End Stage Renal Disease and Medicare

Joel W. Greer, Ph.D.

INTRODUCTION

Since 1972 all persons with end stage renal disease (ESRD) eligible for Social Security are entitled to all Medicare benefits, regardless of age. ESRD patients need continual renal replacement therapy to survive. Although only 1 percent of Medicare beneficiaries suffer from ESRD, they account for roughly 9 percent of all Medicare payments. ESRD patients tend to be economically disadvantaged and belong to ethnic and racial minorities. CMS has developed many programs and regulations specifically for ESRD patients designed to improve care, pay providers fairly, and minimize government expenditures.

Currently, most ESRD patients are covered through a mix of mechanisms within the traditional fee-for-service (FFS) payment system, including:

- The composite rate covers services generally part of a single in-center hemodialysis treatment.
- The monthly capitation payment, which reimburses the physician, such as a nephrologist, who prescribes and monitors the patient's dialysis.
- The payment amount for erythropoietin (EPO) to treat anemia is set by Congress at an allowed charge of $10 per thousand units.

The first two methods act as prospective payment systems (PPSs) for the services covered by the payments. Hospitalizations for ESRD patients are paid through the same PPS as all Medicare patients. Dialysis, hospitalizations, and physicians' dialysis services comprise over 80 percent of Medicare expenditures for the care of dialysis patients. The traditional FFS system for dialysis patients is, in effect, a system of partial capitation.

Medicare is the primary insurer for dialysis patients. Providers, patients, and nonprofit organizations take an active interest in any changes or potential changes to CMS payment or coverage policies. Other insurers and State Medicaid Programs often base their own procedures on those developed by CMS. Research into the efficient care of dialysis and transplant patients is of great interest to Medicare policymakers. Therefore, many people in and out of the government follow and contribute to research issues related to ESRD policy.

This issue of the *Review* contains seven articles reporting findings from policy-relevant research. The first four articles derive from the independent evaluation of the ESRD managed care demonstration conducted by a team from The Lewin Group and the University Renal Research and Education Association. These articles are a subset of the topics covered in the joint final evaluation report (The Lewin Group and the University Renal Research and Education Association, 2002) and the Secretary's Report to Congress (Centers for Medicare & Medicaid Services, 2002). Next, the Kidney Epidemiology and Cost Center at the University of Michigan presents initial results suggesting that data of adequate quality exist to develop a risk-adjustment system for an expanded composite rate bundle. The last two articles deal with long-term issues important to

The author is with the Centers for Medicare & Medicaid Services (CMS). The views expressed in this article are those of the author and do not necessarily reflect the views of CMS.

ESRD patients: improving the quality of care for dialysis patients and increasing the number of kidneys donated and recovered for transplantation.

FINDINGS FROM THE DEMONSTRATION

Existing law prohibits beneficiaries with ESRD from enrolling in Medicare managed care programs, although they may remain in such a plan if they enrolled prior to beginning renal replacement therapy. CMS allowed three managed care plans to enroll patients for the duration of the demonstration. An independent team collected data for a qualitative and quantitative evaluation. One of the plans ceased operations for reasons unrelated to the demonstration, so for the most part; the evaluation covered the remaining two. The overall finding from the demonstration is that the two managed care demonstration sites provided patient care that produced outcomes similar to, and sometimes better than, the outcomes for groups of comparison patients. However, the payment adjustment method used by the demonstration was neither easy to implement nor consistent with general Medicare+Choice (M+C) capitated payment systems. In June 2003, CMS issued a request for proposals to providers interested in participating in a second demonstration designed to assess disease management for ESRD using a different risk-adjustment methodology.

The first article by Oppenheimer, Shapiro, Beronja, Dykstra, Gaylin, Held, and Rubin presents selected results from the evaluation and serves as both an introduction to the demonstration and as a conclusion summarizing the evaluators' qualitative observations. The description and comparison of structures and operations at the demonstration sites are important for interpreting the quantitative results of subsequent articles. The discussion of possible implications of the demonstration is, of necessity, more speculative and of unknown generalizability. The three managed care sites needed to create new systems, procedures, and relationships to provide care for the many new ESRD enrollees. Two of the plans, a closed-system health maintenance organization (HMO) and a preferred provider organization with fee-based provider contracts, were able to achieve commendable health outcomes despite significant initial challenges. The third plan, an HMO partnered with a large local nephrology practice group, experienced major difficulties when the relationship dissolved. Whether the site could have survived is unknowable since financial problems of the parent firm forced closure for reasons unrelated to the demonstration. Development of ESRD managed care programs required a great deal of resources and sustained commitment by both the plans and CMS. At least two of the three sites succeeded, although, as discussed in a later article, the financial results are less clear.

The second article, by Shapiro, Dykstra, Pisoni, Beronja, Gaylin, Oppenheimer, Rubin, and Held shows that the ESRD patients who chose to enroll in the plans were younger, healthier, and needed fewer health care services than a representative comparison group. The plans' marketing and enrollment activities had been carefully monitored indicating that patient self-selection was the probable cause of the biased selection. The self-selection had a major effect on outcomes so that later evaluation findings are based as much as possible on adjusted results. Favorable patient selection is observed across the M+C program suggesting that the ongoing CMS development of a risk-adjusted payment for M+C ESRD patients is important, and

patient selection may not be a valid criterion in deciding whether to maintain or drop the prohibition against ESRD patients freely enrolling in Medicare HMOs.

High levels of patient quality of life and patient satisfaction are primary goals for governments and health care businesses. The third article by Pifer, Bragg-Gresham, Dykstra, Shapiro, Oppenheimer, Gaylin, Beronja, Rubin, and Held shows that patient quality of life scores improved after 1 year in the managed care demonstration. Most other studies of dialysis patients have found quality of life to decrease over time. On the questions about patient satisfaction with their access to and quality of health care, demonstration patients tended to report lower satisfaction than FFS comparison groups, with the notable exception that fewer enrollees reported financial burdens. However, the small differences between demonstration and comparison group satisfaction, are perhaps less important than the fact that over 80 percent of demonstration enrollees reported themselves satisfied on most of the services measured.

The last of the four articles from the independent evaluation of the ESRD managed care demonstration is by Dykstra, Beronja, Menges, Gaylin, Oppenheimer, Shapiro, Wolfe, Rubin, and Held. Their factual findings of the financial evaluation are straightforward. CMS paid the plans more than it would have paid had the patients remained in FFS. Despite this, the demonstration sites experienced losses or modest gains, largely because they provided benefit packages that included unlimited pharmaceuticals and waived all copays and deductibles. Enrollees saved approximately $9,000 annually in out-of-pocket expenses. However, it is questionable whether these findings are relevant to today's M+C environment. Benefit packages similar to those offered by today's M+C plans would eliminate (or at least reduce) losses and also make enrollment less attractive to patients. In January 2004, Medicare will introduce a new risk-adjustment system for ESRD beneficiaries in a new disease management demonstration that includes a full capitation method. This payment may be used for the M+C program in 2005. Finally, in the event that a Medicare drug benefit is enacted, its impact is unknown.

CASE-MIX ADJUSTMENT

Congress has required CMS to develop an expanded composite rate for outpatient dialysis services that includes as many drugs and diagnostic procedures as possible (Public Law 106-554, section 422(c)). Hirth, Wolfe, Wheeler, Roys, Tedeschi, Poznick, and Wright show that there is significant variability among dialysis facilities in their costs of providing dialysis and in Medicare dialysis payments for these costs. Regressing the facility average cost per dialysis session against local wage rates and the treatment modalities offered by the facility explains 5 percent of the variation in costs. Adding 44 case-mix variables taken from the Medical Evidence Forms—submitted when a patient begins dialysis—increases the *R*-squared to 15 percent. Much of the increase comes from explaining differences in the amount of EPO that patients receive. Further research is needed to determine whether a case-mix adjustment methodology using fewer, more clinically certain, and more current variables is feasible.

EFFORTS TO IMPROVE THE QUALITY OF DIALYSIS

CMS has initiated, funded, and implemented several programs to improve the quality of ESRD care. The publication of the *Dialysis Outcome Quality Initiative* by

the National Kidney Foundation (1997) provided clinical practice guidelines and identified outcome and process indicators, sometimes with numerical targets, that CMS used to develop the ESRD health care quality improvement program (HCQIP) and other quality improvement activities. In this issue, McClellan, Frankenfield, Frederick, Helgerson, Wish, and Sugarman describe the evolution of the HCQIP.

Medicare initiated the HCQIP to improve dialysis outcomes by disseminating to providers measures of care that allowed them to identify aspects of care needing improvement. The networks collected data on a sample of dialysis patients that CMS analyzed to produce national and network-level quality indicators. Networks developed programs to help dialysis facilities improve outcomes. The data have been collected and disseminated annually since 1994 to monitor progress. The program underwent a complete review between 1997-1999. Beginning in 1999, data on individual dialysis facility performance were produced and each facility was given its own results. CMS (2003a) released Dialysis Facility Compare on its Web site that provides the public with information and quality indicators for most dialysis facilities. The annual data reports created by CMS show that the dialysis adequacy and anemia treatment has improved continually since the HCQIP began.

IMPROVING EFFECTIVENESS OF ORGAN ACQUISITION

Increasing the supply of kidneys and other organs for transplantation is a priority initiative of the Secretary of the Department of Health and Human Services. ESRD patients treated with a functioning kidney graft live longer, require fewer hospitalizations, and have higher quality of life scores than dialysis patients. Because of the savings in health care expenditures, Medicare recovers the cost of the transplant operation in 2.5 - 3 years and savings continue for the life of the graft. Although the number of living donor kidneys has been increasing rapidly, cadaver donations provide most kidneys, and nearly all other solid organs. Patients may wait years on dialysis until a suitable kidney is available. The number of cadaver organs recovered by the organ procurement organizations (OPOs) has remained nearly unchanged despite numerous programs aimed at improving donation and recovery rates.

Guadagnoli, Christiansen, and Beasley use a previously validated model to predict the number of potential organ donors for individual hospitals within an OPO. The hospital estimates are aggregated to determine the potential pool for the OPO. Expressing actual donations as a percentage of potential donors creates a measure of what the authors call donor efficiency. The OPOs are ranked by their rates. The number of potential donors in the U.S. is estimated to be well under 20,000 per year while there are fewer than 7,000 actual donors. Although there is great room for improvement, even if all OPOs reached a 75-percent level of efficiency, the number of organs donated would still be less than the number of new registrants to the waiting lists. Large improvements in the organ recovery system would slow, but not eliminate, the continuing increase in time patients spend on the waiting list.

Policy-relevant research is less widely reported, but aids in modifying the U.S. health care system to improve access, efficiency, and fairness. Each of the articles in this special edition of the *Review* deals with an important ESRD policy question under consideration by the government. For example, Congress required both CMS (2003b; 2002) and the Medicare Payment Advisory Commission (2002) to submit

reports on enrolling ESRD patients in capitated health plans and on updating the composite rate. The seven articles in this issue provide some of the knowledge base needed for improving the Medicare ESRD program and lives of patients with ESRD.

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Reprint Requests: Joel W. Greer, Ph.D., Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C3-19-07, Baltimore, MD 21244-1850. E-mail: jgreer3@cms.hhs.gov