

The New Medicare Drug Benefit: Potential Effects of Pharmacy Management Tools on Access to Medications

Prepared by:

Haiden A. Huskamp, Ph.D.
Harvard Medical School
Department of Health Care Policy

Nancy L. Keating, M.D., M.P.H.
Brigham and Women's Hospital
Division of General Medicine and Primary Care
Harvard Medical School
Department of Health Care Policy

Prepared for:

The Henry J. Kaiser Family Foundation

July 2004

We are grateful to Tricia Neuman and Gary Claxton for many helpful comments on an earlier draft.

The New Medicare Drug Benefit: Potential Effects of Pharmacy Management Tools on Access to Medications

Prepared by:

Haiden A. Huskamp, Ph.D.
Harvard Medical School
Department of Health Care Policy

Nancy L. Keating, M.D., M.P.H.
Brigham and Women's Hospital
Division of General Medicine and Primary Care
Harvard Medical School
Department of Health Care Policy

Prepared for:

The Henry J. Kaiser Family Foundation

July 2004

Executive Summary

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 represents the most significant expansion of the Medicare program in almost 40 years. The law created Medicare Part D, a voluntary prescription drug benefit to be implemented in 2006. A primary goal of Part D is to increase access to prescription drugs for seniors and Medicare enrollees who have disabilities, particularly those with low incomes and/or catastrophic drug expenses.

The legislation specifies that the prescription drug benefit will be administered by private health care organizations under contract with the Department of Health and Human Services (DHHS). The Congress is relying on these organizations to control benefit costs using pharmacy management tools common in the private sector. These include prescription drug formularies (lists of drugs available for coverage by the plan), patient cost sharing, and drug utilization management programs. The legislation gives Part D plans substantial flexibility in structuring the pharmacy management tools they will use to control utilization and costs. There are two main concerns about how plans may use this flexibility. The first concern is that the application of these tools could restrict access to needed medications for some beneficiaries. The second concern is that plans will use these tools to discourage beneficiaries with high prescription drug expenditures from enrolling. The decisions that plans make regarding formularies, cost sharing requirements and utilization management programs could have important implications for Part D's ability to improve access to needed medications, as could the method that will be used to risk-adjust payments to plans.

Formularies. Three important elements of formulary design that have implications for access to prescription drugs are: 1) definitions of therapeutic categories and classes; 2) selection of formulary drugs and assignment of specific drugs to tiers; and 3) the process for obtaining formulary coverage for non-formulary drugs (i.e., the reconsideration process).

- *Drug category and class definition.* Plans are required to cover only a subset of drugs in each category and class. If a plan defines a class broadly (e.g., all antidepressants) instead of narrowly (e.g., selective serotonin reuptake inhibitors (SSRIs), such as Prozac, Paxil, and Zoloft), the formulary could cover a much smaller number of drugs used to treat a given condition. This would result in more restricted access to medications and could discourage beneficiaries who use those types of drugs from enrolling in the plan. Participation of a given plan is conditional on the Secretary of DHHS not finding “that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan (Conference Report, H.R. 1).” However, it is unclear what criteria the Secretary would use to assess whether plan features would “substantially discourage enrollment” or the extent to which these criteria would be enforced. The way a plan chooses to define categories and classes will affect the relative generosity of the coverage and the group of enrollees attracted to the plan.

- *Selection of formulary drugs and tier assignment.* When selecting a Part D plan, Medicare beneficiaries who use one or more high-cost medications to treat chronic conditions may check the formularies of plans serving their region to see if the medications they take are on the formulary and in which tier. For example, under a three-tier formulary, the first tier typically includes generic drugs with the lowest cost sharing (e.g., \$10 copayment), the second tier includes preferred brand-name drugs with higher cost sharing (e.g., \$25 copayment) and the third tier includes non-preferred brand-name drugs with the highest cost sharing (e.g., \$50 copayment). Beneficiaries may look at each formulary to see whether the drugs they take are on tiers 1 and 2 with lower cost sharing instead of tier 3. As a result, the particular drugs a plan selects for formulary coverage or for tier 2 status on a three-tier formulary will be important for determining which enrollees will be likely to join a particular plan. To take an extreme example, if a plan includes on its formulary only drugs with lower efficacy or more severe side effects than other drugs used to treat a particular condition, individuals with that condition would be less inclined to join the plan. For instance, if a plan includes only lovastatin (the generic version of Mevacor) and Pravachol as cholesterol-lowering medications, patients with particularly high levels of low-density lipoprotein (LDL) levels will be less likely to join since Lipitor has been found to be more effective for patients with high LDL levels (Brown et al.).
- *Formulary coverage reconsideration process.* Each Part D plan is required to have formal procedures that allow enrollees to request reconsideration of drug coverage decisions (i.e., which drugs are considered “non-formulary”) and the application of tiered cost-sharing. For example, if a patient with osteoarthritis does not respond to and/or tolerate the two generic non-steroidal anti-inflammatory drugs (NSAIDs) on the formulary, the patient can request coverage of a non-formulary NSAID. The reconsideration process is particularly important because the costs of non-formulary drugs do not count toward the out-of-pocket maximum for beneficiaries. The rate at which reconsideration requests are granted and the burden placed on patients and providers will have important implications for access as well as whether certain types of enrollees stay enrolled in the plan or switch to another plan.

Coinsurance for Specific Drugs. For the standard benefit packages, the enrollee will pay coinsurance (a percentage of the cost of each prescription) for all drug expenditures between the deductible and initial coverage limit. The legislation requires that plans charge enrollees either 25% coinsurance for all drugs or the actuarial equivalent of an average coinsurance rate of 25% across drugs. Although the legislation is somewhat unclear on this issue, the latter option could mean that plans could impose higher coinsurance rates for classes of very expensive medications and lower coinsurance rates for classes of relatively inexpensive medications, which could discourage individuals who use particularly high-cost medications from enrolling. For instance, a plan could require 60% coinsurance for anti-retroviral medications (extremely expensive drugs used to treat HIV/AIDS) but just 5% coinsurance for inexpensive drugs like thiazide diuretics used to treat hypertension.

Utilization Management Program. Plans are required to implement a utilization management program that provides incentives to use lower-cost medications when appropriate. Plans could choose to focus utilization management activities on a subset of

classes that are particularly high-cost. Utilization management program activities for high-cost medications could include: 1) requiring documentation of certain clinical characteristics before granting approval for coverage of a non-formulary drug; 2) requiring that a patient fail on a generic drug or a lower-cost brand drug before granting approval for a more expensive brand medication; or 3) requiring a patient to obtain reauthorization every few months to use particular drugs. For instance, a plan could have a utilization management program for depression that required patients to fail fluoxetine (the generic version of Prozac) and paroxetine (the generic version of Paxil) before granting approval for patients to use other antidepressants. Through these utilization management techniques, a plan could encourage patients and their physicians to select lower-cost drugs and possibly discourage individuals who use drugs affected by the utilization management programs from maintaining enrollment in a given plan.

Risk Adjustment Methodology. The legislation specifies that plan payments will be adjusted for the financial risk posed by individual beneficiaries who enroll (a process known as “risk adjustment”) so that plans enrolling patients who are expected to require more expensive medications will receive higher payments. The Secretary of DHHS is responsible for developing the risk adjustment methodology. The methodology will affect plan incentives to engage in efforts to avoid the highest-cost enrollees.

Implications. During the congressional debate, much of the attention was focused on nominal benefits (e.g., the size of the deductible, out-of-pocket maximum, and the “doughnut hole”). Relatively little attention was paid to details about how plans would operate and the kinds of cost containment tools they could use. However, these tools are just as important as nominal benefit design in determining enrollee access to medications and subsequent out-of-pocket costs. Strict application of these tools could result in overly restrictive coverage, particularly for the highest-cost drugs.

The regulations being written by the Centers for Medicare & Medicaid Services (CMS) will be critical in filling in some of the details not provided in the legislation. These details, including the specifics of the actuarial valuation process, methods for risk adjusting plan payments and how the Secretary will determine if a plan’s design discourages enrollment by certain types of enrollees, will determine the incentives plans ultimately face and clarify how plans can use cost containment tools to act on these incentives. CMS must pay particular attention to provisions affecting formulary design, cost-sharing and utilization management in order to ensure that individuals most in need of drug coverage (i.e., those with the highest drug expenditures) have access to needed medications. How plans structure these items could have a substantial impact on the generosity of the coverage, the out-of-pocket burden faced by beneficiaries, and, ultimately, the long-term stability of the Part D program.

Key Provisions Related to Pharmacy Management Tools that Have Implications for Access to Medications and Out-of-Pocket Burden

- Plans may choose type of formulary (e.g., three-tier, four-tier, closed)
- Plans may define therapeutic categories and classes as they wish and are required only to include two or more drugs in each category and class
- Non-formulary drugs are not covered by the plan unless a reconsideration request is granted, and expenditures for these drugs do not count toward the beneficiary's out-of-pocket maximum
- For expenditures between the deductible and initial coverage limit, plans can require different coinsurance levels for different drugs (e.g., higher coinsurance for more expensive medications) as long as the actuarial value of coinsurance is 25% on average
- Plans must adopt utilization management programs and could focus them only on the most expensive drugs
- For a plan to be approved, the Secretary of DHHS must not find that the plan's benefit design (including formulary structure) is likely to "substantially discourage enrollment" by certain Part D eligible beneficiaries. The legislation provides no specific criteria by which to evaluate this requirement.

Important Responsibilities Assigned to the Secretary of DHHS

- Development of risk adjustment methodology for plan payments
- Development of guidelines for actuarial valuation process
- Development of criteria and process by which to assess whether "the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan (Conference Report, H.R. 1)."

The New Medicare Drug Benefit: Potential Effects of Pharmacy Management Tools on Access to Medications

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 represents the most significant expansion of the Medicare program in almost 40 years. The law created Medicare Part D, a voluntary prescription drug benefit to be implemented in 2006, as well as an interim drug discount card program and a transitional assistance program to be implemented this year. A primary goal of Part D is to increase access to prescription drugs for seniors and Medicare beneficiaries who have disabilities, particularly those with low incomes and/or catastrophic drug expenses.

The legislation specifies that the prescription drug benefit will be administered by private health care organizations under contract with the Department of Health and Human Services (DHHS). These organizations (also called “plan sponsors” or “Part D plans”) could be pharmacy benefits managers (PBMs) or other managed care organizations. The Congress is relying on these organizations to control benefit costs using pharmacy management tools common in the private sector. These tools include prescription drug formularies (lists of drugs available for coverage by the plan), patient cost sharing, and drug utilization management programs intended to influence which drugs patients use and how long they use them. Because several Part D plans will compete for enrollees in each region and they face some financial risk for drug costs, plans have an incentive to try to minimize drug expenditures to remain competitive in the market.

The legislation gives Part D plans substantial flexibility in structuring the pharmacy management tools they will use to control utilization and costs. There are two main concerns about how plans may use this flexibility. The first concern is that the application of these tools could restrict access to needed medications for some beneficiaries. The second concern

is that plans will use these tools to discourage beneficiaries with high prescription drug expenditures from enrolling. The decisions that plans make regarding formularies, cost sharing requirements and utilization management programs could have important implications for Part D's ability to improve access to needed medications as well as its ultimate cost to the Medicare program.

This report will provide an overview of the new Medicare Part D benefit, describe general incentives created by competition among plans, discuss incentives for plans created by specific features of the legislation regarding pharmacy management tools, and present several case studies of particular medical conditions to illustrate how these features could ultimately affect access to medications used to treat the conditions. The report focuses on the new drug benefit to be implemented in 2006 and not the prescription drug card or the transitional assistance programs.

I. Summary of the New Benefit

Below we summarize features of the Part D program that are important for understanding the financial incentives plans will face and how the legislation allows plans to respond to these incentives. These features include nominal benefit design, the government subsidy and enrollee premiums, financial risk for plans, plan competition, and use of pharmacy management tools including formularies, cost sharing and utilization management.

Basic Structure of Program. Medicare Part D is a voluntary drug benefit available to those eligible for Part A or enrolled in Part B of the Medicare program. The benefit will be delivered either through private drug-only plans (for those enrolled in the Medicare fee-for-service program) or through comprehensive health plans that include drug benefits (formerly called Medicare+Choice plans but renamed Medicare Advantage plans). Currently,

approximately 4.6 million of the 41.7 million Medicare beneficiaries (about 11%) are enrolled in Medicare Advantage plans and the remaining 89% are enrolled in the fee-for-service program (Kaiser Family Foundation). The legislation increases aggregate payment rates for Medicare Advantage plans, which may encourage new plans to enter the program and result in greater managed care plan enrollment in the future. However, in 2006, it is likely that most Medicare beneficiaries will continue to be enrolled in the fee-for-service program and will join a drug-only plan.

Nominal Benefit Design. Plans may offer the standard Part D benefit or basic coverage that is actuarially equivalent¹ to the standard benefit. In addition, they may offer a supplemental benefit plan with more generous coverage.

Under the standard benefit to be implemented in 2006, enrollees will be required to pay a \$250 annual deductible before the plan begins covering drug expenses. After the deductible is met and up to an initial coverage limit of \$2250, the enrollee pays coinsurance (a percentage of the cost of the medication) for each prescription that is actuarially equivalent to an average of 25% of a prescription's cost. For a beneficiary with total drug costs of \$2250, the cost to the patient would be approximately \$750 on average (i.e., \$250 deductible plus 25% coinsurance on \$2000). Enrollees are then responsible for 100% of drug expenditures greater than \$2250 until they reach the out-of-pocket maximum of \$3600 in 2006, often referred to as the "doughnut hole" because of the lack of coverage in the "middle" of the benefit. Once an individual spends over \$3600 out of pocket in a single year, the individual is required to pay the greater of: 1) 5% coinsurance for each prescription, or 2) a \$2 copayment for each generic drug and a \$5 copayment for each brand drug. Plans, which are often able to negotiate discounted prices from drug manufacturers, must allow enrollees access to their

discounted Part D prices for all expenditures up to the out-of-pocket maximum (i.e., even expenditures for which the enrollee is fully responsible).

With the approval of the Secretary of DHHS, plan sponsors wishing to offer basic coverage other than the standard benefit described above may offer any benefit that is actuarially equivalent to the standard benefit as long as the deductible does not exceed \$250, the out-of-pocket maximum does not exceed \$3600 and the coverage between the deductible and the initial coverage limit requires cost sharing of 25% on average (note that it may be possible to use a different initial coverage limit as long as the plan meets the actuarial value requirements – the legislation is somewhat unclear about this). For a higher premium, plan sponsors may also offer a supplemental benefit package with lower cost sharing or a higher initial coverage limit as long as they offer a benefit package with basic or standard coverage in the same region. The benefit design for each supplemental benefit plan will determine the access to medications that the plan will provide.

Government Subsidy and Enrollee Premiums. The legislation specifies that the government will pay a subsidy equal to 74.5% of the national weighted average of standard coverage bids submitted by plan sponsors and adjusted for regional differences in drug prices. This payment can include a combination of direct premium payments by the government and reinsurance payments (described below). Payments to the plans will also be adjusted for the financial risk posed by individual beneficiaries who enroll (a process known as “risk adjustment”) so that plans enrolling patients who are expected to require more expensive medications will receive higher payments. The Secretary of DHHS is responsible for developing the risk adjustment methodology. Additional subsidies are provided for low-income enrollees.

¹ Two plans are considered “actuarially equivalent” if total covered drug expenditures for a particular average

Enrollees will pay a monthly premium equal to the difference between the government subsidy for standard coverage and the cost of the Part D plan they select (i.e., if they select a plan with more generous benefits, they pay the full difference in premiums). The average enrollee premium for standard Part D drug coverage in 2006 is estimated by the Congressional Budget Office (CBO) to be \$35 per month (CBO).

Financial Risk for Plans. Medicare shares risk with the Part D plans for the cost of prescription drugs used by enrollees through two mechanisms: reinsurance and risk corridors. First, the government will provide reinsurance payments for particularly high-cost enrollees. Through this mechanism, the government will reimburse plans for 80% of allowable drug costs after a patient's expenditures have exceeded the out-of-pocket maximum. Thus, the plan is only responsible for 20% of expenditures over the out-of-pocket maximum.

Second, the government shares risk with the plans through risk corridors. Under the risk corridor arrangement, the government sets a target for drug expenditures equal to total premiums minus administrative costs. The government specifies one or more "corridors" of risk around that target and holds plans responsible for some or all of the costs that fall within that window. In 2006, plans will be fully responsible for costs between the target amount and 2.5% of the target amount. Plans will also be responsible for 25% of costs in the risk corridor between 2.5% and 5% of the target and for 20% of costs greater than 5% of the target. As an example, consider a plan with a target of \$1000 but actual costs for a patient equal to \$1100 on average. In 2006, the plan would be fully responsible for costs between the target and 2.5% of the target, or \$25 (i.e., $\$1025 - \$1000 = \$25$). The plan would also be responsible for 25% of costs between 2.5% and 5% of the target (i.e., 25% of the amount between \$1025 and \$1050, or approximately \$6) and 20% of costs greater than 5% of the target (i.e., 20% of the

person would be the same if she enrolled in one plan as if she enrolled in the other plan.

difference between \$1100 and \$1050, or another \$10). In sum, the plan would be responsible for approximately \$41 (\$25+\$6+\$10) of the \$100 by which the plan's actual costs exceeded the target (i.e., \$1100-\$1000). Thus, the government protects plans against some financial risk for high-cost enrollees by sharing losses within the corridors when costs exceed the target. The government also shares savings within the corridors when costs are lower than the target.

Plan Competition. Drug plans will compete for enrollees within a geographic region. A minimum of two plans must be available in each region (one of which must be a private drug-only plan). In areas without two or more approved plans, the Secretary can approve plans that agree to participate at a lower level of financial risk than described above (i.e., limited risk plans). In the event that two plans are still not approved to serve a given region (i.e., even limited risk plans), enrollees can enroll in a "fallback" prescription drug plan identified by the Secretary that places no financial risk for drug costs on the plan sponsor.

Formularies, Cost Sharing and Utilization Management. The legislation allows plans to implement pharmacy management tools, such as formularies (including tiered formularies), cost sharing and utilization management programs to manage drug expenditures, and these strategies will be discussed in detail below. Briefly, formularies are lists of prescription drugs available to enrollees, and tiered formularies provide financial incentives for patients and their physicians to select lower-cost drugs on the list. The formularies must be developed by a pharmacy and therapeutics (P&T) committee, an advisory committee for the plan that reviews the clinical literature and makes recommendations regarding which drugs should be placed on the formulary, usually on the basis on clinical efficacy and cost. The P&T committee must include practicing pharmacists and physicians.

The most common type of tiered formulary used today is the three-tier formulary

(Kaiser/Hewitt). Under a three-tier formulary, the first tier includes generic drugs that require the lowest level of cost-sharing (e.g., \$10), the second tier includes preferred brand-name drugs that require a higher level of cost-sharing (e.g., \$25), and the third tier includes non-preferred brand-name drugs that require the highest level of cost-sharing (e.g., \$50). In 2003, approximately 55% of the largest health plans covering retirees age 65 and older used a three-tier formulary (Kaiser/Hewitt). Approximately two-thirds of the plans with a three-tier formulary required only flat copayments (e.g., \$25) for retail pharmacies while the other third required beneficiaries to pay coinsurance (e.g., 10% of the cost of the prescription). Plans and employers use tiered formularies for two main reasons: 1) to encourage patients and their physicians to choose lower-cost drugs in a class; and 2) to increase bargaining power with pharmaceutical manufacturers, which may allow the plan or employer to negotiate discounts and rebates (Frank). Manufacturers are often willing to negotiate discounts or rebates with plans that list the manufacturer's drugs in tier 2 instead of tier 3 because of the increased prescription volume likely to result from a tier 2 listing with a lower copayment. Plans are permitted to use any type of tiered formulary, including formularies with four or more tiers and formularies that require coinsurance instead of flat copayments.

The legislation states that formularies “must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes (Conference Report, H.R. 1).” The law does not require plans using a three-tier formulary to include drugs in tier 2 for each category and class (instead the plan could place all brand drugs in tier 3, with the highest copayment). The legislation calls on the U.S. Pharmacopeia (a non-governmental organization that sets standards related to purity and strength of prescription and non-prescription drugs) to develop a model classification system for drug categories and classes. However, plans are not required to adopt the model system

and can define therapeutic categories and classes as they wish as long as the Secretary of the DHHS approves the overall plan design. Plans are permitted to change drug category and class definitions only at the beginning of each year. Expenditures for drugs not on the formulary (i.e., “non-formulary drugs”) are not covered by the plan, nor can they be counted towards the out-of-pocket maximum. As a result, patients have a strong financial incentive to choose drugs on the formulary where possible. However, plans are required to have a formal process through which enrollees can request that a non-formulary drug receive formulary coverage.

Plans must adopt a utilization management program that provides incentives to reduce costs when clinically appropriate and a quality assurance program targeted at reducing medication errors. In addition, plans must implement a “medication therapy management program” that targets individuals with multiple chronic conditions and those taking multiple drugs to increase appropriate use of medications by enrollees and to prevent adverse drug events.

II. Adverse Selection: Competition Creates Incentives for Plans to Avoid High-Cost Beneficiaries

The legislation requires that a minimum of two plans compete in each geographic region. In theory, competition between two or more plans in a market is likely to result in lower costs and possibly higher quality as Part D plans compete on these attributes to enroll Medicare beneficiaries.

Plans can minimize their costs for prescription drugs in several ways. First, plans could encourage patients and their physicians to select lower-cost medications. For example, a plan could encourage a physician of a patient newly-diagnosed with depression to prescribe fluoxetine (the generic form of Prozac), instead of the more expensive brand-name drugs in

the class such as brand-name Prozac, or Zoloft or Celexa, for which generic alternatives are not yet available. Second, plans can negotiate lower prices with pharmaceutical manufacturers. For example, the Veterans Health Administration's (VHA) closed national formulary allowed the VHA to negotiate large price decreases from manufacturers (Huskamp, et al.; Institute of Medicine). As with most closed formularies, the VHA formulary typically includes only one or two drugs in a class and does not provide coverage for other drugs unless formulary rules are waived for a particular patient (described below). Third, plans could discourage inappropriate or unnecessary use of medications. For example, long-term use of sedatives or hypnotic agents (e.g., Valium, diazepam) is considered to be inappropriate for most patients. A plan could adopt a utilization management program that required physicians to obtain prior authorization to use a sedative/hypnotic drug over an extended period of time.

An additional and important way that plans can minimize costs is to enroll beneficiaries likely to have low drug expenditures, which can lead to something economists refer to as "adverse selection" in the market. Adverse selection occurs when one or more plans in a market (typically those with more generous coverage) disproportionately attract sicker or higher-cost patients and the plans are unable to charge higher premiums to those expected to have higher expenditures (Cutler and Zeckhauser). All things being equal, individuals with high expected expenditures are more likely to choose generous benefit plans than those people with more modest expected spending. To compensate for the fact that a plan attracted a high-cost patient population, the plan will be forced to raise premiums for all of its enrollees, which will lead healthier enrollees to leave the plan in search of less generous and more affordable coverage. Higher premiums will place the plan at a competitive disadvantage in the marketplace. Adverse selection can lead to instability in the insurance market because plans that disproportionately attract higher-cost enrollees over time may

ultimately withdraw from the market, leaving enrollees to find other coverage. Because no plan wants to risk enrolling a sicker population, plans may try to distort their benefits and other plan features in a way that makes their plan appealing to low-cost individuals and unappealing to high-cost individuals, attempting to achieve “favorable selection” (Cutler and Zeckhauser; Frank, Glazer and McGuire).

In the case of Part D, plan sponsors face some financial risk for drug costs, so they have an incentive to structure their drug plans in a way that will attract enrollees likely to have lower drug expenditures (as well as lower overall medical spending in the case of Medicare Advantage plans). Insurers can use benefit design as one means of controlling utilization of services and discouraging sicker individuals from joining a plan. For example, if a health plan wanted to discourage individuals who have severe and persistent mental illness (and often higher medical as well as behavioral health spending) from enrolling, the plan would restrict coverage of mental health services by using higher deductibles, higher cost-sharing or service caps for mental health care. Other strategies that can be used to control utilization and discourage sicker individuals from enrolling include the size and makeup of the provider network (e.g., a small panel of mental health specialists), the stringency of the utilization management process (e.g., requiring prior authorization for every three mental health visits in order to obtain coverage of the visits) and the structure of drug formularies (e.g., including on the formulary a small subset of drugs used to treat mental illness) (Ma and McGuire; Huskamp).

Adverse selection is a particular problem for goods and services for which use is highly predictable from year to year, such as prescription drugs (e.g., Ellis; Pauly and Zeng; Stuart et al.; Hogan; Wrobel). Today, many of the most expensive medications are used to treat chronic illness. As a result, an individual’s expenditures on these drugs are fairly

predictable from one year to the next. This is particularly true for the elderly, who have a higher prevalence of chronic illness overall. Although the level of knowledge and awareness of features of the Part D program will vary across beneficiaries, some Medicare beneficiaries will consider the drugs they used last year, the status of their chronic conditions and their likelihood of using many of those same drugs in the coming year when selecting a prescription drug plan. For example, a beneficiary who typically has high annual drug expenditures might be willing to pay a higher premium for a supplemental benefit plan that has a lower deductible and lower cost-sharing required for each prescription filled. A beneficiary who takes an expensive medication to treat a chronic condition might look for a plan that has that particular drug on its formulary.

There is some evidence that an individual's previous spending on prescription drugs has a strong influence on which health plan he chooses. In a study of non-elderly employees of a large firm, Ellis found that prescription drug spending in the previous year had a more pronounced effect on plan choice than prior outpatient general medical visits, outpatient mental health visits, lab tests and other ancillary services and inpatient expenditures (Ellis). Although similar evidence for an elderly population is not available, prior-year drug expenditures could have an even greater effect on plan choice among the elderly because drug expenditures may be even more predictable for this population. Offering more limited coverage of prescription drugs by using a restrictive formulary, high cost-sharing or strict utilization management, particularly for the most expensive drugs, would be likely to discourage individuals who expect to have high drug expenditures in the coming year. On the other hand, people with low drug use/costs might happily choose such a plan in order to pay a lower premium.

One way to temper the incentives for adverse selection is to risk-adjust payments to

plans so the plans are paid a higher premium for enrollees likely to have high drug expenditures. Closely linking a plan's payments to the expected prescription drug expenditures of the beneficiaries who enroll would reduce a plan's incentives to try to select the healthier or lower-cost individuals in the market (Newhouse, Buntin, and White). The legislation requires the Secretary of DHHS to develop a methodology for adjusting the bid amount to take into account variation in costs based on "the differences in actuarial risk of different enrollees being served (Conference Report, H.R. 1)."

A simplified example of plan incentives to avoid high-cost enrollees and the importance of risk adjustment of plan payments is provided in Exhibit A. The example is based on several assumptions regarding the level of direct government subsidy, reinsurance, plan administrative costs, enrollee premiums and coinsurance requirements for specific drugs, and is intended to be illustrative rather than definitive. The example does not account for any risk sharing with the government for expenditures in the risk corridors or for any rebates that plans negotiate with drug manufacturers.

The Centers for Medicare and Medicaid Services (CMS) estimated that the government will pay plans \$1306 per enrollee on average in 2006 (CMS). This estimate includes \$906 in direct subsidies and \$400 in reinsurance payments. The Congressional Budget Office (CBO) estimated average enrollee premiums to be \$35 per month (or \$420 per year) in 2006 (CBO). Because plans will not receive reinsurance payments for beneficiaries whose out-of-pocket expenditures are less than \$3600 (the out-of-pocket maximum in 2006), plans will be paid a total of \$1326 on average (\$420 in enrollee premiums and \$906 in direct government subsidies) for these enrollees. The \$1326 payment includes approximately \$146 in administrative costs (based on CBO estimate of 11% of payments), so average payments

for drug costs (i.e., net of administrative costs) for patients whose expenditures are lower than the out-of-pocket maximum are \$1180.

Consider three patients who are described in Exhibit A.² One patient has high levels of low-density lipoprotein (LDL) and no other medical problems. The other two patients have high levels of LDL and also have other comorbid conditions associated with heart disease, including diabetes and hypertension. Patient A uses only Lipitor, which costs approximately \$1000 per year. As described in Exhibit A, Patient A would pay \$437 (not including monthly premiums) and the plan would pay the remaining \$563. Patient B uses Lipitor to lower LDL, Norvasc and Cozaar to treat his hypertension, and metformin and Glipizide to treat his diabetes. Patient B's total annual medication costs are \$2660, an amount greater than the initial coverage limit but less than the out-of-pocket maximum. Patient B pays \$1160 (again, not including monthly premiums) and the plan pays the remaining \$1500. Finally, Patient C uses the same medications that Patient B uses, plus Plavix and atenolol to treat his recent heart attack, Effexor XR to treat major depression that occurred after his heart attack, and Celebrex to treat arthritis. Patient C's total annual medication costs are \$6320, an amount exceeding the out-of-pocket maximum. Patient C pays \$3661 (excluding monthly premiums) and the plan pays \$2659.

Total drug expenditures for Patients A and B are quite different (i.e., \$1000 vs. \$2660). Nevertheless, a plan would receive the same payment (\$1180 on average, net of administrative costs) for each patient in the absence of risk adjustment (Exhibit B). Plans would have an incentive to try to attract patients like Patient A for whom the plan's share of expenditures (in this case, \$563) are lower than the \$1180 average payment received by plans.

² Drug prices were obtained from the www.medicare.gov website on May 17, 2004. The quoted prices apply to pharmacies within 3 miles of residents living in the zip code 02446.

In contrast, plans have an incentive to try to discourage individuals like Patient B from enrolling because the plan's share of B's costs (\$1500) exceed the \$1180 payment the plan will receive.

Patient C's total drug expenditures, \$6320, are substantially higher than both Patients A and B. Because Patient C's out-of-pocket expenditures exceed the out-of-pocket maximum, the plan will receive an additional \$976 in reinsurance payments (i.e., 80% of the \$1220 in costs incurred after the patient hits the out-of-pocket maximum). Thus, the plan will receive a total payment of \$2156 (\$1180 + \$976) in the absence of risk adjustment. Because the plan's share of Patient C's costs (\$2659) exceeds the plan's payment of \$2156, the plan has an incentive to discourage patients with high drug expenditures like Patient C from enrolling.

Risk adjustment could help to reduce plan incentives to discourage patients with the highest costs and ensure that these patients are able to obtain coverage for medications. However, existing prospective methods of risk adjustment have been able to explain a relatively small proportion of variation in drug spending across individuals (Wrobel et al.). As a result, risk adjustment will not eliminate incentives for plans to discourage higher-cost beneficiaries from enrolling and is unlikely to prevent adverse selection completely.

III. Plan Incentives Created by Selected Part D Features: Provisions Governing Use of Pharmacy Management Tools Could Affect Access and Out-of-Pocket Burden

The cost containment techniques used by plans will affect the ultimate impact of Part D on access to medications, out-of-pocket spending by beneficiaries and spending by the Medicare program. In some cases, the intent of the legislation is unclear and the regulations that govern its implementation (not yet written by the Centers for Medicare & Medicaid Services (CMS)) will be necessary for clarification. However, the legislation as written gives

plans significant flexibility with respect to pharmacy management tools, including the structure and content of formularies, the level of cost sharing and the design of utilization management programs.

Formulary Structure and Content. Three important elements of formulary design that have implications for access to prescription drugs include: 1) definitions of therapeutic categories and classes; 2), selection of formulary drugs and assignment of specific drugs to tiers, and 3) the process for obtaining formulary coverage for non-formulary drugs (sometimes called a formulary “reconsideration” or “waiver” process).

Plan definition of therapeutic categories and classes. There is no universally-accepted classification system for therapeutic categories and classes of medications in the U.S. In general, one thinks of a therapeutic category as including drugs of different types used to treat similar conditions (e.g., antihypertensives). A therapeutic class is often viewed as a subset of drugs within a category that have similar properties or mechanisms of action (e.g., ACE inhibitors, calcium channel blockers).

How a plan defines categories and classes is important for two reasons: 1) plans are required to cover only a subset of drugs in each category and class; and 2) the costs of drugs not included on the formulary are not covered by the plan, nor do they count towards the enrollee’s out-of-pocket maximum. As noted above, the legislation states that plans must include “drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes (Conference Report, H.R. 1).” It is unclear whether this statement means that plans must cover two or more drugs in a class or just a single drug in each class (a more conservative interpretation of the language). The interpretation will have important implications for access to medications. For example, a formulary that covered only a single ACE inhibitor (a type of drug used to treat hypertension

and congestive heart failure) would offer no choice for patients for whom that particular drug is not effective or not tolerated.

To illustrate the potential implications of category and class definition, consider two alternative classification schemes for medications used to treat depression. First, a plan could define a drug category as “antidepressants” and a class within that category as selective serotonin reuptake inhibitors (SSRIs), a relatively new class of antidepressants that includes Prozac, Paxil, Zoloft, Celexa and Lexapro. Using this classification system, the plan would be required to include only a subset of SSRIs (e.g., Celexa, Zoloft) as well as a subset of drugs from other antidepressant classes defined in the formulary. Alternatively, a plan could define one category as “central nervous system agents” and a class within that category as “antidepressants,” which would include the tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), SSRIs and other newer antidepressants. TCAs and MAOIs are older drugs that are used less often today than SSRIs and other newer agents, primarily because of a less-favorable side effect profile (as well as dietary restrictions in the case of MAOIs). All TCAs and MAOIs have lost patent protection and have lower-cost generic equivalents available. Most SSRIs and other newer antidepressants have not yet lost patent protection and have significantly higher costs. Using the latter classification scheme where all antidepressants are included in a single class, a plan could, in theory, include only TCAs and MAOIs on the formulary. This type of approach could result in lower plan spending on antidepressants if patients with depression switched from more expensive, newer medications to lower-cost TCAs and MAOIs or if they continued their current medication and paid for it out-of-pocket. Use of the latter class definition might also discourage enrollment of individuals who have high expenditures for psychotropic medications because individuals using one or more of the newer antidepressants would prefer a plan with better formulary

coverage of the newer drugs.

Category and class definition are also important when a new medication that has a different mechanism of action than medications currently available to treat a particular condition is introduced. Consider the case of drugs used to treat Alzheimer's disease, a degenerative illness that affects the parts of the brain that control thought, memory, judgment and language. There is no cure for Alzheimer's disease, but medications called cholinesterase inhibitors (i.e., Cognex, Aricept, Exelon and Reminyl) may temporarily slow progression of symptoms and have been approved for the treatment of mild to moderate Alzheimer's disease. In October 2003, the Food and Drug Administration (FDA) announced approval of a new drug, Namenda, for treatment of moderate to severe Alzheimer's disease. Namenda has a different mechanism of action than the cholinesterase inhibitors (N-methyl-D-aspartate receptor antagonist or NMDA). Available data suggest that Namenda slows disease progression and is effective in patients already being treated with cholinesterase inhibitors (Reisberg et al; Winblad and Poritis; Tariot et al.). A plan could choose to consider NMDAs as a separate drug class and list Namenda as the covered drug for that class. Alternatively, a plan could define a class "Alzheimer's drugs" and include only a subset of the cholinesterase inhibitors on the formulary. Such a plan may be less desirable for patients with Alzheimer's disease and their families than a formulary that defined NMDAs as a separate class.

The legislation states that plan approval is conditional on the Secretary not finding “that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan (Conference Report, H.R. 1).” It is unclear what criteria the Secretary would use to assess whether plan features would “substantially discourage enrollment” or the extent to which these criteria would be enforced. This concept would be

extremely difficult to measure and to monitor over time, particularly given the possibility of annual changes in category and class definition and frequent changes in formulary content. It is likely that only truly egregious cases could be identified. The way a plan chooses to define categories and classes will affect the relative generosity of the coverage and the group of enrollees attracted to the plan. As a result, how this provision of the legislation is interpreted in the regulations may be extremely important in determining the extent to which Part D improves access to medications.

Plan selection of formulary drugs and assignment of specific drugs to tiers. When selecting a Part D plan, Medicare beneficiaries who use one or more high-cost medications to treat chronic conditions will likely check the formularies of plans serving their region to see if the medications they take are on the formulary and in which tier. As noted above, expenditures for non-formulary drugs are not covered by the plan and do not count toward the enrollee's out-of-pocket maximum. Among drugs that are included on the formulary, tier 3 drugs may require substantially higher cost-sharing than tier 2 drugs. As a result, which particular drugs a plan selects for formulary coverage or for tier 2 status on a three-tier formulary may be important in determining the type of enrollees attracted to the plan.

Consider the case of drugs used to treat osteoporosis, a disease that causes an individual's bones to become fragile and substantially increases the risk of fractures. Several drugs have FDA approval for the prevention and/or treatment of osteoporosis, including bisphosphonates like Fosamax and Actonel and the selective estrogen receptor modulator Evista. Although there are insufficient data directly comparing the effects of these different drugs, Evista appears to be less effective than the bisphosphonates in preventing hip fractures (NIH; Ettinger et al.). In addition, although Evista may be associated with a lower risk of breast cancer, it is associated with a greater risk of blood clots (NIH). As a result, a formulary

that includes only Evista or includes Fosamax and Actonel only on a higher tier with the highest copayment might be considered less desirable for many patients with osteoporosis than a formulary that includes only Fosamax or lists Fosamax in tier 2 with a lower copayment. Alternatively, such a formulary may be preferred for a patient who is concerned about having a high risk for breast cancer, even though definitive data demonstrating prevention of breast cancer are currently lacking.

In addition, how a plan addresses entry of a new, less expensive generic version of a brand drug in a class will affect access. Plans are prohibited from changing category and class definitions within a calendar year but the legislation is silent about formulary changes a plan can make when a generic alternative becomes available. An example is a three-tier formulary that listed Prozac and Celexa in tier 2 at the beginning of 2001. Once fluoxetine, the generic version of Prozac, became available in August 2001, the plan could have listed fluoxetine as a tier 1 generic drug and listed all brand SSRIs, including Celexa, in tier 3 with the highest copayment (i.e., have no tier 2 brand SSRIs on the formulary).

Plan process for obtaining formulary coverage for non-formulary drugs. A third key element of formulary design is the reconsideration and appeals process. Each plan sponsor is required to have formal procedures that allow enrollees to request reconsideration of drug coverage decisions (i.e., which drugs are considered “non-formulary”) and the application of tiered cost-sharing. Plans must also have an appeals process that meets certain specifications. As noted above, the reconsideration process is particularly important because the costs of non-formulary drugs do not count toward the out-of-pocket maximum for beneficiaries. A beneficiary can request a reconsideration of formulary coverage rules if his or her physician states that the formulary drug in the class “either would not be as effective for the individual or would have adverse effects for the individual or both (Conference Report, H.R. 1).” This

type of process is common in both the public and private sectors, particularly among plans or organizations that use a closed formulary, although in most cases, the physician, rather than the beneficiary, makes the request. For example, the VHA's formulary allows patients to receive a non-formulary drug only if a waiver is granted. Physicians must apply for a waiver on behalf of the patient. Waivers that allow a patient to receive coverage of a non-preferred drug may be granted if there is a contraindication, adverse reaction or therapeutic failure of a formulary drug or if a patient has previously responded well to a non-formulary drug and switching drugs is considered risky (VHA directive). The prior authorization and preferred drug list programs used by many state Medicaid programs also allow physicians of Medicaid patients to apply for approval to prescribe drugs not on the list (Kaiser Commission on Medicaid and the Uninsured, 2002, 2003). The ease of obtaining formulary coverage for a non-formulary drug varies widely from plan to plan and would likely also vary across Part D plans. In some systems, waiver approval is almost automatic; in others, it can be very difficult to obtain a waiver.

Another important issue is whether patients who are already taking a non-formulary drug upon enrollment would be permitted to secure formulary coverage for that drug (i.e., a "grandfather" provision for formulary coverage) or would instead be expected to switch medications. For example, consider a patient with major chronic depression who previously failed treatment with both Paxil and Prozac but has responded successfully to Zoloft and is currently taking Zoloft. If this person were to join a plan that includes only fluoxetine (the generic version of Prozac) and paroxetine (the generic version of Paxil) on the formulary for the class of SSRIs and does not have a grandfather provision allowing her to receive formulary coverage for Zoloft, the patient would either have to switch medications to a drug that had not been effective for her previously (fluoxetine or paroxetine) or pay the full cost of

Zoloft out-of-pocket, without the cost counting toward the out-of-pocket maximum. A burdensome reconsideration process (for example, extensive paperwork that the physician must complete to document the need for formulary coverage and/or a lengthy application for the enrollee) could serve to discourage enrollees from filing a request and ultimately lead some enrollees to switch plans in the following year.

Decisions about formulary structure and content and the management of the waiver review process could also affect the magnitude of the discounts and rebates that pharmaceutical manufacturers are willing to offer in exchange for the increased volume likely to result from preferred status on the formulary. For example, a manufacturer would presumably be willing to negotiate larger discounts or rebates if its drug were the only drug in a class on the formulary than it would if its drug were one of several on the formulary. If the waiver process is extremely flexible and a large number of waivers are granted, a plan may be unable to deliver volume with a three-tier formulary so manufacturers may be less willing to negotiate discounts and rebates.

Potential for Variation in Coinsurance Required for Specific Drugs. For the standard and alternative benefit packages, the legislation requires that plans charge enrollees either 25% coinsurance or the actuarial equivalent of an average coinsurance rate of 25% across drugs for all drug expenditures between the deductible and the initial coverage limit. Although the legislation is somewhat unclear on this issue, the latter option could mean that plans could require different levels of coinsurance for different drugs as long as the average coinsurance rate across all drugs was 25%. If so, plans could choose to impose higher coinsurance rates for classes of very expensive medications and lower coinsurance rates for classes of inexpensive medications, which could discourage individuals who use particularly high-cost medications from enrolling. For example, a plan could require 50% coinsurance for

expensive medications like protease inhibitors used to treat HIV/AIDS but just 10% coinsurance for relatively inexpensive medications like thiazide diuretics used to treat hypertension, as long as the actuarial equivalent of the proposed coverage equals an average of 25% coinsurance. The legislation provides few details about how actuarial value would be calculated but calls on the Secretary of DHHS to establish a methodology for determining actuarial value.

Design of Utilization Management Programs. As noted above, plan sponsors are required to implement a utilization management program that provides incentives to use lower-cost medications when appropriate. The legislation does not specify which drug classes should be targeted for utilization management activities. Plans could choose to focus utilization management activities on a subset of classes that are particularly high-cost. A utilization management program could require documentation of various factors before granting approval for coverage of particular non-formulary drugs. One factor could be that a patient “fails first,” on a lower-cost drug, i.e., a patient must first try the lower-cost, preferred medication and can obtain approval for a non-preferred drug only if the patient does not respond to or tolerate the preferred drug. In 2003, 28 state Medicaid programs used a fail first approach for at least some drug classes (Kaiser Commission on Medicaid and the Uninsured (2)). In theory, a utilization management program could require reauthorization every few months to use particular drugs. Through utilization management techniques, a plan could encourage patients and their physicians to select lower-cost drugs and possibly discourage individuals who use drugs affected by the utilization management programs from maintaining enrollment in a given plan.

IV. Case Studies

Below are case studies that provide examples of decisions that plan sponsors might make that could influence utilization and spending patterns for drugs used to treat particular medical conditions. The structure of formularies, cost-sharing and utilization management programs could affect patients in two primary ways: 1) by encouraging patients to use lower-cost drugs; and 2) by discouraging patients expected to have high drug expenditures from enrolling or maintaining enrollment in a particular plan. In some cases, the use of these pharmacy management strategies might have relatively little effect on patients. However, in other cases, these practices could reduce access to medications and possibly influence health outcomes. We start with gastroesophageal reflux disease (GERD), a relatively homogeneous condition that is treated with a variety of generic and brand medications that are fairly similar for most patients. Second, we consider osteoarthritis, a disabling condition that affects a large number of elderly individuals. Osteoarthritis is treated with a broad range of pain-relieving medications (both generic and brand agents) that are fairly similar for many patients. Third, we examine high cholesterol and the statin medications used to lower it. Fourth, we focus on depression, a relatively common condition but one that is often underdiagnosed and inadequately-treated. Depression is a biologically heterogeneous illness treated with one or more of a variety of brand or generic medications. Finally, we examine HIV/AIDS, a relatively rare and life-threatening condition that is treated with a combination of extremely expensive brand-name medications.

Case Study 1: GERD. GERD occurs when acid flows backward from the stomach into the esophagus with some regularity. Common symptoms of GERD include heartburn, regurgitation and difficulty swallowing. Two classes of drugs are commonly used to treat GERD: histamine H₂-Receptor antagonists, (H₂ blockers) and proton pump inhibitors (PPIs).

H2 blockers (i.e., Zantac, Pepcid, Tagamet, and Axid) are older drugs that have been shown to be effective in treating GERD and other gastrointestinal conditions (Van Pinxteren; DeVault). Most H2 blockers have generic options available.³ Proton pump inhibitors (PPIs) are a newer class of drugs that have been shown to achieve better control of reflux symptoms than H2 blockers (DeVault). The PPI class includes Prilosec, Prevacid, Nexium, Protonix, and omeprazole (the generic form of Prilosec). Most of the studies that directly compare the efficacy of different PPIs have found that the various PPIs have similar efficacy when given in equivalent doses and that all are effective in treating GERD (Vakil and Fennerty).

Because of the relative homogeneity of GERD and the similarity in efficacy of the PPIs, patients are less likely to select a plan on the basis of whether the plan has the PPI they currently take on its formulary. Thus, selection issues may be less of a concern for drugs used to treat GERD, and patients should be more likely to switch medications in response to financial incentives than users of other drug classes like antidepressants or antiretrovirals. Therefore, formulary structure and cost-sharing requirements may be useful in encouraging the use of lower-cost H2 blockers or the generic PPI omeprazole. A plan might choose to restrict formulary coverage to one PPI or use a fail first program that would require patients to fail on an H2 blocker before using omeprazole or fail omeprazole before receiving coverage for a brand-name PPI. Such a program would be more acceptable to GERD patients than similar programs for certain other drug classes, as long as the reconsideration process is not too burdensome for those that do not respond well to the preferred drug.

³ H2 blockers and omeprazole are also available over the counter at lower doses than available by prescription and for short term use only. We focus on prescription-level medications that would be covered by health plans (i.e., generic and brand medications only).

Example 1: GERD

Mrs. S is a 67-year old woman in good health except for chronic GERD symptoms. She is enrolled in a plan with a formulary that lists generic omeprazole in tier 1 with a \$5 copayment, Protonix in tier 2 with a \$15 copayment, and Nexium in tier 3 with a \$30 copayment. Prevacid and the brand version of Prilosec are non-formulary drugs. Mrs. S's physician initially prescribes Prevacid, but Mrs. S has a financial incentive to take omeprazole or Protonix. Her options are to ask her physician to prescribe a different medication, to request reconsideration of formulary coverage for Prevacid (which would likely not be approved) or pay the full cost of Prevacid (approximately \$115 per month) out-of-pocket (and the cost would not count toward the patient's out-of-pocket maximum) (www.medicare.gov).

Case Study 2: Osteoarthritis. Osteoarthritis, the most common form of arthritis, involves pain and stiffness in the joints and is a common cause of disability in adults. Lifestyle changes such as increased exercise and therapies like physical and occupational therapy may help to decrease pain and increase mobility. However, medications are necessary to relieve pain for most patients with osteoarthritis. There are three main types of drugs used to relieve pain associated with this condition: 1) acetaminophen (Tylenol); 2) nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen (Advil), naproxen (Naprosyn), Lodine, Voltaren); and 3) selective cyclooxygenase 2 (COX-2) inhibitors (Celebrex, Vioxx, and Bextra).

Acetaminophen, a relatively inexpensive medication sold over the counter, is often considered a first-line treatment for patients with osteoarthritis (Hochberg, et al.; Kalunian et al.).⁴ Patients who do not respond well to acetaminophen or who have relatively severe pain may use an NSAID or a COX-2 inhibitor. Several NSAIDs (e.g., ibuprofen, naproxen) are sold in generic form and are relatively inexpensive, even for prescription-strength doses. However, other NSAIDs, for example, Lodine and Voltaren, require a prescription and are sold in brand form only (i.e., no generic equivalent yet available). All COX-2 inhibitors, the

⁴ Several drugs used to treat osteoarthritis (e.g., acetaminophen, ibuprofen and naproxen) are sold at low doses over the counter. We focus on prescription-level doses, and thus generic and brand drugs only.

newest class of drugs used to relieve pain for osteoarthritis patients, require a prescription and are available only in brand form. The average wholesale prices of Lodine, Voltaren and the COX-2s are similar (around \$80/month) and substantially more expensive than the pain-relieving drugs available in generic form (www.medicare.gov), with no evidence to suggest greater efficacy.

Although COX-2 inhibitors are not more effective than NSAIDs in relieving pain associated with osteoarthritis, COX-2 inhibitors have a lower risk of adverse gastrointestinal effects such as peptic ulcer, bleeding and severe indigestion than do NSAIDs (e.g., Silverstein et al.). An Ad-hoc Committee established by the American College of Gastroenterology identified five risk factors for adverse gastrointestinal effects resulting from NSAID use: 1) prior history of ulcer or major gastrointestinal bleeding, 2) over 60 years of age, 3) a high dosage of NSAIDs, 4) concurrent use of glucocorticoids, and 5) concurrent use of anticoagulants like warfarin (Lanza et al.). Physicians are recommended to prescribe a COX-2 over an NSAID for patients with one or more of these risk factors.

Because most patients with osteoarthritis take a single medication to alleviate pain and the average cost of even the most expensive drugs in this class is low relative to many other drug classes, plans have less incentive to focus on discouraging individuals who use these drugs from enrolling. Instead, plans are likely to focus efforts on influencing prescribing towards lower-cost drugs where possible. Because drugs within a class are relatively similar in efficacy and side effect profile, many patients and their physicians may be willing to switch medications in response to lower copayments.

There are several ways that a plan sponsor could encourage patients and their doctors to select the less expensive generic agents like acetaminophen, ibuprofen, or naproxen. For example, a plan could implement a strict utilization management program focused on

decreasing use of COX-2 inhibitors and expensive brand-name NSAIDs in favor of the less expensive agents. Such a program could require that physicians provide extensive documentation of risk factors for gastrointestinal bleeding with NSAID use, which could discourage prescribing of the COX-2 inhibitors. A utilization management program could also require that enrollees fail one or more of the lower-cost drugs before they receive approval for a brand-name NSAID. If the formulary only included lower-cost agents and the administrative burden for the process of reconsideration of formulary coverage were high, this could discourage prescribing of the more expensive medications and decrease their use.

Example 2: Osteoarthritis

Mrs. R is a 75-year-old woman with osteoarthritis and a prior history of a bleeding stomach ulcer. The formulary in her plan includes the generic drugs ibuprofen and naproxen in tier 1 with a \$10 copayment and the COX-2 inhibitor Celebrex in tier 3 with a \$40 copayment. The other COX-2s and NSAIDs are non-formulary drugs, and there are no drugs in tier 2. The plan has a utilization management program that allows the patient and her physician to apply for tier 2 coverage of Celebrex (with a lower copayment of \$25) because of her high risk for NSAID-related gastrointestinal effects.

Case Study 3: High Cholesterol. There are two main types of cholesterol: 1) low-density lipoprotein (LDL), often referred to as "bad cholesterol" and 2) high-density lipoprotein (HDL), often referred to as "good cholesterol." Although having high levels of LDL in your bloodstream is not associated with any physical symptoms, it is a major risk factor for heart disease and heart attack (National Heart, Lung, and Blood Institute). In general, as a patient's LDL levels increase, so does her risk. Today, the primary goal of treatment for high cholesterol is to reduce the LDL to levels that vary based on a patient's risk for coronary heart disease (National Cholesterol Education Program). Treatment recommendations typically include a combination of lifestyle changes (e.g., diet, exercise,

weight management) and use of medications known to lower LDL levels. The drugs used most often to reduce LDL levels are called HMG Co-A reductase inhibitors, or "statins." There are several statin medications currently available in brand form (e.g., Lipitor, Mevacor, Pravachol, Zocor). In addition, a generic version of the brand drug Mevacor (i.e., lovastatin) recently became available.

The clinical literature suggests that Lipitor, the most commonly prescribed statin, achieves greater LDL cholesterol reduction than the other statins (A.S. Brown, et al.). A possible exception may be Crestor, approved by the Food and Drug Administration (FDA) in the fall of 2003. Recent studies have also demonstrated that use of very high-dose Lipitor (i.e., 80 mg) lowers risk of recurrent cardiac events in patients who have had a recent heart attack, regardless of their LDL levels (Cannon et al.). Doses of the other statins that could be high enough to achieve comparable LDL-lowering effects as Lipitor are not recommended because of adverse side effects.

A new drug that manufacturers claim will increase levels of HDL, or "good cholesterol," has not yet received approval from the FDA but is currently being tested. This drug, called torcetrapib, is an inhibitor of cholesteryl transfer protein (CETP). If this drug receives approval, the manufacturer (Pfizer) plans to market only a combination treatment -- a pill that combines trocetrapib and Lipitor to increase HDL and reduce LDL -- instead of selling the two medications separately (Hensley and Winslow).

For patients with no coronary heart disease and modestly elevated LDL levels, the lower-cost generic drug lovastatin may be sufficient to achieve LDL goals. For patients with higher LDL levels or patients who have had a recent heart attack, data support Lipitor as a better choice. To influence utilization, a plan could adopt a utilization management program that required a physician to document a recent heart attack or very high LDL levels for a

particular patient before the patient can receive formulary coverage for Lipitor. Similarly, a fail first program that requires a patient to fail lovastatin before obtaining coverage of Lipitor or other non-formulary drugs could be used to encourage patients to use lower-cost agents.

Because many patients taking statins to lower LDL also take other drugs to treat their cardiovascular disease (e.g., beta blockers to lower risk of heart attack; angiotensin-converting enzyme (ACE) inhibitors to treat hypertension or heart failure), plans have an incentive to discourage enrollment of patients who use statins (Medicare Advantage plans may have a stronger incentive to avoid these patients who are likely to have high medical costs associated with their cardiovascular disease as well). How a plan structures formulary coverage for statins and other cholesterol-altering drugs will influence the types of individuals attracted to the plan. For example, a formulary that includes Pravachol and the generic drug lovastatin as the only statins may be less desirable to a patient taking statins to lower very high LDL levels or to patients who have had a heart attack than a formulary that includes only Lipitor and lovastatin. Similarly, a three-tier formulary that includes Lipitor in the third tier with the highest copayment would be less desirable than one that listed Lipitor in the second tier with a lower copayment.

Category and class definition could also influence the types of enrollees attracted to a plan. Consider a plan that defines "cardiovascular drugs" as a category and "cholesterol-related drugs" as a class. In this case, if torcetrapib receives FDA approval, in theory a plan could choose to cover only drugs that lower LDL (e.g., lovastatin) and not drugs targeted at increasing HDL. How a formulary handles combination drugs is also of interest. Consider a formulary that defined "statins" as a class. It is unclear whether a plan would consider a Lipitor/torcetrapib combination drug (if approved by the FDA) a statin (and if so, possibly not cover this drug in favor of lower-cost drugs like lovastatin) or a separate class of medication.

Example 3: High LDL Cholesterol

Mr. W is a 66-year-old man with diabetes and high blood pressure and an extremely high level of LDL. Mr. W. is enrolled in a Part D plan with a three-tier formulary that requires him to pay \$10 for generic drugs in tier 1, \$25 for preferred brand drugs in tier 2 and \$50 for non-preferred brand drugs in tier 3. His physician wants to prescribe Lipitor to lower his cholesterol. Because Mr. W's plan has a fail first program requiring him to fail lovastatin (in tier 1) before obtaining coverage for other statins, his physician prescribes lovastatin. Because he does not achieve cholesterol goals with the maximum dose of lovastatin, he can receive formulary coverage for Pravachol, which is listed in tier 3. However, his physician thinks that he needs a high dose of Lipitor because of his high LDL level so she writes a prescription for Lipitor 80mg a day. Mr. W. applies for reconsideration of formulary coverage for Lipitor but the plan does not grant formulary coverage for this drug. As a result, he will pay the full cost of Lipitor (approximately \$85 per month) out-of-pocket, without the cost counting toward the out-of-pocket maximum for his plan. The cost of Lipitor would be added to the cost of several other drugs he takes to treat his hypertension and diabetes plus his monthly drug plan premium.

Case Study 4: Major Depression. Major depression is a relatively common chronic condition, with a lifetime prevalence of 7% to 12% for men and 20% to 25% for women (Kessler et al). There is substantial biological heterogeneity within the illness and no specific biological markers to distinguish the different subtypes (Rush and Kupfer; Delgado and Gelenberg).

There are a number of drugs available to treat depression, including the older TCAs and MAOIs, and the relatively newer antidepressants including the SSRIs, Wellbutrin, Effexor and Remeron. We currently do not fully understand the mechanisms of action for various antidepressants, nor can we predict which drug will be the best match for a given patient because of the lack of biological markers for the illness (Delgado and Gelenberg). The clinical literature has found no significant difference in efficacy between the TCAs and the SSRIs, although patients may be less likely to take a TCA for the recommended period of time because of the side effects often associated with TCA use (Mulrow et al.). Many

randomized trials have found that the various SSRIs have similar efficacy overall, although various drugs might not be equally effective for a given patient (Simon). For example, a patient with depression and anxiety may respond better to Paxil or Celexa than Prozac or Zoloft. In addition, prior studies have shown that failure to respond to one SSRI or having severe side effects from the drug does not mean that the patient will have the same experience with a different SSRI (Thase et al.; Brown and Harrison).

Because of the heterogeneity of depression and other chronic mental illnesses, plans are likely to have less success in influencing prescribing patterns for antidepressants and other psychotropic drugs relative to classes of drugs that treat more biologically homogeneous illnesses (Huskamp). Due to the difficulty of finding a good treatment match for many patients, those patients who have responded well to a particular drug and their physicians will be less likely to switch medications in response to lower copayments. As a result, restrictive formularies for antidepressants could result in many patients having to bear the full cost of their medications without these expenditures counting towards the out-of-pocket maximum. It is also possible that some patients could discontinue their prescribed antidepressants because of the lack of coverage.

Although the structure of formularies, cost-sharing and utilization management may not be very effective at influencing prescribing decisions, these items could influence the types of individuals attracted to a plan. To the extent that individuals with chronic depression have higher medication costs (or in the case of Medicare Advantage plans, have higher total medical spending as well), plans have an incentive to discourage enrollment of these individuals. Category and class definition for antidepressants could affect plan selection, as noted in the example above. Alternatively, a plan could choose to use a fail first approach as part of a utilization management program, whereby a patient and their physician would have

to document that the patient tried the generic drugs fluoxetine and paroxetine and failed these medications before receiving coverage for another SSRI. If there was a grandfather provision for new enrollees who were already taking another drug and a flexible reconsideration process for people who fail fluoxetine and paroxetine or for whom there is another reason to prefer a different drug, this approach could be an appropriate strategy for trying to control costs.

Example 4: Major Depression

Mrs. C is currently taking Effexor XR (150mg a day) to treat major depression. She joins a Part D plan with a three-tier formulary that requires 10% coinsurance for generic drugs in tier 1, 20% coinsurance for preferred brand drugs in tier 2, and 40% coinsurance for non-preferred brand drugs in tier 3. The formulary defines a class of older antidepressants (i.e., TCAs and MAOIs) and a class of newer antidepressants (i.e., SSRIs and other newer agents, including Effexor and Wellbutrin). For the class of newer antidepressants, fluoxetine, paroxetine and bupropion (the generic version of Wellbutrin) are listed on tier 1, Zoloft on tier 2, and Lexapro on tier 3. Because she previously failed Prozac, Paxil and Wellbutrin, she and her physician are unwilling to switch from Effexor XR, to which she has responded well. If the plan has a grandfather provision, she could continue to use Effexor XR and pay approximately \$35, or coinsurance equal to 40% of the cost of this medication (i.e., 40% of approximately \$90 per month) in addition to her monthly premium. If the plan does not have a grandfather provision, she will have to pay the full cost of Effexor XR out-of-pocket, and this expenditure will not count toward the out-of-pocket maximum for her plan unless she successfully applies for reconsideration of formulary coverage.

Case Study 5: HIV/AIDS. HIV/AIDS is a relatively rare condition, particularly among the elderly. In 2001, there were an estimated 7,750 Medicare enrollees living with HIV or AIDS (CDC). There have been dramatic advances in the treatment of HIV/AIDS over the past decade with the introduction of a number of antiretroviral medications that limit the ability of the virus to multiply. However, no drugs can eradicate the virus, making HIV/AIDS a chronic illness with which individuals can live for many years.

Antiretroviral drug therapy has resulted in reduced mortality, slower progression from HIV to AIDS, and lower rates of opportunistic infections and hospitalizations for patients who

respond to them (Marschner et al.). The three main types of antiretroviral drugs are: nucleoside reverse transcriptase inhibitors (NRTIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs). The most successful treatments involve a combination of three or more medications at once (U.S. DHHS). Preferred combinations for initial treatment of HIV/AIDS are: 1 NNRTI plus 2 NRTIs; 1 or 2 PIs plus 2 NRTIs; or 3 NRTIs. These combinations are evidence-based and designed so that when the regimen fails, there are drugs of different types as well as other drugs of the same type to which the patient has not been exposed.

There are many factors that must be considered when selecting an antiretroviral regimen for a given patient. These include: the efficacy data for particular combinations; possible adverse effects from the drugs; possible drug interactions; a patient's other medical conditions (e.g., patients with liver disease would need to avoid drugs with potential liver toxicity); and patient preferences, since adherence to the medication regimen is critical to preventing resistance. There is substantial variation across medications and combinations of medications with respect to potential adverse effects, drug interactions and ease of use. Also, over time some patients develop resistance to a particular regimen and physicians have to try a new combination of medications. Because of these factors affecting treatment choice, flexible formulary coverage is particularly important for antiretroviral medications in order to maintain patients on appropriate drug therapy over time.

Antiretroviral medications are extremely costly. The cost of the NRTIs and the NNRTIs is similar, with an average wholesale price of around \$3500 to \$4800 per year for each drug (www.drugstore.com). The PIs, the newest type among the three, have an average annual wholesale price of approximately \$5500-\$7500 per drug. Fuzeon, an entry inhibitor (the first new type of antiretroviral agents approved by the FDA in several years) is used by

patients who have failed on other regimens and costs over \$20,000 per year (Tashima and Carpenter). In addition to antiretroviral therapy, individuals with HIV/AIDS often take medications to prevent opportunistic infections as well as drugs necessary to treat any complications that may arise, such as high blood pressure, lipid disorders and kidney disease. When you add the annual cost of three or more antiretroviral drugs with the cost of other drugs used to treat HIV/AIDS and its complications, it becomes clear that the total annual cost of medications for HIV/AIDS patients can be extremely high.

Given the difficulty of finding an appropriate combination of drugs for a given patient and the seriousness of the condition, physicians and their patients are not likely to change medications or make initial treatment decisions in response to financial incentives to choose particular antiretroviral drugs. As a result, plans are unlikely to have much influence on prescribing decisions using tools like formularies and utilization management. However, HIV/AIDS patients who are on a stable drug regimen are likely to select a plan in part based on formulary coverage of the antiretroviral medications they currently take, so plans can use formularies in efforts to avoid adverse selection. Because of the high cost of these medications, plans have strong incentives to discourage enrollment of patients with HIV/AIDS and other conditions treated with extremely expensive medications. Medicare Advantage plans may have an even stronger incentive to discourage enrollment of HIV/AIDS patients, who are likely to have higher-than-average total medical expenditures in addition to higher-than-average drug expenditures.

In theory, a plan's definition of classes and categories for these drugs could discourage enrollment of HIV/AIDS patients. For example, a plan could define a category broadly as "antivirals" and a class as "antiretrovirals," lumping all types of antiretrovirals together. This would allow a plan to offer a small subset of antiretroviral medications. This class definition

strategy seems unlikely because of the obvious negative implications for patients. A more likely strategy would involve defining classes more narrowly (e.g., PIs are a class) but placing a small number of drugs in each class on the formulary. Since side effects of the different drugs vary greatly as does the efficacy of different drug combinations for a given patient, limiting the number of drugs in each class would severely limit treatment decision making by physicians treating HIV/AIDS patients, with potential negative consequences for patients. Plans could also exclude the most expensive medications like Fuzeon (often used by patients who have failed other treatment regimens).

There are a number of additional ways that individuals with HIV/AIDS might be discouraged to join a particular plan. Plans could use higher coinsurance rates for antiretroviral drugs than for other types of drugs (as long as the average coinsurance rate is 25%). Plans could adopt a utilization management program that requires strict prior authorization to use certain high-cost drugs or use a fail first approach, requiring patients and their physicians to document that the patient failed on the preferred formulary drug before obtaining permission to use a non-formulary drug. The reconsideration and utilization management processes for antiretroviral agents would need to be particularly responsive because patients for whom preferred regimens are not effective or well-tolerated would need to change regimens as soon as possible to prevent deterioration of their condition. Reconsideration and utilization management processes that place a high administrative burden on physicians and their patients (who may be extremely weak or ill) or require a long wait for a response could discourage HIV/AIDS patients from maintaining enrollment in a plan.

Example 5: HIV/AIDS

Ms. N is a 66-year-old woman with AIDS. She did well for some time, but recently her disease has progressed and she has failed several combination regimens of antiretroviral drugs. Her physician prescribes Fuzeon, an extremely expensive medication typically used for patients who have failed other treatment regimens. Her plan requires 40% coinsurance for prescriptions for antiretroviral medications for drug expenditures from the \$250 deductible up to the \$2250 initial coverage limit (although the plan requires much lower coinsurance rates for many other classes of drugs). In addition, Fuzeon is a non-formulary drug. She and her physician request reconsideration of formulary coverage for Fuzeon. If formulary coverage is not granted, she would be responsible for the full cost of the medication (approximately \$20,000 a year) plus the coinsurance required for the other antiretroviral medications that are part of her combination treatment regimen, and her expenditures for Fuzeon would not count towards her out-of-pocket maximum. Even if formulary coverage is granted for the drug, she will still be responsible for the 40% coinsurance up to the initial coverage limit and the copayments or coinsurance required for all medications after her annual expenditures exceed the out-of-pocket maximum of \$3600.

V. Conclusions

With the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Congress attempted to fill a major gap in Medicare coverage. In 1999, over a third of all Medicare beneficiaries had no coverage for outpatient prescription drugs and many others had only limited drug coverage (Laschober).

As with any new Medicare benefit, the costs of adding Part D coverage are of great concern. The legislation relies on competition among plans to create incentives for cost minimization and allows plans substantial flexibility in designing management tools used to control utilization and spending. These tools can be used to minimize costs in two ways: 1) by encouraging physicians and their patients to select lower-cost drugs; and 2) by discouraging enrollment of people who are likely to have high medication costs.

When used appropriately, management tools such as formularies, cost sharing and utilization management can control Part D expenditures without negatively affecting access and quality of care. However, as the case studies illustrate, the potential implications of these

cost containment efforts for patients are likely to be different for different types of conditions and drugs. In the case of drugs used to treat GERD, which are fairly similar for most patients, plans are likely to be able to shift prescribing toward the use of lower-cost medications without serious implications for most patients. In fact, shifting prescribing behavior for these drugs could be considered a reasonable way for a plan to try to control benefit costs.

However, in the case of antiretroviral drugs, plans are unlikely to have much influence on prescribing decisions but have a strong incentive to use pharmacy management tools like formularies and cost sharing as a way to discourage patients with HIV/AIDS from joining the plan. For heterogeneous conditions like depression, patients and their physicians may be unwilling to switch medications when the patient is responding well to a non-formulary drug, requiring the patient to bear the full financial burden for that drug. There is some evidence that seniors without drug coverage are more likely to skip doses or not fill prescriptions for needed medications (Safran). Also, because patients are likely to select a plan based on its coverage of antidepressants, plans have an incentive to use formulary design, cost sharing and utilization management to discourage individuals with chronic major depression from enrolling. Although risk adjustment may temper somewhat plan incentives for selection, it is unlikely that any risk adjustment system developed will explain enough of the variation in drug expenditures across Medicare beneficiaries as to prevent selection completely.

Architects of any new health insurance benefit must balance the potential benefits of competition with the costs associated with adverse selection.

During the congressional debate, much of the attention was focused on nominal benefits (e.g., the size of the deductible, out-of-pocket maximum, and the “doughnut hole”). Relatively little attention was paid to details about how plans would operate and the kinds of cost containment tools they could use. In the context of managed care, these tools are just as

important as nominal benefit design in determining enrollee access to medications. Strict application of these tools could result in overly restrictive coverage, particularly for the highest-cost drugs.

The regulations being written by CMS will be critical in filling in some of the details not provided in the legislation. These details, including the specifics of the actuarial valuation process, risk adjustment methods and how the Secretary will determine if a plan's design discourages enrollment by certain types of enrollees, will determine the incentives plans ultimately face and clarify how plans can use cost containment tools to act on these incentives. CMS must pay particular attention to provisions affecting formulary design, cost-sharing and utilization management in order to ensure that individuals most in need of drug coverage (i.e., those with the highest drug expenditures) have access to needed medications. How a plan structures these items could have a substantial impact on the generosity of the coverage, the out-of-pocket burden faced by beneficiaries, and, ultimately, the long-term stability of the Part D program.

References

- A.S. Brown, R.G. Bakker-Arkema, L. Yellen, et al., "Treating Patients with Documented Atherosclerosis to National Cholesterol Education Program-Recommended Low-Density Lipoprotein Cholesterol Goals with Atorvastatin, Fluvastatin, Lovastatin and Simvastatin," *Journal of American College of Cardiology*, 32(3): 665-672, 1998.
- W.A. Brown and W. Harrison, "Are Patients Who Are Intolerant to One Serotonin Selective Reuptake Inhibitor Intolerant to Another?" *Journal of Clinical Psychiatry*, 56(1): 30-34, 1995.
- C.P. Cannon, E. Braunwald, C.H. McCabe, D.J. Rader, et al., "Comparison of Intensive and Moderate Lipid Lowering With Statins After Acute Coronary Syndromes," *New England Journal of Medicine*, 350(15): 1495-1504, 2004.
- Centers for Medicare and Medicaid Services (CMS), "2004 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," <http://www.cms.hhs.gov/publications/trusteesreport/>, 2004.
- Centers for Disease Control and Prevention (CDC), HIV/AIDS Surveillance Report, Vol. 14.
- Congressional Budget Office (CBO), "H.R.1: Medicare Prescription Drug and Modernization Act of 2003 and S.1: Prescription Drug and Medicare Improvement Act of 2003." Congressional Budget Office Cost Estimate for H.R. 1 and S.1., July 22, 2003.
- N. Coulson and B.C. Stuart, "Persistence in the Use of Pharmaceuticals by the Elderly: Evidence from Annual Claims," *Journal of Health Economics*, 11(3): 315-328, 1992.
- D.M. Cutler and R.J. Zeckhauser, "The Anatomy of Health Insurance," in *Handbook of Health Economics*, A.J. Culyer and J.P. Newhouse, eds., Volume 1A, Chapter 11 (New York: Elsevier), 564-643, 2000.
- P.J. Delgado and A.J. Gelenberg, "Antidepressant and Antimanic Medications," in *Treatments of Psychiatric Disorders*, ed. G.O. Gabbard (Washington: American Psychiatric Publishing), 1137-1180, 2001.
- K.R. DeVault and D.O. Castell, "Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease: The Practice Parameters Committee of the American College of Gastroenterology," *American Journal of Gastroenterology*, 94(6): 1434-42, 1999.
- R.P. Ellis, "The Effect of Prior-Year Health Expenditures on Health Coverage Plan Choice," in *Advances in Health Economics and Health Services Research*, Volume 6, ed. R.M. Scheffler and L.F. Rossiter, (Greenwich, CT: JAI Press), 149-170, 1985.
- B. Ettinger, D.M. Black, B.H. Mitlak, R.K. Knickerbocker, et al., "Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis Treated with Raloxifene: Results from a 3-Year Randomized Clinical Trial," *Journal of the American Medical Association*, 282(7): 637-645, 1999.

R.G. Frank, "Prescription Drug Prices: Why Do Some Pay More than Others Do?" *Health Affairs*, 20(2): 115-128, 2001.

R.G. Frank, J. Glazer, and T.G. McGuire, "Measuring Adverse Selection in Managed Health Care," *Journal of Health Economics*, 19(6): 829-854, 2000.

Health Policy Alternatives, Inc. *Prescription Drug Coverage for Medicare Beneficiaries: An Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Kaiser Family Foundation, January 14, 2004.

S. Hensley and R. Winslow, "Pfizer Makes \$800 Million Bid to Reshape Heart-Care Market: Drug Giant Pins Its Hopes on Treatment that Boosts Levels of Good Cholesterol," *Wall Street Journal*, April 8, 2004: 1.

M.C. Hochberg, R.D. Altman, K.D. Brandt, B.M. Clark, et al., "Guidelines for the Medical Management of Osteoarthritis: Part I, Osteoarthritis of the Hip," *Arthritis and Rheumatism*," 38(11): 1541-1546, 1995.

C. Hogan, "MCBS-Based Study of Prescription Drug Coverage Linked to Medicare Claims," Report delivered to Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Planning and Evaluation under Number BPA-OS-00-0203-A, Washington, DC, October 25, 2000.

H.A. Huskamp, A.M. Epstein and D. Blumenthal, "The Impact of a National Prescription Drug Formulary on Prices, Market Share, and Spending: Lessons for Medicare?" *Health Affairs*, 22(3): 149-158, 2003.

H.A. Huskamp, "Managing Psychotropic Drug Costs: Will Formularies Work?" *Health Affairs*, 22(5): 84-96, 2003.

Kaiser Commission on Medicaid and the Uninsured, "Medicaid and the Prescription Drug Benefit: Cost Containment Strategies and State Experiences," <http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14138>, September 2002.

Kaiser Commission on Medicaid and the Uninsured, "Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003," <http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=30030>, December 2003.

Kaiser Family Foundation, "Medicare Advantage: Fact Sheet," www.kff.org, March 2004.

Kaiser Family Foundation and the Health Research and Educational Trust, "Employer Health Benefits: 2003 Summary of Findings," <http://www.kff.org/insurance/ehbs2003-abstract.cfm>, 2004.

Kaiser/Hewitt, "Retiree Health Benefits Now and in the Future: Findings from the Kaiser/Hewitt 2003 Survey on Retiree Health Benefits," www.kff.org, 2004.

R.C. Kessler, K.A. McGonagle, S. Zhao, C.B. Nelson, et al., "Lifetime and 12-Month Prevalence of DSM-III-R Psychiatric Disorders in the United States: Results from the National Comorbidity Survey," *Archives of General Psychiatry*, 51(1):8-19, 1994.

F.L. Lanza and Members of the Ad Hoc Committee on Practice Parameters of the American College of Gastroenterology, "A Guideline for the Treatment and Prevention of NSAID-induced Ulcers," *American Journal of Gastroenterology*, 93(11): 2037-2046, 1998.

M.A. Laschober, M. Kitchman, P. Neuman, and A.A. Strabic, "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs, Supp Web Exclusives*: W127-38, 2002.

C.A. Ma and T.G. McGuire, "Network Incentives in Managed Health Care," *Journal of Economics and Management Strategy*, 11(1): 1-35, 2002.

I.C. Marschner, A.C. Collier, R.W. Coombs, R.T. D'Aquila, et al. "Use of Changes in Plasma Levels of Human Immunodeficiency Virus Type 1 RNA to Assess the Clinical Benefit of Antiretroviral Therapy," *Journal of Infectious Disease*, 177(1):40-47, 1998.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Report to Accompany H.R. 1, U.S. House of Representatives, Report 108-391, U.S. Government Printing Office, Washington, DC, 2003.

C.D. Mulrow, J.W. Williams Jr., E. Chiquette, C. Aguilar, et al., "Efficacy of Newer Medications for Treating Depression in Primary Care Patients," *American Journal of Medicine*, 108(1): 54-64, 2000.

National Cholesterol Education Program (NCEP), Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults., "Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III)," *Journal of the American Medical Association*, 285(19): 2486-97, 2001.

National Institutes of Health, National Heart, Lung, and Blood Institute, "High Blood Cholesterol: What You Need to Know; Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)," www.nhlbi.nih.gov/health/public/heart/cholesterol, 2001.

J.P. Newhouse, M.B. Buntin, and J.D. Chapman, "Risk Adjustment and Medicare: Taking a Closer Look," *Health Affairs*, 16(5): 26-43, 1997.

NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis and Therapy, "Osteoporosis Prevention, Diagnosis and Therapy," *Journal of the American Medical Association*, 285(6): 785-795, 2001.

M.V. Pauly and Y. Zeng, "Adverse Selection and the Challenges to Stand-Alone Prescription Drug Insurance," National Bureau of Economic Research Working Paper 9919, Cambridge, MA, August 2003.

B. Reisberg, R. Doody, A. Stoffler, F. Schmitt, et al., "Memantine in Moderate-to-Severe Alzheimer's Disease," *New England Journal of Medicine*, 348(14): 1333-1341, 2003.

A.J. Rush and D.J. Kupfer, "Strategies and Tactics in the Treatment of Depression," in *Treatments of Psychiatric Disorders*, ed. G.O. Gabbard (Washington: American Psychiatric Publishing), 1427-1428, 2001.

D.G. Safran, P. Neuman, C. Schoen, J.E. Montgomery, et al., "Prescription Drug Coverage and Seniors: How Well Are States Closing the Gap?" *Health Affairs*, web exclusive W254 (www.healthaffairs.org), July 31, 2002.

F.E. Silverstein, G. Faich, J.L. Goldstein, L.S. Simon, et al., "Gastrointestinal Toxicity With Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis; The CLASS Study: A Randomized Controlled Trial," *Journal of the American Medical Association*, 284(10): 1247-1255, 2000.

G. Simon, "Choosing a First-Line Antidepressant: Equal on Average Does Not Mean Equal for Everyone," *Journal of the American Medical Association*, 286(23): 3003-3004, 2001.

B.C. Stuart, F. Ahern, V. Rabatin, and A. Johnson, "Patterns of Outpatient Prescription Drug Use Among the Elderly: Evidence from the PACE Program," *Health Care Financing Review*, 12(3): 61-72, 1991.

P.N. Tariot, M.R. Farlow, G.T. Grossberg, S.M. Graham, et al., "Memantine Treatment in Patients with Moderate to Severe Alzheimer Disease Already Receiving Donepezil: A Randomized Controlled Trial," *Journal of the American Medical Association*, 291(3): 317-324, 2004.

K.T. Tashima and C.J. Carpenter, "Fusion Inhibition: A Major But Costly Step Forward in the Treatment of HIV-1," *New England Journal of Medicine*, 348: 2249-2250, 2003.

M.E. Thase, S.L. Blomgren, M.A. Birkett, J.T. Apter, et al., "Fluoxetine Treatment of Patients With Major Depressive Disorders Who Failed Initial Treatment with Sertraline," *Journal of Clinical Psychiatry*, 58(1): 16-21, 1997.

U.S. Department of Health and Human Services, "HIV Adult and Adolescent Guidelines Revised," <http://www.aidsinfo.nih.gov/>, revised March 23, 2004.

N. Vakil and M.B. Fennerty, "Direct Comparative Trials of the Efficacy of Proton Pump Inhibitors in the Management of Gastro-esophageal Reflux Disease and Peptic Ulcer Disease," *Alimentary Pharmacology and Therapeutics*, 18(6): 559-568, 2003.

B. Van Pinxteren, M.E. Numans, P.A. Bonis, and J. Lau, "Short-term Treatment with Proton Pump Inhibitors, H2-receptor Antagonists and Prokinetics for Gastro-esophageal Reflux Disease-like Symptoms and Endoscopy Negative Reflux Disease," *Cochrane Database System Review* 2001; (4): CD002095.

Veterans Health Administration (VHA) Directive 97-047-1997.

B. Winblad and N. Poritis, "Memantine in Severe Dementia: Results of the 9M-Best Study (Benefit and Efficacy in Severely Demented Patients During Treatment with Memantine)," *International Journal of Geriatric Psychiatry*, 1999, 14(2): 135-146.

R. Winslow, "Lipitor Prescriptions Surge in Wake of Big Study," *Wall Street Journal*, March 18, 2004: D4.

M.V. Wrobel, J. Doshi, B.C. Stuart, and B. Briesacher, "Predictability of Prescription Drug Expenditures for Medicare Beneficiaries," *Health Care Financing Review*, 25(2): 37-46, 2003-2004.

www.drugstore.com, accessed on March 23, 2004.

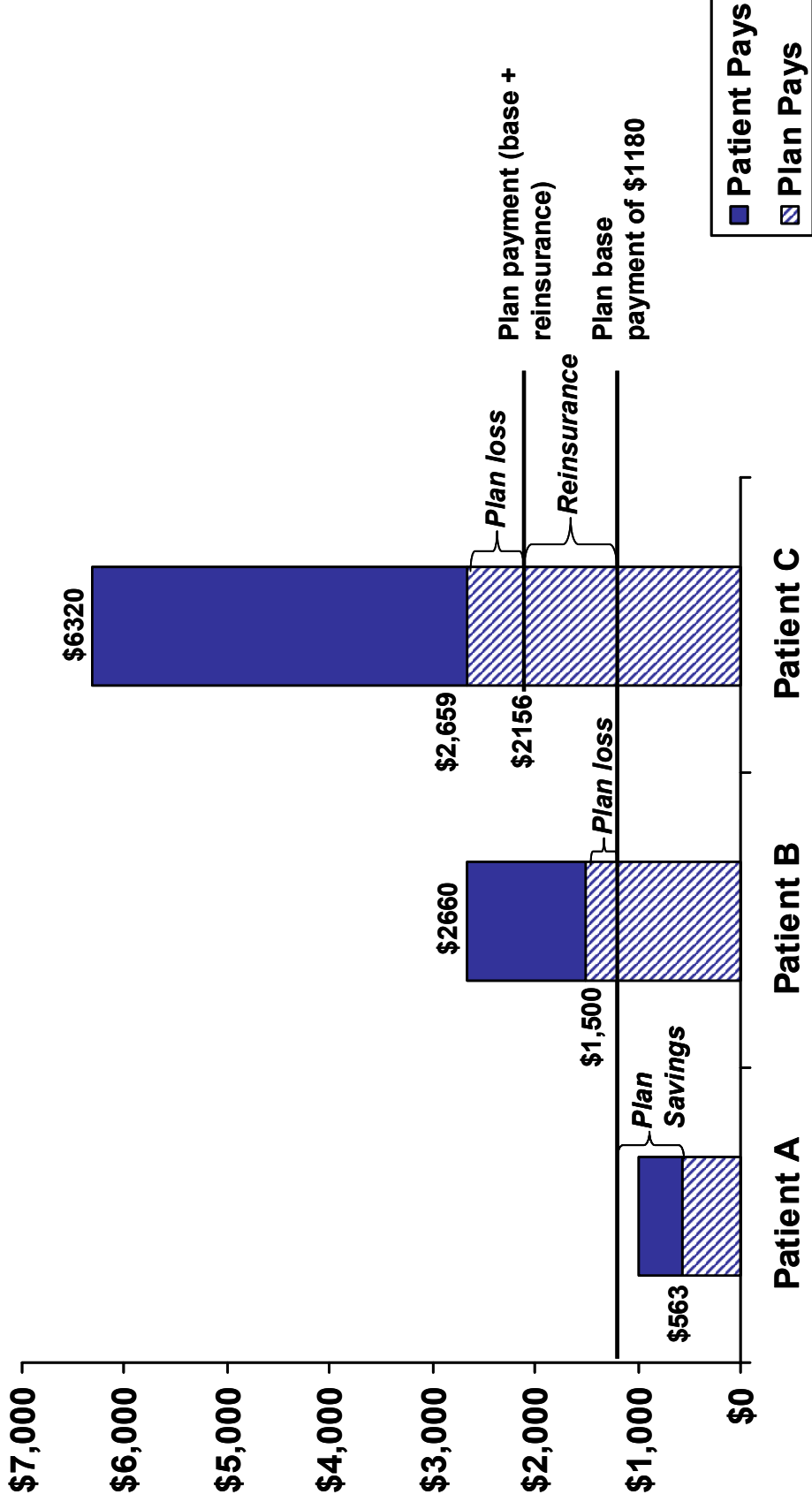
www.medicare.gov, accessed on May 17, 2004.

Exhibit A

Beneficiary A: Patient with High LDL	Beneficiary B: Patient with High LDL, Hypertension and Diabetes	Beneficiary C: Patient Who Recently Had a Heart Attack and Has High LDL, Hypertension, Diabetes, Arthritis, and Depression
Drug/Daily Dose	Drug/Daily Dose	Drug/Daily Dose
Yearly cost of drugs	Yearly cost of drugs	Yearly cost of drugs
Lipitor 80mg <u>\$1000</u>	Lipitor 80mg \$1000	Lipitor 80mg \$1000
Total: \$1000	Norvasc 5mg 480 Cozaar 100mg 700 Metformin 2000mg 300 Glipizide 40mg <u>+180</u> Total: \$2660	Norvasc 5mg 480 Cozaar 100mg 700 Metformin 2000mg 300 Glipizide 40mg 180 Plavix 75mg 1380 Atenolol 100mg 100 Effexor XR 150 mg 1080 Celebrex 200mg <u>+1100</u> Total: \$6320
Patient Pays: \$250 deductible <u>+\$187</u> 25% coinsurance \$437	Patient Pays: \$250 deductible \$500 25% coinsurance up to initial coverage limit <u>+\$410</u> 100% of cost after initial coverage limit (i.e., \$2660-\$2250=\$410) \$1160	Patient Pays: \$250 deductible \$500 25% coinsurance up to initial coverage limit \$2850 100% of costs between initial coverage limit and out-of-pocket max (i.e., \$3600-\$750) <u>+\$61</u> 5% coinsurance after out-of-pocket max (i.e., \$6320-\$5100) \$3661
Plan Pays: <u>\$563</u> 75% of costs after patient pays \$250 deductible (i.e., \$750 x 0.75) \$563	Plan Pays: <u>\$1500</u> 75% of costs after deductible is met up to initial coverage limit (i.e., \$2000 x 0.75) \$1500 Average Payment to Plan: \$1180	Plan Pays: \$1500 75% of costs after deductible is met up to initial coverage limit (i.e., \$2000 x 0.75) <u>+\$1159</u> 95% of costs after out-of-pocket max (i.e., \$6320-\$5100) \$2659 Average Payment to Plan: \$1180 + \$976 Reinsurance = \$2156

Note: This example is based on several assumptions regarding the level of direct government subsidy, reinsurance, plan administrative costs, enrollee premiums and coinsurance requirements for specific drugs, and is intended to be illustrative rather than definitive. The example does not account for any risk sharing with the government for expenditures in the risk corridors or for any rebates that plans negotiate with drug manufacturers. Drug prices were obtained from the www.medicare.gov website on May 17, 2004. The quoted prices apply to pharmacies within 3 miles of residents living in the zip code 02446. The average payment to the plan includes enrollee premiums (on average \$420 a year, as estimated by CBO) and government payments. Patient out-of-pocket payments shown in the bar graph do not include their monthly premiums.

Exhibit B



Note: This example is based on several assumptions regarding the level of direct government subsidy, reinsurance, plan administrative costs, enrollee premiums and coinsurance requirements for specific drugs, and is intended to be illustrative rather than definitive. The example does not account for any risk sharing with the government for expenditures in the risk corridors or for any rebates that plans negotiate with drug manufacturers. The “base” payment for plans includes enrollee premiums as well as direct subsidies provided by the government. The patient share does not include monthly premiums.



The Henry J. Kaiser Family Foundation:

2400 Sand Hill Road
Menlo Park, CA 94025
(650) 854-9400
Facsimile: (650) 854-4800

Washington, D.C. Office:

1330 G Street, N.W.
Washington, DC 20005
(202) 347-5270
Facsimile: (202) 347-5274

Website: www.kff.org

The Kaiser Family Foundation is a non-profit, private operating foundation dedicated to providing information and analysis on health care issues to policymakers, the media, the health care community, and the general public. The Foundation is not associated with Kaiser Permanente or Kaiser Industries.

Additional copies of this publication (#7120) are available on the Kaiser Family Foundation's website at www.kff.org.