Medicare:

A BASIC PRIMER




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Note: The Medicare Modernization Act is lengthy and complex. Many of its provisions will be implemented through the adoption of extensive regulations. This basic primer is only intended to provide an overview, and is neither comprehensive nor complete.

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Introduction

The goal of this Medicare primer is to familiarize individuals with the Medicare program, with an emphasis on prescription drug coverage and utilization. Historically, few outpatient prescription drugs have been purchased through the Medicare program since Medicare coverage has been limited primarily to prescription drugs used during hospital stays or those products infused or injected in a physician's office (eg, cancer chemotherapeutic agents). The Medicare Prescription Drug Modernization Act of 2003 was signed into law on December 8, 2003.

This primer contains two main sections:

- ★ An overview of the Medicare program, its growth over time, and its new structure under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act or MMA).
- ★ A description of the most significant parts of the new Medicare prescription drug law, including the drug discount card, the outpatient prescription drug benefit, and the Medicare managed care program expansions.

I. Medicare Overview

Medicare was created by the federal government in 1965 as a medical insurance program for individuals age 65 and older (the disabled and those with end stage renal disease were added in 1972) to shield them from the catastrophic costs of long hospital stays and expensive medical procedures. Since its establishment, Medicare has grown in the scope of its benefits, in the populations it covers, and in its cost.

Medicare originally covered primarily hospital stays and related doctor services such as surgery; now it covers many more kinds of services provided in a range of healthcare settings, and it offers other health insurance plan options, such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs). The most recent benefit addition is an outpatient prescription drug benefit, which was added by Congress and the President in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. More information about this new expansion is provided in Section II.

The size of the Medicare program also has grown dramatically since it was created, in terms of both the number of people it insures and its cost. Medicare covered 20.1 million Americans in 1970; today, there are approximately 41.0 million Medicare beneficiaries, including almost 7 million persons under age 65 with disabilities. Federal spending on Medicare services has grown from $7.1 billion in 1970 to $261.0 billion in 2002.[1]

Eligibility and Enrollment

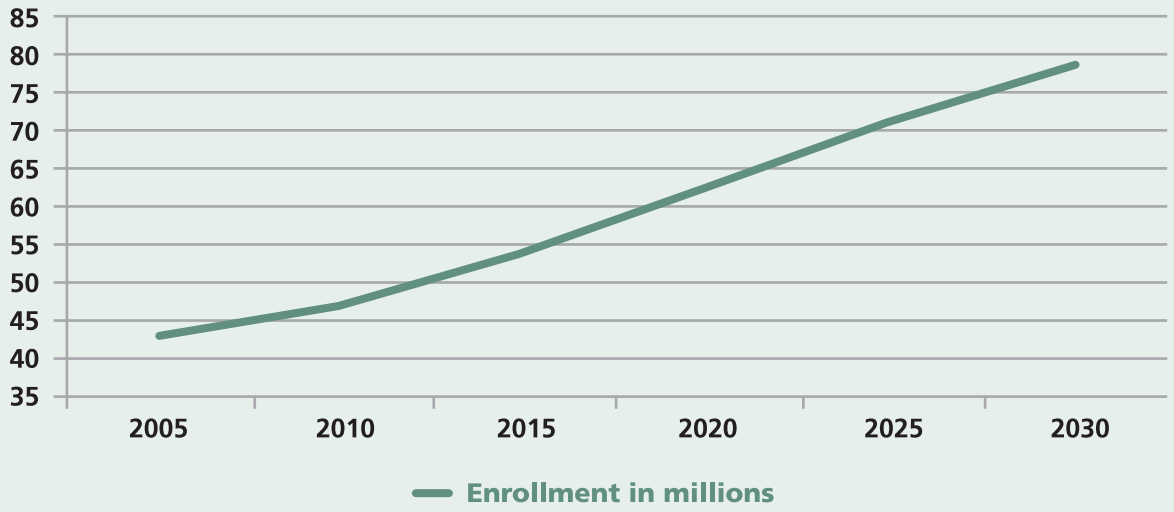
There are three main ways that a person can become eligible for Medicare. First, the vast majority of beneficiaries (approximately 34 million) qualify for Medicare automatically after they or their spouse have worked and contributed payroll taxes toward Medicare for 40 quarters (10 years) and they reach the age of 65. Second, people under age 65 who have been disabled can become eligible for Medicare after they have been receiving disability insurance payments from Social Security for at least two years.[2] Third, people of any age who develop end stage renal disease (ESRD), or kidney failure, also can become eligible for Medicare. The federal government created this Medicare eligibility category in 1972 in recognition of the very high costs of kidney transplants and dialysis treatments. Approximately 7 million (17%) Medicare beneficiaries fall into the disabled or ESRD eligibility groups (about 6.5 million are persons with disabilities and about 500,000 are persons with ESRD).

The 7 million Medicare beneficiaries with disabilities, including those with ESRD, tend to use more and different types of healthcare services, including prescription drugs, than the general Medicare population does. These beneficiaries typically have very poor health status and significant healthcare needs. As a result, the average beneficiary with disabilities fills 28 prescriptions per year, compared to the overall Medicare average of 20 prescriptions per year.[3] The average Medicare beneficiary with disabilities also has approximately 50% higher total spending on prescription drugs.[4] This reflects not only the greater utilization of medications by disabled beneficiaries, but also the use of higher priced drugs. One example of the use of higher priced drugs is the use of biotechnology agents.

[1] 2003 Medicare Board of Trustees Report, Table I.C.1, pg. 3. Spending on services and administration totaled $266 billion in 2002.
[2] Beneficiaries must meet certain requirements to meet the federal government's definition of disabled.
[3] National Economic Council. *Disability, Medicare, and Prescription Drugs*. 2000.
[4] Ibid.

The demographic trends for Medicare enrollment over the next 30 years all point toward an increasing rate of growth; see Figure 1. After the "Baby Boom" generation (people born between 1945 and 1964) starts reaching age 65 in 2010, the federal government expects Medicare's enrollment to increase very rapidly. Between 2003 and 2010, the size of the Medicare population is projected to grow modestly at about 1.5% per year, reaching approximately 46 million by 2010. Just 15 years later, by 2025, there will be over 71 million Medicare beneficiaries, an increase of over 50%.[5]

Figure 1: ***Projected Medicare Enrollment, 2005-2030***



Source: 2003 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, pg. 24

[5] 2003 Medicare Board of Trustees Report, Table II.A4.

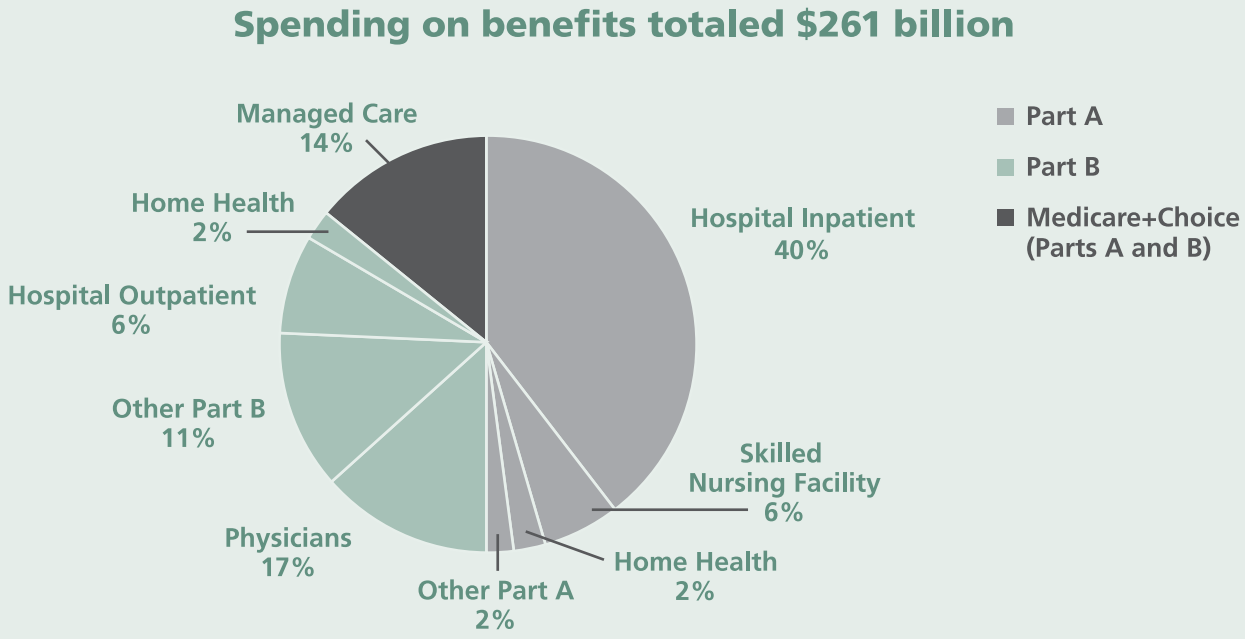
Funding and Spending

Medicare is funded out of a combination of payroll taxes paid by working citizens, general tax revenues from the US Treasury, monthly premiums paid by most Medicare beneficiaries, and cost-sharing amounts paid when a beneficiary receives a covered service. Over the past 20 years, there has been a growing concern that the revenues coming in to fund the program will be insufficient to cover the growing costs of the program. The growth in the number of Medicare beneficiaries due to the aging of the Baby Boom generation brings additional urgency to these concerns.

In 2002, Medicare spent an estimated $261 billion on healthcare services, making it the largest public health insurance program in the country (the combined federal-state Medicaid program is second with spending of $249 billion). Almost half of Medicare spending is for hospital services, with physicians, managed care plans, and nursing home care also making up significant portions; see Figure 2.

Because coverage of prescription drugs currently is limited in the Medicare program, spending on this category comprises a small fraction of total spending; it is captured in "Other Part B" expenditures.

Figure 2: ***Medicare Spending by Type of Provider, 2002***



Source: Calculation by Health Strategies Consultancy based on the 2003 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, pg. 3.

Administration

Medicare is a federal program under the auspices of the US Department of Health and Human Services (DHHS) and administered by the Centers for Medicare and Medicaid Services (CMS). CMS is responsible for all aspects of Medicare's program administration, including making decisions about whether certain items and services will be covered, determining payment rates and policies, administering claims, educating beneficiaries and health-care providers, and conducting research on alternative healthcare delivery systems.

Although most of the program is centrally administered by CMS, the agency contracts on a regional basis with several private companies to perform certain administrative services. Some of these Medicare contractors include: fiscal intermediaries (which administer Part A services), carriers (which administer most Part B services), and durable medical equipment regional carriers (DMERCs). Medicare contractors are the center of the day-to-day operations of the Medicare program at the local level. Many of these contractors also are large private insurance companies, such as AdminiStar Federal (a division of Anthem Blue Cross and Blue Shield) and Palmetto Government Benefits Administrators (a division of Blue Cross Blue Shield of South Carolina). These organizations are responsible for paying claims submitted by providers and re-examining previously denied claims. Not only are they a critical link between providers, beneficiaries, and CMS, they are interpreting Medicare rules and regulations and making local coverage determinations when necessary.

A brief word about Medicare and Medicaid: There are approximately 6 million beneficiaries who are eligible for both Medicare *and* Medicaid; these beneficiaries are referred to as "dual eligibles." Dual eligibles are Medicare beneficiaries who meet the income criteria to also be eligible for Medicaid. While Medicare covers major medical expenses (hospitalization and physician services), copays and deductibles are often unaffordable for this group. Medicaid fills in the gaps by offering health and long-term care coverage, as well as prescription drug benefits.[6] The Medicare Modernization Act significantly changes how these beneficiaries will receive prescription drug coverage starting in 2006 (See Section II).

How Medicare Is Organized

The Medicare program is organized, administered, and funded in four distinct parts:

- ★ Part A (acute inpatient hospital and post-acute care services)
- ★ Part B (physician services, hospital outpatient services and other kinds of ambulatory care, and ancillary services such as clinical laboratory tests and durable medical equipment)
- ★ Part C (managed care plans that offer Part A and Part B services together)
- ★ Part D (prescription drug coverage, which will not take effect until January 2006)

Medicare Part A—Hospital Insurance

The Medicare Hospital Insurance program, also referred to as Part A, is funded through payroll taxes and beneficiary cost sharing. Most Americans are automatically enrolled into Medicare Part A upon turning 65 years old. Part A originally covered care delivered in institutional settings, such as inpatient hospitals and skilled nursing facilities, but it has been expanded to cover home health and hospice care. Part A covers care in a:

- ★ Hospital
- ★ Nursing home
- ★ Home (home health[7] and some hospice services)
- ★ Hospice

[6] The Medicaid program is jointly funded by the federal government and the states and provides health coverage to approximately 47 million low-income people. Within broad national guidelines, which the federal government provides, each of the states administers its own Medicaid program. There is considerable variation across Medicaid programs as each state establishes its own eligibility standards; determines the type, amount, duration, and scope of services; and sets the rate of payment for services.

[7] A portion of federal financing for home health services comes from Part B, but it is administered solely as a Part A benefit.

There is no monthly premium for Part A. However, when patients use hospital and nursing home services, there is significant cost sharing (daily copayments and a deductible for hospital care). Other than nominal cost-sharing for drugs provided by hospice care providers, there are no other copayments required under Part A.

Medicare reimburses providers for beneficiaries' inpatient hospital stays using a payment system known as the Prospective Payment System (PPS) which was developed in the early 1980s. Under PPS, hospitals are paid a flat rate per patient based on the diagnosis-related group (DRG) in which the patient falls. There are slightly less than 500 DRGs, which are developed by CMS, that group patients with similar diseases and treatments into a common payment category. Payments reflect the varying amounts of resources needed to treat patients grouped into a DRG, and are intended to cover all of the costs incurred by the hospital—lab services, surgeries or medical procedures, nursing care, and any pharmaceuticals used in the treatment of the patient. Pharmaceuticals that are related to the admission/diagnosis are provided by the institution to patients during their stay.

Inpatient hospital care accounts for 40% of all spending in Medicare; see Figure 2. There are approximately 12 million discharges from hospitals each year for Medicare beneficiaries.[8]

Medicare coverage for long-term care services is limited (but in some cases these services are covered by state Medicaid programs). Under certain limited conditions, Medicare will pay for short-term nursing home care for beneficiaries who require skilled nursing or rehabilitation services. To be covered, beneficiaries must receive the services from a Medicare-certified skilled nursing facility after a qualifying hospital stay. As in the inpatient setting, pharmaceuticals that are provided by nursing homes for these patients are paid for under Medicare's limited skilled nursing benefit.

Medicare Part B—Supplementary Medical Insurance

Unlike Part A, Part B is not funded by a specific payroll tax, but rather from general tax revenues from the US Treasury, monthly premiums paid directly by beneficiaries, and per-service coinsurance payments from beneficiaries (for most Part B services, Medicare will pay 80% of allowed charges and the beneficiary is responsible for the remaining 20%).

Any person who becomes eligible for Part A is eligible for Part B at the same time, but they must enroll in Part B as soon as they are eligible for Part A, or a "late enrollment" penalty is assessed. To enroll in Part B, a beneficiary agrees to pay a monthly premium, which is the same for all beneficiaries regardless of where they live, but which increases each year. The Part B premium in 2004 is $66.60 per month. The premium is calculated so that beneficiaries altogether pay one quarter of the cost of Part B, while the federal government funds three quarters of the cost. Although enrollment in Part B is voluntary, nearly all (approximately 94%) beneficiaries enroll.[9]

Part B covers a variety of services, including:

- ★ Physician services and non-physician practitioner (eg, physician assistant and nurse practitioner) services
- ★ Hospital outpatient and ambulatory surgical center services
- ★ Durable Medical Equipment (eg, wheelchairs and walkers)
- ★ Prosthetics and Orthotics (eg, artificial limbs and knee braces)
- ★ Clinical laboratory services
- ★ Pharmaceuticals used incident to a physician service (primarily drugs or biologics that must be administered by a physician)
- ★ Vaccines
- ★ Preventive screenings and bone mass measurements
- ★ Ambulance services

[8] Centers for Medicare and Medicaid Services. Key Data on Health Care Financing: The 2001 Medicare and Medicaid Statistical Supplement to the *Health Care Financing Review.* Table 23. Available at www.ems.hhs.gov/review/supp.

[9] Those who choose not to enroll typically have generous retiree coverage from a former employer. For example, retirees from the federal government are offered health insurance that includes prescription drug coverage, and some elect to keep it rather than enroll in Part B.

Prescription drug coverage under Medicare Part B: Medicare currently covers a limited number of prescription drugs (approximately 450) that are provided "incident to" a physician service—in either a physician office or hospital outpatient setting. There are certain exceptions granted through legislative authority for other drugs (eg, coverage of oral antinausea drugs and immunosuppressives). Also, drugs used with Durable Medical Equipment (DME), such as infusion pumps and nebulizers, are covered by Medicare. Many of the drugs covered by Medicare Part B are agents used to treat cancer.

In 2002, Medicare paid an estimated $8.4 billion for the approximately 450 drugs covered by Medicare Part B. Over 77% of Medicare spending for drugs was for cancer drugs. Much of the spending was concentrated on relatively few of the drugs covered by Medicare. Of the $8.4 billion, 7 drugs accounted for 49% ($4.0 billion) and 19 drugs accounted for 75% of spending ($6.2 billion).[10]

Prescription drugs that are administered in a physician's office (and those few oral drugs covered by Part B) are paid separately by Medicare. Until 2004, payment was based on 95% of the average wholesale price (AWP), as published in major commercial drug pricing compendia (eg, *Red Book*). However, the Medicare Modernization Act will bring about significant changes to reimbursement for drugs covered in the physician office setting, substantially lowering the amount reimbursed to physicians (see Section II).

As with drugs provided in the physician office setting, coverage for drugs provided in the hospital outpatient setting is limited only to drugs used in conjunction with physician services or DME. Previously, Medicare paid for prescription drugs provided in the hospital outpatient setting on a "reasonable-cost" basis, but over the past five years, CMS has moved to paying for hospital outpatient services, including prescription drugs, through the hospital outpatient prospective payment system (HOPPS). Some pharmaceuticals (ie, more expensive medications, such as thrombolytics and medications used less frequently) may receive separate, and higher, payment. (See Section II for information about recent changes to payment for drugs covered in the hospital outpatient setting.)

Medicare Part C—Medicare+Choice

Medicare+Choice plans (also referred to as Part C) were established by Congress in the Balanced Budget Act of 1997 to provide Medicare beneficiaries with access to managed care plan options. The Medicare+Choice program was designed to control costs, to expand health plans to markets where access to managed care plans was limited or nonexistent, and to offer a wider variety of managed care plans. Essentially, Part C provides Medicare beneficiaries with more choices and, sometimes, extra benefits by allowing private companies rather than Medicare to manage their benefits.

Similar to commercial health plans, Medicare managed care plans are paid a "per member per month" payment for each Medicare beneficiary that they enroll, and in return must provide at least the full range of Part A and Part B healthcare services covered by regular Medicare. Today, 79% of Medicare beneficiaries have access to the 155 existing Part C plans, but only about 4.6 million Medicare beneficiaries, or about 11%, have chosen to enroll in them.[11] Over the past three years, enrollment in Part C has steadily declined due to a limited choice of plans in many areas, instability in provider participation compared with fee-for-service Medicare, and increased out-of-pocket costs.

[10] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Payment Reform for Part B Drugs," Proposed Rule, August 20, 2003 (68 *Federal Register* 50429).
[11] Centers for Medicare and Medicaid Services, *2003 Data Compendium,* accessed at http://www.cms.hhs.gov/researchers/pubs/datacompendium/2003/03pg7677.pdf.

The Medicare Modernization Act (MMA) replaces the Medicare+Choice managed care program with "Medicare Advantage." Under Medicare Advantage, private health plans can contract with Medicare to provide basic Medicare benefits plus extra healthcare services, often including prescription drugs. The MMA provides immediate increases (averaging 10.6% in 2004) to the government's payments to Medicare Advantage plans in an effort to reverse the exodus of private health plans from Medicare over the past three to four years. Also, in 2006 Medicare Advantage will be expanded to include regional "Preferred Provider Organization" (PPOs) plans.[12] Policymakers hope that the addition of regional PPOs will give more beneficiaries a choice between traditional "fee-for-service" Medicare and coverage through a private health plan.

A brief word about Medigap insurance. "Medigap" plans are not part of Medicare, but are worth mentioning because today some plans include limited coverage of prescription drugs. Medigap plans are private, government-regulated insurance plans that offer "supplemental coverage" to cover an individual's Medicare cost-sharing expenses and certain services not covered by Medicare. Today, there are 10 types of Medigap policies that insurers are allowed to sell, but only three types include outpatient prescription drug coverage. The coverage offered in these plans, however, is limited, with policies providing only 50% coverage and benefits capped at either $1,250 or $3,000 in total drug spending per year, depending on the plan.

The MMA creates two new private Medigap plan options to help Medicare beneficiaries pay their out-of-pocket costs, such as deductibles and coinsurance for Medicare services. In addition, Medigap plans will no longer be able to offer new enrollees coverage for prescription drugs, since that type of coverage will be provided by Medicare directly starting in January 2006. Beneficiaries who already have a Medigap plan that covers prescription drugs will be allowed to continue their plans, but will have great incentives to switch to the new Medicare drug benefit provided under Part D since it will be heavily subsidized and Medigap is not.

[12] Preferred Provider Plans (PPOs) are less restrictive managed care plans that allow beneficiaries to use providers that are out of network at additional cost to the beneficiary.

II. Medicare Part D and the "Medicare Prescription Drug, Improvement and Modernization Act of 2003"

At the end of November 2003, the US Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Medicare Modernization Act or MMA). On December 8, the President signed this legislation into law, initiating the most comprehensive changes to the Medicare program since it was created in 1965. The new law will add a new outpatient prescription drug benefit to Medicare and make several other significant structural and payment changes to existing Medicare benefits.

Most of the changes made by the new Medicare law will be implemented over the next two years. Many program details will need to be worked out through the federal regulatory process. During 2004 and 2005, CMS will engage in the process of drafting, revising, and finalizing extensive regulations that will flesh out many administrative, legal, and operational details that are not specified in the new law.

The Medicare Drug Discount Card Program

The new law mandates the implementation of a Medicare-endorsed prescription drug discount card program in 2004 and 2005.[13] The discount card will serve as an interim measure to reduce prescription drug costs (by an estimated 10%–20% from retail prices) for the several million beneficiaries who currently have no prescription drug insurance coverage. The discount card program is scheduled to end when the prescription drug benefit is implemented in 2006.

Beneficiary eligibility: Any Medicare beneficiary, except those covered by Medicaid, is considered eligible for the drug discount card. According to the implementation schedule set forth by CMS, eligible beneficiaries will be able to enroll in a drug discount card program in May 2004, and the cards will start providing discounted drug prices to their enrollees on June 1, 2004.

Beneficiary enrollment: Beneficiaries will be able to enroll in only one Medicare-endorsed drug discount card program at a time and may be charged up to a $30 enrollment fee, but they also will be able to keep using any non-endorsed drug discount card if they choose to do so. Beneficiaries enrolled in a Medicare managed care plan may only enroll in that plan's discount card program, *if* it offers one. Otherwise, they are free to enroll in a card program offered by another sponsor. Once enrolled, beneficiaries may switch from one Medicare-endorsed discount card plan to another only during a coordinated election period from November 15 through December 31, 2004. There are exceptions to this "lock-in" policy under certain circumstances (eg, if a beneficiary moves outside their original card sponsor's service area, or if a card sponsor terminates its program). CMS estimates that approximately 7.3 million Medicare beneficiaries will enroll in the program in 2004.

Subsidies for low-income beneficiaries: Certain low-income beneficiaries who have no other coverage for prescription drugs (participation in state pharmaceutical assistance programs is an exception) (ie, beneficiaries

[13] Prescription drug discount cards seek to lower the prices of prescription drugs purchased at retail pharmacies for consumers who do not have health insurance with prescription drug coverage. In the past, discount card programs have been sponsored by membership organizations (eg, AARP or AAA), state governments, pharmacy benefit managers (PBMs), retail pharmacies and other entities. Many of these entities subcontract with a PBM to administer the benefit, and in particular to negotiate with other entities in the prescription drug supply chain that determine a drug's retail price. The goal of each discount card program is to give its enrollees access to discounts off of the retail prices of prescription drugs that an individual with no prescription drug coverage otherwise would pay.

with incomes below 135% of the federal poverty level, or $16,362 for a family of two) may also be eligible for "transitional assistance" payments of up to $600 per year to help them purchase prescription drugs. Beneficiaries receiving transitional assistance will have to pay coinsurance of between 5% and 10% on drugs purchased through the discount card program, but will not have to pay the card's annual enrollment fee if one applies. CMS will fund the enrollment fee for these beneficiaries.

Administration: Card sponsors may use cost-containment mechanisms often seen in prescription drug insurance benefits in the private sector, such as:

- ***Pharmacy networks:*** Participating card sponsors must have a contracted pharmacy network that may limit beneficiaries to certain retail outlets, however, beneficiaries must have ready access to a convenient, participating pharmacy.
- ***Formularies:*** While formularies are not explicitly required, they are permitted as long as they conform to certain program requirements. The discount card regulations that CMS issued in mid-December indicate that, at a minimum, all Medicare discount card sponsors must provide access to at least one discounted drug in each of 209 specified therapeutic categories. The regulations also require card sponsors to offer a generic drug alternative in at least 115 of the therapeutic categories that make up 95% of all drugs used by the Medicare population.

Discounts: Card sponsors must negotiate rebates, discounts, or other price concessions from manufacturers and retail pharmacies on covered drugs, and must pass a "share of such concessions" to discount card enrollees. CMS estimates, but does not guarantee, that Medicare discount card holders will see savings of 10%–20% off of the regular retail (cash) price for drugs. The price discounts given to the Medicare prescription drug plans will be excluded from Medicaid best price calculations.

Drug price reporting to Medicare: Card sponsors will be required to report drug-specific pricing information to CMS, as well as aggregate data on savings passed on to discount card enrollees. On April 30, 2004, CMS will establish a drug price comparison Web site for beneficiaries (located at *www.medicare.gov*), which will include the maximum prices (including dispensing fee) for all of the individual drugs offered by the card sponsor.

The New Medicare Prescription Drug Benefit

Beginning in 2006, the new Medicare prescription drug benefit, known in the law as "Medicare Part D," will transform the way that Medicare beneficiaries pay for and receive their prescription drugs. The law lays out three ways a beneficiary may receive Part D benefits: (1) through a "Medicare Advantage" managed care plan; (2) through a stand-alone "prescription drug plan" (PDP); or (3) through a "fallback prescription drug plan" in any area where there are not at least two private plans willing to offer Part D coverage. Under the last option, a Pharmacy Benefits Manager (PBM) or similar entity would contract with Medicare to provide administrative services (eg, claims payment) only, and the federal government would bear the risk of providing the drug benefit. In the first two options, private plans would contract with Medicare to deliver Part D benefits and would bear the risk for the costs of beneficiaries' drug use.

Standard Part D benefit: The new Medicare law specifies certain minimum standards for Part D coverage. It is important to understand that, unlike Medicare Parts A and B, many parts of the standard Part D benefit can be altered by any Part D plan, meaning that plans could look very different from one another, both in terms of what drugs they cover and how much they cost beneficiaries. However, it is also important to have a basic grasp of the standard Part D benefit structure, because many of the plans may simply copy it when the program begins, and in any area of the country where there is only a "fallback" plan, only the standard benefit structure will be available.

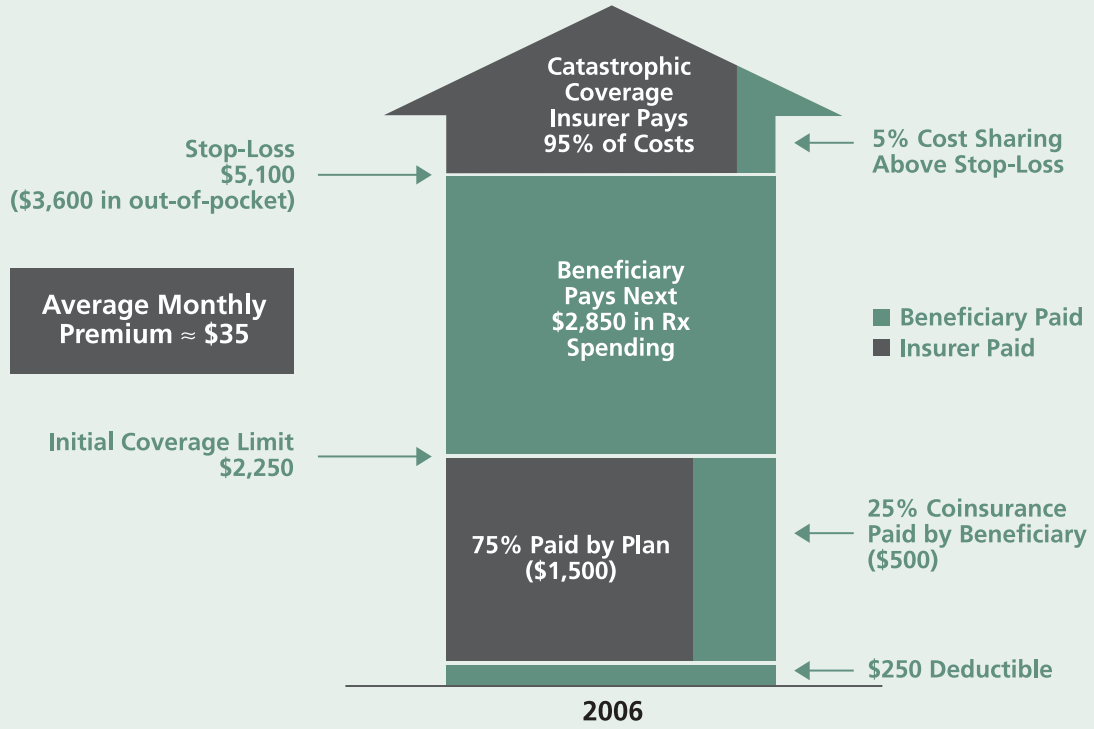
In 2006, the standard Part D benefit will be as follows; also see Figure 3:

- ★ To enroll, a beneficiary must pay a premium of approximately $35 per month (or $420 annually);
- ★ The beneficiary must pay an annual deductible of $250 before Medicare coverage begins;
- ★ For drug expenses between $251 and $2,250, Medicare will pay 75% and the beneficiary must pay the remaining 25%;
- ★ For drug expenses between $2,251 and $5,100, the beneficiary must pay all costs—this is commonly referred to as the "doughnut hole" in Part D coverage;
- ★ For drug expenses beyond $5,100, Medicare will pay 95% and the beneficiary will pay the remaining 5%.

All of these dollar amounts will be increased after 2006 by the rate of growth in Medicare prescription drug spending. Depending on how fast total Medicare spending on prescription drugs grows each year, these amounts could grow substantially from one year to the next.

Beneficiary eligibility and enrollment: In order to be eligible for Part D coverage, an individual must be enrolled in Medicare Part A or Part B. Beneficiaries will be able to choose from at least two private Part D plans per geographic region, except in areas where there is only a "fallback" plan (in which case they may enroll in the "fallback plan" to get Part D benefits). Beneficiaries will be permitted to change plans annually during an open enrollment period, similar to the process used in the current Medicare managed care program. The first open

Figure 3: ***Medicare Part D Prescription Drug Benefit Design in 2006***



enrollment period will begin on November 15, 2005 and will end on May 15, 2006. Part D coverage is scheduled to begin on January 1, 2006. There will be "late enrollment" penalties for beneficiaries who do not initially enroll in the program. These penalties, however, will not apply to those who defer signing up for the program because they have other, comparable drug coverage (eg, from a previous employer).

Subsidies for Part D costs for low-income beneficiaries: In an effort to ensure that Medicare beneficiaries with low incomes can afford their prescription drugs under Part D, the federal government will pay for all or most of the cost sharing that these beneficiaries would otherwise have to pay (see Figure 4). For most low-income beneficiaries, Medicare will pay the monthly premiums, annual deductibles, and almost all of the coinsurance amounts. Most low-income beneficiaries will pay nothing except for "per-prescription" copayments of between $1 and $5.

Administration: As noted above, private-sector entities will administer the Medicare Part D benefit. These entities could include established managed care organizations or new "prescription-drug-only" plans, possibly developed by pharmacy benefit management organizations (PBMs). They may use many of the standard cost-containment tools you are familiar with from commercial health plans or PBMs. These tools include drug formularies, tiered copayment structures, generic drug substitution, therapeutic substitution, and pharmacy networks (eg, incentives to use specified pharmacies).

Figure 4: ***Cost Sharing for Low-Income Beneficiaries Under Medicare Part D***

	Premium	Deductible	Copays	Coverage Gap
Up To 100% FPL	None	None	$1 / $3	None
Up To 135% FPL	None	None	$2 / $5	None
Up To 150% FPL	Sliding Scale	$50	15% of drug cost	None

FPL= Federal Poverty Level. The FPL for a family of two in 2003 is an annual income of $12,120.

Participating plans will negotiate with manufacturers to secure discounts. Plans will be required to report the "aggregate negotiated price concessions…made available to the [plan] by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers." Rebates negotiated on behalf of Medicare beneficiaries will be exempt from Medicaid's best price calculation and reported rebate information will be protected from public disclosure to the same extent as Medicaid best price information is protected.

Plan sponsors may utilize formularies. However, there are certain requirements that must be met:

- ★ The plan's pharmacy and therapeutics (P&T) committee must have a majority of members who are practicing physicians or pharmacists or both, and must include at least one physician and one pharmacist, each of whom has "expertise in the care of elderly and disabled persons."
- ★ The plan's formulary must include *at least two drugs* within each therapeutic category and class of covered Part D drugs.
- ★ The US Pharmacopeia (USP) will develop, in consultation with interested parties, a list of categories and classes that *may* be used by plans as the basis for a formulary. Plans will not be required to use the USP therapeutic categories, but the use of alternative categories will require the additional approval of CMS.[14]
- ★ Plans will be required to have independent clinical review and appeals of coverage denials and tiered cost-sharing decisions. A plan enrollee may appeal to obtain coverage for a drug not on the plan's formulary, if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual or would have adverse effects for the individual or both.

Other Important Prescription Drug Provisions in the New Medicare Law

Coverage for Medicaid "dual eligibles": The approximately 6 million individuals who are eligible for both Medicare and Medicaid (referred to as "dual eligibles") will be allowed to enroll in Medicare Part D. Federal health policy experts expect that virtually all of these individuals will receive their prescription drug coverage through Medicare, not Medicaid, starting in 2006 (ie, Medicare will be the primary source of drug coverage). To the extent dual eligibles enroll in Medicaid, they also will be enrolled in Medicare Part D plans. In some cases, depending on income level and state of residence, these individuals may receive a drug benefit under Medicare that is less generous than their existing Medicaid drug benefits. Partly, this is because they will be required to make small copayments for all prescriptions that are not now required in many Medicaid programs. Similarly, a Medicare Part D plan that they choose may not allow access to all of the same drugs that the person's Medicaid drug benefit did. Dual eligibles who live in a nursing home, however, will not have to pay any copayments.

Although dual eligibles represent less than 40% of Medicaid beneficiaries, they account for over 65% of drug expenditures in Medicaid. The new Medicare law will effectively shift a significant portion of the Medicaid prescription drug market away from the state-administered programs to private Medicare Part D plan sponsors. However, in the near term, states will not realize a significant budgeting windfall from this change. Other provisions in the law require them to continue financing a major portion of the dual eligibles' drug expenses for many years to come.

Incentives for employers providing retiree drug coverage: The law includes incentives to encourage employers to continue to offer and pay for prescription drug coverage for their retirees. Employer- and union-sponsored plans could qualify for federal subsidy payments of up to 28% of the prescription drug costs between $250 and $5,000 per person that are incurred for their plan members who

[14] The US Pharmacopeia is a nonprofit organization that sets safety, appropriate use, and ingredient consistency standards for pharmaceutical products.

are retirees and Medicare beneficiaries. These subsidy payments, which also will be exempt from federal taxation, are estimated to be worth a projected $88 billion between 2006 and 2013.[15]

Payment for drugs covered by Medicare Part B: Although payments for physician services are slated to increase in 2004 and 2005 due to the new Medicare law, Medicare's reimbursements for the prescription drugs currently reimbursed under Part B will be reduced over the next three years (see Section I for a description of the types of drugs covered under Part B and the current payment methodology). In 2006, the law will also change how physicians purchase these drugs. The payment reduction will be phased in as follows:

- ★ In 2004, subject to certain exceptions, Medicare's payment rate for most drugs will be 85% of the drug's average wholesale price (AWP) as of April 1, 2003, compared to the current payment rate of 95% of AWP.[16] However, certain drugs, based on the difference between their AWP and average acquisition costs as noted in a government report conducted in 2000, will be reimbursed at somewhat less than 85% of AWP in 2004.
- ★ In 2005, Medicare will implement new (lower) payment rates based on each drug's average sales price (ASP). For multiple-source drugs, the reimbursement rate will be the weighted average of ASPs for all similar drugs. For single-source drugs, the reimbursement rate will be the lower of the manufacturer's reported ASP or wholesale acquisition cost (WAC). For Medicare, a drug's ASP will be defined in a similar manner to Medicaid "best price"; that is, it will be based on average prices net of most discounts and rebates.[17] The policy also imposes new price/discount reporting requirements on pharmaceutical manufacturers. Specific details of reporting requirements will be determined through the federal regulatory process over the next six to nine months.
- ★ In 2006, Medicare's payments for physician-administered drugs will be based partly on a completely new "competitive acquisition program," which will allow physicians to choose whether to purchase drugs themselves and obtain payment based on ASP, or purchase drugs from third-party vendors that would contract with Medicare to provide drugs to physicians. Third-party vendors would be selected, in part, based on the discounts they can obtain for covered drugs.

Payment for drugs covered in the hospital outpatient setting: Overall, MMA increases payments for most drugs that are currently paid under the hospital outpatient prospective payment system, but reduces payments for pass-through drugs over time. New drugs that have not yet received a temporary reimbursement code will be paid at 95% of AWP. For non–pass-through drugs and biologicals, payment will be as follows:

Type of Drug	2004	2005	2006
Innovator, sole source	88%–95% AWP	83%–95% AWP	Average acquisition cost
Innovator, multiple source	68% AWP or less	68% AWP or less	Average acquisition cost
Non-Innovator, multiple source	46% AWP or less	46% AWP or less	Average acquisition cost

Conclusion

The enactment of the Medicare Modernization Act creates a significant benefit for many patients who need help to secure access to life-saving and life-improving medicines. This will be particularly true for the most vulnerable of Medicare beneficiaries—those with limited incomes or extremely high drug costs.

[15] $88 billion figure is comprised of $71 billion in estimated direct subsidy payments and $17.9 billion in federal tax benefits over 2006-2013. Congressional Budget Office, *Letter to the Honorable Don Nickles providing additional information about CBO's estimate for the conference agreement on H.R. 1,* November 20, 2003 and the Joint Committee on Taxation, "Estimated Revenue Effects of Certain Provisions Contained in the Conference Agreement for H.R. 1," November 21, 2003; as cited in "Large Firms' Retiree Health Benefits Before Medicare Reform: 2003 Survey Results," *Health Affairs Web Exclusive,* January 14, 2004 (accessed at http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.7v1.pdf), endnote 13.

[16] Key exceptions include drugs that are new as of April 1, 2003, blood and blood products, vaccines, and certain drugs administered to dialysis patients. Some drugs will be paid less than 85% of AWP (ie, those included in government reports on drug acquisition costs).

[17] ASP is defined as the price that is net of all discounts and rebates and includes volume discounts, prompt pay discounts, cash discounts, chargebacks, short-dated product discounts, free goods, rebates, and all other price concessions provided by any relevant purchaser; direct sales to hospitals are excluded from ASP. WAC is the price paid by wholesale distributors for drugs purchased from the wholesaler's suppliers (manufacturers). Publicly disclosed or listed WAC prices may not reflect all available discounts to all purchasers (eg, certain manufacturer rebates or chargebacks). Some drug pricing sources equate WAC with actual acquisition cost.

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