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Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues

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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. The issue received renewed attention in the 106th Congress. However, there was no consensus on how the expanded coverage should be structured. The issue is expected to receive continued attention during the 107th 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. The FY2002 budget resolution provides up to $300 billion over the FY2003-2011 period for a reserve fund for Medicare reform and prescription drugs; legislation has not yet been considered by the committees of jurisdiction.

There are a number of design issues facing the development of a drug benefit for the Medicare population. First are a number 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 cost 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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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 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.

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 to the fact 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 35 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, the Congress has considered adding coverage for at least a portion of beneficiaries' drug costs. The issue received renewed attention in the 106th Congress. However, there was 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 role of both 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 until 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 would need to be addressed as Congress considers policy options.

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.[1] 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) following discharge from a hospital for a Medicare covered organ transplant.[2]
- *Erythropoietin (EPO)*. EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.
- *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

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[1]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. Non-PPS hospitals are paid on the basis of reasonable costs, subject to certain limits; reasonable costs include the costs of drugs provided during the patient's stay. A PPS is currently being phased-in for skilled nursing facilities (SNFs). 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.

[2]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.

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.[3]

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). 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

In 1998, only 6.8% of beneficiaries relied solely on the traditional fee-for-service Medicare program for their health benefits; these persons had no supplementary drug coverage. An additional 16.5% 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 (76.7%) had some form of private or public health insurance coverage to supplement Medicare. This coverage *may or may not have included drug benefits*. The majority (59.7%) had private supplemental coverage. Some of these persons (36.1%) obtained this protection through a current or former employer. Other persons (23.6%) obtained coverage through an individually purchased policy, commonly referred to as a "Medigap" policy. Coverage for the remaining 17% of the population was obtained through public sources; 13.2% obtained coverage from

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[3]Medicare also pays for the following drug categories: (1) 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; and (2) supplies (including 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).

Medicaid and 3.8% from other sources such as programs run by the Department of Defense and Department of Veterans Affairs.[4]

Table 1. Medicare Beneficiaries, by Source of Supplementary Health Insurance Coverage, 1998
(in percent)

All beneficiaries	100
Medicare fee-for-service only	6.8
Medicare managed care	16.5
Medicaid	13.2
Employer-based coverage	36.1
Medigap	23.6
All other	3.8

Note: Data is from the 1998 Medicare Current Beneficiary Survey (MCBS). 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.*

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

The scope of benefits available to persons with supplementary protection differs significantly by type of coverage. Many persons with supplementary coverage have either limited or no protection against prescription drug costs. The next sections review the types of supplementary health insurance coverage generally available to the Medicare population. It also examines whether such coverage typically includes drug benefits. The following 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.

[4]There are considerable differences between the types of supplemental coverage held by the aged and disabled. The disabled are much more likely to have Medicaid coverage while seniors are more likely to have either employer-based coverage or individually purchased "Medigap" protection.

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 is being reduced. As a result, capitation payments in many previously high payment areas are seeing relatively small year-to-year increases. The managed care industry has argued that the changes in payment policies have resulted in inadequate reimbursement rates. However, reviews by both the General Accounting Office (GAO)[5] and the Inspector General of the Department of Health and Human Services (HHS)[6] suggest that the payments are still adequate to cover the costs of *Medicare covered benefits*. In many cases, the issue is whether plans can continue to offer a range of additional services at relatively low cost to beneficiaries. Many plans question whether they can continue to be competitive if they drop prescription drug coverage or, alternatively, institute 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.[7]

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. The Health Care Financing Administration (HCFA, the agency that administers Medicare) reports that the percentage of persons with coverage under their basic plans has declined. In 1999, 84.3% had such coverage; the percentage dropped to 72.6% in 2000 and 70% in 2001. Approximately 3.8 million beneficiaries have this coverage.[8] Some beneficiaries have drug coverage available only as an optional supplement. Beneficiaries who have coverage through the high option plan are required to pay a premium for the high option coverage; this premium is in addition to any premium required for basic coverage. The actual number of beneficiaries enrolling in high option plans with drug coverage is not known.

HCFA has not yet released an analysis of drug benefits available under M+C in 2001. In 1999, HCFA issued a report (based on M+C required plan filings) on expected M+C plan characteristics for 2000. It reported that in 2000 the number of

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[5]U.S. General Accounting Office. *Medicare+Choice: Plan Withdrawals Indicate Difficulty of Providing Choice While Achieving Savings*. GAO/HEHS-00-183. September 2000.

[6]U.S. Dept. of Health and Human Services. Office of Inspector General. *Adequacy of Medicare's Managed Care Payments After the Balanced Budget Act of 1997*. Memorandum to HCFA Administrator, A-14-00-00212. September 18, 2000.

[7]For a further discussion of M+C see CRS Report RL30702, *Medicare+Choice*, by Hinda Ripps Chaikind and Madeleine Smith.

[8]HCFA. [http://www.hcfa.gov/medicare/bipahome.htm], April 2001.

beneficiaries nationwide with *access* to an M+C plan offering drug coverage would remain relatively unchanged from 1999. However, in some states the access would decline while in other states it would increase. HCFA also reported that the value of the drug benefit in M+C plans would generally decline from 1999 to 2000.

HCFA reported that 86% of the plans with drug benefits would limit coverage in 2000. About one-third (32%) would have a cap on benefits of $500 or less, and 82% of plans would cap drug coverage below $2,000. Although enrollees would be more likely to have access to unlimited coverage for generic drugs, they would be even more likely to have tighter caps on brand name drugs. HCFA also reported that for the first time all M+C organizations would charge copayments for drugs.[9]

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 2000 survey by Mercer/Foster Higgins shows that over a 8-year period (1993-2000) 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 31%, while the number providing coverage to Medicare-eligible retirees fell from 40% to 24%.[10] Coverage of the Medicare-eligible population increases by size of employer. In 2000, 18% of employers with 500-999 employees offered coverage. This percentage increased to 25% for employers with 1,000-4,999 employees, 39% for those with 5,000-9,999 employees, 43% for those with 10,000-19,999 employees, and 57% for those with 20,000 or more employees.[11]

A report by The Kaiser Family foundation shows similar trends. From 1999 to 2000, the percentage of large employers (with 200 or more employees) offering coverage to their Medicare-eligible retirees dropped from 80% to 67%. Again, coverage of the Medicare-eligible population increases by size of employer. In 2000, 63% of midsize firms (200-999 workers), 76% of large firms (1,000-4,999 workers) and 79% of jumbo firms (5,000+ workers) offered such coverage. [12]

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[9]Health Care Financing Administration. *Medicare+Choice: Changes for the Year 2000; An Analysis of the Medicare+Choice Program and How Beneficiaries Will Be Affected by Changes*. Report. September 1999.

[10]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.

[11]Mercer, William M. *Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans 2000, Report on survey Findings.* April 18, 2001.

[12]The Kaiser Family Foundation and Health Research and Educational Trust. *Employer Health Benefits, 2000, Annual Survey.* 2000.

Drugs represent a large part of plan expenses for retirees. The Mercer/Foster Higgins study reported that drug costs often exceed 50% of the employer's costs. The study noted that while virtually all active-employee plans cover prescription drugs, 17% of plan sponsors exclude drug coverage from their pre-Medicare eligible retiree plans and 21% exclude it from their Medicare-eligible retiree plans. Drug exclusions are more common among smaller employers.[13]

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.[14]

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 1 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 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. [15]

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. Weiss Ratings, Inc., under contract with HCFA, recently announced the results of its inventory of Medigap premiums for 65-year old males. It noted that from 1998 - 2000, the average premium increases were 15.5%

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[13] Mercer/Foster Higgins, 2000.

[14]Hewitt Associates. *Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits*. Report prepared for Henry J. Kaiser Family foundation. October 1999.

[15]For further information on Medigap see: CRS Report RL30094, *Medicare: Supplementary "Medigap" Coverage*, by Jennifer O'Sullivan.

for policies without drug coverage compared to 37.2% for policies with coverage. (**Table 2**) Premiums, and premium increases also varied greatly by location.

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

Plan	1998 Average	2000 Average	% Change
Without drug coverage:			
A	$631.20	$766.14	21.4
B	875.12	1,026.48	17.3
C	1,064.85	1,239.06	16.4
D	899.94	1,049.52	16.6
E	963.02	1,106.78	14.9
F	1,163.58	1,301.11	11.8
G	1,070.50	1,175.03	9.8
			Average: 15.5
With drug coverage:			
H	1,572.61	2,347.38	49.3
I	1,803.05	2,423.16	34.4
J	2,407.99	3,065.26	27.3
			Average: 37.2

Source: Weiss Ratings, Inc. *Prescription Drug Costs Boost Medigap Premiums Dramatically*. Press Release. [http://www.weissratings.com/newsreleases], March 26, 2001.

A number of observers have concluded that only those persons who expect to actually utilize a significant quantity of prescriptions actually purchase 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 standard plans. 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 age 65, persons with prestandard policies

generally have no alternative except Plan A (if their current carrier is willing to sell them this) or Medicare+Choice (if a plan is available in their area).[16]

Medicaid.[17] 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.[18] All states offer this service under their Medicaid plans. In general, these dual eligibles have comprehensive coverage with only nominal cost-sharing.

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 2001, the monthly level is $736 for an individual and $988 for a couple.[19] They must also have assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their 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

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[16]Chollet, Deborah. Senior Fellow Mathematica Policy Research Institute. *Medigap Coverage for Prescription Drugs.* Testimony before Senate Committee on Finance. April 24, 2001.

[17]For a discussion of Medicaid see: CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

[18]Medicaid also offers coverage for long-term care — a potentially very costly item for the population needing these services.

[19]The annual HHS poverty guidelines for 2001 are $8,590 for an individual and $11,610 for a couple; the monthly figures are $716 for an individual and $968 for a couple. The qualifying levels are higher because, by law, $20 per month of unearned income is disregarded in the calculation. [http://www.hcfa.gov/medicaid/dualelig/4732rate.htm].

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 2001, the monthly income limits are $879 for an individual and $1,181 for a couple.[20] 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 2001, the monthly income limit for QI-1 for an individual is $987 and for a couple $1,327. Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium.[21]
- **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 2001, the monthly income limit is $1,273 for an individual and $1,714 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. ($3.09 in 2001).

Other Sources.[22] Some beneficiaries with a military service connection may receive drug coverage through Department of Defense or Department of Veterans Affairs programs.

Recent action taken by the Congress will significantly expand the access of military retirees to prescription drug benefits. On October 30, 2000, the President signed into law P.L.106-398, the Defense authorization bill. This legislation authorizes a permanent comprehensive health care benefit for Medicare-eligible military retirees thereby making all military retirees eligible for health care within

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[20]This is calculated the same way as the QMB level. See preceding footnote.

[21]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.

[22]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 announced in November 2000, that the programs would be listed on its WEB site [http://www.medicare.gov/prescription/home.asp].

TRICARE, the military health care system, effective October 1, 2001. Under the bill, Medicare will pay first and TRICARE will be 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 national mail order pharmacy benefit for all eligible beneficiaries. There are deductibles for use of non-network pharmacies and only 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[23] that as of April 2001, 26 states had authorized some type of pharmaceutical assistance program; with programs in operation in 24 states.

Twenty-two states had enacted laws to create the programs, while the executive branch initiated the programs in 4 other states. Twenty states provided a direct subsidy using state funds while one state provided a subsidy only through a year end tax credit. Nine of these subsidy programs included both seniors and persons with disability,[24] while 12 were limited to the senior population.[25] The remaining 5 states had created programs which offered a discount only (no subsidy) for seniors.[26]

The state programs vary substantially both in design and coverage. A survey by GAO[27] showed that while 14 states had programs in 1999, over 70% of the enrollees resided in just three states- New York, New Jersey, and Pennsylvania. While the number of states offering plans has increased, many are in the initial stages of operation.

Both the NCSL and the GAO report wide variations among programs. The GAO[28] reported that States used income eligibility criteria ranging from 100% to 225% of poverty. Most, though not all states, had some cost-of-living adjustment or similar mechanism to increase the income thresholds each year. Three states had assets limits. States took a variety of approaches to controlling costs. While states

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[23]NCHSL: 1) [http://www.nchsl.org/programs/health/drugaid.htm]; and 2) *Pharmacy Assistance: State-Based Programs*, presentation to National Health Policy Forum, April 25, 2001.

[24]Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, New Jersey, Vermont, and Wyoming.

[25]Florida, Indiana, Kansas (not in operation as of April 2001), Michigan, Minnesota, Missouri (tax credit), Nevada,, New York, North Carolina, Pennsylvania, Rhode Island, and South Carolina.

[26]California, New Hampshire, Iowa (not in operation as of April 2001), Washington, and West Virginia.

[27]U.S. General Accounting Office. *State Pharmacy Programs: Assistance Designed to Target Coverage and Stretch Budgets*. Report GAO/HEHS-00-162. September 2000.

[28]Ibid.

did not generally use formularies,[29] some states did restrict coverage to specific classes of drugs to treat specific conditions. Most states required beneficiary cost-sharing, with copayments and coinsurance charges more common than deductibles or per capita limits on program spending. All state programs included in the GAO survey obtained rebates from drug manufacturers to partially offset program costs. States varied in the degree to which their administrative structures, including eligibility determinations, were integrated with their state Medicaid programs.

Drug Coverage and Spending for the Medicare Population

The previous discussion has 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.

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.**) These figures do not reflect the extent and depth of coverage which varies widely. It should also be noted that not all beneficiaries have coverage for the entire year; for example, in 1997, only 54% of beneficiaries had coverage for the entire year.[30]

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.**)

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[29]Formularies are lists of prescription drugs that a health plan or insurer prefers and may encourage a physician to prescribe and beneficiaries to use.

[30] Poisal, John. Health Care Financing Administration. Testimony before the Subcommittee on Health, House Committee on Ways and Means. March 27, 2001.

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

(in percent)

Type of coverage [a]	With drug coverage	Without drug coverage
All persons	73	27
No supplemental coverage	0	100
Supplemental coverage		
Medicare HMO[b]	92	8
Medicaid[c]	89	11
Employer-sponsored	90	10
Medigap	43	57
All other	89	11

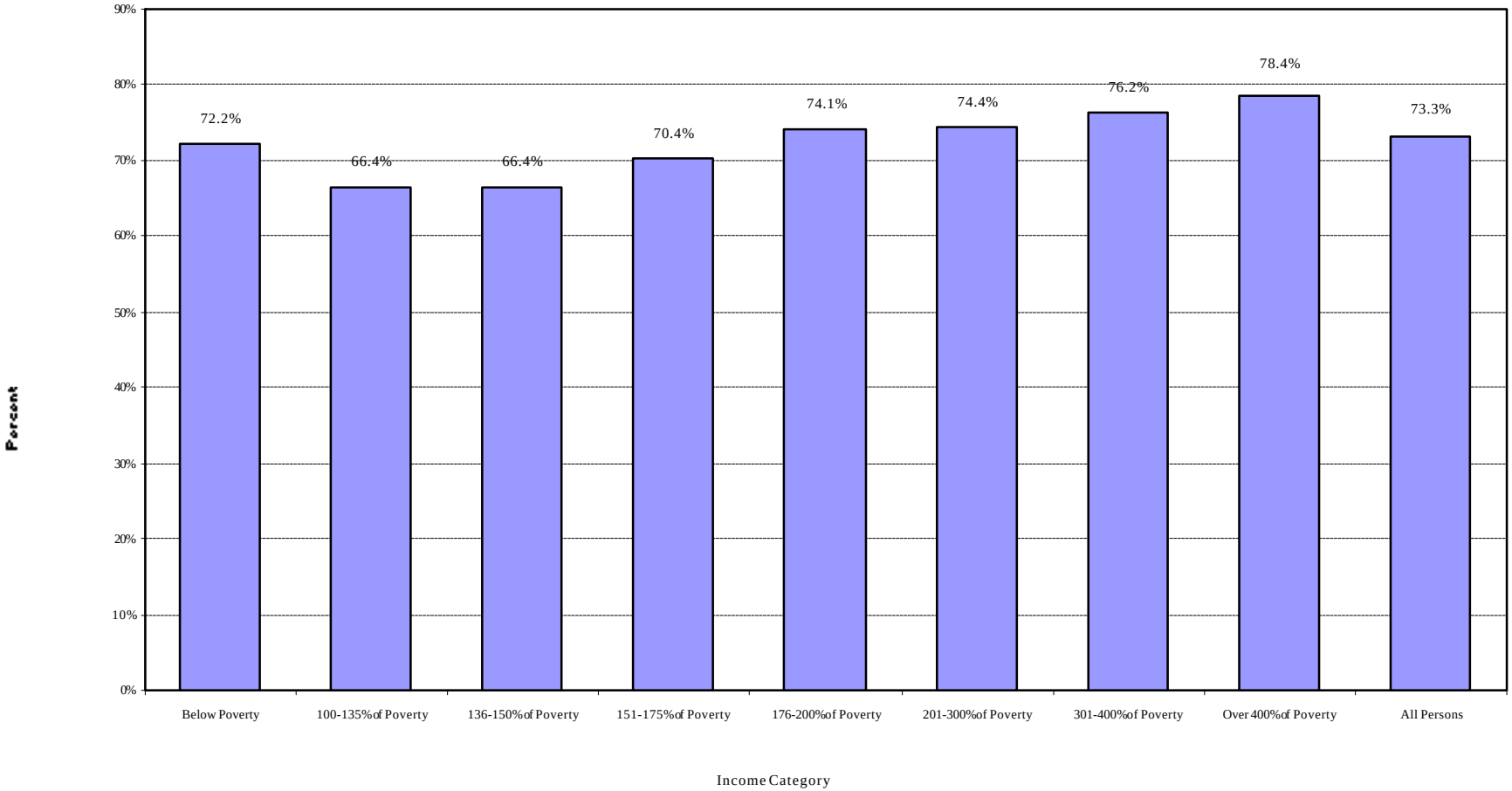
Source: Poisal, John A., and Lauren Murray. *Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage.* Health Affairs, v. 20, no. 2, March/April 2001.

[a] 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)
[b] Includes persons receiving drug coverage through both their basic plans and optional coverage.
[c] 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.[31] 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 includes 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.

[31] HCFA's analysis of the 1998 MCBS (as reported in the March/April 2001 *Health Affairs* article) used federal poverty threshholds. 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



Source: Figure prepared by the Congressional Research Service (CRS) based on 1) Posial and Murray. Growing Differences between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, March/April 2001; 2) personal communication with author.

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

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%.[32]

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.[33] (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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[32]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.

[33]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

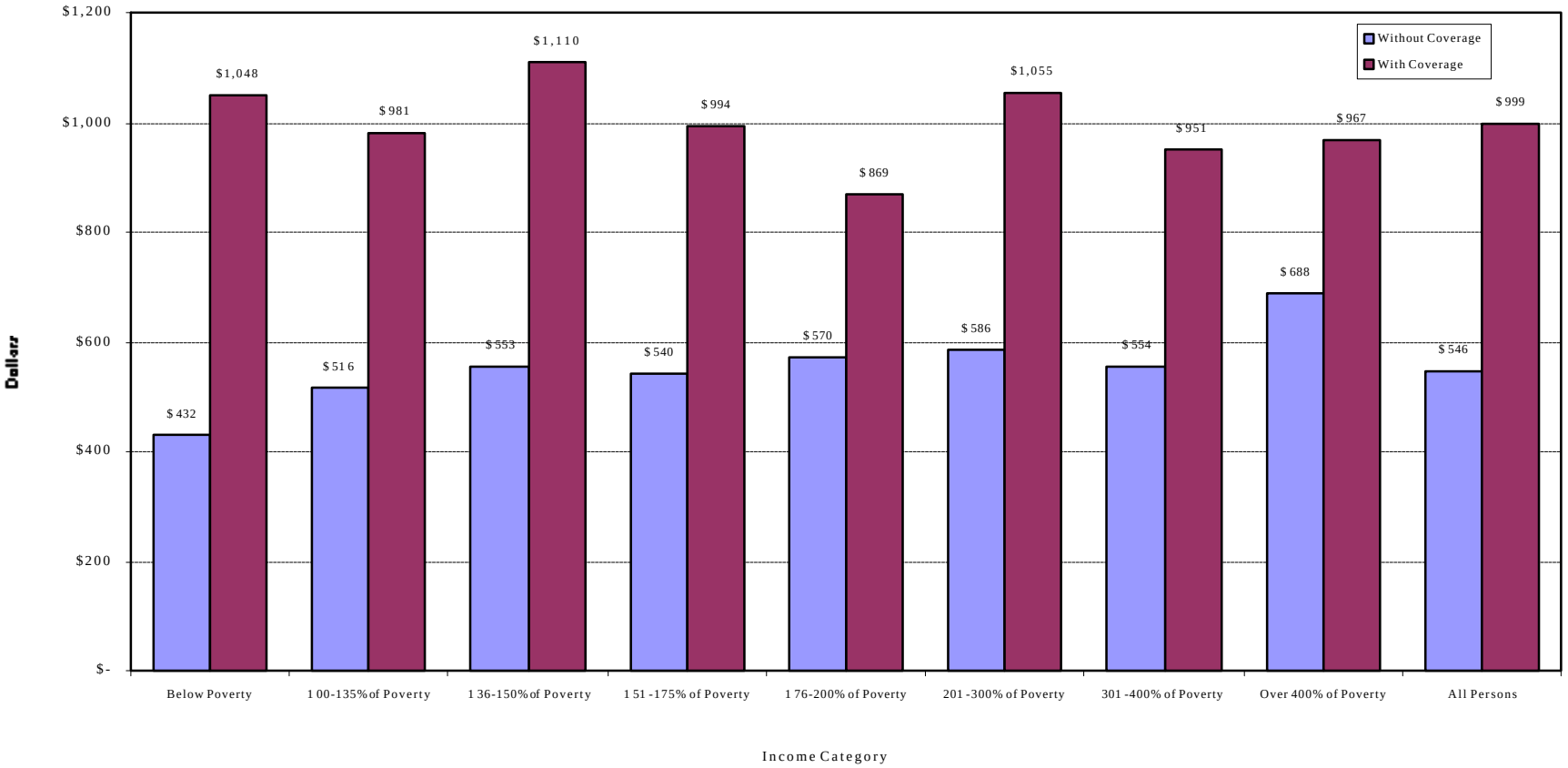


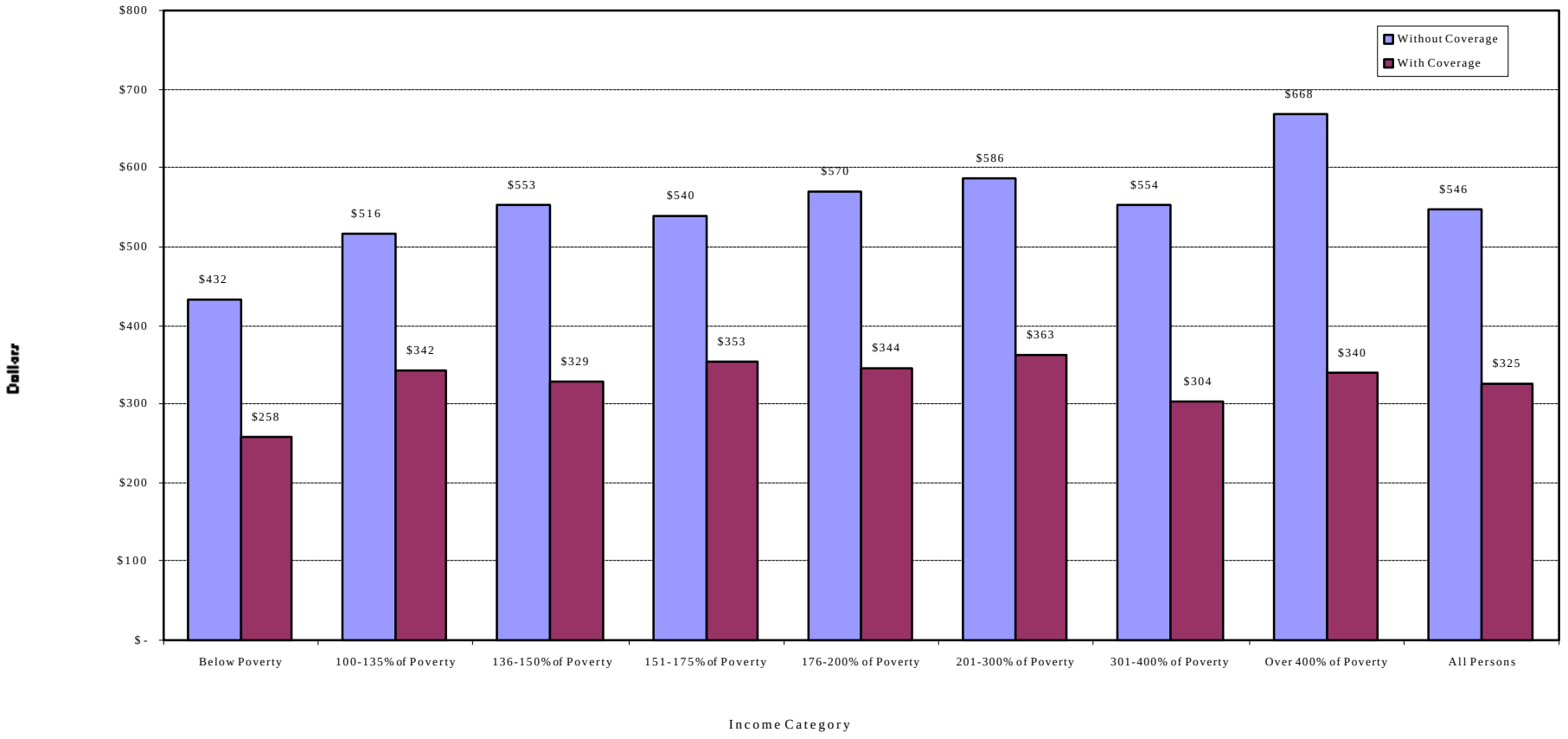
Figure prepared by the Congressional Research Service (CRS) based on 1) Posial and Murray. Growing Differences between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, March/April 2001; 2) personal communication with author.

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

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.[34] 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.

[34]Ibid.

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



Source: Figure prepared by the Congressional Research Service (CRS) based on 1) Posial and Murray. Growing Differences between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs*, March/April 2001; 2) personal communication with author.
Note: 1998 poverty threshold level for the aged with $7,818 for a single and $9,862 for a couple; the corresponding figures for the disabled were $8,480 and $10,972.

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.[35] (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. In March 2000, the Congressional Budget Office (CBO) estimated that drug spending by Medicare enrollees for drugs not covered by the program 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 current 10-year projection period is approximately $1.5 trillion. The later number reflects both higher estimates of per capita drug spending over the entire projection period and the inclusion of a new high cost year (2011) in the current projection window.

Under the 2001 CBO estimates, mean per capita drug spending for the Medicare population would climb from $1,756 in 2001 to $4,818 in 2011; this represents an average annual rate of increase of 10.6%. Total prescription spending for this population group would rise from $70.6 billion in 2001 to $227.7 billion in 2011, for an average annual rate of increase of 12.4%. (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 1.6% per year in the number of Medicare beneficiaries.

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[35]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.

Table 4. Estimated Spending on Outpatient Drugs by or for Medicare Beneficiaries, 2000-2011

Year	Per capita	Total (in billions)
2000	1,525	60.7
2001	1,756	70.6
2002	1,989	80.9
2003	2,238	92.2
2004	2,488	104.0
2005	2,755	116.8
2006	3,049	131.4
2007	3,360	147.5
2008	3,690	165.4
2009	4,040	184.9
2010	4,412	205.2
2011	4,818	227.7

Source: U.S. Congressional Budget Office. Estimates using January 2001 baseline projections. Estimates based on data from the 1997 MCBS with adjustments to account for under reporting by community respondents and for non-response by nursing home residents. January 2001.

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), 12% of beneficiaries will have no drug spending in 2001. About half of total drug spending will be for the 17% of the population spending $3,000 or more in the year. Approximately 28% of spending will be for the 6% of the population spending $5,000 or more in the year. (See **Table 5**.)

Table 5. Estimated Distribution of Medicare Beneficiaries and Amount Spent on Outpatient Prescription Drugs, 2001

Spending category	Percent of beneficiaries	Percent of total dollars
zero	12.3	0.0
greater than zero	87.7	100.0
$500 or greater	65.7	97.2
$1,000 or greater	50.7	90.5
$2,000 or greater	29.9	72.3
$3,000 or greater	17.4	53.8
$4,000 or greater	10.3	39.0
$5,000 or greater	6.3	28.2
$6,000 or greater	3.9	20.4
$7,000 or greater	2.6	15.2
$8,000 or greater	1.6	11.0
$9,000 or greater	1.1	8.3
$10,000 or greater	0.7	5.9

Source: U.S. Congressional Budget Office. Estimates using January 2001 baseline projections. Estimates based on data from the 1997 MCBS with adjustments to account for under reporting by community respondents and for non-response by nursing home residents. Excludes M+C enrollees. January 2001.

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 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 has 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. HCFA estimates that the *population as a whole* spent $99.6 billion in 1999 and $116.9 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 13.4% in 1998, 16.9% in 1999, and 17.4% in 2000; these numbers were substantially higher than the increases of 4.5%, 5.5%, and 8.2% in total personal health spending recorded over the same period. By 2000, spending on prescription drugs accounted for 10.2% of total personal health spending. HCFA estimates over the next decade spending will increase at an average rate of 12.6% per year, reaching 16.0% of personal health spending by 2010.[36] [37]

HCFA attributed the increases in drug spending to a number of factors including the proliferation of private health insurance plans with 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. The increases were reportedly responsible for a large portion of the increase in total health benefit costs and the increases in premium costs for private insurers. Recently third-party payers have attempted to slow growth in drug spending by providing incentives to consumers to use lower cost drugs.

HCFA reported Medicare spending of $2 billion in 1999 on retail outlet sales of prescription drugs.[38] 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[39]

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.

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[36]Heffler, Stephen, et.al. *Health Spending Growth Up in 1999; Faster Growth Expected in the Future*. Health Affairs, v. 20, no. 2, March/April 2001. It should be noted that this article incorporates several major conceptual revisions; therefore the numbers may not be directly comparable to those in previous articles.

[37] Higher drug spending numbers are reported by 2 other groups. The National Institute for Health Care Management Research and Educational Foundation (NIHCM Foundation, a non-profit, non-partisan group that conducts research on health care issues) reported spending of $111.1 billion in 1999 and $131.9 billion in 2000. IMS Health, Westport Connecticut reported $126.3 billion in 1999 and $145.1 billion in 2000. NIHCM Foundation. *Prescription Drug Expenditures in 2000: The Upward Trend Continues*. Report. [http://www.hihcm.org.] May 2001.

[38]Heffler, Stephen, et.al. *Health Spending Growth Up in 1999; Faster Growth Expected in the Future*.

[39]See also: 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.

The National Institute for Health Care Management Research and Educational Foundation (NIHCM Foundation) analyzed spending growth from 1999 to 2000. It reported that spending on retail prescription drugs rose 18.8% from 1999 to 2000. About 42% of the $20.8 billion increase in retail prescription drug spending was attributable to an increase in the number of prescriptions dispensed. About 36% 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 22% was caused by the one-year increase in the price of individual drugs.[40]

The NIHCM Foundation reported that the bulk of the one-year spending growth was attributable to increased expenditures among a relatively small number of prescriptions. Half occurred among just eight categories of medicine - those to treat high cholesterol, arthritis, chronic pain, depression, ulcers and other stomach ailments, high blood pressure, diabetes, and a predisposition to seizures. Looked at another way, sales for just 23 individual drugs accounted for over half of the total spending growth. Sales rose 40.2% for the 50 drugs contributing most to the one-year spending increase ; sales of all other drugs increased 7.9%.[41]

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.[42] Some studies suggest that the first of these factors is the most important.[43] 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.

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[40]NIHCM Foundation. *Prescription Drug Expenditures in 2000: The Upward Trend Continues.* Report. [http://www.hihcm.org]. May 2001.

[41]Ibid.

[42]Sonderegger Research Center School of Pharmacy. University of Wisconsin and Kaiser Family Foundation. *Prescription Drug Trends: A Chartbook.* Kaiser Family Foundation. July 2000.

[43]Lu, Z. John and William Connor. *Strategic Pricing of New Pharmaceuticals*. The Review of Economics and Statistics. February 1998.

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.

The consumer's price depends on how payment is made for the drug.[44] 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. Cash customers represent a declining portion of drug purchasers. 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.[45]

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.[46] 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.[47]

As noted, cash paying customers pay the highest prices. Cash paying customers include Medicare beneficiaries without supplemental drug coverage. This group also includes most Medicare beneficiaries with Medigap drug coverage. Cash paying customers are unable to take advantage of discounts offered to large purchasers. 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.[48]

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[44]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.

[45]Ibid.

[46]For a discussion of Medicaid see: CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

[47]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.

[48]DHHS, *Prescription Drug Coverage*, April 2000.

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 has been the major deterrent to its implementation. Over the past 14 years, three major attempts have been 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 this most recent attempt, significant policy differences, coupled with election year politics, 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.[49, 50] 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% 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

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[49]The coinsurance would have been 20% for drugs used in connection with the new home intravenous drug therapy benefit.

[50]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.

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 106th 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.[51]

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 alternative."

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 106th Congress. Some measures would have provided assistance to states to enable them to establish, on a voluntary basis, programs for their low-income populations.

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 106th 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.

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[51]For a discussion of the major Medicare drug bills considered during the 106th 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.

Proposed Benefit: Program Design Issues

The issue of prescription drug coverage for the Medicare population is expected to receive continued attention during the 107th 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 appears to be a growing consensus that something should be done. However, to date a consensus has not been reached on many of the major design issues.

The following sections address some of these 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 2029).[52] 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

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[52]See CRS Report RS20173, *Medicare: Financing the Part A Hospital Insurance Program*, by Jennifer O'Sullivan and Heidi Yacker.

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.

In response to these competing concerns, some observers have suggested the possibility of an interim approach. The FY 2002 Budget, submitted by President Bush, includes the Immediate Helping Hand proposal. Under this proposal, federal funds would be provided for a temporary state-administered benefit for the low-income and those with catastrophic drug expenses. This is viewed as an interim approach until Medicare reform is enacted. Proponents of this approach argue that it would help those most in need of assistance. Opponents argue that it would fail to provide coverage to many individuals; further, it could delay passage of a benefit for all Medicare beneficiaries.

Degree of Private Involvement. One issue that was the focus of considerable discussion during 2000 was 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 was presented. At one end of the spectrum was the House-passed bill. Under this bill, access to a drug benefit would have been provided *only* through private insurance companies and similar private entities that wished to offer the benefit. At the federal level, the program would have been administered to assure beneficiaries access to at least two plans. If necessary to ensure access, financial incentives would have been authorized. Private plans would also have received federal reinsurance payments to cover a percentage of costs for persons with high drug bills. The private entities would have assumed the remainder of the financial risk for covered benefits.

Another approach (offered by Senators Breaux and Frist) would also have utilized private entities to provide drug benefits. All persons would have received assistance for at least 25% of their drug premiums. In addition, plans would have received reinsurance payments for drug costs exceeding a specified threshold. The private entities would have assumed the remainder of the financial risk for covered benefits. However, unlike the House-passed bill, the federal government would have been required to establish procedures for the provision of prescription coverage to each person residing in an area where there were no drug plans or M+C plans providing coverage. This approach is included in S. 357 introduced by Senators Breaux and Frist in the 107th Congress.

Unlike the measures emphasizing the private sector, President Clinton's plan, and similar bills, would have established a uniform benefit nationwide as part of the current Medicare program. Under these bills, the federal government would have assumed all, or virtually all, of the financial risk.

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. They point to provisions that would have required government subsidies in order to encourage insurers to participate in the program. Instead, these persons 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.[53] 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. 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 may also 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.[54]

A number of questions have been raised regarding whether PBMs could employ the same tools, and achieve comparable savings, 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 what level of federal involvement there is 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

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[53]For a discussion of PBMs, see: CRS Report RL30754, *Pharmacy Benefit Managers*, by Christopher J. Sroka.

[54]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.

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 Health Care Financing Administration (HCFA) is the federal agency which is charged with the administration of the Medicare program. Some proposals would designate a newly established 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 HCFA administration of Medicare. Other observers contend that HCFA's shortcomings are primarily attributable to inadequate resources. Further they suggest that splitting responsibility for Medicare among 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 1997 MCBS, a cut off at 135% of poverty would provide protection for the 30% of beneficiaries with incomes below 135% of poverty. At the same time, it would extend benefits to the 35% 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 35 % of beneficiaries with incomes below 150% of poverty and extend benefits to 42% of those without drug coverage. These percentages would rise to 50% of beneficiaries and 60% without other drug coverage, if the cut off was set at 200% of poverty.[55]

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. Also, any threshold has the potential for establishing a sharp cut off point for coverage.

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 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.[56] 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.

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[55] Definitions of poverty are based on poverty guidelines. CRS estimate based on 1997 MCBS.

[56] See CRS Report 98-7, *Medicare: Part B Premium Penalty*, by Jennifer O'Sullivan.

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., 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 2001, 29.9% of beneficiaries (excluding M+C enrollees) would spend $2,000 or more per year on drugs, accounting for 72.3% of drug spending for the Medicare population. In the same year, an estimated 6.3% of fee-for-service beneficiaries would spend $5,000 or more on drugs, accounting for 28.2% of drug spending for the group. These number increase dramatically by 2011. In 2011, 58.5% of beneficiaries (excluding M+C enrollees) would spend $2,000 or more per year on drugs, accounting for 94.4% of drug spending for the Medicare population. In the same year, an estimated 32.8% of fee-for-service beneficiaries (excluding M+C enrollees) would spend $5,000 or more per year on drugs, accounting for 75.3% of drug spending for the Medicare population.

Assistance for the Low-Income Population. Virtually all of the pending drug proposals (except those limited to the low-income population) 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. Many proposals would set the income cut-off level at 135% of poverty ($11,844 for an individual in 2001[57]). This is generally the QMB/SLIMB population.[58] Persons meeting the income criteria, and *not* eligible for full Medicaid benefits, would have their premium and cost-sharing costs paid by the federal government.

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[57]See footnote number 19.

[58]See discussion of QMB/SLIMB population under discussion of supplementary coverage under Medicaid.

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. Some plans 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 ($11,844-$13,128) for an individual in 2001) would have a sliding scale subsidy for the premium but no coverage for cost-sharing charges.

State Medicaid programs could potentially save some costs for services because they would be picked up under a new federal program. However, they could potentially be faced with larger expenditures for the QMB/SLIMB population. Enrollment in the QMB and SLIMB 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.

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.[59]

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 up 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

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[59]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.

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.[60] None of the major proposals, 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 drug 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. In many cases, this 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.

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 predict the response of the industry to the discounts. For example, would prices to

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[60]Some bills before the 106th Congress dealt directly with the prices seniors pay for drugs; however, they did not add a new benefit for this population group. For a discussion of these measures see: 1) CRS Report RS20750, *The Prescription Drug Import Provisions of the FY2001 Agriculture Appropriations Act, P.L.106-387,* by Donna U. Vogt and Blanchard Randall IV; and 2) 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.

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.

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 be passed along directly to consumers. Consumers would 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 drug spending for the Medicare population at $1.5 trillion over the 2002 - 2011 period. A drug benefit for this population is potentially very costly. To date, a consensus has not been reached on the funding sources. Possible sources include federal general revenues, earmarked funds from the federal budget surplus, and tobacco taxes. Virtually all proposals contemplate that the beneficiaries themselves, except for very low-income persons, will assume a portion of the costs.

Prospects for the 107th Congress

The FY 2002 budget resolution provides up to $300 billion over the FY 2003-2011 period for a reserve fund for Medicare reform and prescription drugs. Under the resolution, the spending levels for Medicare could be increased if a bill containing such provisions or a conference report containing such provisions is filed. The conference report accompanying the resolution states that it would be appropriate for the cost of such legislation, but no other legislation, to be funded in whole or in part from the surpluses in the Medicare Part A trust fund.

Several bills have been introduced and hearings have been held on reform and drug issues. The Chairman and subcommittee Chairmen for the Committees of jurisdiction (House Ways and Means, House Energy and Commerce, and Senate Finance) have indicated that they expect to markup bills this summer. As of this writing, no markup has been scheduled.[61]

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[61]For a discussion of selected prescription drug bills considered during the 106th Congress, see: 1) CRS Report RL30584, *Medicare: Selected Prescription Drug Proposals in the 106th Congress*, by Jennifer O'Sullvian; and 2) CRS Report RL30754, *Pharmacy Benefit Managers*, by Christopher Sroka.