggests that the systems in other countries have resulted in savings, particularly for brand-name drugs.²⁹ All countries with relevant experience, however, have heavily regulated health care systems, including regulated retail pharmacies, and their experience is therefore of limited applicability to the United States.

Risk sharing with PBMs strengthens incentives for reducing prices and quantities because the PBM also will share in any savings. Because the current U.S. PBM market is dominated by administrative services only (ASO) contracts with no risk sharing, there is no systematic domestic evidence of the effect of adding risk to PBM carve-out contracts. In other parts of the health care sector, however, passing even limited financial risk for claims costs onto managed care organizations has led to large reductions in spending.³⁰

■ **Spending on new drugs.** The evidence clearly shows that spending on new brand-name drugs has contributed strongly to the recent overall increase in prescription drug spending.³¹ The effect of our proposal on new-drug spending therefore depends on how incentive pricing is implemented. If price classes are broad, most new drugs will be part of the incentive price system. In this case, spending on “me-too” drugs would tend to be diminished, consistent with a belief that there have been few true breakthrough drugs. On the other hand, if reference price classes are narrow, more new drugs will be available without a surcharge, which would generally lead to a continuation of premiums being paid on modest improvements in products. For brand-name drugs with high Medicare shares and no close substitutes, costs will clearly depend on how prices are set.

■ **Prescription volume.** We expect effects on volume from DUR programs to be modest. Indeed, to the degree that such programs detect underdosage, use could theoretically increase.³² We would, however, include some financial incentives for meeting performance standards on appropriate prescribing and compliance with treatment guidelines, because that would probably reduce total medical spending, even if it raised drug spending. Also, the size of the base copayment, if any, could have a substantial effect on volume.³³

■ **Alternative approaches.** We contrast the ability of our proposal, which relies on competition for contracts and incentive pricing, to control costs with three other approaches to organizing a Medicare prescription drug benefit.

Competition for enrollees by multiple PBMs in a local market. As already mentioned, such competition would result in adverse selection. The problems stemming from adverse selection in the individual Medigap market prior to the reforms of the 1990 Omnibus Budget Reconciliation Act (OBRA), which to some degree continue to plague that market, would likely appear in this market as well, including greater risk from the higher premiums in the plans preferred by the sick.³⁴ Relative to our proposal, such a method would cater more to individual variation in taste, especially if drug classes or formularies and cost-sharing provisions were not standardized across PBMs, but that, of course, is precisely what brings about selection. Also, competition among PBMs for enrollees would result in higher PBM marketing and other administrative costs than would our proposed approach or the other approaches described below.

Three-tier copayment. Under this approach, which is increasingly common in private-sector insurance, cost sharing is lowest for generic drugs, higher for brand-name drugs that are on the formulary, and highest for brand-name drugs that are not on the formulary, an approach that has obvious similarities to our incentive pricing proposal. The level of risk for enrollees depends on the copayment amounts set for each tier. The three-tier copayment approach, however, would lead to higher prices for nonformulary, brand-name drugs and/or would lead to greater use of price setting than our proposal would. To see why, consider two methods for procuring drugs. First, PBMs or the government could obtain bids from manufacturers. The manufacturer would receive the bid price, and the government would pay the difference between the bid price and the patient's cost sharing from tax or premium revenue. In this case, manufacturers of brand-name drugs who expected their drugs not to be in the formulary would bid a higher amount than they would under our system. The reason is that a higher bid would not affect sales because the consumer copayment for nonformulary drugs does not rise with the bid under most three-tier arrangements, whereas it would rise dollar for dollar with our proposal.³⁵ While private-sector PBMs can credibly threaten to drop a drug altogether if its price is too far out of line and close substitutes are available, it is not clear that such a threat could be made under traditional Medicare. Second, the government could negotiate or simply set a take-it-or-leave-it price. As already noted, however, we prefer to minimize the extent of government price setting because of the negative effect it

could have on pharmaceutical R&D.

Unmanaged benefit with high enrollee cost sharing and benefit limits. Like an old-style major medical-type policy, this approach would use high cost sharing and an annual benefit cap to control costs. Particularly if employer-sponsored and individual indemnity Medigap coverage reimbursed cost sharing, this approach could lead to very high drug prices. By contrast, Medicare enrollees without additional coverage would be exposed to a high level of financial risk.

We believe that our approach of competition for regional contracts and incentive pricing would be the most efficient method by which Medicare could procure drugs. It is not, however, without some drawbacks. Relative to a single national contract, regional PBM contracts would result in some additional administrative costs. Also, the administrative costs of the exceptions process are not likely to be trivial, but the alternative of a no-exceptions process would be undesirable.

Final Score?

Our goal in this paper was to set out some specifics about the institutional arrangements governing the application of managed care to a prescription drug benefit. We sought to preserve the use of decentralized market forces found in the private sector while protecting Medicare beneficiaries from substantial risk.

Our approach has at its heart three main strategies: (1) competition for contracts by PBMs in a substantial number of local areas; (2) incentive pricing; and (3) risk sharing between PBMs and Medicare. Although their likely impact on drug spending remains highly uncertain, evidence from other types of managed care contracts indicates that they will result in greater ability to control spending than is typical in today's private PBM marketplace. Moreover, the enhanced cost control would be achieved through mechanisms that would strictly limit inefficiencies from adverse selection, limit the role of government primarily to that of a purchaser, and expand the technologies and forces at play in private markets into the public sector. In particular, competition instead of regulation is the main method by which prices would be set. Our proposal recognizes local differences in the health of populations and in patterns of care, and these could be used to define markets for PBMs.

Our discussion, however, has pointed to a number of difficult issues that need to be addressed to put these ideas into practice. In particular, establishing administrative processes for granting exceptions for individuals for nonreference drugs might be quite burdensome and create incentives to circumvent cost controls. Furthermore, setting up and defining procedures for the organization that

would determine drug classes pose difficult choices. All of these decisions must be made so as not to impose significant harm on an industry that is one of the most dynamic and innovative in America.

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The authors acknowledge financial support from the Alfred P. Sloan Foundation's Managed Care Industry Center at Harvard University. We are grateful to Patricia Danzon for helpful discussions and to Ernie Berndt, Barbara Cooper, Tom Croghan, Judy Lave, Tom McGuire, Murray Ross, Gail Wilensky, and three anonymous reviewers for comments. The views represented here are those of the authors alone.

NOTES

1. National Bipartisan Commission on the Future of Medicare, *Building a Better Medicare for Today and Tomorrow* (Washington: Bipartisan Commission, 16 March 1999); *Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 1999*, 106th Cong., 1st sess., H.R. 2925, November 1999; National Economic Council/Domestic Policy Council, *The President's Plan to Modernize and Strengthen Medicare for the Twenty-first Century* (Washington: The White House, 2 July 1999); and *Access to Rx Medications in Medicare Act*, 106th Congress, 1st sess., S. 841, 20 April 1999.
2. U.S. General Accounting Office, *Pharmacy Benefit Managers: FEHBP Plans Satisfied with Savings and Services, but Retail Pharmacies Have Concerns*, Pub. no. HEHS-97-47 (Washington: U.S. Government Printing Office, 21 February 1997).
3. H. Grabowski and C. Mullins, "Pharmacy Benefit Management, Cost-Effectiveness Analysis, and Drug Formulary Decisions," *Social Science and Medicine* 45, no. 4 (1997): 535-544.
4. Statement of Dan L. Crippen, director of the Congressional Budget Office, on the president's proposal for Medicare reform before the U.S. Senate Finance Committee, 18 March 1999.
5. Others have considered these issues, including L. Etheredge, "Purchasing Medicare Prescription Drug Benefits: A New Proposal," *Health Affairs* (July/Aug 1999): 7-19; and M. Gluck, *A Medicare Prescription Drug Benefit* (Washington: National Academy of Social Insurance, April 1999).
6. C. Copeland, *Prescription Drugs: Issues of Cost, Coverage, and Quality*, EBRI Issue Brief no. 208 (Washington: Employee Benefit Research Institute, April 1999).
7. R.G. Frank, T.G. McGuire, and J.P. Newhouse, "Risk Contracts in Managed Mental Health Care," *Health Affairs* (Fall 1995): 50-64.
8. Calculated from data in L.A. McCormack et al., "Medigap Reform Legislation of 1990: Have the Objectives Been Met?" *Health Care Financing Review* (Fall 1996): 157-174.
9. See D. Cutler and S. Reber, "Paying for Health Insurance: The Tradeoff between Competition and Adverse Selection," *Quarterly Journal of Economics* (May 1998): 433-466; and Etheredge, "Purchasing Medicare Prescription Drug Benefits."
10. See *Merk-Medco Managed Care LLC v Rite Aid Corporation et al.*, District of Columbia Court of Appeals, 7 September 1999.
11. P. Diamond, "Organizing the Health Insurance Market," *Econometrica* (November 1992): 1233-1254, discusses a similar approach for health care in general. Because most health care is local, it can be difficult to maintain competition for overall health care in the smaller local markets. Other than retail distribution, managing a pharmacy benefit is not inherently local, so maintaining competition for this particular benefit is less difficult than for health care as a whole.

12. The number of enrollees could vary among regions if enrollment were voluntary as for Medicare Part B. If the benefit were sufficiently subsidized to avoid selection, numbers should not vary much across regions.
13. Just as one carrier administers benefits in multiple regions, one PBM could administer benefits in multiple regions.
14. "PBM Industry Stabilizing amid Mergers and Spinoffs," *Managed Care* (May 1999): 60, online at www.managedcaremag.com/archive/MC/9905/9905.outlook.gif.
15. If retail pharmacies were permitted to bid on the contracts, competition could be restricted in the future. Consider the case of a retail chain that is the region's incumbent contractor and has the largest market share in that region. Say that the chain decides to bid on a subsequent contract for the region. For competitive reasons, the chain is unlikely to agree to be a part of a competing bidder's distribution network, so competition would be restricted in the future as other possible bidders are discouraged from bidding in that region.
16. PBM Institute, personal communication, 7 September 1999.
17. The threat to switch contractors is reduced if a contract bestows substantial advantages on an incumbent or requires or generates a high level of assets for the initial successful bidder that are not readily transferable to other bidders. Fortunately, this has not been the experience in procurements by states such as Massachusetts and Maryland or private employers.
18. *Incentive pricing* is sometimes termed *reference pricing*. We use the term *incentive pricing* because *reference pricing* is sometimes used to describe a system in which prices are a function of prices in other countries (something we are not proposing), and we wish to avoid confusion.
19. Such copayments are often used to address moral hazard on the part of consumers by making consumers more sensitive to the costs of services used, and the current prominent proposals include use of them. We do not take up the issue of the proper-size copayment, if any, for the reference drug.
20. P. Danzon, "Reference Pricing: Theory and Evidence" (Working Paper prepared for the Conference on Reference Pricing, Barcelona, December 1998).
21. Allowing beneficiaries to pay above the Medicare benefit in such cases would vitiate the financial protection of the benefit.
22. F. Morton, "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," *RAND Journal of Economics* (Summer 1997): 269–290. We also considered British-style rate-of-return regulation, but that seems difficult to apply to a subset of drugs.
23. British Columbia does this for all new drugs within the context of a fixed budget. Such a device may be necessary here if HCFA were to negotiate prices.
24. S. Kunzi, "National Drug Formularies," *Pharmaceutical Executive* (April 1999): 80–90.
25. In the case of a drug used to treat a chronic illness, an exemption once granted should automatically renew each year.
26. There could be considerable change in the distribution of drugs in the future, in particular, that more distribution will shift to mail or to the Internet. The Medicare benefit should not inhibit such change. Moreover, PBMs should have the option at set periods to negotiate new dispensing fees.
27. J. Poisal et al., "Prescription Drug Coverage and Spending for Medicare Beneficiaries," *Health Care Financing Review* (Spring 1999): 15–27, Table 2, gives spending by Medicare beneficiaries on prescription drugs in 1995 as \$22 million. K. Levit et al., "National Health Expenditures, 1995," *Health Care Financing Review* (Fall 1996): 175–214, Table 5, gives total drug spending in 1995 as \$55.5 million.
28. The lack of data on utilization patterns for potential enrollees within each of the defined markets in the first round of procurement will result in uncertainty with respect to the appropriate claims target and fee for a PBM to bid.

- Thus, the level of risk passed to each PBM could be limited for the first contract, and additional risk could be passed to PBMs in subsequent rounds.
29. Danzon, "Reference Pricing." In its 1998 Annual Report, the New Zealand Pharmaceutical Management Agency Limited (PHARMAC), a quasi-public company that manages the national pharmaceutical schedule on behalf of the Health Funding Authority, reports that Novartis agreed to lower the price of Voltaren by 25 percent on average, and the incentive pricing system resulted in the price of most nonsteroidal anti-inflammatory drugs (NSAIDs) dropping to the new Voltaren price. Similar savings have not been achieved for generics largely because these products are typically already subject to intense price competition. In fact, Danzon notes that the generic price is sometimes higher under incentive pricing if the original generic price was less than the incentive price for the therapeutic class. This should not happen if the generic price is the incentive price.
 30. Savings of 20–40 percent have been observed. See, for example, J.J. Callahan et al., "Mental Health/Substance Abuse Treatment in Managed Care: The Massachusetts Medicaid Experience," *Health Affairs* (Fall 1995): 173–184; R. Frank and T. McGuire, "Savings from a Medicaid Carve-Out for Mental Health and Substance Abuse Services in Massachusetts," *Psychiatric Services* 48, no. 9 (September 1997): 1147–1152; W. Goldman, J. McCulloch, and R. Sturm, "Costs and Use of Mental Health Services before and after Managed Care," *Health Affairs* (Mar/Apr 1998): 40–52; and C.A. Ma and T.G. McGuire, "Costs and Incentives in a Behavioral Health Carve-Out," *Health Affairs* (Mar/Apr 1998): 53–69.
 31. K. Levit et al., "National Health Expenditures in 1997: More Slow Growth," *Health Affairs* (Nov/Dec 1998): 99–110, shows that total U.S. drug spending grew 26 percent between 1995 and 1997, whereas the number of prescriptions filled grew by 9 percent. The Consumer Price Index (CPI) (as well as the producer price index, or PPI) for prescription drugs, which priced a constant market basket of drugs, grew 6 percent in these two years (<http://146.142.4.24/cgi-bin/srgate>). Inferentially, the difference in spending growth and what can be accounted for by spending on existing drugs, 10 percent, is attributable to new drugs (.10 = 1.26–(1.09)(1.06)). Furthermore, much of the 9 percent growth in prescriptions is also likely attributable to new drugs.
 32. There is substantial evidence of duplicative and inappropriate prescribing, so this outcome is possible. See Institute of Medicine, *To Err Is Human: Building a Safe Health Care System*, ed. L.T. Kohn, J.M. Corrigan, and M.S. Donaldson (Washington: National Academy Press, 1999).
 33. A.L. Hillman et al., "Financial Incentives and Drug Spending in Managed Care," *Health Affairs* (Mar/Apr 1999): 189–200.
 34. McCormack et al., "Medigap Reform Legislation of 1990"; and T. Rice, M.L. Graham, and P.D. Fox, "The Impact of Policy Standardization on the Medigap Market," *Inquiry* (Summer 1997): 106–116.
 35. Under some three-tier copayment arrangements, an enrollee must pay a percentage of a third-tier drug's price as cost sharing. For these arrangements, enrollee cost sharing rises with price but not dollar for dollar as under our proposal.