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The Nuts and Bolts of PDPs

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OVERVIEW — *This issue brief provides an overview of Medicare prescription drug plans (PDPs), with a focus on fundamentals such as enrollment, premiums, formularies, cost sharing, prices, payment, cost management, and appeals and grievance processes. It also highlights major changes to the PDP landscape between 2006 and 2007.*

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The Nuts and Bolts of PDPs

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 established a voluntary outpatient prescription drug benefit for Medicare beneficiaries starting January 1, 2006. Medicare subsidizes the cost of the benefit, generally paying about 75 percent of its costs. Between 2006 and 2015, the federal cost is estimated to be $746 billion.[1] The drug benefit is administered through private entities called prescription drug plans (PDPs) for beneficiaries in fee-for-service (traditional) Medicare or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare managed care. Employers and unions offering retiree coverage that is at least as generous as Medicare's drug benefit and meeting other requirements may also qualify for Medicare subsidies to defray the cost of providing a drug benefit to their retirees.

Most Medicare beneficiaries participate in traditional Medicare and receive their drug coverage through PDPs if they choose to enroll. What makes PDPs unique in the Medicare market is that they offer "stand-alone" prescription drug insurance that complements other Medicare benefits. PDPs are licensed in the state(s) in which they offer plans[2] and assume partial financial risk for the drug costs of members. The assumption of financial risk by a plan only offering a drug benefit, not a comprehensive health insurance package, is a new concept in Medicare and is not common in the health insurance market. The majority of PDPs are sponsored by large health insurance companies that have experience providing drug benefits in the context of other health benefits, but not as a stand-alone benefit for an aged population. Many PDP sponsors are Medicare managed care organizations or insurers that provide Medicare supplemental insurance (known as Medigap). For them, Medicare PDPs are an additional product line.

Part D was designed with the assumption that competition for beneficiary enrollment among private plans, rather than direct government action, would shape the Medicare prescription drug market and contain overall costs. PDPs compete for beneficiary enrollment through the premiums they charge, the number and type of drugs included on the formulary, the cost-sharing amounts they require, the reputation of the company sponsoring the PDP, the pharmacies in their networks, customer service, and other factors. The desire to attract enrollees with varying needs and preferences has contributed to the great number of PDPs and the diversity of their benefit offerings.

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PLAN PARTICIPATION IN PART D: STANDING ROOM ONLY?

When Part D was enacted in December of 2003, there was some concern on the part of policymakers that too few private plans would participate, leaving beneficiaries little, if any, choice of plans and precluding competition among plans. Indeed, the MMA included provisions for "fallback" plans that would quickly ramp up to offer the drug benefit if no plans (or only one plan) were offered in a particular geographic area. However, as it turned out, over 1,400 PDPs were available across the nation in 2006, and over 1,900 will be available for 2007.[3] This increase is attributable to several factors, including (i) new entrants into the PDP market, (ii) more companies offering PDP products nationwide (17 companies will offer products nationwide in 2007, up from 10 in 2006), and (iii) some companies offering more product choices than they did in 2006.

The MMA permits a fair amount of variability in the drug benefit designs PDP sponsors may offer.

The large increase in the number of PDPs available to beneficiaries between 2006 and 2007 likely is a signal that companies believe PDPs are profitable, require little investment, or are a low-risk venture.

Not all plans are available to each Medicare beneficiary. In implementing the drug benefit, the Centers for Medicare & Medicaid Services (CMS) divided the country into 34 PDP regions.[4] In each of these regions, beneficiaries may choose among the PDPs available. Most regions had roughly 40 to 45 PDPs in 2006, with a high of 52 (in Pennsylvania and West Virginia) to a low of 27 (in Alaska). For 2007, the number of PDPs generally available in each region increased to the range of 50 to 55, with a high of 66 (in Pennsylvania and West Virginia) and a low of 45 (in Alaska).

While beneficiaries generally have dozens of PDP choices, most are offered by a much smaller number of companies. For example, in New York state for 2007, 61 plans are being sponsored by 26 companies. In California, 55 plans are being offered by 23 companies. Many companies offer multiple plans in each region in an effort to appeal to beneficiaries with different needs and preferences. Over time, there may be some contraction in the number of plans as it becomes clearer which plans are most appealing to beneficiaries.

BENEFIT DESIGN OPTIONS

The MMA permits a fair amount of variability in the drug benefit designs PDP sponsors may offer. The benefit designs generally fit into one of three categories: standard, actuarially equivalent,[5] and enhanced. In 2006, the majority of beneficiaries expressed a strong preference for actuarially equivalent plans by enrolling in them in great numbers.

The Part D **standard benefit** for 2006 is defined in statute to include a $250 deductible; 25 percent coinsurance[6] for covered drug spending between $250 and $2,250; and 100 percent coinsurance for drug spending

between $2,250 and $5,100. This full responsibility for payment by the beneficiary in the $2,250 to $5,100 range is popularly known as the "donut hole" but referred to as the "coverage gap" for purposes of this issue brief. After $3,600 in beneficiary true out-of-pocket (known as "TrOOP")[7] spending is reached, catastrophic coverage begins and beneficiaries are responsible for cost sharing (the higher of 5 percent of the negotiated price, or $2 for generic and preferred brand or $5 for nonpreferred drugs).[8] While the Medicare drug benefit is often described in the media in terms of this standard benefit package, only 132 PDPs—about 9 percent of all PDPs—actually offer this benefit design.[9] According to the Medicare Payment Advisory Commission (MedPAC), 22 percent of enrollees are in plans with a standard benefit design.[10]

The majority of beneficiaries—61 percent according to MedPAC—are enrolled in PDPs with **actuarially equivalent coverage**. Actuarially equivalent coverage may include cost-sharing requirements that are different from the standard benefit as long as (i) the cost sharing is actuarially equivalent to the cost sharing included in the standard benefit design, and (ii) catastrophic coverage begins when $3,600 in TrOOP spending is reached. Actuarially equivalent plans may include, for example, lower cost sharing on preferred drugs or on drugs purchased at preferred pharmacies. All PDP sponsors must offer at least one drug plan that is either a standard or actuarially equivalent benefit. Just under half of the PDPs offered designs in 2006 that were actuarially equivalent to the standard benefit design.

Beneficiaries appear generally satisfied with the drug coverage they have chosen.

PDPs may also offer a package with extra benefits called **enhanced coverage**. According to MedPAC, about 43 percent of PDPs offered plans with this benefit design in 2006,[11] but only 17 percent of beneficiaries are enrolled in them.[12] Enhanced coverage may include a $0 deductible, coverage of more drugs, lower cost sharing, or coverage in the coverage gap. However, these enhanced benefits come with generally higher premiums, which may have contributed to lower enrollment in these plans. For some beneficiaries, enrolling in a higher-premium plan that offers enhanced benefits is the most cost-effective option, depending on the number and type of prescription drugs the beneficiary takes.

When Medicare beneficiaries choose a PDP, they likely do not know whether the PDP they are enrolling in is a standard, actuarially equivalent, or enhanced plan. However, they have clearly voted with their feet for plans other than standard plans. Time will tell whether enhanced coverage plans become more popular with beneficiaries because of their additional benefits despite generally higher premiums. In any event, beneficiaries appear generally satisfied with the drug coverage they have chosen. According to a recent survey, 81 percent of enrolled beneficiaries are satisfied with their Part D plan, and 74 percent of enrolled beneficiaries report that they would select the same plan again.[13]

ENROLLMENT

The first opportunity for most current Medicare beneficiaries to sign up for prescription drug insurance through Medicare began November 15, 2005, and ended on May 15, 2006. The next opportunity to enroll (or switch plans) is November 15 through December 31, 2006, for coverage effective January 1, 2007.

As of June 11, 2006, about 16.5 million Medicare beneficiaries were enrolled in PDPs and 6 million beneficiaries were enrolled in MA-PD plans. An additional 6.9 million beneficiaries were receiving prescription drug coverage through a former employer who is receiving a Medicare retiree drug subsidy to provide drug coverage.

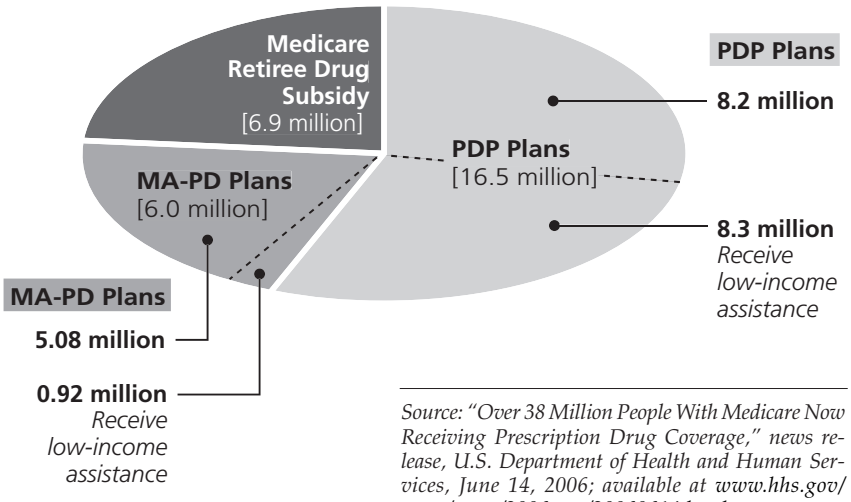
Enrollment in PDPs is concentrated in plans sponsored by a relatively small number of companies. Forty-five percent of Medicare beneficiaries in 2006 were enrolled in a plan sponsored by either United Health Care–PacifiCare (including plans that are co-branded with AARP) or Humana, Inc. Only five companies account for 65 percent of PDP enrollment.[14] So, while there are a great many PDPs, enrollment is concentrated in plans offered by relatively few companies. In contrast, a fair number of PDPs had enrollment of less than 100 members in 2006. Given that only a few companies were able to garner the lion's share of enrollment in 2006, the number of new companies and additional plan offerings for 2007 is surprising to some observers.

Of the roughly 16.5 million individuals enrolled in PDPs in 2006, 8.3 million were low-income beneficiaries who received partial (or full) subsidies from Medicare.

In addition to the concentration of enrollment in a relatively small number of PDPs, another notable fact is that low-income beneficiaries account for about half of the enrollment in PDPs. Of the roughly 16.5 million individuals enrolled in PDPs in 2006, 8.3 million were low-income beneficiaries who have the beneficiary premium and cost sharing partially (or fully) subsidized by Medicare. By contrast, 1 million of the 6 million beneficiaries enrolled in MA-PDs are receiving such additional benefits. This is because beneficiaries who are dually eligible for both Medicare and Medicaid (called "dual eligibles") were automatically enrolled (or "auto-enrolled") by CMS in PDPs but not in MA-PDs, unless the beneficiary was already enrolled in a Medicare Advantage plan. Auto-enrollment of these beneficiaries, all of whom had prescription drug coverage through Medicaid until implementation of Part D, was intended to ensure continuity of drug coverage. About 6.1 million dual eligibles were auto-enrolled in PDPs in 2006. Low-income beneficiaries who are not dual eligibles had their enrollment "facilitated" by CMS; that is, as of May 15, 2006, beneficiaries were enrolled in PDPs with lower-than-average premiums if they qualified for low-income assistance but had not yet chosen a plan on their own.[15]

Figure 1 shows the distribution of beneficiaries enrolled in PDPs, MA-PDs, or employer-sponsored plans receiving retiree drug subsidies under Part D. All of this drug coverage is subsidized directly by Medicare. There are also additional beneficiaries—almost 9 million of them according to CMS—who have drug coverage from other sources including: TRICARE (1.9 million), Federal Employees Health Benefit Plan or FEHBP (1.6 million), Veterans Administration (2 million), active workers with drug coverage through their employer (2.6 million), and other sources (about 900,000).[16]

FIGURE 1
Beneficiaries with Drug Coverage Through Medicare
(as of June 11, 2006)



Source: "Over 38 Million People With Medicare Now Receiving Prescription Drug Coverage," news release, U.S. Department of Health and Human Services, June 14, 2006; available at www.hhs.gov/news/press/2006pres/20060614.html.

THE ABCs OF PDPs

Almost every PDP is unique, offering different premiums, formularies, co-payment amounts, cost management approaches, and a host of other features. Plans offered by the same company often have different premiums in different geographic areas of the country. It could be said that "if you've seen one PDP, you've seen one PDP." Many believe that the variation observed is the basis for competition among PDPs and, therefore, critical to maximizing both choice and cost containment. Others believe that the variation makes it difficult for Medicare beneficiaries to compare plans and make informed choices about enrollment.

To attract enrollment and manage costs, PDP sponsors craft a benefit package that includes a formulary, deductible and co-payment amounts, utilization management tools, and other features. They also arrange a network of pharmacies to dispense prescriptions and interface with beneficiaries. Drug discounts and rebates are negotiated with drug manufacturers, and

dispensing fees are negotiated with pharmacies. Sponsors submit bids to Medicare to provide proposed benefits, and monthly beneficiary premiums are determined. The PDP sponsors hope that the benefit package (and cost management features) they have assembled, coupled with the monthly premium, will represent an attractive offering to beneficiaries. Sponsors may change benefit package features each calendar year.

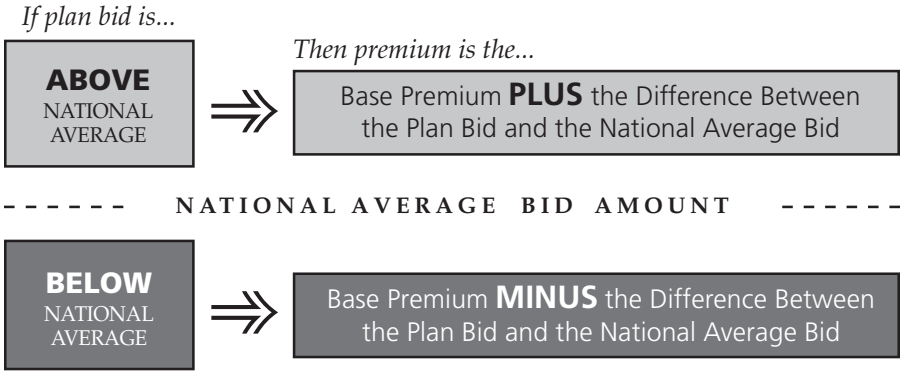
In comparing PDP features between 2006 and 2007, there are a few noteworthy observations. First, as discussed above, there will be significantly more PDPs available both nationwide and in each region in 2007. The number of plans offering coverage in the coverage gap will increase, although nearly all of this coverage is for generic, not brand name, drugs. Consistent with 2006, a relatively small number of PDPs will have premiums above $60 in 2007. The appendices include comparative information for both 2006 and 2007 for all 34 regions.

Beneficiary Premiums and PDP Payments

Beneficiaries enrolled in PDPs typically pay a monthly premium for Medicare drug coverage. Beneficiary premiums are calculated based on the relationship between the plan's bid and the average bid of all plans. This provides incentives for PDP sponsors to bid competitively so that beneficiary premiums are as low as possible, thus attracting enrollment. Plans that bid lower have lower beneficiary premiums, and plans that bid higher have higher premiums. Because beneficiaries selected plans with below-average premiums in 2006, PDP sponsors had very clear incentives to bid low for 2007 (Figure 2).

FIGURE 2
Monthly Beneficiary Premiums for a PDP

The monthly premium amount for a PDP is determined by comparing the PDP's bid to the national average bid. Lower premiums tend to attract enrollment, thus creating competitive pressure.



The national average bid is calculated using enrollment-weighted premiums; therefore, the premiums of plans with very large enrollment count more in the national average bid calculation than the premiums for plans with lower enrollment. Because such a large share of beneficiaries is enrolled in plans with lower-than-average premiums in 2006, the effect of using enrollment weighting would have been to increase 2007 beneficiary premiums for many plans. To avoid this effect, CMS used its demonstration authority[17] to phase in this weighting over several years. The phase-in will moderate premium increases due to enrollment weighting.[18] There is a federal cost associated with the premium demonstration, but its magnitude is not yet known.

Premiums for identical plans offered by the same sponsor can vary depending on the geographic area in which the beneficiary resides. Nationally, monthly PDP premiums range from a low of $9.50 to a high of $135.70 for 2007.[19] In 2006, monthly PDP premiums ranged from a low of $1.87 to a high of $104.89. Some plans with higher premiums are offering enhanced coverage designs. Enrollment in PDPs in 2006 tends to be concentrated in plans with lower premiums. According to CMS, 38 percent of PDPs had premiums below what is known as the base beneficiary premium of $32.20 in 2006. A large majority of beneficiaries in 2006 are enrolled in such plans,[20] in large part due to the auto-enrollment of low-income beneficiaries into low-cost plans.

The weighted-average PDP premium that beneficiaries paid in 2006 was $24.[21] The PDP average premium will be higher in 2007 than in 2006.[22] Also, the distribution of premiums for PDPs with basic benefits is tighter for 2007. That is, some higher-premium PDPs lowered their premiums for 2007. On the other hand, enhanced coverage plans, on average, have higher premiums in 2007 than in 2006.[23]

In addition to premiums paid by beneficiaries, PDPs receive payments from Medicare to subsidize the cost of providing the benefit, including direct premium payments toward monthly beneficiary premiums (estimated $20.2 billion in 2006), reinsurance and risk corridor payments toward catastrophic and unexpectedly large drug expenses (estimated $12.0 billion in 2006), and low-income subsidy payments toward premium and cost-sharing assistance for low-income beneficiaries (estimated $17.6 billion in 2006).[24]

These and other payments represent Medicare's financial contribution to drug coverage. Payments to individual plans are generally made monthly, with a reconciliation process for correcting under- and overpayments.

Despite significant Medicare payments to PDPs, non–low-income Medicare beneficiaries enrolled in PDPs may still pay a sizeable share of their drug expenses. CMS actuaries estimate that—on average—Medicare Part D will pay about half of the total drug costs for typical, non–low-income beneficiaries in 2006, not taking monthly beneficiary premiums into account. For an individual beneficiary, however, Medicare may end up paying more or less than half, depending on such factors as the drug plan chosen, drugs taken, and annual drug spending.

Cost Sharing

In addition to paying monthly premiums, beneficiaries enrolled in PDPs typically pay cost sharing that may include an annual deductible and co-payments or coinsurance on each prescription, as well as covered drug costs in the coverage gap.[25] Most PDP sponsors—85 percent in 2006—offer a $0 deductible plan option. As of May 3, 2006, 69 percent of PDP enrollees (and 90 percent of MA-PD enrollees) were in plans with $0 deductibles.[26] The amount beneficiaries pay in co-payments or coinsurance varies among PDPs and by type of drug (for example, brand versus generic or preferred versus nonpreferred).

Some PDPs offer partial coverage in the coverage gap. Most of these plans offer coverage of generic drugs only, although a few PDPs offer coverage of brand name drugs in the coverage gap as well. PDPs that provide coverage of brand name drugs in the coverage gap may experience selection effects; that is, beneficiaries with relatively high brand name drug needs may be more likely to enroll in them.

A Kaiser Family Foundation study found that most large, national PDPs have three tiers of cost sharing, as well as a specialty tier for very high-priced or specialty drugs.[27] The study found that the median co-payment for plans with a three-tier model in 2006 was $5 for first-tier drugs, $25 for second-tier drugs and $53 for third-tier drugs. The coinsurance amount for the specialty tier among large national plans was most commonly 25 percent of the negotiated price for that drug, but many plans charged between 30 and 33 percent of the negotiated price for those drugs.

Formularies

Virtually all PDPs use formularies, or lists of covered drugs, that effectively limit the number and type of drugs paid for by the plan. Formularies are used to steer enrollees to less expensive products, thereby keeping costs—and premiums—down. Some products may be less expensive than others because of manufacturer rebates or price discounts negotiated on certain products. Manufacturers of multiple-source drugs (that is, drugs for which there is a brand name or generic alternative available in the market) offer price discounts and/or rebates to PDPs in exchange for exclusivity or preferred status (which usually means lower cost sharing) on the formulary.[28] The competition among manufacturers to have their drug, not their competitors' drugs, on the formulary and preferably on a lower cost-sharing tier, is a critical cost management tool. In most cases, manufacturers are willing to offer a lower price (or a higher discount) for a drug if its competitors' similar drugs are not included on the formulary. PDPs need to balance the lower prices attainable through the use of a more restrictive formulary with enrollees' desire to have more medicines (or popular ones) available to them.

The competition among manufacturers to have their drug on the formulary and on a low cost-sharing tier, is a critical cost management tool.

In an effort to prevent PDPs from systematically discouraging beneficiaries with certain health conditions from enrolling, the MMA requires PDPs to offer a relatively broad range of drugs on their formularies. PDP formularies generally must include a minimum of two drugs in each clinical class and must include drugs that treat certain medical conditions. PDPs must cover all, or "substantially all" drugs in six "classes of clinical concern" identified by CMS: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[29] In general, drugs in classes commonly used by Medicare beneficiaries may be included on higher formulary tiers (that is, they may have higher coinsurance or co-payments) only when an equivalent drug is included on a lower formulary tier. Together, these protections are intended to ensure

that beneficiaries have access to a broad range of drugs, while also giving PDPs room to negotiate price discounts with manufacturers. Although coverage of the drugs detailed above is a requirement, PDPs have some latitude regarding the tier the drugs are on.

Research on PDP formularies indicates that there is a fair amount of variation in the number and type of drugs covered by PDPs. The Kaiser Family Foundation study noted above found that, among national PDPs, an average of 81 percent of brand name and generic drugs commonly used by beneficiaries were included on PDP formularies in 2006.[30] The most restrictive formulary included in the study covered 64 percent of these drugs, whereas the least restrictive formulary included 97 percent of them. The study also indicated that inclusion of commonly used drugs varies depending on the class or category of the drug. For example, 90 percent of antidepressants are on the formularies studied, but only 60 percent of drugs known as proton pump inhibitors (used to treat certain gastrointestinal problems) are included. This difference in the number of drugs covered in various classes is sometimes the result of the requirements to cover drugs in certain classes, as described above. If there are alternative drugs available within the same cost-sharing tier, a lower number of drugs may or may not signal an access problem.

Negotiated Prices

PDP sponsors negotiate rebates and discounts with drug manufacturers and dispensing fees with pharmacies. Together, these two negotiations contribute to the PDP's "negotiated price" for a drug.[31] Any coinsurance paid by the beneficiary is a percentage of the negotiated price. And, for beneficiaries with no coverage (in other words, paying 100 percent coinsurance) in the coverage gap, the amount paid in the coverage gap *is* the negotiated price. Therefore, the effectiveness of PDPs in negotiating with manufacturers and pharmacies directly affects how much beneficiaries pay for drugs. It is also one of the factors that may affect the beneficiary premium the PDP offers; better negotiated prices may mean lower premiums.

The negotiation between manufacturers and PDPs is among the most important determinants of the overall cost of the Medicare drug benefit as it is currently designed. Indeed, the MMA includes a "noninterference provision," which prohibits the Secretary of Health and Human Services from interfering in the negotiations between PDPs and manufacturers. This provision has been controversial, and its repeal has been discussed by some.

Repeal of the noninterference provision could pave the way for the Secretary to negotiate prices directly with manufacturers. But some believe that PDPs can conduct such negotiations more effectively than federal agencies, and that the current provision already results in the lowest prices. The Congressional Budget Office has reported that there would be no savings to Medicare if the noninterference provision was repealed.[32] Others, however, believe that negotiations conducted by the Secretary would result in larger discounts on prescription drugs and lower prices to beneficiaries.

The effect of the repeal would clearly depend on what statutory language would be inserted in its place. Permitting or requiring the Secretary to negotiate prices for all drugs, certain high-priced drugs, most-used drugs, or required minimum discounts are among the many possibilities. Who would negotiate pharmacy dispensing fees (the Secretary or PDP sponsors) would also be an issue. If all PDPs offered the same prices as negotiated by the Secretary, competition among PDPs would no longer be based on the drug prices PDPs were able to negotiate. The basis for competition among PDPs would be less clear.

The effect of the repeal of the noninterference provision would clearly depend on what statutory language would be inserted in its place.

It is difficult to assess how the prices offered by PDPs compare to prices offered by private insurance or other sources of discounts. CMS studies of prices indicate that the lowest-cost PDPs tend to secure prices that are comparable to or better than third-party insurance plan prices for commonly used drugs.[33] However, the results of comparative studies such as these can differ, depending on the drugs selected, the mix of generic and brand name drugs chosen, the plans used in the analysis, and whether the comparison is drug-specific or based on groups of drugs.

Drug Utilization Management Tools

PDP sponsors, like virtually all insurers, commonly use protocols to manage drug costs, such as limiting the quantity of a dispensed drug, conducting prior authorization before a drug is dispensed, and/or requiring the enrollee to use lower-cost alternative medicines before approving payment for a higher-cost drug (step therapy). These tools can also be helpful in limiting drug-to-drug interactions, over- or underdosing, or side-effects. Knowing whether a particular drug is on a PDP's formulary is important, but knowing whether the drug is subject to utilization management tools is also key to determining access.

A commonly used utilization management tool is quantity limits (for example, placing limits on the amount of medication per prescription or limits on the number of prescriptions for a particular medication in a fixed time period). Quantity limits are easy to implement and relatively easy for beneficiaries to understand. According to a recent study, step therapy is used less often than quantity limits and is most commonly used on drugs such as proton pump inhibitors and certain drugs used to treat hypertension. Prior authorization (that is, requiring that the plan approve a particular drug before it is dispensed) is a tool used slightly less often than step therapy. Because prior authorization requires review by the PDP, it is an expensive utilization management tool likely reserved for more costly or perhaps risky therapies. For example, in the Kaiser study, 86 percent of tumor inhibitors examined were subject to prior authorization.

The types of utilization management tools and the extent to which they are used varies widely among PDPs.[34] Utilization management techniques are

more likely to be applied to brand name drugs than generic drugs, and they vary depending on the type of drug. About half of national PDPs use at least one technique on 5 out of 10 widely used brand name drugs.

Grievances, Coverage Determinations, and Appeals

The MMA includes provisions for grievances, coverage determinations (including exceptions), and appeals procedures. PDPs must provide information about their exceptions and appeals procedures to beneficiaries who enroll in the plan.

Grievances are complaints by an enrollee about the PDP that do not involve a coverage issue. A grievance may include a complaint about facts in marketing materials or complaints about a rude employee. A PDP's decision on a grievance is final; there is no appeals process for a grievance.

Coverage determinations are intended to provide a straightforward way for PDP enrollees to obtain medically necessary drugs that are not on the PDP's formulary or to obtain drugs at a more favorable cost-sharing level. PDPs grant **exceptions** to formulary rules when the plan determines that it is medically appropriate to do so. PDPs must make a determination on an exceptions request as expeditiously as possible, but no later than 72 hours after the request has been made. For enrollees with serious health conditions, an expedited decision must be made within 24 hours. If a plan denies an exceptions request, the enrollee or his or her representative (in some cases, the prescribing physician) may **appeal** the plan's decision. If at any point in the process the enrollee receives a favorable decision, the appeals process ends. A beneficiary may appeal a plan's decision to the following parties (in successive order): the PDP, an independent review entity, a Medicare administrative law judge, the Medicare Appeals Council, and federal district court.

The number of appeals and grievances a PDP experiences may be an indication of a larger problem within a plan or across plans. A large number of appeals or grievances, particularly if clustered around a particular issue, may signal a problem with clarity of marketing material, for example, or it may indicate that a PDP is not providing a clear rationale for not covering a particular drug. Some have argued that the processes for grievances, coverage determinations, and appeals are too difficult for Medicare beneficiaries to navigate, particularly for those with cognitive impairments.

The data released by CMS on the overall magnitude of appeals and grievances to date indicate that a small number of grievances and appeals have been filed relative to the number of claims filed.[35] It remains to be seen whether this small number is due to enrollee satisfaction with plans or a lack of knowledge of the procedures and options available for disputing an issue.

Additional Benefits for Low-Income Beneficiaries

Medicare contributes to the cost of the prescription drug benefit for all enrolled beneficiaries, with higher contributions (subsidies) made on behalf

of low-income beneficiaries. Medicare pays for additional benefits for low-income Medicare beneficiaries with incomes below 150 percent of the federal poverty level ($14,700 for an individual in 2006) and meeting certain asset requirements. As stated earlier, almost half of beneficiaries enrolled in PDPs are low-income individuals. Figure 3 summarizes the additional benefits low-income beneficiaries receive, by income and asset level.

FIGURE 3
The Low-Income Subsidy: Extra Assistance in 2006 for Beneficiaries with Limited Means

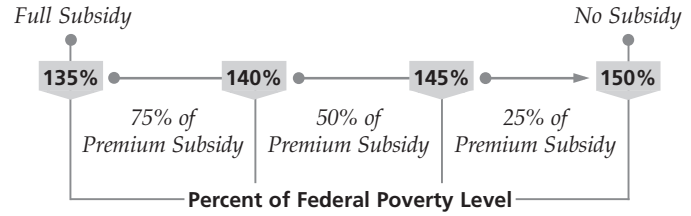
Over 13 million Medicare beneficiaries have annual incomes of less than 150 percent of the federal poverty level *($14,700 for an individual)* and meet certain asset requirements, making them eligible for financial help with their Part D premiums, deductibles, and co-pays. The amount of assistance available depends on the income and asset levels of the beneficiary.

	BENEFICIARY GROUPS				
	Full Benefit Dual Eligibles*		Non-Full Benefit Dual Eligibles		
Income	≤100% FPL	>100% FPL	<135% FPL		≥135% to 150% FPL
Assets Individual	N/A†	N/A†	$6,000	>$6,000 *but* ≤$10,000	≤$10,000
Assets Couple	N/A†	N/A†	$9,000	>$9,000 *but* ≤$20,000	≤$20,000
Premium Subsidy (%)	100%‡	100%‡	100%‡	100%‡	Partial *(see "Sliding Scale")*
Deductible	None	None	None	$50	$50
Copay (generic/brand)§	$1/$3	$2/$5	$2/$5	15% coinsurance	15% coinsurance
Above Catastrophic Limit?¶	No cost sharing	No cost sharing	No cost sharing	$2/$5 co-pay	$2/$5 co-pay

Premium Subsidies Taper Off for Dual Eligibles with Larger Incomes

For beneficiaries with incomes at or above 135% FPL and with assets valued above $10,000 *(for an individual, or $20,000 for a couple)*, the amount of premium subsidy decreases. Beneficiaries with incomes at or above 150% FPL receive no drug plan premium subsidy.

Sliding Scale: Partial Premium Subsidies



* *Individuals who are not living in an institution. Institutionalized dual eligibles are exempt from all cost sharing.*

† *Asset tests vary by state for full-benefit dual eligibles.*

‡ *No premium is required if the individual selects a PDP with a premium less than or equal to the low-income benchmark.*

§ *Co-payment and deductible amounts are indexed in future years.*

¶ *The catastrophic limit is defined as the point at which an individual has spent $3,600 out of pocket on covered drugs in 2006. Because the beneficiaries described here pay low or no co-pays or coinsurance, the vast majority will never reach the catastrophic limit.*

Source: CMS-4068-F, Federal Register, *January 28, 2005, pp. 4388–4389.*

Most beneficiaries qualifying for low-income assistance receive a premium subsidy that pays the monthly beneficiary premium for plans with below-average premiums. Some low-income beneficiaries who are not dually eligible for both Medicare and Medicaid or who have assets pay a portion of the premium. For 2007, most low-income beneficiaries will be able to choose among 15 to 22 PDPs with $0 premium. Low-income beneficiaries also pay reduced cost sharing (including lower or no co-pays and deductibles).

The Medicare drug benefit is a comprehensive and relatively generous benefit for most low-income beneficiaries, particularly those dually eligible for both Medicare and Medicaid. For 2006, Medicare will have paid for an average of about 96 percent of drug spending for low-income beneficiaries, and 98 percent for dual eligibles.

CONCLUSION

A healthy dose of skepticism accompanied passage of the Medicare drug benefit in 2003. Some questioned whether private plans would participate, others questioned whether implementation would be consistent with statutory deadlines or smooth. Implementation initially was marred by computer and other glitches that led to uncertainty around coverage for many beneficiaries, particularly low-income beneficiaries. Anecdotal reports of beneficiaries leaving pharmacies without needed drugs caused serious concern, and, more recently, some beneficiaries have had trouble with monthly premiums being deducted correctly from their Social Security checks. There were a number of computer, financial, and other issues involving states and the transition of low-income beneficiary drug coverage from Medicaid to Medicare. CMS worked to address these and a number of other issues throughout the first year of the program.

On the other hand, participation by private plans in Part D has far exceeded expectations in 2006 and 2007. Concerns about insufficient plan participation are a faded memory. Beneficiary satisfaction seems reasonably high, and beneficiary premiums and overall program expenditures will be lower than expected for 2006 and 2007. As the second year of this benefit begins, it is too soon to make an accurate assessment of the overall success of the new program. Time, and continued analyses of its major features, will tell.

ENDNOTES

1. Mark McClellan, Centers for Medicare & Medicaid Services (CMS), testimony before the Committee on Ways and Means, U.S. House of Representatives, June 14, 2006, p. 7; available at www.cms.hhs.gov/HearingsTestimony/Downloads/0614FinalTestimony.pdf.

2. A PDP sponsor that is not licensed by a state in which it wishes to operate may request a waiver of licensure requirements from the Secretary of Health and Human Services (HHS). The waiver applies for a limited period, and the potential PDP must meet certain requirements, including solvency. Concerns have been raised regarding licensure waivers, and the adequacy of consumer protections when federal law pre-empts state law in this area.

Endnotes / continued ➤

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3. HHS, "Landscape of Local Plans State-By-State Breakdown," updated October 17, 2006; available at www.medicare.gov/medicarereform/local-plans-2007.asp.

4. A map indicating the 34 geographic regions may be found at www.cms.hhs.gov/PrescriptionDrugCovGenIn.

5. For purposes of this issue brief, "actuarially equivalent" plans also include plans that CMS refers to as "basic alternative" benefit plans.

6. The standard benefit may have cost sharing below the initial coverage limit that is actuarially equivalent to 25 percent.

7. Not all drug spending counts toward TrOOP spending. Actual out-of-pocket spending by the beneficiary and some qualified state programs counts toward TrOOP, but payments made by other insurers or third parties generally do not count toward TrOOP spending.

8. Cost sharing in the catastrophic range can be actuarially equivalent to these figures. The benefit parameters cited here for 2006 are updated annually by the Medicare actuary. For 2007, if the deductible is $265, the initial coverage limit is $2400, and the out-of-pocket threshold is $3850, then spending at the out-of pocket-threshold would be $5451.25 and co-payments in the catastrophic coverage range would be $2.15 and $5.35.

9. Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Increasing the Value of Medicare*, June 2006; available at www.medpac.gov/publications/congressional_reports/Jun06_EntireReport.pdf.

10. MedPAC, "Part D: Trends in enrollment and payment issues," staff presentation to the Commission, October 5, 2006, pp. 268–297; transcript available at www.medpac.gov/public_meetings/transcripts.cfm?sid=3&subid=0.

11. MedPAC, *Report to the Congress: Increasing the Value of Medicare*, p. 155.

12. MedPAC, "Part D: Trends in enrollment and payment issues."

13. Kaiser Family Foundation, "Chartpack: Seniors' Early Experiences with Their New Medicare Drug Plans," July 2006; available at www.kff.org/kaiserpolls/7546.cfm.

14. CMS enrollment figures as of April 27, 2006; available at www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp.

15. For more in-depth information on the effect of Part D on low-income individuals, please see Mary Ellen Stahlman, "A Closer Look at the Medicare Part D Low-Income Benchmark Premium: How Low Can It Go?" National Health Policy Forum, Issue Brief 813, August 2, 2006; available at www.nhpf.org/pdfs_ib/IB813_LowIncomeBenchmark_08-02-06.pdf.

16. "Over 38 Million People With Medicare Now Receiving Prescription Drug Coverage," news release, HHS, June 14, 2006; available at www.hhs.gov/news/press/2006pres/20060614.html.

17. The Secretary of HHS is authorized to conduct demonstrations involving Medicare payment under 42 U.S.C. Section 1395b-1(a)(1)(A). Medicare Part D demonstration authority is included under section 1860D-42(b) of the MMA.

18. Sol Mussey, "Release of the 2007 Part D National Average Monthly Bid Amount, the Medicare Part D Base Beneficiary Premium, the Part D Regional Low-Income Premium Subsidy Amounts, and the Medicare Advantage Regional Benchmarks," note to Medicare Advantage organizations, Medicare prescription drug plan sponsors, and other interested parties, August 15, 2006; available at www.cms.hhs.gov/medicareadvtgspecratestats/Downloads/ptcd2007_20060815.pdf.

19. Several plans in Puerto Rico offer lower premiums ($1.90 to $8.40). Excluding one company that offers a $135.70 premium, the premium range for the 50 states and the District of Columbia would be $9.50 to $110.30.

20. Mark B. McClellan, "Implementation of the Medicare Prescription Drug Benefit," testimony before the Committee on Ways & Means, Subcommittee on Health, U.S. House of Representatives, May 3, 2006, pp. 23–24; available at www.hhs.gov/asl/testify/t060503a.html.

21. "Over 38 Million People," HHS, June 14, 2006.

Endnotes / continued ➤

Endnotes / continued

22. CMS has indicated that the (weighted) average 2007 premium for PDPs and MA-PDs together will be about $24. Because MA-PDs generally have lower premiums than PDPs (including many plans with $0 premiums), we know that the average 2007 PDP premium will be higher than in 2006. "Medicare Releases Data on 2007 Drug Plan Options," news release, HHS, September 29, 2006, available at www.hhs.gov/news/press/2006pres/20060929.html; and "National Benchmark Shows Impact of Strong Competitive Bidding and Smart Beneficiary Choices," news release, CMS, August 15, 2006, available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1945.

23. MedPAC, "Part D: Trends in enrollment and payment issues," pp. 281–282.

24. *2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, May 1, 2006, p. 151; available at www.cms.hhs.gov/ReportsTrustFunds.

25. A few PDPs offer coverage of generic and/or brand name drugs in the coverage gap.

26. McClellan, testimony, May 3, 2006.

27. Jack Hoadley *et al.*, "An In-Depth Examination of Formularies and Other Features of Medicare Drug Plans," Kaiser Family Foundation, April 2006; available at www.kff.org/medicare/7489.cfm.

28. In limited instances, a beneficiary may have access to a drug not on a plan's formulary by requesting coverage through the plan's appeal process. A drug on a higher tier may also be available to a beneficiary for the lower cost sharing associated with a preferred drug if the beneficiary successfully appeals.

29. CMS's formulary guidance refers to "all or substantially all" drugs in these six classes. Drugs that may be excluded are: a drug that is identical to another drug already covered, the extended-release form of a drug when the immediate-release version is included, products with the same active ingredient, and interchangeable forms of the drug (for example, tablets versus caplets). For more information, see CMS, "Formulary Guidance," updated May 4, 2006; available at www.cms.hhs.gov/Pharmacy/07_Formulary%20Guidance.asp.

30. Hoadley *et al.*, "An In-Depth Examination." This report also includes near-national PDPs, that is, PDP organizations with plans in nearly every region of the country.

31. The negotiated price may or may not represent the actual ingredient price negotiated because PDPs may use rebate or other price concession dollars to reduce the monthly beneficiary premium or offset other costs of the benefit.

32. Douglas Holtz-Eakin, CBO, "Estimate of the Effect of Striking the "Noninterference" Provision as Added by P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," letter to the Honorable William H. Frist, U.S. Senate, January 23, 2004, available at www.cbo.gov/showdoc.cfm?index=4986&sequence=0; and Douglas Holtz-Eakin, CBO, "Authority to Negotiate Prices for Single-Source Drugs for Medicare Beneficiaries," letter to the Honorable Ron Wyden, U.S. Senate, March 3, 2004, available at www.cbo.gov/showdoc.cfm?index=5145&sequence=0.

33. CMS, "Medicare Drug Coverage Provides Significant Price Discounts and Savings – Updated Fact Sheet," September 21, 2006; available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1970. CMS studies of prices are posted on the Medicare Prescription Drug Plan Finder section of the CMS Web site at www.medicare.gov/MPDPF.

34. Hoadley *et al.*, "An In-Depth Examination."

35. CMS, "Part D Reconsideration Appeals Data," fact sheet, September 21, 2006; available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1972.

NATIONAL HEALTH POLICY FORUM

The National Health Policy Forum is a nonpartisan research and public policy organization at The George Washington University. All of its publications since 1998 are available online at ***www.nhpf.org.***

APPENDIX 1: Stand-Alone Medicare Prescription Drug Plans, 2006

Region	States	No. of Plans	No. of Orgs.	Range of Premiums	Premiums (No. of Plans)			Deductibles (No. of Plans)			Low-Income Benchmark Premium (LIBP)	No. of Plans Below LIBP
					≤19.99	$20 – 39.99	$ 40+	$ 0	$50 – 199	$200 – 250		
1	ME, NH	42	17	$19.60 – 65.39	1	25	16	25	3	14	$ 36.09	18
2	CT, MA, RI, VT	45	17	$ 7.32 – 65.58	4	27	14	29	3	13	$ 30.27	16
3	NY	47	20	$ 4.10 – 85.02	6	27	14	26	5	16	$ 29.83	20
4	NJ	45	18	$ 4.43 – 66.53	4	27	14	26	3	16	$ 31.37	17
5	DE, MD, DC	48	20	$ 6.44 – 68.91	3	25	20	27	3	18	$ 33.46	19
6	PA, WV	53	22	$10.14 – 68.61	2	26	25	31	5	17	$ 32.59	20
7	VA	42	17	$ 8.81 – 68.61	2	23	17	24	3	15	$ 34.42	20
8	NC	39	15	$13.27 – 65.03	2	18	19	23	3	13	$ 36.30	17
9	SC	46	19	$16.57 – 69.72	1	26	19	25	3	18	$ 34.88	20
10	GA	43	17	$17.91 – 73.17	1	26	16	25	3	15	$ 33.15	20
11	FL	44	18	$10.35 – 104.89	4	20	20	26	5	13	$ 29.07	9
12	AL, TN	42	17	$14.08 – 69.98	1	22	19	24	2	16	$ 32.33	12
13	MI	41	17	$13.75 – 65.69	1	24	16	24	3	14	$ 33.22	18
14	OH	44	18	$14.43 – 68.05	3	23	18	26	3	15	$ 30.69	15
15	IN, KY	43	17	$12.30 – 70.72	1	21	21	26	3	14	$ 35.69	19
16	WI	46	17	$11.42 – 63.23	4	25	17	30	3	13	$ 31.27	20
17	IL	43	16	$13.32 – 65.04	1	26	16	26	4	13	$ 31.60	20
18	MO	42	16	$10.29 – 68.26	2	22	18	26	3	13	$ 31.37	15
19	AR	41	15	$10.31 – 67.98	2	20	19	25	3	13	$ 35.45	18
20	MS	39	15	$11.60 – 70.59	2	18	19	24	3	12	$ 36.39	17
21	LA	40	16	$17.06 – 70.59	1	18	21	25	3	12	$ 34.14	15
22	TX	48	20	$10.31 – 68.41	2	26	20	28	3	17	$ 31.68	19
23	OK	43	16	$10.07 – 70.79	2	21	20	26	4	13	$ 35.13	17
24	KS	41	15	$ 9.48 – 67.88	2	23	16	26	3	12	$ 33.44	17
25	IA, MN, MT, NE, ND, SD, WY	42	16	$ 1.87 – 99.90	3	24	15	24	4	14	$ 33.11	18
26	NM	44	17	$10.65 – 62.38	6	24	14	27	4	13	$ 25.95	11
27	CO	44	17	$ 8.62 – 65.88	3	25	16	27	3	14	$ 28.92	13
28	AZ	44	18	$ 6.14 – 64.86	4	28	12	26	3	15	$ 24.62	9
29	NV	45	18	$ 6.42 – 64.63	3	27	15	26	3	16	$ 23.46	9
30	OR	46	20	$ 6.93 – 64.99	5	27	14	26	3	17	$ 30.60	20
	WA	45	18	$ 6.42 – 64.63	3	27	15	26	3	16	$ 30.60	18
31	ID, UT	45	18	$ 6.33 – 68.88	3	21	21	24	4	17	$ 33.62	19
32	CA	48	17	$ 5.41 – 66.08	6	34	8	29	3	16	$ 23.25	13
33	HI	30	11	$17.18 – 64.43	3	21	6	18	3	9	$ 27.44	11
34	AK	28	10	$20.05 – 61.93	0	16	12	18	3	7	$ 34.66	11

Source: Zip-code specific data is available through the General Plan Search function of the Find and Compare Plans button on CMS's "The Medicare Prescription Drug Plan Finder" Web page (www.medicare.gov/MPDPF). This tool defaults to 2007 plan information; 2006 plan information is available by following the "click here to display 2006 plan data" link on plan list page. Low Income Benchmark subsidy amounts for 2006 are available at www.cms.hhs.gov/MedicareAdvtgSpecRateStats/RSD.

APPENDIX 2: Stand-Alone Medicare Prescription Drug Plans, 2007

Region	States	No. of Plans	No. of Orgs.	Range of Premiums	Premiums (No. of Plans)			Deductibles (No. of Plans)			Low-Income Benchmark Premium (LIBP)	No. of Plans Below LIBP
					≤$19.99	$20 – 39.99	$ 40+	$ 0	$50 – 199	$200 – 265		
1	ME, NH	53	22	$13.70 – 82.30	1	32	20	32	4	17	$ 30.72	22
2	CT, MA, RI, VT	51	21	$13.40 – 87.40	3	33	15	31	3	17	$ 27.35	18
3	NY	61	26	$ 9.50 – 82.10	5	41	15	36	4	21	$ 24.45	15
4	NJ	57	24	$10.20 – 135.70	5	30	22	34	3	20	$ 28.12	22
5	DE, MD, DC	55	23	$12.20 – 103.20	4	32	19	34	3	18	$ 29.65	20
6	PA, WV	66	28	$14.80 – 104.50	4	39	23	41	4	21	$ 28.45	24
7	VA	53	22	$13.40 – 92.20	2	29	22	32	3	18	$ 30.52	20
8	NC	51	21	$17.80 – 85.90	1	27	23	31	3	17	$ 32.13	17
9	SC	59	25	$16.60 – 104.20	1	36	22	36	3	20	$ 31.41	20
10	GA	55	23	$17.40 – 96.40	2	31	22	33	3	19	$ 31.07	20
11	FL	57	24	$10.20 – 83.70	4	35	18	35	5	17	$ 22.63	5
12	AL, TN	56	23	$18.20 – 123.80	2	32	22	35	4	17	$ 29.60	17
13	MI	54	23	$17.90 – 86.90	2	31	21	33	3	18	$ 30.79	18
14	OH	60	26	$16.00 – 95.90	2	37	21	38	3	19	$ 28.51	16
15	IN, KY	53	23	$17.70 – 108.30	2	30	21	32	4	17	$ 32.42	21
16	WI	54	23	$14.80 – 80.30	2	33	19	33	3	18	$ 29.67	22
17	IL	56	23	$17.10 – 106.00	2	34	20	34	3	19	$ 29.66	20
18	MO	53	22	$14.90 – 119.50	3	30	20	32	4	17	$ 27.88	13
19	AR	58	24	$13.90 – 93.20	3	35	20	36	4	18	$ 30.51	22
20	MS	52	22	$14.60 – 103.00	2	29	21	32	3	17	$ 31.70	19
21	LA	52	22	$16.00 – 110.40	2	29	21	32	4	16	$ 28.45	11
22	TX	60	24	$11.00 – 96.50	6	33	21	36	3	21	$ 26.93	16
23	OK	56	23	$15.00 – 96.50	1	32	23	33	4	19	$ 30.35	17
24	KS	53	22	$11.30 – 102.30	2	30	21	32	3	18	$ 30.56	20
25	IA, MN, MT, NE, ND, SD, WY	53	22	$10.60 – 110.30	4	33	16	32	4	17	$ 29.50	20
26	NM	57	23	$15.50 – 83.50	5	39	13	35	4	18	$ 22.72	11
27	CO	55	23	$16.60 – 83.30	3	36	16	32	4	19	$ 27.37	18
28	AZ	53	22	$10.40 – 78.10	6	33	14	31	4	18	$ 21.37	9
29	NV	54	22	$10.60 – 84.30	6	34	14	32	4	18	$ 20.56	7
30	OR, WA	57	24	$15.00 – 78.10	2	34	21	33	4	20	$ 28.71	19
31	ID, UT	56	23	$13.30 – 75.50	2	30	24	32	5	19	$ 31.77	21
32	CA	55	23	$ 9.70 – 80.90	8	37	10	33	1	21	$ 21.03	10
33	HI	46	20	$10.80 – 74.90	4	31	11	27	4	15	$ 26.35	15
34	AK	45	19	$11.70 – 77.30	1	26	18	27	3	15	$ 33.56	17

Source: Zip-code specific data is available through the General Plan Search function of the Find and Compare Plans button on CMS's "The Medicare Prescription Drug Plan Finder" Web page (www.medicare.gov/MPDPF). Low Income Benchmark subsidy amounts for 2007 are available at www.cms.hhs.gov/MedicareAdvtgSpecRateStats/RSD.