

# Report for Congress

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## **Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues**

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# Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues

## Summary

Medicare is a nationwide health insurance program which offers health insurance protection for 40 million aged and disabled persons. The program provides broad coverage for the costs of many, primarily acute, health services. However, there are many gaps in program coverage. The most notable shortcoming is the fact that Medicare has a very limited prescription drug benefit.

Most beneficiaries have some form of private or public health insurance to cover expenses not met by Medicare. However, many of these plans either do not offer drug coverage or offer very limited protection for drug expenses. Though 73% of beneficiaries had some drug coverage in 1998, they paid approximately 44% of their total drug expenses out-of-pocket. The total average annual drug expenditure for Medicare enrollees living in the community was \$878 in 1998. Total spending for persons with some drug coverage was \$999 compared to \$546 for those with no coverage. Furthermore, out-of-pocket costs were higher for those without coverage (\$546) than those with coverage (\$325).

These spending patterns have suggested to policymakers the need for better drug coverage for the Medicare population. On several occasions, the Congress has considered adding coverage for at least a portion of beneficiaries' drug costs. In the summer of 2002, the House passed a prescription drug measure. The Senate spent several weeks debating various proposals, but were unable to come to an agreement on a plan. The 107<sup>th</sup> Congress did not take final action on a prescription drug measure. It is expected that the issue will be considered again early in the 108<sup>th</sup> Congress. In part, this reflects the prominence that this issue has assumed over the last couple of years. In part, it also reflects the likely continued attention that will be focused on the prices seniors pay for drugs and the inability of some seniors to pay these drug bills.

There are a number of design issues facing the development of a drug benefit for the Medicare population. First are several of broad organizational and administrative questions. These include whether a drug benefit should be enacted prior to or as part of overall structural reform of the Medicare program; whether the new benefit should be part of the Medicare program itself or administered as a separate program; and the degree of reliance that should be placed on the private sector, both for administering the benefit and assuming a portion of the financial risk. Another series of issues relate to benefit design. These include: whether the benefit should be extended to the entire population or limited to particular groups such as low-income persons and those with catastrophic expenses; how beneficiary cost-sharing would be structured; the level of assistance that would be provided for the low-income population; and the definition of covered drugs. Also at issue is what cost control strategies, if any, would be established at the federal level. The final questions relate to the potential costs of a new benefit and how these costs would be financed over time. This report will be updated as additional data become available.

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# Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues

## Background

The Medicare program provides significant health insurance coverage for its 40 million aged and disabled beneficiaries. The program provides broad coverage for the costs of many, primarily acute, care services. However, many observers believe that Medicare's benefit structure fails to adequately respond to beneficiaries' health care needs. The program includes cost-sharing charges for most services, provides only limited protection for some other costs (such as nursing home care) and includes no protection against the costs of some other services (such as hearing aids). Further, the program includes no upper limit ("catastrophic limit") on cost sharing charges.

The most notable shortcoming is the fact that Medicare has a very limited prescription drug benefit. Most beneficiaries have some form of private or public health insurance to help cover expenses not met by Medicare. However, many of these plans either do not offer drug coverage or offer very limited protection for drug expenses. As a result, beneficiaries still pay over 40% of their total drug expenditures out-of-pocket. This can pose a hardship for some beneficiaries, particularly those with low-incomes and persons with chronic diseases. In fact, some reports have suggested that some seniors skip medication doses or fail to get prescriptions filled because of cost-concerns.

Many persons have recommended the establishment of a drug benefit for the Medicare population which tends to use more drugs than the non-Medicare population. They point out that most medium and large employers offer prescription drug coverage for the working population under age 65. They further suggest that if the program were being designed today, rather than 37 years ago, it would include a drug benefit.

The absence of an adequate prescription drug benefit has been of concern to policymakers since the enactment of Medicare in 1965. On several occasions, most recently in 2002, the Congress has considered adding coverage for at least a portion of beneficiaries' drug costs. However, to date, there has been no consensus on how the expanded coverage should be structured. One of the key concerns is the potential cost of a new benefit and how costs would increase over time. Another issue is the appropriate roles of the federal government and the private sector in assuming the financial risk of coverage and administering the benefit. A related issue is whether the new benefit should be part of the Medicare program itself or administered as a separate program. A further consideration is whether a major new benefit should be added before structural reforms are made to the Medicare program as a whole.

This report provides an overview of prescription drug coverage currently available to the Medicare population, presents information on drug spending by the target population, and outlines some of the major issues that are being addressed as Congress considers policy options. For a discussion of major prescription drug bills that were under consideration in the 107<sup>th</sup> Congress, see CRS Report RL31496, *Medicare: Major Prescription Drug Provisions of Selected Bills*.

## Sources of Existing Coverage

Proponents of expanding Medicare's coverage of prescription drugs cite the uneven coverage available to the aged and disabled populations under existing public and private programs. This chapter reviews the limited drug coverage currently available under Medicare and outlines the types of supplementary coverage generally available to beneficiaries. The next chapter provides data on the extent of supplementary protection.

### Medicare

Medicare beneficiaries who are inpatients of hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs.<sup>1</sup> Medicare also makes payments to physicians for drugs or biologicals which *cannot be self-administered*. This means that coverage is generally limited to drugs or biologicals administered by injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, the law specifically authorizes coverage for the following:

- ! *Immunosuppressive Drugs*. Drugs used in immunosuppressive therapy (such as cyclosporin) for individuals who have received a *Medicare covered organ transplant*.<sup>2</sup>
- ! *Erythropoietin (EPO)*. EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.

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<sup>1</sup> Most hospitals are paid under a prospective payment system (PPS); under PPS, a predetermined payment is made per case based on the patient's diagnosis. The prospective payment is intended to cover all services, including drugs, provided during the patient's stay. Skilled nursing facilities (SNFs) are also paid under a PPS. The per diem rate that is paid to SNFs covers the cost of most drugs. Additional payments, over the per diem amount, are authorized for certain specified drugs.

<sup>2</sup> Prior to January 1, 2001, Medicare coverage was limited to drugs provided within a specified time frame (a minimum of 3 years) following a covered transplant. The Consolidated Appropriations Act of 2001 (P.L. 106-554) removed the time limitation, effective on enactment (December 21, 2000). Coverage for immunosuppressive drugs continues only if the individual continues to be eligible for Medicare. Persons, under age 65, whose Medicare eligibility was based solely on the fact that they had end-stage renal disease, lose their Medicare eligibility (and therefore the drug coverage) 3 years after a successful kidney transplant.

- ! *Oral Anti-Cancer Drugs.* Drugs taken orally during cancer chemotherapy providing they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service. Also included are oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen.
- ! *Hemophilia clotting factors.* Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.
- ! Drugs that are necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment (e.g., tumor chemotherapy agents used with an infusion pump).<sup>3</sup>

The program also covers the following immunizations:

- ! *Pneumococcal pneumonia vaccine.* The vaccine and its administration to a beneficiary if ordered by a physician.
- ! *Hepatitis B vaccine.* The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.
- ! *Influenza virus vaccine.* The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

Payments for these drugs and immunizations are made under Medicare Part B. The payment for a drug equals 95% of the average wholesale price (AWP).<sup>4</sup> Medicare pays 80% of this amount after the beneficiary has met the \$100 Part B deductible. The beneficiary is liable for the remaining 20% coinsurance charges. These Part B cost-sharing charges do not apply for pneumococcal pneumonia or influenza vaccines.

## Supplementary Coverage

Most Medicare beneficiaries have some form of public and/or private coverage to supplement their Medicare benefits. *This supplemental coverage may or may not include drug benefits.* Some beneficiaries have this supplemental protection throughout the year while others may only have the protection for a portion of the year. Different studies rely on different measurements and therefore yield somewhat

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<sup>3</sup> Medicare also pays for an injectable osteoporosis drug approved for treatment of post-menopausal osteoporosis provided by a home health agency to a homebound individual whose attending physician has certified suffers from a bone fracture related to post-menopausal osteoporosis and the individual is unable to self-administer the drug.

<sup>4</sup> For a discussion of the current payment system, see CRS Report RL31419, *Medicare: Payments for Covered Prescription Drugs*, by Jennifer O'Sullivan.

different data.<sup>5</sup> The most recent study looks at beneficiaries' insurance status coverage in the fall of 1999.

In the fall of 1999, 12.5% of noninstitutionalized beneficiaries relied solely on the traditional fee-for-service Medicare program for their health benefits; these persons had no supplementary drug coverage. An additional 17.3% of beneficiaries relied on coverage provided through their Medicare managed care organization; the majority of these persons had access to at least some supplemental drug coverage. (See **Table 1**).

Most beneficiaries (70.2%) had some form of private or public health insurance coverage to supplement Medicare in the fall of 1999. The majority (57.4%) had private supplemental coverage. Some of these persons (33.1%) obtained this protection through a current or former employer. Other persons (24.3%) obtained coverage through an individually purchased policy, commonly referred to as a "Medigap" policy. Coverage for the remaining 12.9% of the population was obtained through public sources; 10.9% obtained coverage from Medicaid and 1.9% from other public sources.

**Table 1. Medicare Beneficiaries, by Source of Supplementary Health Insurance Coverage, Fall 1999**

(in percent)

All beneficiaries	100
Medicare fee-for-service only	12.5
Medicare managed care	17.3
Medicaid	10.9
Employer-based coverage	33.1
Medigap	24.3
Other Public	1.9

**Source:** Laschober, Mary et al. Trends in Medicare Supplemental Insurance and Prescription Drug coverage, 1996-1999. *Health Affairs*, Web Exclusive. February 27, 2002.

**Note:** Data is from Barrents group analysis of 1996-1999 Medicare Current Beneficiary Survey (MCBS) Access to Care data. Beneficiaries were classified by their primary health insurance and were counted in only one category (in hierarchical order for beneficiaries with more than one type). Supplementary health insurance coverage *may or may not include drug coverage*.

The scope of benefits available to persons with supplementary protection differs significantly by type of coverage. Many persons with supplementary coverage have

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<sup>5</sup> For example, Poisal and Murray looked at beneficiaries who had coverage *at any point* during 1998 rather than at a specific point in time; under this study only 6.8% of the population had no supplementary coverage during the year. (Poisal, John and Lauren Murray. Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, v. 20, no. 2. March/April 2001.)



either limited or no protection against prescription drug costs. The next section reviews the types of supplementary health insurance coverage generally available to the Medicare population. It also examines whether such coverage typically includes drug benefits. The subsequent chapter provides information on the extent of coverage for prescription drug costs.

**Medicare Managed Care Organizations.** Since the early 1980s Medicare beneficiaries have been able to enroll in health maintenance organizations (HMOs). Beneficiaries get all their Medicare services through the HMO and Medicare makes a monthly capitation payment to the plan on their behalf. The Medicare+Choice (M+C) program, which became effective January 1, 1999, expanded the types of managed care arrangements that could potentially serve Medicare beneficiaries. However, HMOs remain the primary managed care arrangement available to them.

Traditionally, Medicare payments to HMOs varied considerably throughout the country. In areas where payment rates were high, HMOs were typically able (and were often required) to offer services in addition to those covered under the basic Medicare program. Of particular importance was the ability of a number of plans to offer prescription drug coverage *at little or no additional cost to beneficiaries*. Conversely, in lower payment areas, plans typically did not offer a similar scope of additional benefits. If they did cover additional benefits, they charged the beneficiary a premium (which was in addition to the Part B premium which all enrollees are required to pay).

Under M+C, the variation in payment rates across the country has been reduced. As a result, capitation payments in many previously high payment areas have seen relatively small year-to-year increases. The managed care industry has argued that the changes in payment policies have resulted in inadequate reimbursement rates. While the payment amounts may be adequate to cover the costs of *Medicare covered benefits*, many plans have found it difficult to offer a range of additional services at relatively low cost to beneficiaries. These plans have questioned whether they could continue to be competitive if they dropped prescription drug coverage or, alternatively, instituted significant cost-sharing requirements for the coverage. These concerns, coupled with other business considerations, have led a number of M+C organizations to reduce their service areas or pull out of the program entirely.<sup>6</sup> Thus, while **Table 1** shows that 17.3% of beneficiaries had supplementary coverage through M+C or similar plans in the fall of 1999, subsequent reports indicate that this percentage declined to 14% in 2002.

The Centers for Medicare and Medicaid Services (the agency that administers Medicare)<sup>7</sup> reports that the percentage of the total Medicare population with access to any M+C plan with drug coverage has declined. In 1999, 65% of Medicare beneficiaries had such access; this percentage declined to 64% in 2000, 53% in 2001, and 50% in 2002. In 2002, 63% of the Medicare population in counties that are part

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<sup>6</sup> For a further discussion see CRS Report RL31224, *Medicare+Choice: Plans Leaving the Program*, by Paulette Morgan, Madeleine Smith, and Hinda Chaikind.

<sup>7</sup> Prior to June 14, 2001, this agency was known as the Health Care Financing Administration (HCFA).

of Metropolitan Statistical Area (MSA) counties had such access, while only 8.9% of those in non-MSA counties had access. Three states (New Jersey, Illinois, and Louisiana) saw significant declines in the availability of drug coverage for M+C enrollees,<sup>8</sup> though access to M+C plans themselves remained relatively stable. One state (North Carolina) had a large increase. Access did not change in 29 states.<sup>9</sup>

Prescription drug benefits may be offered by a M+C plan as part of the *basic* package or may be included in a high option package. In 2002, 71.8% of plans available from a M+C organization included drug coverage in their basic plan, while 13% only made such coverage available in a higher priced plan. No drugs were available in any plan offered by 15.2% of M+C organizations. Enrollment in basic plans with drug coverage declined from 3,549,301 persons in 2001 to 3,509,936 in 2002. The number of enrollees with coverage for brand name drugs in their basic plans declined, with generic only coverage rising sharply. CMS reports that for 2002, unlimited coverage for brand name drugs virtually disappeared, while unlimited coverage for generic drugs also became less common.<sup>10</sup>

## Private Supplementary Coverage

**Employer-Sponsored Plans.** Employers may offer their retirees health benefits. Several surveys have attempted to quantify the percentage of employers offering this coverage. Since each survey uses a different data base, the numbers differ somewhat. However, all show that the number offering such plans has declined in recent years.

A 2001 survey by Mercer/Foster Higgins shows that over an 8-year period (1993-2001) the number of employers (with over 500 employees) offering health plan coverage to retirees (both current and future retirees) under age 65 fell from 46% to 29%, while the number providing coverage to Medicare-eligible retirees fell from 40% to 23%.<sup>11</sup> Coverage of the Medicare-eligible population increases by size of employer. In 2001, 17% of employers with 500-999 employees offered coverage. This percentage increased to 25% for employers with 1,000-4,999 employees, 37% for those with 5,000-9,999 employees, 37% for those with 10,000-19,999 employees, and 54% for those with 20,000 or more employees.<sup>12</sup>

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<sup>8</sup> Louisiana had a 99% drop, Illinois a 76% drop, and Louisiana a 23% drop.

<sup>9</sup> Centers for Medicare and Medicaid Services. M+C Changes in Access, Benefits and Premiums, 2001-2002. [[http://www.CMS.gov/healthplans/mplusc\\_changes.pdf](http://www.CMS.gov/healthplans/mplusc_changes.pdf)], accessed October 2002.

<sup>10</sup> Ibid.

<sup>11</sup> It should be noted that many employers report that they are grandfathering in coverage for current retirees and those close to retirement, while cutting back on benefits for younger workers.

<sup>12</sup> Mercer, William M. *National Survey of Employer-Sponsored Health Plans, Key Findings for 2001*. April 8, 2002.

A joint study done by The Kaiser Family Foundation, Health Research and Educational Trust (HRET) and the Commonwealth Fund shows similar trends.<sup>13</sup> From 1997 to 2001, the percentage of large employers (with 200 or more employees) offering coverage to all retirees dropped from 37% to 34%. For Medicare-eligible retirees, the percentage offering benefits dropped from 31% to 23%. Virtually all (99%) of Medicare-age retirees in firms offering health benefits had prescription drug coverage in the firm's largest retiree plan.

Prescription drug benefits represent a large part of plan expenses for retirees.<sup>14</sup> As a result, plans are taking a number of actions to contain these costs. The report done by Kaiser Family Foundation, HRET, and Commonwealth Fund showed that the majority of plans imposed either a two-tiered cost-sharing (one payment for generic drugs and another for brand name drugs) or three-tiered cost-sharing (one payment for generic drugs, another for brand name drugs with no generic substitute and a third for brand-name drugs with a generic substitute). The survey reported that additional firms were planning on increasing retiree cost-sharing requirements for drugs in the next 2 years.<sup>15</sup>

Increasing costs of drug coverage is one factor influencing employer decisions about retiree health coverage. For example, a 1999 Hewitt study surveyed large employers on their expectations for retiree benefits in the future (assuming no changes in Medicare). Most large employers (80% of those answering the survey) said they would consider increasing premiums or cost-sharing for Medicare-eligible enrollees. Forty percent said they would consider cutting back on prescription drug coverage. Thirty percent said they would consider terminating coverage prospectively for retirees 65 and older, while only 17% said they would consider improving benefits.<sup>16</sup> Similarly, the report done by Kaiser Family Foundation, HRET, and Commonwealth Fund showed that a significant percentage were planning to increase cost-sharing requirements for drugs and/or make other changes in retiree health coverage in the following 2 years (2002-2003).<sup>17</sup>

Longer term projections suggest that employers' contributions to retiree health care costs will continue to decline. A recent study by Watson Wyatt Worldwide estimates that employer financial support will shrink to less than 10% of total retiree medical expenses by 2031. It cited a number of actions already being taken by

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<sup>13</sup> Henry J. Kaiser Family Foundation, Health Research and Educational Trust, and the Commonwealth Fund. *Erosion of Private Health Insurance Coverage for Retirees, Findings from the 2000 and 2001 Retiree Health and Prescription Drug Coverage Survey*. April 2002.

<sup>14</sup> A 1999 study estimated that these costs represented 40%-60% of retiree plan costs for the age 65 and older population; it further expected the percentage would rise significantly in the ensuing years. Hewitt Associates. *Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits*. Report prepared for Henry J. Kaiser Family foundation. October 1999.

<sup>15</sup> The Kaiser Family Foundation, HRET, and the Commonwealth Fund. *Ibid.*

<sup>16</sup> *Ibid.*

<sup>17</sup> The Kaiser Family Foundation, HRET, and the Commonwealth Fund. *Ibid.*

employers. Twenty percent of those studied have eliminated retiree plans for new hires, and another 17% will require new hires to pay the full premium for coverage. Other employers are capping their contributions, linking contributions to the retirees' length of service or imposing stricter minimum service requirements for future retirees. The study attributed the cutbacks to several factors including escalating health costs, growing retiree populations, uncertain business profitability and federal regulations that discourage employers from pre-funding retiree medical benefits.<sup>18</sup>

**Medigap.** Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals who first purchase a Medigap policy on or after July 30, 1992, select from one of 10 basic standardized plans, though not all 10 plans are offered in all states. The 10 plans are known as Plan A through Plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. A change authorized by the Balanced Budget Act of 1997 (BBA 97) added two high deductible plans to the list of 10 standardized plans. With the exception of the high deductible feature, the benefit packages under the high deductible plans are the same as under Plan F or Plan J. Reportedly, few insurers are offering these high deductible plans.<sup>19</sup>

Only three of the standardized plans, Plans H-J, offer prescription drug coverage. All three plans impose a \$250 drug deductible. Plans H and I cover 50% of the next \$2,500 in costs up to a maximum benefit of \$1,250 (\$2,750 total spending). Plan J covers 50% of the next \$6,000 in costs up to a maximum benefit of \$3,000 (\$6,250 total spending). The premiums for these plans are higher than those for the other seven Medigap plans, in large measure due to the drug coverage.

There is wide variation in Medigap premiums for both drug and non-drug policies nationwide. This reflects a number of factors including differences in the benefits of Plan A through Plan J, differences in medical underwriting practices, and differences in pricing structures. Periodically, Weiss Ratings, Inc., under contract with CMS, reports on its inventory of Medigap premiums for 65-year old males. Over the 2-year period 1998-2000, the average premium increases were 15.5% for policies without drug coverage compared to 37.2% for policies with coverage. The rate slowed substantially in 2002, with only a 2.4% increase recorded for all policies over the previous year. For all 3 years, premiums, and premium increases vary greatly by location.

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<sup>18</sup> Watson Wyatt Worldwide. *Companies Accelerating Cutbacks in Retiree Health Benefits, Watson Wyatt Study Finds*. Press Release. [[Http://www.watsonwyatt.com](http://www.watsonwyatt.com)]. September 16, 2002.

<sup>19</sup> For further information on Medigap see CRS Report RL31223, *Medicare: Supplementary "Medigap" Coverage*, by Jennifer O'Sullivan.

**Table 2. Average Nationwide Medigap Premiums for a 65-Year Old Male, 1998, 2000, and 2002**

Plan	1998 average	2000 average	2002 average
Without drug coverage:			
A	\$631	\$766	\$864
B	875	1026	1139
C	1065	1239	1372
D	900	1050	1218
E	963	1107	1172
F	1164	1301	1432
G	1071	1175	1285
With drug coverage:			
H	1573	2347	2738
I	1803	2423	2734
J	2408	3065	3344

**Sources:** (1) Weiss Ratings, Inc. *Prescription Drug Costs Boost Medigap Premiums Dramatically*. Press Release. March 26, 2001; and (2) Weiss Ratings, Inc. *Rate of Medigap Premiums Slows Dramatically in 2002*. Press Release, August 7, 2002 and information provided by Weiss official.

A number of observers have concluded that only those persons who expect to actually utilize a significant quantity of prescriptions actually purchase Medigap drug coverage. This is because there is a significant price difference between premiums for policies with drug coverage versus those for policies without drug coverage. This adverse selection tends to further drive up the premium costs.

A recent analysis of the Medigap market concluded that this market is not a good source for prescription drug coverage. This study found that about 60% of policyholders have no drug coverage. This figure includes the 90% of beneficiaries purchasing standardized plans (i.e., Plans A- J, first purchased on or after July 30, 1992). Three out of four Medigap policyholders with prescription drug coverage are in prestandard Medigap plans; many of these plans offer coverage that is even less generous than that available under standard plans. Enrollees in prestandard plans are at least 74 years old. Since in most states Medigap insurers can deny issuance of Medigap policies after the open enrollment period at age 65, persons with prestandard policies who wish to change plans generally have no alternative except Plan A (if their current carrier is willing to sell them this) or Medicare+Choice (if a M+C plan is available in their area).<sup>20</sup>

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<sup>20</sup> Chollet, Deborah. Senior Fellow Mathematica Policy Research Institute. *Medigap* (continued...)

**Medicaid.**<sup>21</sup> Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Medicaid is a federal-state program which provides health insurance coverage to certain low-income individuals. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to *full* coverage under Medicaid. Persons entitled to *full* Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these “dual eligibles” Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare. Perhaps the most important service for the majority of dual eligibles is prescription drugs.<sup>22</sup> In general, beneficiaries entitled to full Medicaid protection are entitled to drug benefits. These dual eligibles typically have comprehensive coverage with only nominal cost-sharing.<sup>23</sup>

Federal law specifies several population groups that are entitled to more *limited* Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLIMBs), and certain qualified individuals. QMBs and SLIMBs are not entitled to Medicaid’s prescription drug benefit unless they are also entitled to full Medicaid coverage under their state’s Medicaid program. Qualifying individuals are *never* entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits). As discussed later in this report, many prescription drug bills would target one or more of these population groups for special assistance for their drug costs.

The following are the four coverage groups:

- ! **Qualified Medicare Beneficiaries (QMBs).** QMBs are aged or disabled persons with incomes at or below the federal poverty level. In 2002, the monthly level is \$759 for an individual and \$1,015 for a couple.<sup>24</sup> They must also have assets below \$4,000 for an individual and \$6,000 for a couple. QMBs are entitled to have their

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<sup>20</sup> (...continued)

*Coverage for Prescription Drugs.* Testimony before Senate Committee on Finance. April 24, 2001.

<sup>21</sup> For an overview of Medicaid drug coverage see CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

<sup>22</sup> Medicaid also offers coverage for long-term care — a potentially very costly item for the population needing these services.

<sup>23</sup> For a detailed discussion the various ways dual eligibles can obtain drug coverage under Medicaid, see CRS Report RL31485, *Prescription Drug Coverage for Medicare Beneficiaries: Medicaid and State Pharmaceutical Assistance Programs*, by Julie Stone and Heidi Yacker. (Hereafter cited as CRS Report RL31485, *Prescription Drug Coverage*.)

<sup>24</sup> The annual HHS poverty guidelines for 2002 are \$8,860 for an individual and \$11,940 for a couple; the monthly figures are \$738 for an individual and \$995 for a couple. The qualifying levels are higher because, by law, \$20 per month of unearned income (rounded to the next dollar) is disregarded in the calculation. [<http://www.hcfa.gov/medicaid/dualelig/4732rate.htm>].

Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is *not* entitled to coverage of Medicaid plan services) unless the individual is otherwise entitled to Medicaid.

- ! **Specified Low-Income Medicare Beneficiaries (SLIMBs).** These are persons who meet the QMB criteria, except that their income is over the QMB limit. The SLIMB limit is 120% of the federal poverty level. In 2002, the monthly income limits are \$906 for an individual and \$1,214 for a couple.<sup>25</sup> Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is *not* entitled to coverage of Medicaid plan services) unless the individual is otherwise entitled to Medicaid.
- ! **Qualifying Individuals (QI-1).** These are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. Further, they are *not* otherwise eligible for Medicaid. In 2002, the monthly income limit for QI-1 for an individual is \$1,017 and for a couple \$1,364. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium.<sup>26</sup>
- ! **Qualifying Individuals (QI-2).** These are persons who meet the QMB criteria, except that their income is between 135% and 175% of poverty. Further, they are *not* otherwise eligible for Medicaid. In 2002, the monthly income limit is \$1,313 for an individual and \$1,762 for a couple. Medicaid protection is limited to payment of that portion of the Part B premium attributable to the gradual transfer of some home health visits from Medicare Part A to Medicare Part B. (\$3.91 in 2002).

**Other Sources.**<sup>27</sup> Some beneficiaries with a military service connection may receive drug coverage through Department of Defense or Department of Veterans Affairs programs.

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<sup>25</sup> This is calculated the same way as the QMB level. See preceding footnote.

<sup>26</sup> In general, Medicaid payments are shared between the federal government and the states according to a matching formula. However, expenditures under the QI-1 and QI-2 programs are paid for 100% by the federal government (from the Part B trust fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. Any expenditures beyond that level are paid by the state. Total allocations are \$200 million in FY1998, \$250 million for FY1999, \$300 million for FY2000, \$350 million for FY2001, and \$450 million for FY2002. Assistance under the QI-1 and QI-2 programs is available for the period January 1, 1998 to December 31, 2002.

<sup>27</sup> Some pharmaceutical companies have patient assistance programs that provide free prescriptions for low-income persons without other assistance. The programs have not been well publicized; further, the application process for many programs can be difficult and time consuming. In an effort to address these concerns, the Health Care Financing Administration (now CMS) announced in November 2000, that the programs would be listed on its WEB site [<http://www.medicare.gov/prescription/home.asp>].

Recent action taken by the Congress significantly expanded the access of military retirees to prescription drug benefits. On October 30, 2000, the President signed into law P.L. 106-398, the Defense department authorization bill. This legislation authorized a permanent comprehensive health care benefit for Medicare-eligible military retirees thereby making all military retirees eligible for health care within TRICARE, the military health care system, effective October 1, 2001. Under the bill, Medicare pays first and TRICARE is the secondary payer, subject to a \$300 deductible. Previously, individuals lost their TRICARE eligibility when they became eligible for Medicare. The bill also authorized, effective April 1, 2001, a comprehensive retail and mail order pharmacy benefit and a national mail order pharmacy benefit for all eligible beneficiaries. There are deductibles for use of non-network pharmacies and co-payments for pharmaceuticals received from the National Mail Order Pharmacy and from retail pharmacies.

**State Programs.** Some beneficiaries also have coverage through state pharmaceutical assistance programs which provide financial assistance to low-income persons who do not qualify for Medicaid. The National Conference of State Legislatures (NCSL) reports<sup>28</sup> that as of August 2002, 34 states had authorized some type of pharmaceutical assistance program with some states having more than one program. Twenty states had subsidy programs;<sup>29</sup> some of these programs were limited to seniors, while others included other low-income groups. Eight states operated pharmaceutical discount programs for the purchase of prescription drugs.<sup>30</sup> Two additional states provided assistance under a Medicaid waiver.<sup>31</sup>

The state programs vary substantially both in design and coverage. While the number of states offering plans has increased, some are in the initial stages of operation. Several additional states have authorized plans but have not yet implemented them. Programs were actually in operation in 26 states.

Virtually all states set income eligibility standards, ranging from 100% to 400% of poverty. All plans require some level of beneficiary financial participation in the form of premiums, deductibles, copayments, or a combination of these. The level of coverage also varies among the states. Some set a maximum payment. Others provide coverage only after a person has incurred a certain level of expenses (known as a “catastrophic cap”). Some states cover all prescription drugs while others limit coverage to those on an approved list known as a formulary.<sup>32</sup>

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<sup>28</sup> NCSL: [<http://www.nchsl.org/programs/health/drugaid.htm>], accessed August 23, 2002.

<sup>29</sup> Connecticut, Delaware, Florida, Illinois, Indiana, Kansas, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Vermont, and Wyoming.

<sup>30</sup> California, Florida, Iowa, Maryland, Maine, Massachusetts, New Hampshire, and West Virginia.

<sup>31</sup> Maine and Vermont.

<sup>32</sup> CRS Report RL31485, *Prescription Drug Coverage*.



## Drug Coverage and Spending for the Medicare Population

The previous discussion focused on drug insurance coverage potentially available to the Medicare population. This section reviews the proportion of this population with drug coverage and provides data on drug spending. The most detailed information on these issues comes from the 1998 Medicare Current Beneficiary Survey (MCBS) data on non-institutionalized Medicare beneficiaries. Most analyses of this data shows the number of beneficiaries who had drug coverage *at any point during the year*. A more recent study (by Lashober et al) of 1999 MCBS data shows the percentage with coverage *at a particular point in time*, namely the fall of 1999. As noted earlier, many beneficiaries have coverage at some point during the year, but not throughout the entire year. The Laschober study therefore shows a lower percentage than the MCBS analysis of the population with drug coverage. A detailed update of the MCBS data is not yet available; later data may show different trends from those discussed below.

### Drug Coverage

In 1998, 73% of the non-institutionalized Medicare population had drug coverage at some point during the year; the remaining 27% had no coverage. (See **Table 3.**) In the fall of 1999, 62% of the non-institutionalized Medicare population had coverage while 38% did not.<sup>33</sup> These figures do not reflect the extent and depth of coverage which varies widely by source of coverage.

**Coverage By Source of Supplemental Insurance.** The likelihood that a beneficiary has prescription drug coverage varies by the source of supplemental health insurance coverage. In 1998, beneficiaries enrolled in HMOs were the most likely to have drug coverage while those in Medigap plans were the least likely to have such coverage. (See **Table 3.**)

**Table 3. Distribution of Noninstitutionalized Medicare Beneficiaries, by Type of Supplemental Insurance and Presence of Drug Coverage, 1998**

(in percent)

Type of coverage <sup>a</sup>	With drug coverage	Without drug coverage
All persons	73	27
No supplemental coverage	0	100
Supplemental coverage		
Medicare HMO <sup>b</sup>	92	8
Medicaid <sup>c</sup>	89	11
Employer-sponsored	90	10

<sup>33</sup> Laschober, Mary et al. Trends in Medicare Supplemental Insurance and Prescription Drug coverage, 1996-1999. *Health Affairs*, Web Exclusive. February 27, 2002.

Type of coverage <sup>a</sup>	With drug coverage	Without drug coverage
Medigap	43	57
All other	89	11

**Source:** Poisal, John A., and Lauren Murray. Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, v. 20, no. 2, March/April 2001.

<sup>a</sup> Beneficiaries were classified by their primary health insurance and were counted in only one of the categories (in the hierarchical order as shown in the table for beneficiaries with more than one type).

<sup>b</sup> Includes persons receiving drug coverage through both their basic plans and optional coverage.

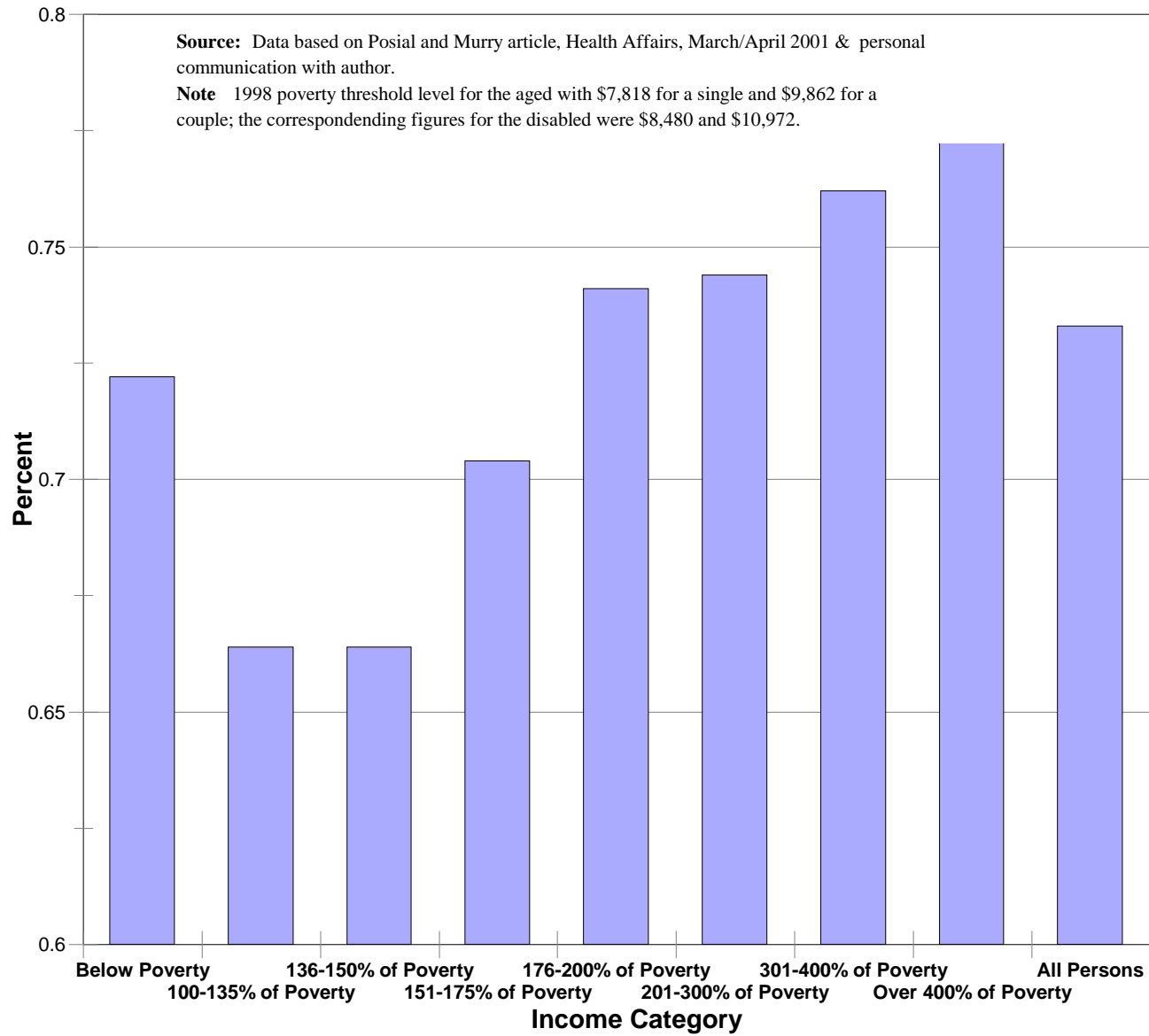
<sup>c</sup> The Medicaid number reflects the percentage of all persons on the Medicaid rolls, including the QMB-only and SLIMB-only population (who do not have drug coverage). If just the population with full Medicaid coverage were taken into account, the percentage should be closer to 100%.

**Drug Coverage By Income Level.**<sup>34</sup> In 1998, persons in higher income brackets were more likely to have drug coverage. This reflects the fact that these persons were more likely to have drug coverage through a former employer. Persons below poverty had coverage levels slightly higher than persons just above poverty. This reflects the fact that many individuals below poverty were eligible for full Medicaid benefits which include drug benefits. The lowest levels of coverage were for persons between 100% and 175% of poverty. These persons are the least likely to have access to employer-based coverage or Medicaid. (See **Figure 1.**) The 1998 number reflects a slight improvement for the low-income population over previous years. However, 1998 was the first year since 1992 that overall coverage levels had not increased from the previous year.

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<sup>34</sup> CMS's analysis of the 1998 MCBS (as reported in the March/April 2001 *Health Affairs* article) used federal poverty thresholds. These are slightly different than the federal poverty guidelines; federal poverty guidelines are used for the QMB and SLIMB programs, discussed earlier in this report.

**Figure 1. Medicare Beneficiaries with Drug Coverage by Income Category, 1998**



**Impact of Coverage on Utilization.** There are significant differences in utilization patterns for persons with drug coverage versus those without it. In 1998, the average beneficiary with drug benefits filled almost eight more prescriptions than those without coverage (24.3 versus 16.7 per person). Utilization rates for those with coverage increased 9% from 1997, while rates for those without coverage declined 2.4%.<sup>35</sup>

Data for 1999 show similar patterns. Beneficiaries with drug coverage report filling 25.1 prescriptions that year compared to 17.7 for those without coverage. These disparities in usage were reported even for those with five or more chronic conditions; those with drug coverage reported filling 44.4 prescriptions while those without coverage reported filling 38.7 prescriptions.<sup>36</sup>

A recent eight-state survey found similar patterns. In 2001, one-quarter of seniors without drug coverage reported not filling a prescription due to costs and skipping doses to make prescriptions last longer. Only about one in 10 seniors with coverage reported these forms of foregone care. Further, one in five seniors without coverage reported spending less on basic necessities to pay for medicines – a rate which was twice that for those with coverage. While these actions were reported for all income groups, the rates were higher for the low-income. Forty-one percent of poor seniors without coverage had not filled a prescription in the past year due to cost, compared to 19% of poor seniors with coverage. Thirty-six percent of low-income seniors without coverage skipped doses, while only 21% with coverage did so. The depth of coverage was shown to be an important variable. For example, those who had employer-based coverage were less likely to forgo care than those with Medigap; this reflects the relatively higher out-of-pocket costs under Medigap plans.<sup>37</sup>

## Drug Spending

**Total Spending.** Per capita drug spending and out-of-pocket spending by Medicare beneficiaries is available from the 1998 MCBS. Medicare beneficiaries spent \$878 per capita on drugs in 1998.<sup>38</sup> (This figure includes amounts spent by insurers on behalf of beneficiaries.) In that year, beneficiaries with drug coverage averaged \$999 per year, while those without coverage averaged \$546. (See **Figure 2.**) Overall, drug spending is highly associated with the presence of drug coverage. Higher drug spending appeared to be more closely associated with the presence of drug coverage rather than income level.

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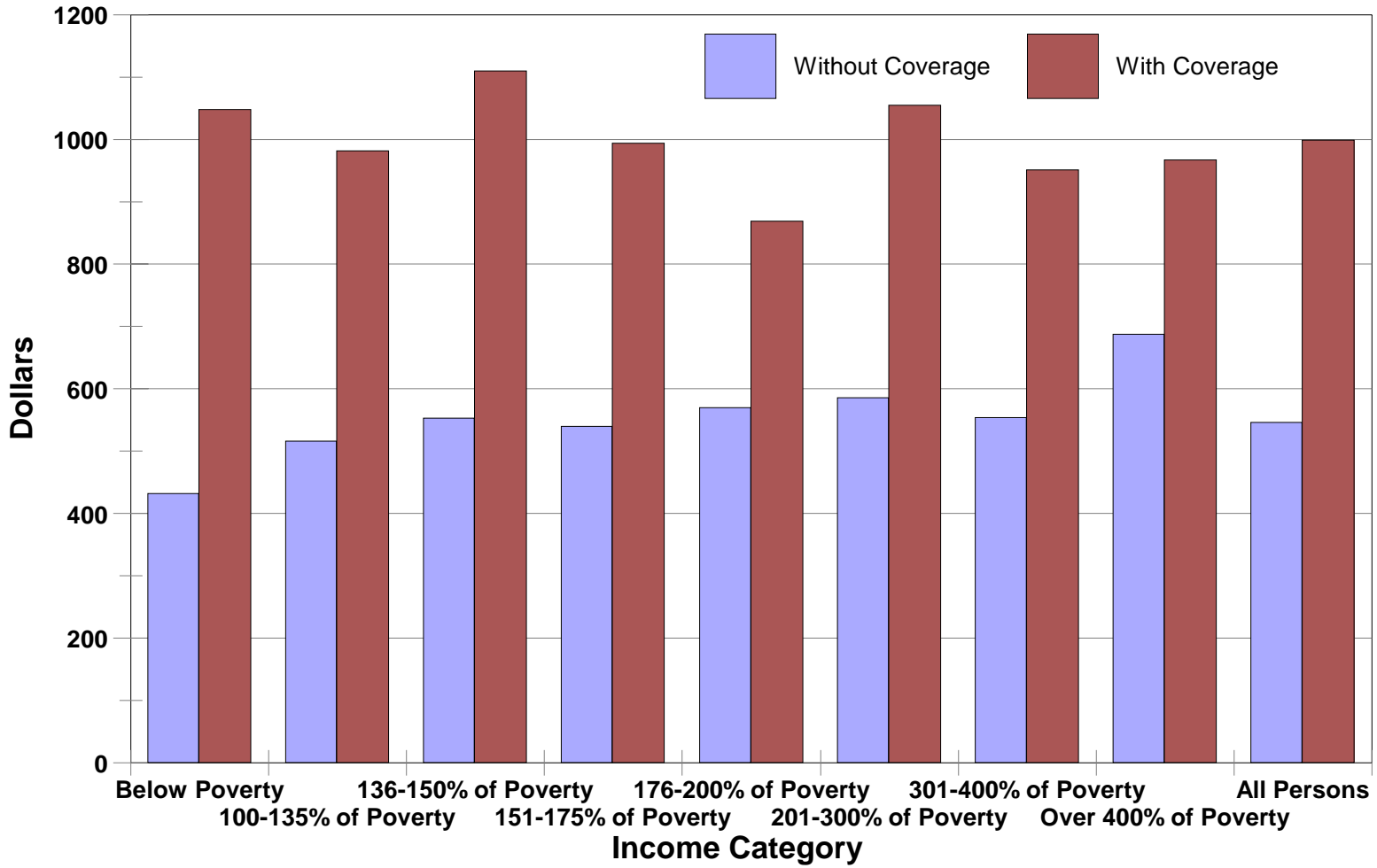
<sup>35</sup> Poisal, John A., and Lauren Murray. Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, v. 20, no. 2, March/April 2001.

<sup>36</sup> Department of Health and Human Services. Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative. Final rule. *Federal Register*, v. 67, no. 171, September 4, 2002. p. 56619.

<sup>37</sup> Safran, Dana Gelb, et.al. Prescription Drug Coverage and Seniors: How Well Are States Closing the Gap? WEB Exclusive. *Health Affairs*, July 2002.

<sup>38</sup> Personal communication with HCFA official, May 2001.

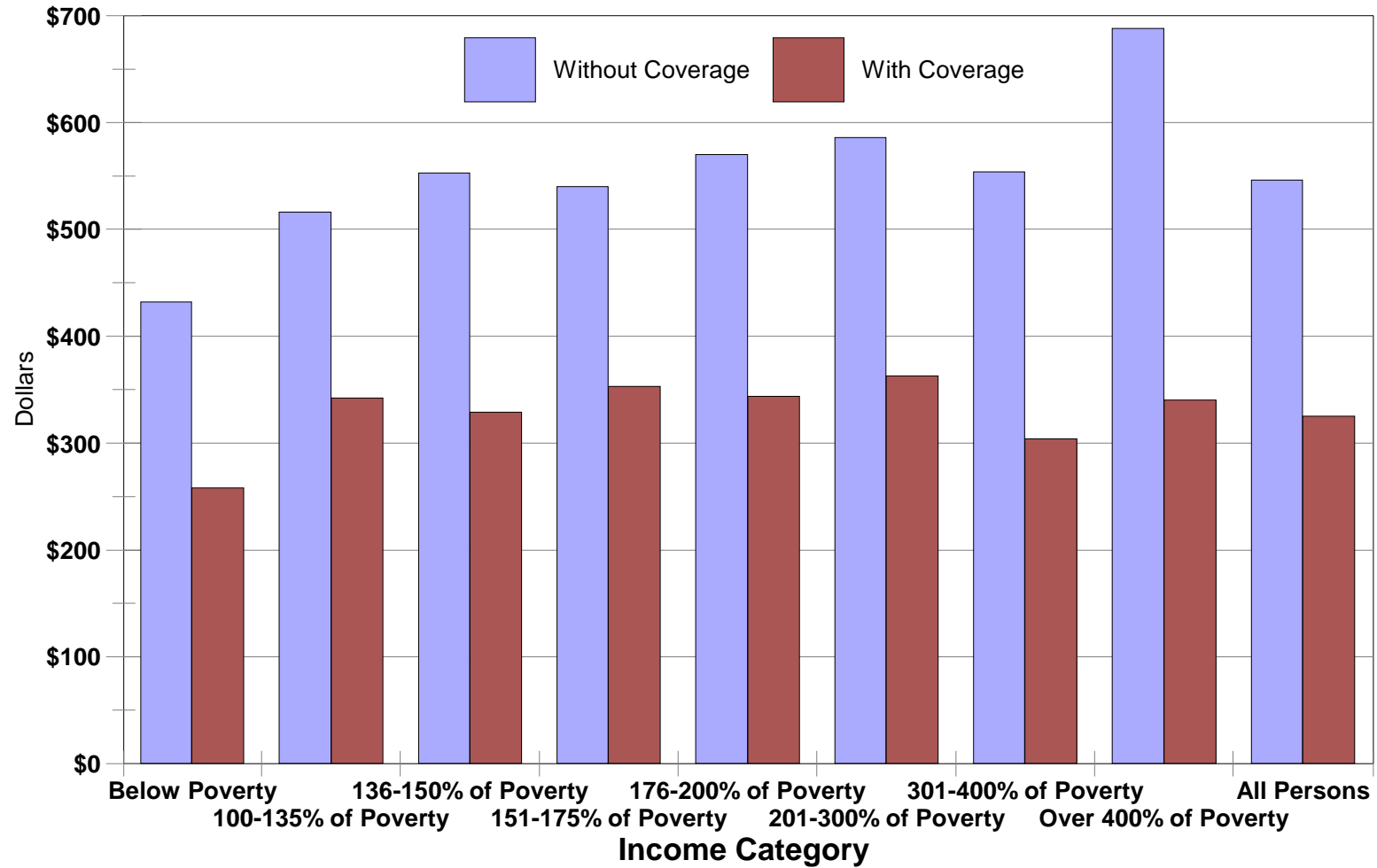
**Figure 2. Average Annual Per-Capita Spending for Prescription Drugs for Medicare Beneficiaries by Presence or Absence of Drug Coverage and by Income Category, 1998**



**Source:** Data based on article by Posial and Murray. Health Affairs, March/April 2001 and personal communication with author.

**Note:** 1998 poverty threshold level for aged with \$7,818 for single and \$9,862 for couple; corresponding figures for disabled, \$8,480 and \$10,972.

**Figure 3. Average Annual Out of Pocket Spending for Prescription Drugs by Medicare Beneficiaries by Presence or Absence of Drug Coverage and by Income Category, 1998**



**Source:** Data based on article by Posial and Murray, Health Affairs, March/April 2001 and personal communication with author.

**Note:** 1998 poverty threshold level for the aged with \$7,818 for single and \$9,862 for couple; corresponding figures for disabled, \$8,480 and \$10,872.

**Out-of-Pocket Spending.** Despite the presence of insurance, beneficiaries pay almost half of their total drug bills out-of-pocket. On average, beneficiaries paid \$384 out-of-pocket or 43.8% of their total \$878 drug bill in 1998.<sup>39</sup> The amount an individual actually pays depends on whether or not he or she has supplementary coverage. **Figure 3** shows average annual out-of-pocket expenditures for persons by income level and by whether or not they have coverage. Persons without coverage paid their whole \$546 bill out-of-pocket. Persons with drug coverage paid \$325 out-of-pocket, or roughly one-third of their total bill. Higher overall out-of-pocket costs are more closely associated with the absence of drug coverage than with income level.

**Out-of-Pocket Drug Spending as a Percentage of Income.** Out-of-pocket drug costs represented 1% of income for covered beneficiaries and 2.2% of income for non-covered beneficiaries in 1996. Out-of-pocket costs represented a larger proportion of income for persons with the highest drug costs (defined as the top 20%). Among the highest spenders, those with coverage spent 2.6% of their incomes on drugs while those without coverage spent 8.1%. Among the highest spenders, *non-covered* beneficiaries below 200% of poverty spent over one-fifth of their incomes on drugs, while those under 100% of poverty spent over one-quarter.<sup>40</sup> (As can be seen from **Figure 1**, one-quarter or more of those below 200% of poverty were without coverage in 1998.)

**Estimates of Future Spending.** The 1998 spending data described in the preceding sections were derived from the 1998 MCBS. For the last 3 years, the Congressional Budget Office (CBO) has projected drug spending for Medicare beneficiaries for drugs not covered by the program. This includes spending by supplemental plans as well as beneficiaries' out-of-pocket costs. In March 2000, the CBO estimated that such spending would total \$1.1 trillion over the CY 2001-CY 2010 period. In January 2001, CBO issued revised figures. For the same 10-year period, it estimated spending at \$1.3 trillion, or 18% higher than the previous projection. The estimate for CY2002-2011, the then current 10-year projection period, was approximately \$1.5 trillion. In March 2002, the estimate for the CY2002-2011 period was increased to \$1.6 trillion. Estimates for CY2003-CY 2012 are \$1.8 trillion. (Any new Medicare benefit would pick up a portion of these costs.) Projection increases reflect both higher estimates of per capita drug spending over the entire projection period and the inclusion of a new high cost year (currently 2012, the second year of the baby boom) in the projection window.

Under the 2002 CBO estimates, mean per capita drug spending for the Medicare population would climb from \$2,149 in CY2002 to \$5,816 in CY2012; this represents an average annual rate of increase of 10.5%. Median prescription spending would also rise at the same rate, from \$1285 in CY2002 to \$3486 in CY2012. Mean spending is higher than median spending because mean spending is highly influenced by the relatively small portion of the population with very high drug costs.

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<sup>39</sup> Ibid.

<sup>40</sup> U.S. Dept. of Health and Human Services. *Prescription Drug Coverage, Spending, Utilization, and Prices*. [<http://www.Aspe.hhs.gov/health/reports/drugstudy>]. April 2000.

Total prescription spending for the Medicare population group would rise from \$86.9 billion in CY2002 to \$278.3 billion in CY2012, for an average annual rate of increase of 12.3%. (See **Table 4**.) The majority of the increase reflects increases in per capita spending; the remainder of the overall increase is attributable to an increase of 1.7% per year in the number of Medicare beneficiaries.

**Table 4. Estimated Spending on Outpatient Drugs by or for Medicare Beneficiaries, 2002-2012**

Year	Mean Per capita	Total (in billions)
2002	\$2149	\$86,893
2003	2439	99,663
2004	2744	113,421
2005	3059	128,063
2006	3380	143,491
2007	3712	160,200
2008	4071	179,102
2009	4458	199,703
2010	4874	222,484
2011	5324	248,132
2012	5816	278,311

**Source:** U.S. Congressional Budget Office. Estimates using March 2002 baseline projections. Estimates based on data from the 1999 MCBS with adjustments to account for under reporting by community respondents and for non-response by nursing home residents. March 2002.

Drug spending is very unevenly distributed across Medicare beneficiaries. A relatively small proportion of the population accounts for a relatively large portion of total spending. CBO estimates that (excluding M+C enrollees), 10.3% of beneficiaries will have no drug spending in 2002. About three-fifths of total drug spending will be for the 22% of the population spending \$3,000 or more in the year. Approximately 29% of spending will be for the 6% of the population spending \$6,000 or more in the year. (See **Table 5**.)

**Table 5. Estimated Distribution of Medicare Beneficiaries and Amount Spent on Outpatient Prescription Drugs, 2002**

Spending category	Percent of beneficiaries	Percent of total dollars
zero	10.3	0.0
greater than zero	89.7	100.0
\$500 or greater	70.1	97.8
\$1,000 or greater	56.8	92.9
\$2,000 or greater	35.6	77.7



Spending category	Percent of beneficiaries	Percent of total dollars
\$3,000 or greater	22.4	61.8
\$4,000 or greater	13.7	47.1
\$5,000 or greater	9.0	36.8
\$6,000 or greater	6.0	28.9
\$7,000 or greater	4.3	23.6
\$8,000 or greater	3.2	19.4
\$9,000 or greater	2.2	15.3
\$10,000 or greater	1.6	12.7
\$11,000 or greater	1.2	10.2
\$12,000 or greater	0.9	8.4

**Source:** U.S. Congressional Budget Office. Estimates using March 2002 baseline projections. Estimates based on data from the 1999 MCBS with adjustments to account for under reporting by community respondents and for non-response by nursing home residents. March 2002.

## Drug Spending and Pricing

### National Spending

One factor sparking the intense interest in coverage of drugs for the Medicare population has been the sharp rise in drug prices in recent years. Many seniors are particularly hard hit by these increases because they use more drugs than younger persons, they frequently have limited insurance protection for the costs, and they frequently pay for these drugs out of modest incomes. Further, seniors without insurance coverage are forced to pay the highest retail prices for their drugs because they do not have access to discounts that are available to large purchasers such as HMOs or insurance companies. At the same time, the projected increases in spending have raised concerns about the affordability of a drug benefit and the potential increases in costs of the benefit over time.

Drug spending is currently the fastest growing segment of national health care spending. CMS estimates that the *population as a whole* spent \$87.2 billion in 1998, \$103.9 billion in 1999 and \$121.8 billion in 2000 on retail outlet sales of prescription drugs. During the 1998-2000 period, spending on prescription drugs increased at a faster rate than that for any other personal health category. Drug spending increased 15.1% in 1998, 19.2% in 1999, and 17.3% in 2000; these numbers were substantially higher than the increases of 5.3%, 5.2%, and 6.4% in total personal health spending recorded over the same period. By 2000, spending on

prescription drugs accounted for 10.8% of total personal health spending.<sup>41</sup> CMS estimates that from 2001-2011 spending will increase at an average rate of 11.3% per year, reaching 17.1% of personal health expenditures by 2011.<sup>42</sup>

The increases in drug spending are attributable to a number of factors including the assumption by private insurance plans of a significant portion of the costs (with consumers responsible for low copayments, thereby contributing to the per capita increase in prescription use), direct-to-consumer advertising, and substitution of newer higher priced drugs for less expensive ones. In particular, the number of new drugs, particularly blockbuster drugs, entering the market has had a direct impact on the increase in spending. The recent increases in drug spending are reportedly responsible for a large portion of the increase in total health benefit costs and the increases in premium costs for private insurers. Many third-party payers are attempting to slow this growth by providing incentives to consumers to use lower cost drugs. These efforts, as well as overall changes in the economy, are reflected in slightly lower projected rates of increase than had previously been forecast.

CMS reports Medicare spending of \$2.3 billion in 2000 on retail outlet sales of prescription drugs.<sup>43</sup> This represents a small portion of overall drug spending by beneficiaries, since the program does not pay for most outpatient prescription drugs.

## Factors Affecting Spending Increases

Several studies have attempted to quantify the components of spending growth. While both the methodologies and findings vary somewhat among the studies, it is clear that price increases alone are not the total explanation. A significant factor is the introduction of new brand name drugs. Some of these new drugs replace existing treatments, while others are for conditions for which treatment was not previously available.

The National Institute for Health Care Management Research and Educational Foundation (NIHCM Foundation) analyzed spending growth from 2000 to 2001. It reported that spending on retail prescription drugs rose 17.1% over the period. About 39% of the \$22.5 billion increase in retail prescription drug spending was attributable to an increase in the number of prescriptions dispensed. About 24% was caused by a shift in the mix of drugs dispensed; the shift was from lower priced to higher priced medicines, many of which were approved in the last 5 years. The remaining 37% was caused by the 1-year increase in the price of individual drugs. The average price

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<sup>41</sup> Levit, Katherine, et al. Inflation Spurs Health Spending in 2000. *Health Affairs*, v. 21, no. 1, January-February 2002.

<sup>42</sup> Heffler, Stephen, et al. Health Spending Projections for 2001-2011: The Latest Outlook. *Health Affairs*, v. 21, no. 2, March/April 2002.

<sup>43</sup> Heffler, Stephen, et.al. *Health Spending Growth Up in 1999; Faster Growth Expected in the Future*.

for a prescription rose 10.1% from \$45.27 to \$49.84. (This increase reflects both the increase in price and the shift to more expensive medicines.)<sup>44</sup>

The NIHCM Foundation continues to report that the bulk of year-to-year spending growth is attributable to increased expenditures among a relatively small number of prescriptions. Half of the 2000-2001 growth occurred among just nine categories of medicine – antidepressants, cholesterol reducers, antiulcerants, oral diabetes, narcotic painkillers, antihypertensives, antiarthritic, oral antihistamines, and antipsychotics. Looked at another way, sales for just 27 individual drugs accounted for over half of the total spending growth. Sales for the 50 best selling drugs (accounting for 44% of total spending) rose 21.4% for the period compared to 13.8% for the rest of the market. By comparison, sales for the 50 drugs contributing most to the 1-year spending increase rose 43.3%; sales for all other drugs increased 6.7%.<sup>45</sup>

## Consumer Prices

The prescription drug debate has highlighted the fact that different consumers pay substantially different prices for drugs. Large purchasers are generally able to negotiate discounts, and also, in some cases, manufacturer rebates. Cash paying customers do not have access to discounts and are therefore forced to pay the highest prices.

The price of a drug is influenced by decisions made at each level of the distribution chain. The most important pricing determination is made at the manufacturing level. Manufacturers price drugs based on a number of factors including: (1) perceived value and incremental value of a therapeutic advancement; (2) recovery of research and development costs; (3) funding of ongoing research and innovation; (4) financing marketing efforts to stimulate sales; and (5) generating profits from drugs while under patent protection.<sup>46</sup> Some studies suggest that the first of these factors is the most important.<sup>47</sup> Actual manufacturer pricing decisions for a particular drug are considered proprietary and are therefore not made public.

The next stages in the distribution chain are wholesalers which distribute drug products to pharmacies, the pharmacies themselves, and finally the consumer. Wholesalers add a markup to their acquisition cost before selling the drug to the pharmacist. In turn, the pharmacist adds a retail markup to its own acquisition cost.

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<sup>44</sup> NIHCM Foundation. *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, Report. [<http://www.nihcm.org>]. Revised May 6, 2002.

<sup>45</sup> Ibid.

<sup>46</sup> Sonderegger Research Center School of Pharmacy. University of Wisconsin and Kaiser Family Foundation. *Prescription Drug Trends: A Chartbook*. Kaiser Family Foundation. July 2000.

<sup>47</sup> Lu, Z. John and William Connor. Strategic Pricing of New Pharmaceuticals. *The Review of Economics and Statistics*. February 1998.

The consumer's price depends on how payment is made for the drug.<sup>48</sup> Prices are highest for cash customers; these are persons without insurance or those with indemnity insurance coverage who file a claim after the transaction is completed. Most people with private group insurance coverage have a managed drug benefit which is administered by a pharmacy benefit manager (PBM) or sometimes directly by an HMO or other insurer. Payment is made by the third party at the point of sale. These third parties may negotiate discounts from manufacturers and retailers; such discounts may take a variety of forms including a reduction from the AWP. Little information exists on the size of these discounts. In addition, they may receive rebates from manufacturers; rebate agreements are confidential and good information about them is not available.<sup>49</sup>

Some persons obtain their drugs through Medicaid which pays pharmacies using fixed cost limits and fixed dispensing fees. In addition, the Medicaid program receives rebates from manufacturers.<sup>50</sup> Generally, the lowest prices paid for drugs are for those purchased directly from the manufacturer by the Veterans Administration (VA) and other specified purchasers under the Federal Supply Schedule (FSS). FSS prices are negotiated with the manufacturer by the VA.<sup>51</sup>

Cash paying customers are unable to take advantage of discounts offered to large purchasers. Cash paying customers include Medicare beneficiaries without supplemental drug coverage. This group also includes most Medicare beneficiaries with Medigap drug coverage. In 1999, excluding the effect of rebates, the typical cash customer paid nearly 15% more than the customer with third party coverage; for some drugs the difference was even greater. For the most commonly prescribed drugs, the price difference between cash customers and those with third party coverage grew considerably larger between 1996 and 1999.<sup>52</sup>

To address the concerns of cash-paying customers, President Bush has proposed a Medicare-Endorsed Drug Discount Card Initiative. This program would provide for the endorsement by Medicare of qualified privately-administered prescription drug discount cards. Beneficiaries could obtain these cards free or for a nominal enrollment charge; the card would provide access to discounts on prescription drugs. While this plan would not establish a Medicare drug benefit, it was intended to provide access to the same kinds of discounts as are available to the under age 65 population under private insurance plans. The program was viewed as an interim

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<sup>48</sup> For a discussion of drug pricing see: U.S. Department of Health and Human Services. *Prescription Drug Coverage, Spending, Utilization, and Prices*. [<http://www.Aspe.hhs.gov/health/reports/drugstudy>]. April 2000.

<sup>49</sup> *Ibid.*

<sup>50</sup> For a discussion of Medicaid see CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

<sup>51</sup> For a discussion of payments under federal programs see CRS Report RS20295, *Outpatient Prescription Drugs: Acquisition and Reimbursement Policies Under Selected Federal Programs*, by Heidi Yacker.

<sup>52</sup> DHHS, *Prescription Drug Coverage*, April 2000.

approach until a drug benefit was enacted and implemented. However, to date, implementation of the card program has been held up by court action.<sup>53</sup>

## **Previous Efforts to Expand Medicare's Coverage of Prescription Drugs**

The absence of an adequate prescription drug benefit has been of concern to policymakers since the enactment of Medicare in 1965. The projected cost of such a benefit, as well as differences over the appropriate role of the private sector vis-a-vis the public sector in administering the benefit, have been major deterrents to its implementation. Over the 1987-2000 period, three major attempts were made to add drug coverage to Medicare. The first attempt came in 1987 and led, in 1988, to the passage of the Medicare Catastrophic Coverage Act of 1988. This legislation, which included a catastrophic prescription drug benefit for the Medicare population, was repealed the following year. The second attempt was made as part of the health reform debate of 1994. The third attempt was made in 2000; in that year, significant policy differences, intensified in an election year, resulted in no final action being taken.

### **Medicare Catastrophic Coverage Act of 1988**

The Medicare Catastrophic Coverage Act of 1988 (MCCA, P.L. 100-360) would have phased-in *catastrophic* prescription drug coverage as part of a larger package of benefit improvements. This legislation was repealed in 1989 (P.L. 101-234). The repeal of MCCA was attributable to a number of factors. These included a significant increase in the program's cost estimates (particularly drug cost estimates) made shortly after enactment and the opposition by a number of seniors to the income tax surcharge (labeled a supplemental premium) which was to be imposed on higher income beneficiaries.

Under MCCA, catastrophic prescription drug coverage would have been available beginning in 1991 for all outpatient drugs, subject to a \$600 deductible and 50% coinsurance.<sup>54, 55</sup> The deductible was slated to go to \$652 in 1992 and be indexed in future years so that 16.8% of beneficiaries would reach the deductible each year. The coinsurance was scheduled to be lowered to 40% in 1992 and 20%

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<sup>53</sup> For a discussion of the card program see CRS Report RL31316, *President Bush's Proposed Medicare-Endorsed Drug Discount Card Initiative: Status and Issues*, by M. Angeles Villarreal.

<sup>54</sup> The coinsurance would have been 20% for drugs used in connection with the new home intravenous drug therapy benefit.

<sup>55</sup> A limited benefit would have been available in 1990 with coverage for: (1) home intravenous drugs, including antibiotics and other drugs approved by the Secretary, (furnished in connection with the new home intravenous drug therapy benefit); and (2) immunosuppressive drugs after the first year following a covered transplant. (The drugs were already covered under Part B for the first year only. See Medicare discussion for current coverage levels.) The 1990 deductible would have been \$550.

in 1993. The benefit was to be financed through a combination of an increase in the Part B premium and a portion of the new supplemental premium which was to be imposed on higher income enrollees.

When MCCA was enacted in 1988, limited data were available on which to base cost estimates for the new prescription drug program. At the time of enactment, CBO estimated FY1990-FY1993 costs at \$5.7 billion. By July 1989, the estimates had more than doubled to \$11.8 billion. The revised estimates reflected the availability of new data which suggested that both the average number of prescriptions used by enrollees and their average price had risen more than had been estimated previously.

## **Health Care Reform — 1994**

The issue of prescription drug coverage was again considered as part of the health care reform debate of 1994. The Health Security Act, proposed by the Clinton Administration, would have added a prescription drug benefit to Medicare Part B beginning in 1996. Under the bill, Medicare would have paid 80% of the cost of each prescription once the beneficiary met a \$250 annual deductible. Beneficiaries would have been responsible for the remaining 20% with an annual limit on out-of-pocket expenses of \$1,000. The Administration estimated that approximately 58% of beneficiaries would use the proposed drug benefit each year — a much larger percentage than the targeted 16.8% under MCCA.

As is the case for other Part B benefits, the Clinton Administration's plan would have been funded through general revenues (approximately 75%) and beneficiary premiums (approximately 25%). The beneficiary share for prescription drugs was estimated at \$9 per month; this would have been added to the regular Part B premium. The Administration estimated net federal costs, after offsetting premiums, at \$69.1 billion over the FY1996-FY2000 period. CBO estimated that the benefit would cost \$19 billion in 2000, approximately \$2 billion higher than the Administration's estimate for that year.

## **The 1999-2000 Debate**

The issue of prescription drug coverage for the Medicare population became a major issue in the 106<sup>th</sup> Congress as well as one of the major issues in the 2000 presidential campaign. The debate highlighted a wide difference of opinion over how a benefit should be structured, the degree of financial risk that should be assumed by the public sector versus the private sector, whether a benefit should be available to all beneficiaries, and whether or not federal resources should be focused primarily on the low-income.

The focus of the initial debate was the National Bipartisan Commission on the Future of Medicare. This Commission, established by the Balanced Budget Act of 1997 (BBA 97, P.L. 105-33), was charged with making recommendations on a number of program issues. The recommendations were to be submitted to the Congress by February 1, 1999. The Commission failed to get the required 11 of 17

Commissioners' votes for a reform proposal. However, its deliberations focused renewed attention on the program's lack of a comprehensive drug benefit.

Following the conclusion of the Commission's activities, the focus turned to the Congress. A number of bills were introduced which would have established a prescription drug benefit under Medicare. Some of the measures added a new benefit to the Medicare program itself, while other proposals would have established a separate benefit for the Medicare population outside of the Medicare program itself.<sup>56</sup>

In 1999, President Clinton outlined a plan which would have established, under Medicare, an optional prescription drug benefit which would be available to all beneficiaries. In 2000, he announced a revision in the implementation schedule. Under the revised proposal, the program would have paid for 50% of a beneficiary's costs up to a specified limit; the maximum program payment would have been \$1,000 in 2002, rising to \$2,500 in 2008 when the program was fully phased-in. In addition, there would be a cap on beneficiary out-of-pocket payments, \$4,000 in the first year. The premium would have been set at \$25 a month in the first year. Additional assistance would have been provided for low-income beneficiaries. In addition to the Administration plan, a number of similar measures were introduced in both the House and Senate. Several of these bills were referred to as the "Democratic alternatives" to the Republican bills (discussed below).

The House passed the Medicare Rx 2000 Act on June 28, 2000. Under this bill, reliance would have been placed on private insurance companies and other private sector entities to provide coverage. These entities would have been partially subsidized for assuming the risk of prescription drug costs. At a minimum plans would have had to provide "qualified coverage," defined as "standard coverage" or coverage that was actuarially equivalent (i.e., had an equivalent dollar value). "Standard coverage" was defined as having a deductible (\$250 in 2003), 50% cost-sharing up to the initial coverage limit (the next \$2,100 in 2003, accounting for total spending of \$2,350), and full coverage after an annual limit in out-of-pocket spending (\$6,000 in 2003) had been reached. Additional assistance would have been provided to low-income seniors. The drug benefit and the M+C program would have been administered by a new Medicare Benefits Administration. The CBO cost estimate for the new drug program, including associated administrative costs, was \$38 billion over the FY2001-FY2005 period and \$148 billion over the FY2001-FY2010 period. The bill (which passed the House on a 217-214 vote) was frequently referred to as the House Republican plan.

A number of other approaches were presented during the 106<sup>th</sup> Congress. Some measures would have provided assistance to states to enable them to establish, on a voluntary basis, programs for their low-income populations.

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<sup>56</sup> For a discussion of the major Medicare drug bills considered during the 106<sup>th</sup> Congress, see: (1) CRS Report RL30584, *Medicare: Selected Prescription Drug Proposals*, by Jennifer O'Sullivan; and (2) CRS Report RL30593, *Medicare: Side-by-Side Comparison of Selected Prescription Drug Bills*, by Jennifer O'Sullivan and Heidi Yacker.

While there were major differences between the various approaches, the majority moved away from some of the elements that had characterized the 1988 and 1994 bills. In particular, most measures considered during the 106<sup>th</sup> Congress would not have had the government setting drug prices. Instead, it was anticipated that such determinations, as well as the general day-to-day administration of the benefit, would be undertaken by pharmacy benefit managers (PBMs) or similar entities.

## 107<sup>th</sup> Congress Debate

The 107<sup>th</sup> Congress again considered Medicare prescription drug legislation. On June 28, 2002, the House passed the Medicare Modernization and Prescription Drug Act of 2002 (H.R. 4954). This measure was a modified version of the bill passed by the House in the 106<sup>th</sup> Congress. Under H.R. 4954, a new optional benefit would be established, effective January 1, 2005. The program would rely on private plans to provide drug coverage and to bear some of the financial risk for drug costs; federal subsidies would be provided to encourage participation. Coverage would be provided through prescription drug plans (PDPs) or Medicare+Choice (M+C) plans. Beneficiaries could purchase either a standard plan or an actuarially equivalent plan. Low-income subsidies would be provided for persons with incomes below 175% of poverty. A new Medicare Benefits Administration (MBA) would be established within the Department of Health and Human Services (HHS) to administer the benefit and the M+C program.

In July 2002, the Senate considered and passed the Greater Access to Affordable Pharmaceuticals Act (S.812, Schumer et. al); this legislation would revise provisions of the “Hatch-Waxman Act” concerning the timing of generic drug availability.<sup>57</sup> S. 812 served as a vehicle for the consideration of several Medicare prescription drug amendments. These were the Medicare Outpatient Prescription Drug Act of 2002 (S.Amdt. 4309 to S. 812, Graham et al.); the Medicare Prescription Drug Cost Protection Act of 2002 (S.Amdt. 4345, also known as the Graham-Smith amendment), the Voluntary Medicare Outpatient Prescription Drug Discount and Security Program (S.Amdt 4315 to S. 812, Hagel et.al.); the 21<sup>st</sup> Century Medicare Act (S. 2729, Grassley et al.), sometimes referred to as the “tripartisan bill.” The “tripartisan bill” was introduced as S. 2 and S.Amdt. 4310 to S. 812. All of the measures failed to garner the necessary 60 votes to override a budget point-of-order.<sup>58</sup>

The 107<sup>th</sup> Congress did not take final action on a prescription drug measure. It is expected that the issue will again be on the agenda for the 108<sup>th</sup> Congress.

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<sup>57</sup> See CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (“The Hatch-Waxman Act”)*, by Wendy H. Schacht and John R. Thomas

<sup>58</sup> For further details, see CRS Report RL31496, *Medicare: Major Provisions of Selected Bills*, by Jennifer O’Sullivan.



## Proposed Benefit: Program Design Issues

Several key issues are driving the prescription drug debate. These include whether the benefit should be administered as part of the current Medicare program or by private entities, the degree of financial risk that should be assumed by the federal government, and what the benefit structure should look like and whether it should be the same nationwide. The following sections provide an overview of some of the key design questions. The first sections address some of the larger organizational and administrative issues while subsequent sections focus on benefit design.

### Structural Issues

**Relationship to Overall Medicare Reform.** Many observers contend that the existing Medicare program needs reform. This view is based both on the fact that Medicare's current financing mechanism will be unable to sustain it in the long run as well as the view that the existing benefit structure is outdated.

Medicare is actually two programs – Medicare Part A and Medicare Part B. When people refer to the pending insolvency of Medicare, they are actually referring to the projected insolvency of Part A. Passage of BBA 97, coupled with improved economic conditions, have considerably delayed the Part A projected insolvency date (currently slated for 2030). However, the fund remains substantially out of balance over the long term. Under the current financing mechanism, the funds are insufficient to cover the health care costs of the baby boom generation (persons born between 1946 and 1964) through their retirement years.

Many are also concerned that the program's structure, which in large measure reflects both the health care delivery system as well as political considerations at the time of enactment in 1965, has failed to keep pace with the changes in the health care system as a whole. A related concern is whether the program's benefit structure adequately responds to the health care needs of today's aged and disabled population.

These concerns have led to a number of calls for a thorough reexamination of the Medicare program itself. Some observers suggest that the existing program is essentially sound and note its popularity with the senior population. These observers recommend modifications to the current program, rather than a more extensive overhaul. Other analysts contend that more extensive reforms are required.

The issue of Medicare reform becomes even more complex when the issue of drug coverage is raised. Many persons have stated that it would be inappropriate to add a new costly, benefit before the financial soundness of the basic program is assured. Some of these observers also contend that the program's benefit structure should be viewed as an integrated whole. They suggest that drug coverage should not be added until the whole benefit structure is reexamined. Other observers have stated that seniors, particularly low-income seniors, need a drug benefit. They contend that these persons should not be required to wait for benefits until resolution of the entire restructuring issue. Further, some of these persons also argue that the program does not need major structural reform.

Regardless of when a drug benefit is enacted, it would take a couple of years to implement. In the interim, a number of persons have recommended addressing the issue of the price seniors pay for drugs. As noted earlier, the Administration has issued regulations which would establish a Medicare-endorsed prescription drug card initiative. Under the initiative, private sector discount card sponsors (such as pharmacy benefit managers, insurers, and pharmacies) could apply for Medicare endorsement. Only sponsors that secured rebates or discounts from manufacturers would be eligible for endorsement. Implementation of the card program has been held up by court action.

**Degree of Private Involvement.** One issue that has been a major focus of the drug debate has been the degree of reliance that should be placed on the private sector, both for administering a drug benefit and for assuming a portion of the financial risk of the benefit. A wide range of options has been presented. At one end of the spectrum is the bill that passed the House in the 107<sup>th</sup> Congress.. Under this bill, access to a drug benefit would be provided *only* through private insurance companies and similar private entities that wished to offer the benefit. In general, the private plans would be at risk for any costs in excess of federal subsidy payments and federal reinsurance payments. (Reinsurance payments are made to cover a portion of the costs paid by plans for individuals incurring high costs.) The Administrator of the new Medicare Benefits Administration would administer the program in a manner such that eligible individuals would be assured access to at least two plans. If necessary to ensure access, the Administrator would be authorized to provide financial incentives in addition to the federal subsidy and reinsurance payments. The “tripartisan bill” from the 107<sup>th</sup> Congress would also rely on private entities to provide benefits and require plans to assume some of the financial risk for the cost of covered benefits. In order to assure access, the Administrator of the new Medicare Competitive Agency would be authorized to provide financial incentives, in addition to reinsurance payments, for an entity to establish a plan. Proponents of these bills stated that the financial incentives would be sufficient to assure access throughout the country. Opponents argued that these bills do not specifically detail what would occur if, in spite of the incentives, plans were not available in some areas.

Unlike the measures emphasizing the private sector, several measures in the 107<sup>th</sup> Congress (the House Democratic bill, the Graham amendment, and the Graham-Smith amendment) would have added the new benefit to Medicare. It would be administered at the federal level like other Medicare benefits and the federal government would bear most of the financial risk of coverage. The actual operation of the benefit would be through contracts with private entities such as pharmaceutical benefit managers (PBMs). PBMs currently administer the drug benefit, including negotiating price discounts, for many private insurance plans. Under these bills, a portion of the administrative fees for these entities would be put at risk; specifically, an adjustment would be made in administrative payments to ensure that entities complied with requirements relating to performance goals.

Proponents of measures that rely on private entities argue that this approach would give consumers choice among competing plans; they suggest that this would enable beneficiaries to obtain coverage that most directly meets their needs. Opponents of this approach argue that the actual options available to seniors would be limited because most private plans would be unwilling to bear the financial risk

associated with a new benefit. Proponents of the bill that passed the House in the 107<sup>th</sup> Congress noted that the bill provided for federal payments equal to an estimated 67% of the value of the standard benefit. Opponents of the private-sector approach advocate the provision of a single benefit which would be available nationwide under Medicare. They argue that this mechanism would assure the availability of an affordable benefit for all beneficiaries both because the purchasing power of the largest possible group would be maintained and because the risk would be spread over a large population.

**Administration of Benefit.** There is a divergence of opinion over the appropriate role of the federal government in assuring drug coverage for seniors. However, virtually all of the major proposals would place responsibility on the private sector for the day-to-day administration of the benefit.

**In General; PBMs.**<sup>59</sup> It is expected that pharmacy benefit managers (PBMs) or similar entities would handle the processing of claims, utilization review, and similar functions. PBMs are companies which manage pharmacy benefits for private health plans and HMO sponsors. Reportedly, PBMs administered 71% of third-party payments for drugs in 1999.<sup>60</sup> Typically they are charged with controlling pharmacy costs and they employ a variety of strategies to achieve this goal. PBMs may develop a retail pharmacy network arrangement; in this case, prices are negotiated with pharmacies which accept discounts in return for attracting or retaining plan enrollees. PBMs may also operate mail order pharmacies. They often utilize formularies (see discussion below). They are also likely to operate drug utilization management programs.

Many observers argue that using PBMs to administer drug benefits for the Medicare population would allow them to build on purchasing strategies they have used for the non-Medicare population. At the same time, the federal government would be distanced from pricing decisions and day-to-day administrative functions.<sup>61</sup> Some, however, have voiced the concern that the use of PBMs actually encourages the use of brand name over less costly generic drugs. This is because PBMs negotiate rebates with manufacturers for brand name but not generic drugs. The rebates are typically shared with insurers, reducing their expenditures. Some have argued that PBMs are motivated to boost sales of these drugs by including them as preferred drugs in the plan's formulary.<sup>62</sup>

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<sup>59</sup> For a discussion of PBMs, see CRS Report RL30754, *Pharmacy Benefit Managers*, by Christopher J. Sroka.

<sup>60</sup> Levit, Katherine et al. Inflation Spurs Health Spending in 2000. *Health Affairs*, v. 21, no. 1, January/February 2002.

<sup>61</sup> For a further discussion of the issue see: Cook, Anna, Thomas Kornfield, and Marsha Gold. *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*. Mathematica Policy Research report prepared for Henry J. Kaiser Family Foundation, January 2000.

<sup>62</sup> Levit, et.al. Ibid.

A number of questions have been raised regarding what level of savings PBMs could achieve if they managed a drug benefit for the Medicare population. A key consideration is the degree of flexibility individual PBMs are given. The flexibility that PBMs have will depend, to a considerable degree, on the level of federal involvement in defining covered drugs, establishing prices for drugs, setting utilization criteria, and establishing appeals processes for noncoverage decisions.

Arguably, if a single drug benefit is established under Medicare, it would be politically difficult to allow a wide variation among PBMs (for such items as covered drugs and appeals procedures), particularly if only one PBM is administering the benefit in a geographic area. However, it should be noted that even under the current Medicare program, there is some variation in local coverage policies (for example, when a new procedure or supply is considered a covered service).

A number of observers have suggested that PBMs could have more flexibility, and therefore be more effective in controlling costs, if more than one operated in a geographic area. In this case, beneficiaries could potentially choose between PBMs based on such factors as size of discounts obtained from participating pharmacies, accessibility of pharmacy networks, and drugs included on the formulary. The range of choices could potentially be greater if PBMs were administering the benefit on behalf of a private insurer which had contracted with Medicare rather than administering a single nationwide Medicare benefit.

While the potential for cost savings is potentially larger if the multiple PBM approach is selected, it would be difficult to avoid adverse selection. Adverse selection could occur because competing PBMs could attempt to design their benefit packages (for example, through the use of restrictive formularies) as well as marketing strategies, to appeal to those with low drug costs. Those with potentially higher drug costs might not be able to find an affordable package that met their needs.

Compounding the question of PBM design is the degree of financial risk that these entities would assume. If PBMs assumed little or no financial risk, they would have little incentive to aggressively pursue cost control strategies. Conversely, there would be significant incentives to pursue such strategies if they assumed a substantial portion of the risk. In this case, mechanisms would have to be developed to assure that all beneficiaries, regardless of their spending profile, continued to have access to affordable benefits.

**Federal Administration.** The Centers for Medicare and Medicaid Services (CMS) is the federal agency which is charged with the administration of the Medicare program. Some proposals would establish a new agency which would assume responsibility for any of the functions assigned to the federal government under a new program. In addition, some of these proposals would also transfer to the new agency the administration of some other functions such as administration of the Medicare+Choice program. Proponents of establishing a new agency cite perceived inadequacies in the current CMS administration of Medicare. Other observers contend that CMS's shortcomings are primarily attributable to inadequate resources. Further they suggest that splitting responsibility for Medicare between

two agencies would cause serious problems. They question how coordination with the rest of Medicare would be achieved and how duplication could be avoided.

## Benefit Design Issues

**Persons Covered.** Some observers have recommended extending prescription drug coverage to the entire Medicare population. Other observers have recommended that the federal role be limited to assuring coverage for those most in need, with need generally defined on the basis of income. Regardless of which approach is taken, virtually all proposals would specify an income level below which a beneficiary would be liable for little or no costs in connection with *covered* services. (See discussion on Assistance for Low-Income Population, below.)

If a new benefit were limited to those below a specified income threshold, the income level chosen would directly determine the percentage of persons who would benefit under the plan. Based on information from the 1998 MCBS, a cut off at 135% of poverty would provide protection for the 29% of beneficiaries with incomes below 135% of poverty. At the same time, it would extend benefits to the 36% of the population without supplementary drug coverage (i.e., those with Medicare coverage *only* or those who have supplementary coverage without drug benefits). A cutoff at 150% of poverty would provide protection for the 34 % of beneficiaries with incomes below 150% of poverty and extend benefits to 42% of those without drug coverage. These percentages would rise to 51% of beneficiaries and 58% without other drug coverage, if the cut off was set at 200% of poverty.<sup>63</sup> These percentages would, of course, be lower if an assets test were imposed. Most of the pending bills would use the assets test used for the current QMB and SLIMB programs (\$4,000 for an individual and \$6,000 for a couple).

Proponents of setting an income cut-off argue that, given the potential cost of a new drug benefit, it is appropriate to limit it to those most in need of assistance. However, others argue that the benefit should not be restricted to the low-income since many persons without supplemental coverage or with high drug costs would exceed the income thresholds. Further, any threshold has the potential for establishing a sharp cut off point for coverage. Some have suggested that as a first step, the new program could target the benefit on the low-income population and those persons with catastrophic expenses (see discussion below). This is the general approach included in the Graham-Smith amendment.

**Program Enrollment.** Virtually all proposals would specify that enrollment in a new drug benefit would be optional. However, the proposals vary on whether or not this enrollment opportunity could be exercised only once. Some view one-time enrollment as necessary to avoid adverse selection. Adverse selection would occur if only those who think they would use the benefit in a given year actually sign up. This would drive up the per capita costs, making the benefit more unaffordable for future enrollees. If one-time enrollment were offered, this would generally occur

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<sup>63</sup> Definitions of poverty are based on poverty guidelines. CRS estimate based on 1997 MCBS.

when an individual first became entitled to Medicare, or, for current beneficiaries, when the drug benefit first went into effect.

Instead of limiting eligibility to those that enroll at the first opportunity, a penalty could be imposed for late enrollment. This is the approach currently used for Medicare Part B.<sup>64</sup> The Part B program has successfully avoided adverse selection, because virtually the entire eligible population has enrolled voluntarily. It is not, however, clear what the enrollment levels would be for a new optional drug plan. The final benefit design (including beneficiary liability for premiums and cost-sharing charges) would have a direct effect on beneficiary enrollment decisions.

**Scope of Benefit.** There are a number of issues related to benefit design. The first is whether there should be a uniform national benefit or, alternatively, a minimum benefit level. Generally, those advocating a uniform national benefit would provide the coverage through Medicare. Conversely, those advocating a minimum benefit would rely primarily on private entities to provide the coverage. Under the latter option, beneficiaries could potentially select from alternative benefit packages provided the coverage was at least actuarially equivalent to (i.e., had the same dollar value as) the minimum benefit.

A second series of issues relate to the scope of coverage offered under either a uniform or minimum benefit package. Items to be addressed include the amount of the deductible, if any; the amount of required beneficiary cost-sharing; and the total value of the benefit package. A deductible is a specified out-of-pocket amount (e.g., \$250) which a beneficiary has to meet before the program begins making payments. Cost sharing charges could take the form of copayments (e.g., \$10 per prescription) or coinsurance (e.g., 20% or 50% of the cost of a prescription). The value of the package could be limited by setting an annual per capita limit on federal spending (e.g., \$2,000).

A related issue is whether a catastrophic benefit would be included. A catastrophic benefit would provide coverage for all drug costs once a beneficiary had reached a certain dollar threshold. The higher this threshold is set, the fewer people that would benefit in any given year. Some observers have suggested that, with the exception of assistance for the low-income population, the new benefit should be limited to catastrophic coverage. They suggest that the limited federal dollars should be targeted toward those most in need.

A catastrophic benefit (with or without other coverage) is potentially very expensive. While the number of beneficiaries is potentially small, they represent a disproportionate amount of spending. As noted earlier, the CBO has estimated that in 2002, 35.6% of beneficiaries (excluding M+C enrollees) would spend \$2,000 or more per year on drugs, accounting for 77.7% of drug spending for the Medicare population. In the same year, an estimated 9.0% of fee-for-service beneficiaries would spend \$5,000 or more on drugs, accounting for 36.8% of drug spending for the group. These numbers increase dramatically by 2012. In 2012, 63.5% of beneficiaries (excluding M+C enrollees) would spend \$2,000 or more per year on drugs,

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<sup>64</sup> See CRS Report 98-7, *Medicare: Part B Premium Penalty*, by Jennifer O'Sullivan.

accounting for 95.7% of drug spending for the Medicare population. In the same year, an estimated 36.4% of fee-for-service beneficiaries (excluding M+C enrollees) would spend \$5,000 or more per year on drugs, accounting for 80.2% of drug spending for the Medicare population.

Some proposals (including the House-passed bill and the “tripartisan” plan from the 107<sup>th</sup> Congress) have what has been labeled a “doughnut.” Under these proposals, program assistance is provided until an individual’s drug spending reaches a specified dollar amount (e.g., \$2,000 under the House plan), then no coverage until a beneficiary’s expenses reach a specified “catastrophic threshold” level (\$3,700 out-of-pocket costs with \$4,800 in total spending). At this point, all costs (or virtually all costs) would be assumed by the program. The range of spending for which no program spending is provided is labeled a doughnut.<sup>65</sup>

**Assistance for the Low-Income Population.** Most of the recent drug proposals would require beneficiaries to pay a monthly premium for program coverage. In addition, beneficiaries would be responsible for cost-sharing charges when they used covered services.

Most proposals would exempt the low-income population from some or all of these payments. Most proposals would set the minimum income cut-off level at 135% of poverty (\$11,961 for an individual and \$16,119 for a couple in 2002<sup>66</sup>). This is generally the QMB/SLIMB population.<sup>67</sup> Some plans would provide partial or full low-income assistance to persons at higher income levels. Persons meeting the minimum income criteria, and *not* eligible for full Medicaid benefits, would have their premium and cost-sharing costs paid (generally in full) by the federal government.

Those eligible for *full* Medicaid benefits (including drugs) would typically have the new program pay first with Medicaid picking up costs not paid under the new federal program. This would include premium and cost-sharing charges as well as any costs above the federal program’s benefit limit. The current federal-state matching rate for Medicaid services could apply; alternatively, the federal government could assume a larger share of these costs.

One concern with an income limit, is that some persons would have a fairly generous benefit while persons with incomes slightly above the income cutoff would have no assistance with premiums and cost sharing charges. A number of proposals have responded to this concern by providing a phase-out in coverage. For example, full coverage would be offered for those below 135% of poverty. Those between 135% and 150% of poverty (\$11,961-\$13,290 for an individual in 2002) would have a sliding scale subsidy for the premium but no coverage for cost-sharing charges.

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<sup>65</sup> For a discussion of how benefit design affects beneficiary out-of-pocket costs, see CRS Report RL31525, *Medicare: Beneficiary Cost-Sharing Under Proposed Prescription Drug Benefits*, by Christopher Sroka.

<sup>66</sup> CRS Report RL31485, *Prescription Drug Coverage*.

<sup>67</sup> See discussion of QMB/SLIMB population under discussion of supplementary coverage under Medicaid.

State Medicaid programs could potentially save some costs because some drug spending would be picked up under a new federal program. However, they could also face increased costs because of increased enrollment in the QMB/SLIMB programs. Enrollment in these programs has traditionally been low, though the enrollment in the QMB program has recently increased. It is likely that enrollment would increase substantially if drug coverage were offered for this population group. Under current law, this would have the effect of increasing federal and state costs for the *basic* QMB/SLIMB benefits (i.e., cost-sharing and premium charges associated with non-drug benefits). Some proposals would provide full federal funding for these additional costs.

**Relationship to Private Coverage.** Questions have been raised regarding the role of existing private coverage (i.e., employer-based and Medigap) with the implementation of a new drug benefit.

**Employer-Based Coverage.** The addition of a new benefit could result in savings for employers who currently offer drug benefits to their retirees. Some employers might choose to supplement the federal benefit, for example by paying some of the cost-sharing charges.

In order to contain federal costs, some proposals would encourage employers to continue to provide their current benefit package to retirees instead of having these individuals enrolled under the federal plan. Under these proposals, a premium subsidy would be provided to employers who offered coverage at least as good as that under the new federal plan. It is difficult to determine how many employers would elect to continue to provide coverage under their own plans.

A recent study suggests that in the short term (3-5 years) most large employers would not terminate coverage solely in response to a new benefit; rather, they would continue coverage by wrapping around the new benefit.<sup>68</sup> However, it is difficult to predict employer actions over the longer term. As noted earlier in this report, employers are cutting back, and in some cases discontinuing retiree health coverage, particularly for new hires.

**Medigap.** If a new drug benefit were enacted, the existing standardized Medigap packages would need to be revised. Decisions would need to be made regarding whether packages with drug benefits should continue to be offered.

**Covered Drugs; Formularies.** Drug proposals offered in recent years would generally provide coverage for outpatient prescription drugs approved by the Food and Drug Administration (FDA) as well as biologicals and insulin. Many bills link the definition to that applicable under the Medicaid program.<sup>69</sup>

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<sup>68</sup> Hewitt Associates for Henry J. Kaiser Family Foundation. *The Implications of Medicare Prescription Drug Proposals for Employers and Retirees*. July 2000.

<sup>69</sup> The Medicaid law permits exclusion of certain categories of drugs including those for weight loss or cosmetic purposes and those for smoking cessation. Some Medicare proposals would include coverage of drugs for smoking cessation.



Many proposals contemplate the use of *formularies* which could potentially restrict coverage to certain drugs. Formularies are lists of drugs which are preferred for use by a health plan. A plan that has adopted an “open formulary” allows coverage for both formulary and non-formulary medications. A plan that uses a closed formulary limits coverage to the specified drugs. Another approach, increasingly utilized by private insurers, involves the use of an open formulary, coupled with higher copayments for use of off-formulary drugs. Some plans use “*tiered copayments*” with the lowest copayment level applied to generic drugs (drugs no longer having patent protection), a middle level applied to brand-name drugs on the formulary and the highest level applied to off-formulary brand-name drugs. A similar approach could be applied for the Medicare population.

Many proposals would either explicitly or implicitly leave the specification of drugs included on a formulary to the PBM or other entity administering the benefit in the area. This approach raises the possibility that different formularies could apply in different geographic regions. How restrictive a formulary is may depend, in part, on whether there is more than one PBM in an area. If there is only one PBM, it is less likely that it would be able to significantly restrict coverage. If, however, more than one PBM operated in a region (as would be the case if the benefit were offered by private insurers) each could potentially compete on the basis of what was included in its formulary.

The ability of a formulary to restrain costs is dependent, in part, on how easy it is to obtain off-formulary drugs. Some proposals would essentially permit the use of off-formulary drugs in any case where the physician certified that the use of the drug was medically necessary. Other proposals would make the use of off-formulary drugs more difficult by, for example, requiring appeals of non-coverage decisions.

**Other Cost Control Strategies.** Formularies and tiered copayments are just two of the cost control strategies that could be utilized by a PBM or other administering entity. There are a number of other strategies which could be employed. In broad terms, these could be mandated by law or left to the discretion of individual PBMs. Possible strategies include utilization management and implementation of quantity limits (for example drugs limited to a 30-day or 60-day supply and/or a limit on the number of refills in a specified period). A number of cost control strategies could also be designed to assure quality of services provided to beneficiaries.

**Payments for Drugs.** Perhaps one of the more contentious issues underlying the prescription drug debate is how payments for drugs would be determined. Under the current Medicare program, payments for covered services are based on federal laws and regulations. The resulting policies, which vary by service category, have been labeled *administered pricing*. Critics of this approach claim that it is cumbersome and results in micro-managing at the federal level. In fact, administered pricing is cited by many as the main argument for overall Medicare restructuring.

**Pricing.**<sup>70</sup> None of the major proposals considered in the 107<sup>th</sup> Congress, including those establishing a nationwide benefit under Medicare, would have set detailed federal rules for drug payments. In part, this reflects the very strong opposition by the pharmaceutical industry to federally determined payment policies. The industry has registered its strong opposition to price controls and argues that such controls would stifle research and innovation. It argues that in order to develop new drugs, stockholders must be willing to invest in companies that are conducting research; and that, in many cases, this necessary research does not lead to new drugs. However, there must be at least the possibility of financial return to attract investors. Other observers contend that there will still be sufficient money for research. They point both to the rapid increases in drug spending and the large profits of the pharmaceutical industry.

Many observers contend that it is unrealistic to suggest that a new program, involving substantial federal dollars, could be implemented without some way to control costs. While most proposals would leave pricing decisions to the PBMs, they do attempt to limit the overall federal exposure or risk, for example, by limiting the per capita federal expenditure. Other approaches would encourage the use of less costly generic drugs. For example, S. 812 as passed by the Senate in the 107<sup>th</sup> Congress, would have provided for an accelerated date of approval for a generic drug application.

However, controlling overall expenditures (in the absence of a specific dollar limit) may be a difficult task. There are a number of factors that will affect potential program costs, many of which are difficult to predict at this juncture. For example, what will be the increased use of drugs (known as induced demand) that will result from the addition of a new benefit? How effective will PBMs be in negotiating discounts? How will pricing and coverage decisions be made for new breakthrough drugs? Finally, if a catastrophic benefit is included, how would this affect utilization and expenditures. The answers to these and related questions will affect the overall cost of the program.

**Purchasing Discounts.** One of the issues driving the discussion of a Medicare drug benefit is the concern that seniors without supplementary drug coverage pay higher prices than other persons for the same drugs. Most proposals presume that PBMs will be able to negotiate purchasing discounts for Medicare beneficiaries. Some proposals also require that beneficiaries continue to have access to discounted prices, even when their spending exceeds the limits of the federal program (and no program payments are being made). At this point it is difficult to predict the size of the discounts which could be expected. It is also difficult to

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<sup>70</sup> Some of the bills before the 107<sup>th</sup> Congress deal directly with the prices seniors pay for drugs; however, they do not add a new benefit for this population group. For a discussion of these measures see: (1) CRS Report RL31503, *Importing Prescription Drugs*, by Blanchard Randall, IV and Donna U. Vogt; (2) CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas; and (3) CRS Report RL30373, *The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches*, by Resources, Science, and Industry Division, Transportation and Industry Analysis Section.

predict the response of the industry to the discounts. For example, would prices to other purchasers be raised to offset some of the losses from discounts for the Medicare population?

**Rebates.** One potential method for controlling program expenditures is that of rebates. Rebates are a monetary return to a health insurer or payer from the manufacturer. The amount of the rebate is based on the utilization of drugs by program recipients or drug purchases by providers. The federal-state Medicaid program uses rebates. Manufacturers are required to enter into rebate agreements in order to have their drugs paid for under the program. However, some of the pending drug proposals would specify that the Medicaid rebate provisions would not apply if a state elected to use the prices negotiated under a new Medicare Part D program for its Medicaid program.

If a rebate approach were adopted for Medicare, the program itself (or individual insurers or PBMs) would end up recouping some costs. The savings would not necessarily be passed along directly to consumers. If they were not, consumers could still be paying coinsurance charges on the basis of the pre-rebate price. However, overall program costs would be lower. If the program were financed in part through beneficiary premiums, lower program costs should translate into lower premium costs.

## Financing

As noted earlier, CBO has estimated prescription drug benefit spending for the Medicare population at \$1.6 trillion over the 2002-2011 period and \$1.8 trillion over the 2003-2012 period. A drug benefit for this population is potentially very costly; the actual cost of a plan is dependant on what portion of overall costs is assumed under a new program. To date, a consensus has not been reached on the funding sources for a new program. Possible sources include a combination of federal general revenues and beneficiary premiums. Previously, some observers had recommended using a portion of the projected budget surplus for a drug benefit; however, this is no longer an option. It should be noted that under virtually all proposals, beneficiaries would continue to be responsible for a portion, and in some cases a substantial portion, of their drug costs themselves.

## Prospects

As noted, during 2002, the House passed a prescription drug measure, but the Senate was unable to come to an agreement on a plan. Thus, the 107<sup>th</sup> Congress did not take final action on a drug benefit. It is expected that the 108<sup>th</sup> Congress will again consider prescription drug legislation; at this point it is difficult to predict whether it will be able to develop a consensus package.