Published in final edited form as:
Health Aff (Millwood). 2012 September ; 31(9): 2051–2058. doi:10.1377/hlthaff.2012.0368.

Medicare's Payment Strategy For End-Stage Renal Disease Now Embraces Bundled Payment And Pay-For-Performance To Cut Costs

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Abstract

Since 1973 Medicare has provided health insurance coverage to all people who have been diagnosed with end-stage renal disease, or kidney failure. In this article we trace the history of payment policies in Medicare's dialysis program from 1973 to 2011, while also providing some insight into the rationale for changes made over time. Initially, Medicare adopted a fee-for-service payment policy for dialysis care, using the same reimbursement standards employed in the broader Medicare program. However, driven by rapid spending growth in this population, the dialysis program has implemented innovative payment reforms, such as prospective bundled payments and pay-for-performance incentives. It is uncertain whether these strategies can stem the increase in the total cost of dialysis to Medicare, or whether they can do so without adversely affecting the quality of care. Future research on the intended and unintended consequences of payment reform will be critical.

In 1972 Medicare instituted coverage for all patients, regardless of age, with end-stage renal disease—a condition in which the kidneys permanently cease to function at a level that will support life. Dialysis, developed in the 1960s, can replace the function of the kidneys, but its high cost prevented its widespread expansion to all people requiring such treatment.[1] Therefore, for four decades Medicare has been the country's primary payer for the provision of dialysis care among patients with end-stage renal disease.

Initially Medicare paid dialysis providers using the same fee-for-service cost-based reimbursement method used in the traditional Medicare program. For example, dialysis providers received separate payments for the provision of dialysis, for each billable medication, for each ordered laboratory test, and for each ancillary dialysis-related service. These fee-for-service reimbursements provided a powerful incentive to increase the volume

and intensity of services.[2] Put simply, maximizing the dollar amount of reimbursable services would yield greater revenue to the dialysis provider.

The fee-for-service reimbursement system in end-stage renal disease thus provides little incentive for the enrollment of healthier patients, who by definition will need fewer services and thus present fewer opportunities for revenues. In contrast, the selection of healthier patients may be more common in managed care settings, where reimbursement is not simply tied to the total quantity of services provided.[3]

Medicare spending on dialysis care underwent spectacular growth over the past two decades, fueled largely by the introduction and rapidly increasing use of erythropoietin stimulating agents. These biologic drugs are used to treat anemia, a common condition among patients with end-stage renal disease. As with other dialysis-related treatments, Medicare reimbursed the provision of erythropoietin stimulating agents on a fee-for-service basis, with payments made according to the quantity of drugs administered.[4]

Ultimately, erythropoietin stimulating agents became the single largest drug expenditure in the Medicare program and caused the end-stage renal disease program to take center stage in discussions of Medicare payment reform. Furthermore, the rapid growth in use of these agents[5] was accompanied by emerging evidence from clinical trials suggesting that they could have adverse effects for patients with mild anemia.[6–8] This development illustrated the potential pitfalls of the fee-for-service payment method, which financially rewarded the increasing use of these agents, even among patients who might not benefit from them or who could even be harmed by them.

Spurred by the rapid growth of health spending for patients with end-stage renal disease, Medicare's payment policy for dialysis care has periodically been altered. The changes have included the introduction, in 1983, of a composite rate, which is a fixed rate paid to providers for each dialysis session irrespective of whether the dialysis was performed in a facility or at home. The program also experimented with capitation during 1990–91 and, most recently, adopted bundled dialysis payments with pay-for-performance incentives during 2010–11.[9]

In this article we review the history of payment policy changes in the end-stage renal disease program and the conditions that motivated these reforms. These changes reflect Medicare's broader effort to restrain spending growth. The factors that drive rapid growth in overall Medicare spending—the development of new technology, fee-for-service payment incentives, and the increasing numbers of eligible patients with chronic conditions—are intensified in the end-stage renal disease program, given the unique high-cost population it serves.

The Program's Early Years: 1973–82

In 1973 Congress extended Medicare coverage to all patients, regardless of age, with end-stage renal disease. This decision was motivated by the prohibitive cost of dialysis to individual patients and the expectation that the total cost to Medicare would be low because only 16,000 patients required dialysis in 1972.[10,11]

In its early years, Medicare reimbursed independent dialysis facilities on the so-called reasonable charge basis, which is an amount determined by the insurance carriers that process Medicare claims for the federal government and is based on the customary charge for that service in that part of the country. At the same time, Medicare reimbursed hospital-based dialysis facilities on the so-called reasonable cost basis, which is the cost actually incurred by the hospital minus any cost found to be unnecessary in the delivery of dialysis

services. On average, this payment structure translated into roughly $138 per dialysis treatment at an independent facility and $156 per treatment at a hospital-based facility.[12]

Medicare sought to restrain spending by reimbursing providers for no more than three dialysis sessions per patient per week. However, the program lacked clarity because there was no cap on an overall reimbursement rate. Total expenditures for the end-stage renal disease program grew from $229 million in 1973 to about $1.8 billion in 1982.[13] Over the same period, the number of patients increased from about 16,000 to about 64,000.[13]

By 1982 the program accounted for about 4 percent of overall Medicare expenditures, which motivated Medicare to test alternative payment methods to contain the growth of spending.[14,15]

Introduction Of The Composite Rate: 1983–89

In response to the sharp increase in spending for end-stage renal disease, the Omnibus Budget Reconciliation Act of 1981 contained two provisions that were designed to control program costs.

First, Medicare introduced a composite rate per dialysis treatment, fixed at $131 per treatment in hospital-based facilities and $127 per treatment in freestanding facilities. This composite rate included the labor and capital costs of dialysis; the cost of the dialysis machine; and the cost of tubings, the permeable membranes that filter blood. The rate was a “composite” of home and in-center dialysis costs, which was intended to provide an incentive to use home dialysis, given its considerably lower cost.

However, the prevalence of home dialysis did not increase substantially, contrary to the expectations of economic theory. The introduction of the composite rate lowered the reimbursement of hospital-based facilities by $25 per treatment and the reimbursement of freestanding renal facilities by $11 per treatment, relative to the reimbursement prevalent in the first decade of the program.[12]

Second, the nominal composite rate remained fixed throughout the decade. This meant that in real terms, providers received progressively less in the years after 1983. Given the prevailing rates of inflation, by 1989 dialysis providers received roughly 65 percent of what they had received in 1983.[16]

It is important to note that about 15 percent of patients begin dialysis covered by an employer-sponsored health insurance plan. Dialysis providers can charge these private payers more than they can charge Medicare. The private insurer continues as the primary payer for the first thirty-three months of dialysis, thereby cushioning the impact of Medicare’s declining payment rates.

The composite rate payment in end-stage renal disease care was similar to, and introduced concurrently with, Medicare’s prospective payment system for reimbursing hospitals for inpatient care. The prospective payment system paid a fixed amount to hospitals for all people within a particular diagnostic group category.

Erythropoiesis Stimulating Agents And Payment Reforms: 1989–2006

Patients undergoing dialysis commonly suffer from severe anemia, which often requires frequent blood transfusions and is associated with impaired physical functioning and mortality. The pharmaceutical company Amgen spent considerable resources in the 1980s to develop a synthetic version of the hormone erythropoietin, which treats anemia by

stimulating the production of red blood cells. The erythropoietin stimulating agent was approved for use in dialysis patients in June 1989.

At the outset, the Centers for Medicare and Medicaid Services (CMS) used a capitated method to pay for the use of erythropoietin stimulating agents at a rate of $40 per dose for every dose less than 10,000 units and an additional $30 per dose for every dose greater than 10,000 units.[12] Thus, if a dialysis patient received 10,000 units of erythropoietin or fewer at each of three dialysis sessions per week for a total of 156 sessions per year, the total cost of erythropoietin for this patient would be $40 times 156, or $6,240 per year. This payment scheme provided incentives for providers to “conserve” the dose because providers received $40 per dose for any dose between 1 and 10,000 units. This payment scheme resulted in less-than-optimal doses, with an average dose of about 2,400 units, even though the recommended average dose was closer to 4,000 units.[17–19]

In 1991 Medicare adopted the fee-for-service system to reimburse erythropoietin stimulating agents—a policy that was to remain in place over the next two decades. Fee-for-service reimbursement for the use of the agents, coupled with the decline in real value of the composite rate for dialysis, motivated providers to increase their use of the agents. Amgen provided quantity discounts to larger providers, allowing the company to maximize profits.[20]

Since the 1990s the use of erythropoietin stimulating agents and the actual provision of dialysis have been standard features of care for patients with end-stage renal disease. However, Medicare’s reimbursement method for erythropoietin stimulating agents prescribed to dialysis patients was very different from its reimbursement method for the actual provision of dialysis.

Providers were reimbursed a fixed amount for evaluation and management of patients—fixed at the composite rate of $127 per treatment for up to three treatments per week in a dialysis facility. Thus, one facility that dialyzed patients for three hours per treatment was paid $127 by Medicare, while another facility that dialyzed patients for four hours per treatment was also paid $127 by Medicare. There was virtually no financial incentive to provide more dialysis.

In contrast, given a reimbursement rate of $10 per every 1,000 units of erythropoietin stimulating agents, a facility that used 100,000 units of the agents per patient per week would receive $1,000 per patient per week, while a facility that used 10,000 units of the agent per patient per week would receive $100 per patient. The margin between Medicare’s reimbursement price for the drugs and the provider’s acquisition costs gave the dialysis provider an incentive to use more of the drug.[21]

By the beginning of 2005, erythropoietin stimulating agents had become the single largest drug expenditure within the entire Medicare program, with total annual expenditures on the drug for dialysis patients approaching $2 billion. In addition, and more worrisome, was the emergence of evidence from randomized trials that showed that excessive use of the drug among patients with mild anemia may result in harm for these patients.[22] In 2007 the Food and Drug Administration issued a warning that urged prudence in use of the drug for patients with mild anemia.

Even prior to that warning, Medicare’s reimbursement for erythropoietin stimulating agents had drawn criticism from the Office of Inspector General. In a series of reports,[23,24] the Office of Inspector General noted that many providers received reimbursement for erythropoietin stimulating agents at rates much higher than that of the provider cost of acquiring and using the drug. Although reimbursement rates for other drugs, such as

parenteral iron, were also higher than acquisition costs, Medicare's Part B expenditures on erythropoietin stimulating agents was substantially higher than expenditures on any other drug.

In particular, the Medicare Payment Advisory Commission noted that the total expenditure on these agents was $3.9 billion in 2007.[9] In contrast, $1.1 billion was spent on the drug that ranked second on the list, rituximab—a drug used in the treatment of particular types of cancer.[9] Accordingly, erythropoietin stimulating agents remained the lightning rod in the debate on drug pricing prior to 2003 passage of the Medicare Prescription Drug, Improvement, and Modernization Act.

During the debates preceding the act's passage, some policy makers and other observers reasoned that Medicare pricing for injectable drugs must be based on the cost of acquiring the drug. However, in the end, the law stipulated that the Medicare price should equal the average sales price of the drug plus a markup of 6 percent.

These changes did not alter the basic incentives imbedded in the fee-for-service system. Using data from the Renal Management Information System[25] and Renal Dialysis Cost Reports,[26] we found that the use of erythropoietin stimulating agents varied predictably across providers. In 2009 Medicare reimbursed providers $9.20 for every 1,000 units of erythropoietin stimulating agents administered. Providers for which the average cost of using erythropoietin stimulating agents was less than $9.20 per 1,000 units used erythropoietin for more than 80 percent of their dialysis encounters. But providers for which the average cost of using the agents was greater than $9.20 per 1,000 units used them in only approximately 20 percent of their dialysis encounters.

Growing Momentum For Payment Policy Reform

The growth in Medicare's expenditures on erythropoietin stimulating agents, coupled with evidence that its excessive use can adversely affect health, produced substantial changes in the mode of dialysis payment. As early as 2003 the Medicare Payment Advisory Commission[27] recommended that Medicare build financial incentives for quality into its provider payments.[28] This recommendation was based on the rationale that linking payment to provider performance may improve the quality of care[29] and on evidence showing that a large number of beneficiaries fail to receive recommended care.[30–31]

There was also growing policy momentum to test alternative payment methods that aggregate, or "bundle," payments across providers or by episodes of care. In the 1990s Medicare began a series of demonstration projects to test the usefulness of bundled payments for heart bypass surgery.[32] By 2006 evidence had accumulated on the cost-saving potential of bundled payments. Two years later, the Medicare Improvements for Patients and Providers Act directed CMS to incorporate aspects of both pay-for-performance incentives and bundled payments into reimbursement.

Bundled Payments

Medicare launched the bundled payment system in January 2011. Some observers contended that bundling was an "uncontrolled experiment,"[33] because no prior demonstration had examined the possible consequences. However, one of the possible effects of bundling, the incentive to select healthier patients,[34] is greatly reduced in the case of dialysis because almost everyone with end-stage renal disease is entitled to Medicare.

Even so, the potential for selection was partly addressed in the payment bundle by offering a higher rate for potentially high-cost patients. Nevertheless, it is still possible that the

financial risks will also vary for smaller providers, such as independent facilities, that have a limited ability to pool risks compared to larger providers.

Perhaps another contributing factor in the adoption of this new payment model was the general consensus on what should be "bundled." Because erythropoietin stimulating agents contributed greatly to the increase in costs, it was decided early on to include the cost of using these agents in the bundled rate. Providers were given a choice of "transitioning" into the bundled payment system over a four-year period, but most decided to accept bundled payments starting January 1, 2011.

Under the bundled payment scheme laid out in the *Federal Register*,[35] providers would, on average, receive $230 dollars per dialysis treatment per patient. This would include the actual cost of dialysis, the cost of providing all injectable medications or their oral equivalents (erythropoietin stimulating agents, iron, and vitamin D), and the cost of any of a list of fifty-three dialysis-related laboratory tests. However, drugs administered to the end-stage renal disease patient, but not specifically for care related to the disease, would be reimbursed separately under the Medicare Part D prescription drug program. Therefore, in this new payment regime, providers could no longer maximize their Medicare reimbursements by increasing the use of erythropoietin stimulating agents or other dialysis-related services.

Pay-For-Performance Initiatives

In 2003 the Medicare Payment Advisory Commission had noted that many dialysis patients received inadequate dialysis and anemia management.[27] The commission had recommended that two measures—urea and hemoglobin levels—be incorporated into pay-for-performance incentives for dialysis to treat end-stage renal disease. The urea reduction ratio—the ratio of urea in the blood after dialysis treatment compared with the pretreatment level—is an important indicator of the adequacy of the treatment. The hemoglobin level in a patient's blood reflects the relative success of anemia management. The Food and Drug Administration had recommended that the ideal targeted hemoglobin level in patients undergoing dialysis should be 10–12 grams per deciliter.

Ultimately, the final end-stage renal disease pay-for-performance rule published by CMS[36] included three performance measures: the percentage of Medicare patients with average hemoglobin levels of less than 10 grams per deciliter; average hemoglobin levels of greater than 12 grams per deciliter; and average urea reduction ratios of greater than 65 percent. The first measure counts for 50 percent weight of the final score, while the other two measures count for 25 percent each.

The performance standard for each of the three performance measures in payment year 2012 will be equal to a national benchmark or the performance of the specific facility in each category in calendar year 2007, whichever is less. The national standards for payment year 2012 are 2 percent or less for patients with hemoglobin levels of less than 10 grams per deciliter; 26 percent or less for patients with hemoglobin levels greater than 12 grams per deciliter; and 96 percent or more for patients with a urea reduction ratio greater than 65 percent.

For each percentage point below or above the performance standard, two points are deducted from the provider's total performance score. Based on these scores, payment reductions would be calculated using the following score-payment function: no reduction for a score of 26–30; 0.5 percent for a score of 21–25; 1 percent for a score of 16–20; 1.5 percent for a score of 11–15; and 2 percent for a score of 10 or lower.

We note that the pay-for-performance approach in this program represents a novel structuring of incentives: They are exclusively negative—all sticks and no carrots. Furthermore, given the maximum payment reduction of 2 percent, the pay-for-performance program, which was implemented as a complement to payment bundling, might not independently make a serious dent in total health care costs.

Discussion

Per capita dialysis spending is a function of the reimbursement rate for each dialysis session, the frequency of dialysis, and the costs of ancillary services delivered during the dialysis session. In the initial years, Medicare attempted to restrain dialysis spending by controlling only the frequency of dialysis without controls on the reimbursement rate or the use of dialysis-related medications and laboratory tests. In the next iteration of payment reform, Medicare controlled both the frequency of dialysis and the payment rates, but actual costs still surpassed projected ones with the advent and use of complementary new technology, erythropoietin stimulating agents. Finally, Medicare responded to changes in use of the agents and other associated complementary services by bundling dialysis payments with other associated dialysis-related diagnostic and treatment care.

It is uncertain whether bundling of dialysis payments can stem the increase in the total cost of dialysis to Medicare.[37] Leading researchers in the dialysis industry have suggested that policy makers must work with the renal professional and patient communities to ensure that financing approaches to control costs do not adversely impact the quality of care.[38] That point assumes even greater relevance today in the aftermath of sweeping changes in dialysis payment methodologies.

For example, dialysis providers may respond to bundled payments by reducing their use of erythropoietin stimulating agents in patients who may benefit from these agents. Yet several observational studies have demonstrated measurable benefits, including lower death risk, with higher hemoglobin levels. Reduced use of erythropoietin could result in more severe anemia, increased offsetting use of costly blood transfusions and hospital care, and higher mortality.[39,40]

The response to these new payment initiatives will undoubtedly factor into future changes in policies. Future research on the intended and unintended consequences of payment reform is critical, given the important interplay between financial and regulatory changes, health care spending, and the quality of care.

It is also uncertain whether the consequences of bundling dialysis payments can inform implementation of bundled payments in other clinical contexts. Bundling in dialysis is unique in that there is only a single provider affected by bundling. In other words, a single provider makes decisions related to dialysis, the administration of erythropoietin stimulating agents, and the use of other tests and services. In contrast, other Medicare bundling demonstrations currently under way aggregate payment for care that occurs across hospitals, postacute providers, and outpatient physician practices.

For example, the Episode of Care Payment Demonstrations, authorized by the Affordable Care Act, require CMS to experiment with bundling Medicare Part A and Part B payments for inpatient and postacute care. Coordination of care and agreement on how cost savings are shared across multiple providers can pose challenges.

Finally, payment reforms in other areas of Medicare may have implications for the costs of end-stage renal disease. For example, beginning in 2005, Medicare patients became eligible for free diabetes screenings. Patients with diabetes constitute almost half of all of the

dialysis patients who begin treatment each year. To the extent that screening identifies patients earlier, it may help reduce the number of patients with diabetes who progress to end-stage renal disease. Improving the screening and management of chronic conditions that predispose patients to end-stage renal disease may be a particularly successful strategy in stemming the growth in costs.

Four decades after its introduction, Medicare's end-stage renal disease program has reached a crossroads in its quest to lower health care costs and promote better quality of care. After relying almost exclusively on the fee-for-service reimbursement method, the program has recently introduced two touted payment reform strategies: pay-for-performance and bundling. Although end-stage renal disease payment policy initially reflected programwide changes in Medicare, its payments are now a vanguard of policy innovation and experimentation, with the potential to drive changes in payment methods in the rest of the Medicare program.

Acknowledgments

This article was supported by funding received from the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health (Grant No. 1R21DK095485-01).

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