Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Public Law 108-173

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173). The legislation could provide enhanced benefits for many kidney patients, especially those who currently have no insurance to pay for oral prescription medications. However, it is important to remember that the various benefits will only be available to kidney patients who are entitled to Medicare at the time the respective provisions of the law go into effect.

Although the federal government will provide some assistance for the purchase of drugs in the 2004 and 2005 calendar years, through a drug discount card program, the drug insurance program, which is voluntary and will be available under a new "Part D" of Medicare, is not effective until January 1, 2006. Furthermore, the Centers for Medicare and Medicaid Services (CMS) must issue regulations to implement this statute and the impact of many of the provisions in the law will not be clear until that regulatory process is completed. Additionally, the legislation lays the foundation for some potentially problematic changes in Medicare but does not specify a time frame for those changes. For example, Section 1860D-42 requires the Secretary to submit a report to Congress containing recommendations for providing benefits under Part D for drugs currently paid for under Part B of Medicare (e.g. immunosuppressive medications required by transplant recipients, chemotherapy agents, erythropoietin, vitamin D analogs). Similarly, the Secretary is required to report to Congress on the design and implementation of a fully case-mix adjusted, bundled prospective payment system for services furnished by ESRD facilities, including, to the extent feasible, drugs, laboratory tests and other items for which ESRD facilities can bill CMS separately at the present time.

With these limitations in mind, this report will attempt to describe the framework that Congress has created and, hopefully, will provide the basis for future updates when various stipulations and specifications are clarified.

With the exception of individuals whose income is below 135% of the federal poverty level (footnote), in order to be eligible for the benefits that become effective on January 1, 2006, it will be necessary to pay a monthly premium. In addition, as of January 1, 2006, no Medigap drug policy can be sold, issued or renewed, except that an individual already enrolled in a Medigap plan with drug coverage, who chooses not to enroll in Part D, may renew that kind of Medigap coverage. Finally, the legislation could cause low-income Americans to lose access to free drugs provided by pharmaceutical companies and impair medication benefits for kidney patients who are entitled to both Medicare and Medicaid. (These individuals are often called "dual-eligible.")

Drug Discount Card and Transitional Assistance Program

On March 25, 2004, the Secretary of Health and Human Services endorsed 28 prescription drug discount card programs. It is estimated that these drug discount card

programs will enable Medicare beneficiaries to save 15%-25% on the purchase price of their prescriptions, beginning June 1, 2004. Medicare beneficiaries, except those who have outpatient prescription drug coverage through Medicaid, can enroll as early as May 3, 2004. The cards will cost no more than $30 per year. In addition, the discount card program will assist individuals whose income is less than 135% of the federal poverty level to purchase $600 of prescriptions drugs per year. Individuals who qualify for the $600 credit do not have to pay any enrollment fee. The card program will expire on January 1, 2006. It will be discontinued after Medicare Part D becomes available. The only people who aren't eligible for the drug discount card program are those who have outpatient prescription drug coverage under Medicaid.

Medicare Part D

Public Law 108-173 establishes a new, voluntary Medicare Part D prescription drug benefit that will be administered by private prescription drug plans. As noted above, a monthly premium will be required to obtain Medicare Part D benefits and Part D coverage will not be effective until January 1, 2006. It is estimated that the initial monthly premium will be $35. Late enrollment penalties will be applied after the beneficiary's initial enrollment period. These penalties will be one percent of the national average monthly premium for each uncovered month.

Under Part D the first $250 in drug expenses each year are the responsibility of the beneficiary. (This is called the deductible.) Part D also requires the beneficiary to bear 25% of drug expenditures between $250 and $2,250 per year. (This is known as co-payment.) If a Medicare beneficiary incurs large annual medication costs, Part D will cover 95% of the cost of his/her medications but this "catastrophic" benefit does not kick in until after the beneficiary has spent $3,600, out-of-pocket, for his/her prescription drugs including the deductible and co-pays (i.e. $5,100 in total drug costs). This gap in coverage—beneficiaries must bear 100% of drug expenses between $2,250 per year and $3,600 per year-- has been described as the "doughnut hole." On the other hand, the legislation provides graduated relief from the deductible and co-payment requirements (as well as the "doughnut hole") for beneficiaries with income below 150% of the poverty level, below 135% of the poverty level and below 100% of the poverty level. There are also asset restrictions on this relief. For Medicare beneficiaries whose income is above 150% of the poverty level, it is estimated that, on average, Medicare Part D will cover half the cost of their prescriptions.

Should Chronic Kidney Disease Patients and Dialysis Patients Enroll in Part D?

Based upon their individual financial circumstances, Part D could help Medicare beneficiaries, who have chronic kidney disease, or who are on dialysis, pay for self-administered prescription drugs, such as:

Medications for High Blood Pressure Management
Medications to Control Blood Sugar for Patients with Diabetes
Lipid Lowering Drugs

Oral Vitamin D in Prescription Form
Phosphate Binders

The statute specifies that drugs covered under Part B cannot be reimbursed under Part D. On the other hand, some have argued that Part D should cover injectable drugs normally administered in the dialysis clinic as a Part B benefit (e.g. erythropoietin, iron and vitamin D analogs) for home dialysis patients. It has yet to be determined whether this will be allowed. Conversely, will there be an economic incentive to shift in-center hemodialysis patients to oral iron and vitamin D analogs when these drugs are covered under Part D?

Should Transplant Recipients Enroll in Part D?

As noted above, Part D coverage will be available only to individuals who are entitled to Medicare. Therefore enrollment will be limited to the following categories of kidney transplant recipients: a) senior citizens, b) individuals who have received SSDI payments for 24 months, or c) ESRD-only Medicare beneficiaries whose 36 month post-transplant Medicare eligibility has not expired. The legislation does not extend the length of immunosuppressive drug coverage under Medicare beyond that provided under the Benefits Improvement and Protection Act of 2000, i.e. additional coverage for immunosuppressive drugs will not be available under Part D.

Coverage for immunosuppressive drugs will continue to be provided pursuant to Medicare Part B until Congress legislates otherwise. Under Part B, Medicare pays 80% of the cost of medications and the transplant recipient must pay the balance. (The cost to the beneficiary is called a co-payment). While the 20% co-payment that is required under Part B is less than the cost sharing required under Part D, transplant recipients will not be able to count out-of-pocket expenses for Part B drugs in determining whether they have spent $3,600 for medications and are thereby entitled to “catastrophic coverage” under Part D.

Based upon their individual financial circumstances, and total medication needs, Part D could help Medicare beneficiaries who are transplant recipients pay for self-administered prescription drugs, such as:

Oral Medications for High Blood Pressure Management
Medications to Control Blood Sugar for Patients with Diabetes
Lipid Lowering Drugs
Oral infection treatments and antiviral agents

Intravenous Immune Globulin

Other Provisions Affecting Transplant Recipients

A section of Public Law 108-173 cuts Medicare payments to retail drug stores and mail-order pharmacies for medications covered under Medicare Part B, effective January 1,

2004. This will also reduce the amount that a transplant recipient who is a Medicare beneficiary must pay to meet the 20% cost-sharing requirement under Part B. However, we will need to monitor the impact of this reduction to make sure that it does not affect the availability of specific immunosuppressive drugs needed by transplant recipients if pharmacies determine they cannot stock a medicine without incurring a financial loss.

The Act provides for payment of a supplying fee to pharmacies that fill prescriptions for immunosuppressive drugs, presumably to mitigate the impact in the reimbursement levels for these medications. However, in a Notice of Proposed Rulemaking, the Centers for Medicare and Medicaid Services declined to implement this provision.

Access to Specific Medications under Part D

Plans providing Part D benefits after January 1, 2006, can establish formularies that limit the drugs that they will cover. If a sponsor uses a formulary, the formulary must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes. A Medicare beneficiary enrolled in a prescription drug plan may appeal to obtain coverage for a drug not on the formulary but only 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 beneficiary or would have adverse effects for the beneficiary or both.

Other Provisions Affecting Drugs Administered in Dialysis Clinics

Beginning in 2005, Medicare will change the way it pays for drugs administered in dialysis clinics (e.g. erythropoietin and vitamin D analogs). It appears that the change is designed to control the growth in Medicare expenditures for these drugs. We will need to monitor the impact of this change to be sure that it doesn't affect patient outcomes.

Part D Benefits for Kidney Patients with Medicare and Medicaid (Dual Eligibles):

Dually-eligible kidney patients who have incomes above 150% of the poverty level may have more out-of pocket expenses for medications after January 1, 2006 since their prescription drugs will be covered under Medicare Part D rather than their state Medicaid program. Medicare Part D will have higher deductibles and require larger co-payments than typical for Medicaid programs. While dually-eligible individuals will not be limited to drugs on a Medicaid agency's preferred list after January 1, 2006, the plans that administer Part D benefits may impose similar restrictions. Dual-eligible individuals will not be subject to limits on the number of prescriptions they can have filled per month, as is currently the case in several states. As noted above, dual eligibles with income below 150% of the poverty level will be provided relief from the deductible and co-payment requirements under Medicare Part D. State Pharmacy Assistance Programs may be able to assist dually-eligible kidney patients with income above 150% of the poverty level with the Part D cost-sharing requirements but this has yet to be determined. Such assistance has been referred to as "wraparound relief."

Medigap Provisions

As noted above, Medicare beneficiaries enrolled in Part D will not be able to purchase Medigap policies that provide coverage for the self-administered medications that will be covered under Part D, i.e. Medigap policies in the H, I and J series. However, we assume that basic Medigap policies will continue to cover the 20% co-payment required for oral immunosuppressive drugs and injectable drugs provided in the dialysis clinic that are currently reimbursed under Part B.

Pharmaceutical Company Assistance Programs

Unless pharmaceutical company assistance programs are amended, when low-income Americans enroll in Part D, they could lose access to the free medications that drug manufacturers would otherwise provide. The eligibility requirements of industry-sponsored pharmaceutical assistance programs typically exclude individuals who have Medicare coverage for the drugs they are taking.

New Screening Benefits for Patients with Chronic Kidney Disease

Effective January 1, 2005, Medicare will pay for blood tests used to screen Medicare beneficiaries for cardiovascular disease and diabetes. This new benefit is designed for early detection of these diseases and will be available to individuals who are considered to be at risk for diabetes and cardiovascular disease. For example, it will help to pay for follow-up testing provided to participants in the National Kidney Foundation Kidney Early Evaluation Program (KEEP) who are enrolled in Medicare. Traditionally, Medicare has paid for these kinds of tests only if there is a pre-existing diagnosis of diabetes or cardiovascular disease.

Disease Management for Chronic Kidney Disease

Section 721 of the Act established a pilot program, for improving the care of Medicare beneficiaries with chronic diseases, through disease management strategies. Chronic kidney disease is not specifically mentioned in the statute but related illnesses (diabetes, congestive heart failure) are.

Competition

Beginning in 2010, traditional fee-for-service Medicare will face competition from private health plans in six metropolitan areas. It is possible that that only patients needing extensive medical services will remain in the traditional Medicare fee-for-service program once competition is introduced. This could escalate the cost-sharing that will be required of individuals opting for traditional fee-for-service Medicare. That would be problematic for ESRD patients who have been prohibited from joining managed care plans by Section 1876 of the Social Security Act.

2004 Poverty Guidelines for the 48 Contiguous States and the District of Columbia

Size of family unit	Poverty Guideline
1	$9,310
2	12,490
3	15,670
4	18,850
5	22,030
6	25,210
7	28,390
8	31,570

For family units with more than 8 members, add $3,180 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

2004 Poverty Guidelines for Alaska

Size of family unit	Poverty Guideline
1	$11,630
2	15,610
3	19,590
4	23,570
5	27,550
6	31,530
7	35,510
8	39,490

For family units with more than 8 members, add $3,980 for each additional member. (The same increment applies to smaller family sizes also, as can be seen in the figures above.)

2004 Poverty Guidelines for Hawaii

Size of family unit	Poverty Guideline
1	$10,700
2	14,360
3	18,020
4	21,680
5	25,340
6	29,000
7	32,660
8	36,320

For family units with more than 8 members, add $3,660 for each additional member.
(The same increment applies to smaller family sizes also, as can be seen in the figures above.)