Promise or Peril? Impact of the Medicare Drug Benefit on the ESRD Population

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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 became law on December 8, 2003 (Public Law 1008-173). Although the law will eventually make significant changes in the way Medicare provides payment for dialysis services, as drug reform legislation, it will affect, and possibly improve, the medical management of the growing population of end-stage renal disease (ESRD) patients in the United States. Patients with ESRD have multiple complications that require pharmacotherapy. A major impact of the legislation could be on the utilization of drugs that control hypertension and, with it, cardiovascular disease. (In addition, the law includes Medicare coverage for 2 new benefits, cardiovascular screening blood tests and diabetes screening tests for individuals deemed to be at risk for diabetes mellitus, which could assist in identifying individuals also at high risk for chronic kidney disease.)

An estimated 50 million Americans have hypertension, and antihypertensive drugs are estimated to cost $15.5 billion annually.1 Issued by the U.S. Department of Health and Human Services in December, The National Healthcare Quality Report indicated that only 23% of those with hypertension have it under control. Hypertension affects the majority of ESRD patients, with antihypertensive agents among the most commonly prescribed drugs and multiple drug use frequently required.2 Yet, hypertension is controlled adequately in less than one-third of affected patients.3 Inadequate control of hypertension, particularly systolic hypertension, is related in part to the out-of-pocket cost burden.2 End-stage renal disease patients commonly have low incomes and huge drug bills and may spend more than 10% of their income on prescription drugs.4 The cost of medications such as antihypertensives is a barrier that must be overcome if blood pressure control is to improve in the ESRD population. For that reason alone, the Medicare Reform Drug Act on 2003 is likely to improve care by providing relief from high drug prices. However, the impact on the ESRD population has not been adequately analyzed.

Health-care costs continue to be the dominant pocket-book issue in the United States. Relentlessly, the increase in overall health-care spending, which doubled between 1990 and 2000 to a level of $1.2 trillion, continued in 2002, to $1.55 trillion. With the United States, Great Britain, and nations in Scandinavia and other parts of Europe adopting more “constricted” views of the role of government,5 services are being scaled back; a common strategy for dealing with the high costs of health care is to discourage utilization through imposition of copayments.6 The cost of health-care premiums increased by 13% in the past year, the biggest increment since 1990, after 5 consecutive years of increases over 5%.5 Almost half the health-care costs in the United States are being borne by persons with 1 or more of 5 chronic conditions, which include diabetes mellitus and hypertension.7 The cost endured by patients has increased proportionately. For Medicare, which has been a secure source of affordable health-care coverage for elderly and disabled Americans, costs are anticipated to rise more than in any other major government program over the next few decades. In addition to 40 million current recipients, nearly twice as many will begin retiring later in this decade.

The biggest single contributing factor to the ongoing rise in health-care costs and rising health insurance premiums for the individual patient is increased spending on prescription drugs. Drug costs tripled from $40 billion in...
1990 to $122 billion in 2000, during which time they rose from 6% to 10% of total health-care expenditures, and totaled $162.4 billion in 2002. (For historical comparison, that portion had previously fallen from 10% to 5% before 1980.) Further, expenditures for prescription drugs are the fastest rising component of personal health care, now increasing by 15% to 18%, because of greater utilization, price inflation, and more expensive new products. Drug prices are known to have a substantial effect on the amount of health that can be purchased by the individual. By 1997, almost 10% of elderly Medicare beneficiaries were spending more than 10% of their annual income on prescription drugs, despite the fact that 75% of those beneficiaries had some level of prescription drug coverage. Each additional chronic medical condition increased the annual expenditures on prescription drugs. At the time of the passage of the legislation, about 60% of the public already had some amount of drug coverage, ranging from corporate retirement packages to state Medicaid programs. Three-quarters of the elderly population had some drug coverage. The distribution of drug coverage plans in Medicare beneficiaries is shown in Figure 1.

In 2003, Medicare beneficiaries spent about $95 billion on prescription drugs; only 60% of that was covered by private and government insurance, leaving 40% to be paid by the individual. Elderly Medicare beneficiaries with secondary insurance are known to take more medications than those without secondary insurance. For Medicare beneficiaries, annual out-of-pocket expenses for prescription drugs reached $644 in 2000 and is expected to more than double, to $1450, by 2006, the first year of coverage under the new Medicare bill. In parallel, Medicare premiums, currently $58.70 a month, are expected to double by 2012, with additional expenses for drug coverage estimated to be $25 to $33 a month at the start of the program.

**Previous Medicare Drug Coverage**

In 2003, Medicare provided health-care coverage for the elderly and disabled for a total cost to the taxpayer of $263 billion. Along with inadequate protection against lengthy, high-cost hospitalizations and the slow Medicare approval of new diagnostic tests and procedures, the failure to provide drug coverage has been one of the major problems with Medicare. With over 80% of recipients receiving traditional fee for service, Medicare has covered the costs for beneficiaries almost exclusively for medications administered within the hospital setting. For over a decade, Medicare beneficiaries have increasingly sought supplemental drug coverage. The major sources of supplemental prescription coverage for Medicare beneficiaries are medicare health maintenance organizations (HMOs),

![Figure 1. Percent of Medicare beneficiaries with drug coverage, by source of coverage (2002 projection).](image1)

![Figure 2. Patient distribution by insurance coverage at initiation of ESRD by race and ethnicity. M&M, Medicare and Medicaid; M/caid, Medicaid only; M/care, Medicare only. Patients with Medicare coverage accompanied by employer-based or other insurance coverage are more likely to be white, whereas minority populations are more likely to have Medicare/Medicaid or no insurance coverage. The data reported here have been supplied by the United States Renal Data System (USRDS).](image2)
retiree health-care plans, and Medigap supplemental insurance policies. At ESRD initiation, 5% to 10% of patients have Medicaid only and 10% to 20% have both Medicare and Medicaid (Fig 2). Whereas Medicare, in fact, covers almost 400 out-patient drugs, these are primarily cancer treatments or medications administered to the patient in a physician’s office. Even before recently passed drug reform legislation, the Bush administration was beginning to weigh government cost as a factor in determining whether Medicare would pay for new drugs. For example, the federal government refused to pay the full asking price for the anemia drug Aranesp, cutting payment for cancer patients by 39%. One year ago, Medicare began to adopt a new policy of coverage decisions based on “functional equivalence,” preferring cheaper generic or brand drugs when available. Federal officials interpreted Medicare law as providing them with powerful discretion to set payment for drugs based on what they deem to be equitable. The new Medicare law prevents the Center for Medicare/Medicaid Services (CMS) from declaring that 2 products are “functionally equivalent” for the purposes of reimbursing medications at the same level.

The Drug Reform Bill

The Drug Reform legislation of 2003 was the most expensive expansion of Medicare since its creation in 1965, with a projected cost of $400 billion over 10 years. It provides some relief from the high prices of prescription drugs, with a new taxpayer-subsidized drug benefit to elderly and disabled Medicare beneficiaries. Even at $40 billion a year, however, the bill will cover only a fraction of consumer drug expenses, still leaving beneficiaries to face substantial drug costs. Although it promises protection against catastrophic drug expenses, establishing in theory a limit of $3,600 a year on out-of-pocket expenses, the new legislation is expected to reimburse only about one-third of the total out-of-pocket drug costs for the typical Medicare recipient. In a given year, the beneficiary would pay the first $250.00 plus 25% of drug expenses from $251.00 to $2,250.00, plus 100% of the next $2,850.00. Because of the huge coverage gap in the middle, the beneficiary would face the peril of paying $3,600.00 of the initial $5,100.00. After that, the standard benefit would pay 95% of the cost of each prescription.

The peril of greater cost to the individual patient could also come from other directions, and these costs may offset any cost-saving measures achieved by Medicare for the taxpayer and beneficiary. For the beneficiary, this mix of other concerns will include Medicare deductibles, premiums, and benefit caps. Furthermore, no private “Medigap” drug policies will be allowed by the legislation. Another peril is a worsening of the price for individual drugs. The drug benefit program will be administered privately; that is, Medicare will not directly implement delivery of drugs. Instead, prescription medications will be distributed by private insurance companies or by specialized drug distribution companies. Each entity will have to bargain separately for the best drug values, bringing differential cost savings and the potential for unequal access by beneficiaries across the country. Another peril amid the promise is the likelihood of increasingly restrictive drug options. Will the legislation in fact limit coverage of drugs for beneficiaries? Each plan could
have its own list of covered formulary drugs and prices. Incentive-based or tiered formularies with lists of preferred drugs, often less costly drugs with no generic substitute available, are allowed by the prescription drug benefit. Furthermore, off-formulary medications will not be counted toward the $3,600 out-of-pocket expense limit.

Insurance Coverage for ESRD Patients

Medicare started the ESRD program as Public Law 92-603 in 1973 as a result of the 1972 Social Security Amendments. For the ESRD dialysis patient already on Medicare, the primary insurance role is assumed by Medicare at the time of initiation of renal replacement therapy. Otherwise, Medicare coverage begins at 90 days after initiation, with Medicare becoming the secondary payer if another primary insurance exists; after 3 years, Medicare coverage becomes primary. Among the ESRD population, Medicare is the sole or primary source of payment in about 80% of patients, with Medicaid ranked second as the sole or primary source of payment, for under 10%. Other payers, including private insurance, HMOs, and the Veterans Administration, are primary for about 10%. Fewer than 5% have no insurance or are self-pay. Insurance coverage of incident ESRD patients according to the 2003 United States Renal Data System (USRDS) is shown in Figure 2. The highest proportion of ESRD patients covered solely by Medicare is found in the South and along the East Coast.

ESRD is an increasingly high-cost illness. Although patients with ESRD represent only 0.79% of all Medicare beneficiaries, care of ESRD patients accounts for 7.30% of all Medicare expenditures. At the time of passage of drug reform legislation, only 2 independent categories of outpatient prescription drugs were covered by the Medicare ESRD program: immunosuppressive medications for the kidney transplant recipient, and erythropoietin, used to treat anemia in dialysis patients. Coverage of immunosuppressive drugs began with the passage of the Omnibus Budget Reconciliation Act (OBRA) in 1986, in response to increasing transplant drug costs, but applies only for transplant recipients with Medicare as the primary or secondary payer. Coverage for transplant medications was subsequently extended to a full 3 years of Medicare eligibility after a successful transplant for ESRD beneficiaries and for the life of the graft for aged and disabled beneficiaries with a Medicare transplant. (Of note, the Secretary of Health and Human Services is required by law to report to Congress no later than January 2005 with recommendations for providing benefits under Part D [the new drug benefit] for outpatient drugs presently covered under Medicare Part B). The financial burden of immunosuppressive medications has increased over the past decade, with the introduction of new drugs such as mycophenolate mofetil.

Coverage of prescription drugs is among those items and services provided to beneficiaries of Medicaid by all states in the U.S., although the provision is optional. Spending by Medicaid programs on prescription drugs increased annually by more than 16% between 1990 and 2000 and are expected to increase another 14% annually over the next decade. Experiencing worsening fiscal crises, states are using multiple strategies to hold down the growth of expenditure on drugs. The highest proportion of the population covered solely by Medicaid at the time of initiation resides in California and Arizona, parts of Washington and Oregon, and along the Gulf Coast and Atlantic seaboard.

Hypertension and ESRD

In the general population, treatment of hypertension has led to a remarkable decline in cardiovascular disease over the past half century, establishing itself as one of the few medical interventions to have an impact on mortality trends. The prevalence of hypertension is high in patients with chronic kidney disease. Hypertension may be documented in over 80% of adult hemodialysis patients, unrelated to age, and is a major modifiable risk factor for cardiovascular disease, the leading cause of morbidity and mortality in patients with ESRD. Cardiac disease is almost 4 times more likely in hypertensive patients compared with nonhypertensive patients. Hypertension is associated with increased risk of left ventricular hypertrophy, coronary artery
disease, congestive heart failure, and cerebrovascular complications. Volume expansion and increased systemic vascular resistance are dominant causes of ESRD hypertension.

Hypertension control constitutes a fundamental area of drug intervention in ESRD patients. The 3 most prescribed drug types in hemodialysis patients in general are related to calcium/phosphorous metabolism, hypertension, and anemia. The prescription of antihypertensive agents, regardless of drug category, is associated with reduced age-adjusted mortality in ESRD patients. Hypertension frequently necessitates the use of several antihypertensive agents. Unfortunately, there is a lack of prospective, randomized clinical trial data and a lack of consensus regarding the pharmacologic treatment of the ESRD patient with hypertension. Furthermore, despite recognition of its prevalence and the frequent use of antihypertensive drugs, hypertension is controlled in only 30% of ESRD patients. Previous studies have established a role for beta-blockers and renin-angiotensin block in the ESRD population. In a recent study of almost 3,000 incident hemodialysis and peritoneal dialysis patients in the United States, calcium channel blockers were the most frequently prescribed antihypertensives, being prescribed more than twice as often as beta-blockers or angiotensin-converting enzyme inhibitors in ESRD patients, even in those with cardiovascular disease. In addition, calcium channel blockers were associated with reduced all-cause mortality.

Conclusion

The Medicare Prescription Drug act of 2003 carries both promise and peril for the ESRD patient. The greatest potential peril is inadequate allocation of funds for the program, minimal cost savings (and, for some, greater cost to bear) for the individual, restriction of drug formularies, and the cost of drugs not held in check. Other possible concerns include the fate of dual eligible (Medicare and Medicaid) patients, for whom Medicare will assume drug costs from Medicaid; the fate of senior drug programs presently operated by some states; future restrictions on choices of medications, as well as likely premium increases if the 10-year budget estimate is surpassed; and the fate of employer-based retiree coverage.

The promise is of broad benefit to the majority of ESRD patients, who already are Medicare entitled, regardless of age or disability. The potential is improved medical management for chronic but treatable comorbid conditions such as hypertension and cardiovascular disease. Whether the majority of Medicare beneficiaries who do have additional coverage will fare better or worse financially under the new system is unclear. The future status of the program, after the 2006 implementation, will depend, in part, on which political party controls the White House. The promise and peril of the benefit for the large ESRD population awaits more complete analysis, as the details of the program become clearer.

Acknowledgment

The author gratefully thanks Troy Zimmerman, Director of Government Relations for the National Kidney Foundation, for his expert contributions to the manuscript.

References