Evaluation of the ESRD Managed Care Demonstration Operations

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Individuals with end stage renal disease (ESRD), most of whom are insured by Medicare, are generally prohibited from enrolling in Medicare managed care plans (MCPs). CMS offered ESRD patients the opportunity to participate in an ESRD managed care demonstration mandated by Congress. The demonstration tested whether managed care systems would be of interest to ESRD patients and whether these approaches would be operationally feasible and efficient for treating ESRD patients. This article examines the structure, implementation, and operational outcomes of the three demonstration sites, focusing on: the structure of these managed care programs for ESRD patients, requirements needed to attract and enroll patients, and the challenges of introducing managed care programs in the ESRD arena.

INTRODUCTION

The ESRD population in the U.S. represents the only outright disease-specific form of Medicare eligibility.[1] All persons with ESRD, subject to Social Security requirements, are eligible for Medicare regardless of age. ESRD patients, who suffer from kidney failure, need either dialysis (which artificially replaces the function of the kidney) or a kidney transplant to survive. Both options are expensive and require substantial health care and financial resources. To ease the burden of this disease among ESRD patients and their caregivers, about 30 years ago Congress extended Medicare to individuals with ESRD. In addition to being the only outright disease-specific form of Medicare entitlement, the Medicare ESRD program is unusual in that despite wide-scale movement of other privately and many publicly insured populations into managed care arrangements, the vast majority of ESRD patients receive care in the fee-for-service (FFS) environment, and are legally barred from enrolling in Medicare MCPs.

Managed care's popularity has soared in recent decades due to its promise of reduced health care costs and superior quality of care. It attempts to achieve these goals by emphasizing preventive care, requiring patients to receive care from a network of participating providers, and coordinating the care of patients with complex or chronic health conditions. Yet, ESRD patients —whose health care is both costly and complex—are barred from choosing this system.[2] In 1998, CMS

[1] Technically, there is also another type of disease-specific Medicare entitlement, which is the waived waiting period for the disabled if they have amyotrophic lateral sclerosis.

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[2] Under current law, patients enrolled in a health maintenance organization (HMO) who develop ESRD are permitted to stay in the MCP plan and patients with ESRD who are enrolled in an HMO that withdraws from the service area are permitted to join another HMO.

launched a demonstration program to study the experience of offering managed care options to Medicare ESRD beneficiaries. Simultaneously, an evaluation of the program was undertaken to evaluate the efficacy and cost of HMO participation for Medicare beneficiaries with ESRD. This evaluation compared the structure, process, and outcomes for patients enrolled in the demonstration sites with those of a similar set of ESRD patients in the FFS sector.

Results from the evaluation of clinical and financial outcomes of the demonstration are presented elsewhere (Dykstra et al., 2003; Pifer et al., 2003; Shapiro et al., 2003; The Lewin Group and the University Renal and Education Association, 2002). The purpose of this article is to describe the operational outcomes of the demonstration with regard to three aspects:

- What was the structure of these managed care programs for ESRD patients?
- What was required to attract and enroll patients?
- What do these sites' experiences tell us about the challenges of introducing managed care programs in the ESRD arena?

The sites' experiences provide a context for the clinical outcomes of the demonstration and, importantly, can help forecast the potential sustainability of ESRD managed care programs should the law change to open managed care as an option to Medicare ESRD patients. These experiences also illuminate critical organizational issues relevant to the entire ESRD community.

BACKGROUND ON THE ESRD POPULATION

From an initial count of about 7,000 patients in 1972, the ESRD program today provides health insurance for 378,862 patients (U.S. Renal Data System, 2002). The cost of treatment for individual patients with ESRD can be very high; for instance, spending[3] on hemodialysis (the most common type of treatment for ESRD patients) and associated care is more than $65,000 per patient annually (The Lewin Group, 2000). In aggregate, the ESRD program has consumed a growing share of the Medicare budget, and program costs have continued to rise beyond policymakers' expectations (Eggers, 2000). In 2000 alone, Medicare expenditures for ESRD amounted to $12.3 billion, representing 71 percent of total U.S. ESRD costs ($17.9 billion) (U.S. Renal Data System, 2002).

The reasons behind the growth in ESRD program costs are similar to reasons health care costs have increased generally. An increasing number of people are diagnosed with ESRD as the prevalence of chronic diseases that lead to ESRD, such as diabetes and hypertension, continue to rise (U.S. Renal Data System, 2002). The ESRD community has also experienced a disproportionate increase in the number of costlier patients (e.g., elderly patients or those with comorbidities) (U.S. Renal Data System, 2002).

Pharmaceutical costs have also played a role in the rising costs of the Medicare ESRD program. In 1989, Medicare authorized coverage of recombinant erythropoietin (EPO) therapy for dialysis patients and EPO is now prescribed for the majority of patients (Greer, Milan, and Eggers, 1999).[4] The cost of immunosuppressive drugs, required by transplant recipients to avoid graft rejection, has also contributed to rising costs in the Medicare ESRD program. Prior to 1993, Medicare covered immunosuppressive drugs for 12 months. Various legislative initiatives extended the duration

[3] Includes spending by Medicare as well as other payers.

[4] Erythropoietin is a hormone produced by the kidney which stimulates bone marrow to make red-blood cells; with the loss of kidney function anemia is common among ESRD patients. EPO is a synthetically produced drug that has helped reduce the rates of anemia among dialysis patients (National Kidney Foundation, 2000a).

of coverage and the Beneficiary Improvement and Protection Act of 2000 (BIPA) eliminated the time limitation for aged and disabled transplant recipients who were Medicare eligible at the time of transplant.

ESRD patients have traditionally received their care in the FFS system, which many believe is characterized by a lack of attention on cost management and fragmented service provision. Many ESRD patients have numerous comorbidities along with their kidney failure (e.g., diabetes, heart disease), and could benefit from a more coordinated approach. Additionally, the FFS system poses challenges for systematic implementation of patient care guidelines to encourage best practices. In the case of ESRD patients, examples of such guidelines include vascular access (the means by which the patient's blood stream is connected to a dialysis machine) and anemia management. Despite these shortcomings, the FFS system has been a salvation for thousands of ESRD patients, enabling these patients to receive lifesaving health care services.

DEMONSTRATION FRAMEWORK

One of the most important tools available to CMS in its quest to improve the quality and cost-effectiveness of the Medicare Program is demonstration authority (Centers for Medicare & Medicaid Services, 2003a). CMS has the authority under certain statutes to waive specific provisions of the Medicare Program, thus allowing it to test alternative approaches to health care delivery and/or payment. Demonstration initiatives can provide the basis for informed and rational program and policy decisions. Generally speaking, demonstration initiatives must be budget neutral, i.e., costs under the demonstration should not exceed the costs in the absence of a demonstration, and must hold promise for replicability on a national basis. Often, Congress mandates the development and implementation of specified demonstration initiatives prior to enactment of full-scale program changes through legislation.

The ESRD managed care demonstration was initiated as a mechanism to test expanded access to managed care systems for ESRD program beneficiaries. Congress originally barred ESRD patients from participation in MCPs to address HMOs' concerns regarding the expense of ESRD enrollees; the enrollment restriction has remained in place to protect ESRD patients because concern exists over the potential incentives under managed care to undertreat patients with a chronic disease (Tax Equity and Fiscal Responsibility Act of 1982; Omnibus Budget Reconciliation Act of 1993; Renal Physicians Association and American Society of Nephrology, 1995). In recent years, however, there have been a number of proposals to permit ESRD beneficiaries to enroll in HMOs under the same conditions as other Medicare beneficiaries, particularly since HMOs have had increasing experience with ESRD patients. Moreover, managed care offers certain advantages over FFS care, typically including additional benefits (e.g., prescription drugs) and reduced fragmentation and more coordination across the range of services required by ESRD patients (Brown et al., 1993). In addition, all other Medicare beneficiaries—including those with chronic illnesses other than ESRD—have the opportunity to choose among health plan types on a voluntary basis. In response to consumer pressure and the uncertainty surrounding what might happen if ESRD beneficiaries were given the opportunity to choose an MCP, Congress mandated a demonstration project in 1993 to test whether ESRD patients could be successfully treated in a managed care setting.

Table 1

Essential Service Components of the End Stage Renal Disease (ESRD) Managed Care Demonstration Programs: 1996

Service Integration and Case Management. Demonstration sites were required to invest in the structuring of care delivery in order to better coordinate services and improve outcomes of care and satisfaction for patients. Organizations were expected to provide all Medicare-covered health services, including kidney transplants, plus additional benefits, and to use a case manager in fully integrating these services at the level of the individual beneficiary. Basic functions of case managers include initial screening, assessment, care planning, service provision and/or referral, monitoring, and reassessment.

Clinical Protocols. Demonstration sites were required to develop and implement clinical protocols for common clinical events. Protocols were to be used proactively in disease management rather than just reactively as a strategy for problem management.

Extra Benefits. Demonstration sites were required to provide a benefit package that included all services covered by the sites' regular Medicare risk programs (which included coverage of Medicare coinsurance and deductibles and prescription drugs), plus additional services of special interest to ESRD patients (e.g., nutritional supplements). Expanded benefits were seen as a means to encourage voluntary enrollment in the capitated plan and to enhance the breadth, integration, and quality of delivered medical care. The costs of the extra, ESRD-specific benefits were intended to be covered by higher payments from Medicare than were paid to health maintenance organization risk contractors outside of the demonstration.

SOURCE: Centers for Medicare & Medicaid Services ESRD Managed Care Evaluation.

Specifically, the Omnibus Budget Reconciliation Act of 1993 required CMS to conduct a social HMO (S/HMO) demonstration project for ESRD patients (Omnibus Budget Reconciliation Act of 1993). S/HMO demonstrations provide for the integration of health and social services under the direct financial management of a provider of services. The intent was to see whether extending an integrated system of care to ESRD beneficiaries was operationally feasible, efficient, and able to improve patient outcomes compared to the current FFS system (Cooper, Eggers, and Edington, 1997). Congress wished to determine whether it would be feasible to permit ESRD patients to enroll in managed care settings that were not only responsible for the total medical care of ESRD enrollees, but also provided a specific case management function and additional benefits of particular interest to the ESRD population.

The demonstration was intended to test the feasibility and effectiveness of the following:

- Permitting year-round enrollment and disenrollment options for ESRD beneficiaries to enroll in participating HMOs.
- ESRD-focused case management, with particular emphasis on whether outcomes of care were improved.
- Preventive and supportive interventions and more comprehensive benefit coverage for ESRD patients.
- Integrated administrative and financial arrangements among providers of services to ESRD beneficiaries.
- An ESRD payment and risk-adjustment system that was an alternative to both FFS and the current capitation payment for ESRD patients in HMOs.

The elements that CMS required each demonstration program to contain are identified in Table 1. Demonstration sites were required to have year-round open enrollment for eligible ESRD patients who were served in the FFS system, including both dialysis patients and those with functioning kidney grafts who were still Medicare eligible (e.g., within 3 years since transplant). The demonstration sites were required to undertake active efforts to publicize the potential for demonstration enrollment to all ESRD patients in the service area and they were required to attempt to enroll at least 600 patients.

A key component of the demonstration was to test the impact of risk-adjusted ESRD capitation rates. Enrollees were partitioned into three discrete treatment status categories: maintenance dialysis, a transplant episode (defined as 1 month

prior to, the month of, and the month following a transplant), and the post-transplant period of a functioning transplant. Rates for the maintenance dialysis and functioning transplant period were further adjusted for three age categories (under 20, 20-64, and 65 or over), and whether or not diabetes was the primary cause of ESRD. Demonstration payments were updated annually based on the Medicare+ Choice county update factors (typically about 2 percent). Dykstra et al. (2003) describe the financial structure of the demonstration in further detail.

Demonstration Evaluation

Demonstration programs often set out to address far-reaching and ambitious goals only to hit numerous obstacles and pitfalls along the way. CMS demonstrations have frequently encountered slow ramp-up and enrollment, difficulties obtaining beneficiary buy-in, and limited ability to adequately test the hypothesis within the short duration of the initiative (typically 3-5 years) (Centers for Medicare & Medicaid Services, 2003a).

In an effort to both document obstacles and evaluate outcomes, an evaluation of the ESRD managed care demonstration began in August 1997, after the demonstration sites were selected by CMS. Its goals were to determine how well the demonstration worked and to offer CMS guidance for the potential future implementation of a managed care component to the ESRD program. In particular, the evaluation assessed the degree to which managed care approaches could be successfully applied to ESRD. It analyzed differences in costs, access, structure, process, and outcomes of care between managed care and FFS ESRD patients. It also sought to determine if covering additional services, such as pharmaceuticals, offered advantages in ESRD treatment. In short, the evaluation attempted to provide the answer to whether the new care delivery and payment structures resulted in similar or better quality care than FFS, at equal or lower cost to the government.

Much of the evaluation entailed collection of patient-level clinical, outcomes, and quality-of-life data as well as plan-level financial data. However, the evaluation also captured qualitative information on the structure and operations of the demonstration sites. This article provides descriptions of how the participating managed care organizations (MCOs) structured their programs at the outset of the demonstration, and reviews the sites' experiences operationalizing the demonstration (including discussion of some of challenges of implementation that have relevance beyond the demonstration). The information presented herein is drawn from 15 site visits conducted between October 1997 and May 2002 by evaluation team members from The Lewin Group and University Renal Research and Education Association.

DEMONSTRATION OPERATIONS

The demonstration was initiated in September 1996 with a planning period at participating sites; patient enrollment began in 1998. All ESRD-eligible patients in the service area who had Medicare Part A and Part B coverage, and for whom Medicare was the primary payer, were eligible for enrollment in the demonstration. Enrollment was allowed throughout the demonstration period and the 3-year mandated demonstration operations ended in early 2001.

The Medicare ESRD demonstration was begun at three sites across the country: Health Options, Inc. (HOI), a subsidiary of

Blue Cross® Blue Shield® of Florida, based in Miami, Florida; Kaiser Permanente Southern California Region (Kaiser), based in Los Angeles, California; and Xantus Health Care Corporation (Xantus), based in Nashville, Tennessee. Kaiser and HOI both met the enrollment goals with Kaiser ultimately enrolling a total of 1,649 beneficiaries and HOI enrolling a total of 967 beneficiaries (including, for both sites, those who later disenrolled or died). Xantus terminated its demonstration program in early 2000 due to financial difficulties experienced in its other operating units, having enrolled only 50 ESRD beneficiaries. Thus, this article primarily recounts the experiences of Kaiser and HOI. We also provide a brief summary of the Xantus demonstration and review the reasons behind the demonstration program's closure.

Demonstration Programs Structure

The three demonstration plans represented different models of care (Table 2). The Kaiser demonstration plan was a closed-practice plan for specialist and inpatient care (i.e., providers enter an exclusive arrangement with Kaiser, and Kaiser operates the majority of facilities). At the outset, the majority of outpatient dialysis services were provided under FFS provider contracts, although over the course of the demonstration, Kaiser built or acquired its own dialysis centers. The HOI site had primarily FFS contracts with the majority of its providers, with the exception of capitation arrangements made with primary care nephrologists and certain specialists. The Xantus program was a joint effort between an HMO and a single-specialty physician practice.

Kaiser Site

Of the three sites selected for participation in the demonstration, Kaiser had the most well-established managed care program with experience in treating ESRD patients. In seeking participation in the demonstration, Kaiser sought to contribute to knowledge surrounding care management for the chronically ill.

Kaiser is a large, closed-system MCO. When the demonstration began, more than 2 million covered lives were enrolled in Kaiser. Of the 2 million, 168,000 enrollees were Medicare beneficiaries, of whom about 2,000 had ESRD. Kaiser had been operating a Medicare risk plan, the Senior Advantage program, since 1987.

Kaiser owns and operates the large majority of medical service sites related to providing care under the demonstration. At the time of application, Kaiser operated 10 medical centers and more than 90 medical offices throughout Southern California. The medical staff includes physicians, nurses, and health educators, and the organization has academic and residency affiliations with the five medical schools in Southern California. Kaiser operates its own medical laboratory and more than 130 pharmacies throughout the region. Inpatient hospital services provided to demonstration patients were provided by Kaiser hospitals and specialty care was also provided using Kaiser's own network of specialists.

To supplement the 25 nephrologists and other clinical staff in place for its Senior Advantage program, Kaiser recruited an additional 120 providers and 112 facilities to provide for demonstration services. Transplant services were provided through contractual

Table 2

Structure of the End Stage Renal Disease (ESRD) Managed Care Demonstration Sites: 1998-2001

Feature	Kaiser[1]	HOI[2]	Xantus[3]
Primary Health Maintenance Organization Model	Group Health Maintenance Organization	Network Model	Network Model
ESRD Beneficiaries in Service Area	20,519	5,860	900
Start Date of Enrollment	February 1, 1998	June 1, 1998	September 1, 1998
Total Enrollment (Gross)	1,649	967	50
Demonstration Service Area	Los Angeles, Orange, Western San Bernadino, Western Riverside, and San Diego counties.	Palm Beach, Dade, and Broward counties.	Davidson County.
Outpatient Dialysis Treatments and Ancillaries	Mostly contracted facilities. Negotiated fee-for-service: Kaiser and contracted facilities.	All contracted facilities. Fee-for-service comparable to 100 percent of Medicare allowable charge.	All contracted facilities. All inclusive per treatment rate comparable with Medicare payment levels.
Inpatient Hospital and Payment	Mostly Kaiser hospitals, internal payment.	All contracted hospitals, per diem rate.	All contracted hospitals, per diem rate.
Nephrologists: Outpatient/Inpatient	Contract nephrologists in unit, Kaiser nephrologists as primary care physician (PCP) and inpatient physician.	Community nephrologists as PCP and as inpatient physician.	Community nephrologists as PCP and as inpatient physician.
Nephrologist Payment	Kaiser nephrologists on salary, risk-adjusted capitated rates for contract nephrologist.	One capitated rate for outpatient and inpatient care.	Comprehensive capitation.
Transplant Services	Contracted with University of California at Los Angeles, University of California at San Diego, and Loma Linda University (in Loma Linda, California). Paid on a case rate, adjusted for living or deceased (donor).	Contracted with Jacksonville Methodist Hospital (Jacksonville, Florida).	Contracted with Centennial Medical Center and Saint Thomas Hospital both in Nashville, Tennessee.
Use of Case Managers and Team Make Up	Case Managers: Yes. Team: M.D., R.N., M.S.W., R.D., pharmacist, and specialists.	Case Managers: Yes. Team: M.D., R.N., M.S.W., R.D., pharmacist, and specialists.	Case Managers: Yes. Team: M.D., R.N., M.S.W., and R.D.
End of Data Collection	August 2000 (manual); September 2001 (electronic).	August 2000 (manual); September 2001 (electronic).	January 2000 (manual).

[1] Kaiser Permanente Southern California Region, Los Angeles, California.

[2] Health Options, Inc., a subsidiary of Blue Cross® /Blue Shield®, based in Miami, Florida.

[3] Xantus Health Care Corporation, based in Nashville, Tennessee.

NOTES: M.D. is Doctor of Medicine. R.N. is Registered Nurse. M.S.W. is Master of Social Work. R.D. is Registered Dietician.

SOURCES: Oppenheimer, C. C., and Gaylin, D.S., National Opinion Research Center, Shapiro, J. R., Centers for Medicare & Medicaid Services, Beronja, N., The Lewin Group, Dykstra, D. M., and Held, P.J., University Renal Research and Education Association, and Rubin, R. J., Georgetown University School of Medicine, 2003.

arrangements with three university hospitals using a case rate, based on whether the procedure involved a deceased or living donor.

Payments to contracted providers were made on a capitated basis with adjustments for age, diabetes, and graft status. Kaiser also paid contracted nephrologists and dialysis facilities a process-based incentive to compensate for additional care provided to demonstration patients.

During the demonstration period, Kaiser moved to develop and operate dialysis services through a partnership with Fresenius, a large dialysis facility chain. In developing this new facility network, a Kaiser nephrologist assumed the role of medical director in each of the new facilities. Physicians received monetary incentives based on dialysis adequacy,[5] quality assurance, serum albumin levels,[6] and reductions in hospitalization rates. Kaiser's expansion into ownership and operation of dialysis facilities strained relationships with community providers who were concerned about losing patients to these new Kaiser facilities.

Kaiser developed its demonstration program based on the pre-ESRD and ESRD care it was already providing to its current ESRD beneficiaries. The program was based on a multidisciplinary team approach to patient-centered care management. Each ESRD enrollee was assigned to a team including, at minimum, a nephrologist, an ESRD case manager, a renal social worker, a dietitian, and a pharmacist; other relevant providers were included as needed. The care management team used a standardized care plan template to develop goals for each patient and help coordinate efforts among the team; quarterly meetings were held to review patients' care plans.

Each demonstration patient was assigned a Kaiser nephrologist to serve as the clinical director of the management team, sometimes in addition to the patient's community nephrologist (if that patient was receiving care in a non-Kaiser facility). In most cases, the Kaiser nephrologist also served as the patient's primary care provider as well as the inpatient provider. The Kaiser nephrologist was expected to see all demonstration patients at least quarterly.

Case managers were expected to be in daily contact with the nephrologist and coordinate the multidisciplinary team. Responsibilities of the case managers included: (1) monitoring ESRD patient care and promoting quality improvement; (2) coordinating and managing patient needs; (3) providing early intervention, educating patients, and encouraging prevention; (4) collecting data on ESRD patient population and conducting analyses; and (5) managing the care and cost of ESRD patients. Caseloads of managers were adjusted for three acuity levels of the patients.

Finally, transplant coordinators were also involved in patient care. These individuals provided case management for all transplant patients and worked to obtain transplants for qualified patients as quickly as possible. The coordinator also provided patient education and long-term post-transplant followup.

Kaiser Quality Improvement

As with the general structure of the program, Kaiser used its pre-existing quality assurance program as the basis for such

[5] Dialysis adequacy refers to measurements about the average dose of dialysis that patients receive. Dose is a function of patient characteristics (e.g., weight), the amount of time a patient spends on dialysis, and characteristics about the dialysis process (e.g., size of the dialyzer, speed of blood flow). (Daugirdas and Ing, 1994)

[6] Serum albumin is important marker of nutrition (Blumenkrantz et al., 1980) and is predictive of mortality (Leavey et al., 1998; Goldwasser et al., 1993). ESRD patients typically have lower albumin levels compared to the non-ESRD population and clinical guidelines for ESRD care suggest routine monitoring of albumin levels (National Kidney Foundation, 2000a).

activities for the demonstration. Key components of the program included physician and facility report cards, facility site inspections, quality-of-life questionnaire, quality outcomes assessment tool, and vascular access tracking tool. Kaiser developed a monthly Dialysis Center and Provider Report Card to monitor variables on patients, dialysis units, and attending nephrologists. Outcomes were regularly monitored against established standards. Kaiser used this report card data to identify patient outliers and the case managers worked with providers to develop a plan of action.

Kaiser also implemented several drug- or disease-specific quality initiatives. For example, the plan implemented a review system to monitor the usage of EPO for the demonstration patients as plan administrators had noticed that some units were using particularly large quantities of EPO. Under the new initiative, medical justification was required in order to receive the drug, and the Kaiser quality improvement team monitored the dose patients received. Additionally, Kaiser worked closely with providers to shift from intravenous to subcutaneous administration of EPO. EPO is expensive and should be used as efficiently as possible. The literature substantiates that for the majority of dialysis patients, subcutaneous administration of EPO is more effective, on average, by about 33 percent. That is, the dose can be reduced from three times a week, given intravenously, to the same dose given only twice a week if given subcutaneous (National Kidney Foundation, 2000b). Kaiser's attempts to encourage subcutaneous administration met with resistance from providers, many of whom suggested that patients did not tolerate subcutaneous administration well. Kaiser suggested that oversight was needed to ensure that patients switched to subcutaneous administration of EPO actually continued to receive it that way. By the end of the demonstration in 2000, Kaiser had successfully achieved a subcutaneous administration rate of 67 percent.

Kaiser also had an aggressive program to ensure that fistulas were patients' primary access sites. Three major kinds of vascular access dominate ESRD practice: arterial venous fistulas involve using a patients' own vein; synthetic grafts are placed using a synthetic tube implanted under the skin; and catheters. Outcomes are superior for fistulas though grafts are more common (U.S. Renal Data System, 2002; Young, 2002). Specific guidelines were implemented as part of a vascular access continuous quality improvement process. These guidelines addressed triage, timelines for service provision, and access type. In 1999 Kaiser reported a primary fistula rate of 69 percent among new accesses placed.

HOI Site

In contrast to Kaiser's group-model managed care structure, HOI is a wholly owned for-profit subsidiary of Blue Cross®/Blue Shield® of Florida that relies on contracts with an independent network of providers to provide patient care. Providers are paid based on capitation, FFS, diagnosis-related groups, and per-diem rates. At the time the demonstration was initiated, HOI was the second largest HMO in southern Florida, with total enrollment nearing 300,000 covered lives. When it applied for the demonstration, HOI had been operational for 11 years, but it did not yet have an established ESRD program.

Advanced Renal Option (ARO) was the demonstration program run by HOI; while HOI operates throughout Florida, the organization limited demonstration operations to Dade, Broward, and Palm Beach counties. ARO was designed to operate as a separate program within HOI's organization, with a mixture of administrative staff being

dedicated to the demonstration and drawing on HOI staff in some instances (e.g., marketing staff).

HOI's provider arrangements and contracting for the demonstration were consistent with its traditional structure (Table 2). When HOI applied for the demonstration, its network of more than 2,800 physicians included 77 nephrologists. The network of participating nephrologists for the demonstration consisted primarily of those clinicians with whom HOI contracted for nephrology services for all HOI enrollees prior to the demonstration. HOI had preexisting relationships with 51 dialysis units in the target area and established demonstration-specific contracts with at least several dozen of the dialysis facilities, relying on a contract with one of the major national chains to secure the services of about 20 units. As with the nephrology contracts, HOI generally limited its network of dialysis facilities to those with which the plan had existing contracts. Dialysis facilities were selected based on where the nephrologists practiced.

Nephrologists were compensated in the form of a global capitation rate, based on primary care services delivered in the inpatient and outpatient settings, renal care and management of dialysis in both settings, and referral to other specialties. Dialysis units were paid on a negotiated composite rate inclusive of equipment, supplies, labor, selected drugs, and medications, similar to the way Medicare currently pays for these services.

HOI intended to use incentive programs with nephrologists and with dialysis facilities, though the structure of the initial incentive program for nephrologists raised concerns at CMS about the potential negative impact on patients' hospitalization. Specifically, the original incentive plan for nephrologists included bonus payments for meeting target hospitalization rates, along with other targets such as 75 percent of patients receiving appropriate preventive services and 60 percent of patients participating in educational programs. The incentive program was restructured with government approval; however the plan included the requirement that the medical loss ratio had to reach 90 percent before HOI would make physician payments.[7] This financial point was never reached, effectively eliminating HOI's incentive program.

HOI used established contracts with the 36 hospitals in the area to provide needed care for demonstration patients, with payment based on per diem rates. Transplant services were provided through a contract with Jacksonville Methodist Hospital, located about 300 miles from HOI's demonstration service area.

Access to non-nephrology specialists (e.g., vascular surgeons, cardiologists, etc.) by demonstration patients was gained through HOI's established network of providers. Some specialists in ARO's network were paid on a capitated basis while others were paid on an FFS basis. Additionally, part way through the demonstration, HOI contracted with freestanding clinics to provide routine vascular access services.

HOI also developed a multidisciplinary team approach to providing care. Each team included a nephrologist, nurse practitioner, case manager, social worker, dietitian, facility nurse, technicians, radiologist, and a vascular surgeon. Additional specialists that could have participated in a patient's care plan included cardiologists and endocrinologists.

[7] Medical loss ratio refers to the aggregate costs of medical services as a percentage of total HMO premium revenue, and is commonly used in the insurance industry as an index of how well payment levels to the HMO match up with the costs of delivering the medical services covered by the health plan. In the HMO industry, a medical loss ratio close to 85 percent is considered reasonable, with the remaining 15 percent or so of revenue available to cover administrative costs and profit (Dykstra et al., 2003).

The nephrologist served as the primary care physician and provided referrals, authorizations, and arrangements for specialty and hospital care. The nephrologist was responsible for: (1) establishing a plan of care for all patients; (2) assessing transplant candidacy; (3) determining modality and access type (when appropriate); (4) working with the patient to identify an appropriate rehabilitation plan; and (5) determining dietary, nutritional, and pharmaceutical prescriptions.

The nurse practitioner's role was to work with the nephrologist and serve as the primary caregiver for both renal and non-renal services. It was anticipated that the nurse practitioner would see patients on a weekly basis and would be in a position to identify and treat potential problems early on.

The case manager's role was to coordinate all aspects of clinical and supportive care. According to HOI's job description, the ESRD care manager was responsible for "…evaluating and monitoring ESRD care services for quality, continuity, case management intervention, timely reports, coordinating/managing meetings, and patient education." Additionally, the case manager focused the plan of care for each patient to "…continually improve the quality of renal patient care." Upon enrollment in the demonstration, the case manager met with the patient at the dialysis facility and collaborated with the patient, family, and members of the health care team to develop the plan of care. The case manager also held quarterly meetings with nephrologists, and participated in monthly facility care management meetings at the dialysis facility. On average, each case manager handled 50 patients. Toward the end of the demonstration, when HOI resources for the demonstration were strained and the program was winding down (Dykstra et al., 2003), case managers' case loads increased to approximately 70 patients.

HOI Quality Assurance

Although HOI had anticipated developing demonstration-specific quality assurance activities, the basic operations of the demonstration demanded all the resources HOI allocated to the project, and HOI did not implement planned activities.

HOI did implement an initiative to identify why drug costs were higher than expected in the early phase of the demonstration. Dialysis-related costs were slightly elevated due to high utilization of EPO in certain practices. After an investigation into EPO use and implementation of a new initiative, HOI was able to decrease EPO use to more normal levels. Specifically, the new initiative was a review system for every instance that a physician prescribed more than a level determined potentially excessive by HOI. The review used clinical guidelines to determine whether the prescribed dose was actually warranted, approving it for those extreme cases. However, if the high-dose prescription was determined to be unnecessary, the clinic was responsible for its cost.

Xantus Site

A private, for-profit corporation chartered by Tennessee, Xantus was an HMO dedicated to serving the State's Medicaid population. In joining the demonstration, Xantus sought to prove that a program of care for ESRD patients could be developed from scratch, relying on a small, locally designed program. The Xantus site was distinguished from the other sites in that it did not treat Medicare or ESRD patients prior to the demonstration.

For reasons described later in this article, the Xantus demonstration site never hit its stride, enrolling only 50 patients prior to its early withdrawal from the program. Nevertheless, basic structures were in place to provide care for its enrollees. Specifically, all HMO management services (e.g., marketing, claims processing, and utilization management office function) were provided by Xantus. A for-profit network independent practice association model HMO, licensed to operate throughout Tennessee, Xantus operated through individual contracts with providers. For the demonstration, Xantus had contracts with all of the nephrologists in the region and nearly 20 dialysis facilities. The hospitals contracted for the demonstration were those hospitals in the demonstration service area with existing Xantus contracts. Similarly, non-nephrologist physicians were also among those with current Xantus contracts. Xantus also contracted with various other entities for the provision of ancillary services, including home health, durable medical equipment, skilled nursing facilities, transportation, pharmacy, and psychiatry. Transplantation was available at two locations.

Nephrologists served as primary care providers, working with Xantus-employed case managers. The case managers visited newly enrolled patients at their homes and met with patients at least bimonthly. Case managers reportedly were successful at facilitating communication between patients and nephrologists.

Attracting Patients to the Demonstration

One goal in evaluating the marketing and enrollment activities of demonstration sites is to determine whether programs sought to attract a favorable mix of patients, encouraging comparatively healthier, and thereby less costly, patients to the demonstration. The service packages offered in each site and a review of marketing and enrollment activities are described below, and Shapiro et al. (2003) provide a detailed description of the patients that chose to enroll in the demonstration.

The basic service package offered at demonstration locations was similar and is summarized in Table 3. All sites eliminated co-insurance and deductibles on services and offered coverage for prescription drugs, as well as provided nutritional supplements at no cost to the enrollee. Consistent with the CMS requirements, the sites offered extra benefits beyond the services offered in the traditional Medicare Program. The benefits were supposed to equal the additional 5 percent payment the sites were receiving above the 95 percent rates paid to regular Medicare-risk contractors. Beyond the nutritional supplements and health education services, the additional services offered at each site were different. Kaiser covered dental services, and eye care; and HOI provided transportation to dialysis, home health services, and a rehabilitation program. Xantus covered home visits and educational seminars and videotapes.

Kaiser Enrollment and Marketing

Kaiser used a two-pronged marketing approach to attract patients to the demonstration. First, Kaiser contacted patients directly to publicize the demonstration and highlight the enhanced benefits and services they expected to be attractive to patients. Second, they expanded provider contracting arrangements in order to expand the pool of beneficiaries who might be eligible to enroll in the demonstration without having to change nephrologists. For all marketing activities Kaiser developed materials that included brochures,

letters, open houses, and videos. In actuality, most of their marketing focused on patients, reflecting in part the provider community's ambivalence toward the demonstration caused by concern that patients who joined the demonstration would remain Kaiser patients at the conclusion of the program. Kaiser's marketing to patients was seen as essential in order to counteract these attitudes by the non-Kaiser provider community. As a result of this intense outreach, marketing costs for the demonstration were significantly higher than anticipated (Dykstra et al., 2003).

Enrollment processes were in place by the time the first patients joined the demonstration. To facilitate enrollment and data collection, Kaiser had established a database to track the enrollment issues that influenced ESRD patients' willingness and ability to participate in the demonstration. However, Kaiser reported that there was a 45- to 60-day gap between the submission of the enrollment application and the start of service delivery. Much of this delay was caused by the process of eligibility screening with CMS, as it was difficult to determine when patients did not pay their Part B premiums, and therefore lost eligibility for the demonstration.

Enrollment of rollover patients—ESRD patients already in Kaiser's existing managed care plan that were otherwise eligible for the demonstration—occurred once a CMS-set minimum number of patients new to Kaiser through the demonstration program had enrolled. Kaiser sent a letter to its ESRD patients explaining the demonstration to them and offering them participation. For every two new demonstration patients Kaiser enrolled, it was allowed to enroll one rollover patient.

Kaiser's administrators reported the impression that patients enrolled in the demonstration primarily for financial reasons. Patients without supplemental insurance and those who had recently lost their insurance were both likely to enroll in the demonstration. Medi-Cal (California's Medicaid Program) patients who had a cost share also saw some cost savings by joining the demonstration, although Medi-Cal patients with no cost share tended not to enroll. As the demonstration proceeded, Kaiser reported that a reputation for high quality of care became a factor in patients' reported decisions to enroll.

Kaiser was concerned about the initial enrollment, which was lower than expected. Discussions with patients and providers revealed three main concerns about enrolling in the demonstration: (1) what would happen to patients at the end of the demonstration; (2) concerns about participating in managed care, and (3) a lack of knowledge about the demonstration among providers. Kaiser implemented several steps to address patient concerns. These activities included developing additional contracts with nephrologists that allowed patients to enroll in the demonstration without changing providers, paying CMS to send out additional mailings to patients; distributing informational materials to dialysis units, working with facility social workers to encourage demonstration referrals, and speeding up the contacting of rollover patients by using electronic files to track enrollment. These initiatives to boost enrollment were successful. By the end of the demonstration Kaiser had enrolled 1,649 patients, 50 (3 percent) of whom disenrolled (including patients who left the service area) before the end of the demonstration, and another 243 died while in the demonstration. Table 4 provides demographic characteristics by modality for the sample of Kaiser's enrollees included in the data collection effort for evaluation.

Table 3

Services and Benefits Covered Beyond Medicare for the ESRD Managed Care Demonstration Sites: 1998-2001

Service/Benefit	Kaiser[1]	HOI[2]	Xantus[3]
Coinsurance and Deductibles	No copay for physician services (including physicals and immunizations), inpatient stays, skilled nursing facility (SNF) stay covered 100 days per period, emergency room services, therapies, home health, and lab tests.	No copay for physician services (including annual physical and access to preventive services).	$70 monthly premium (roughly equivalent to the monthly out-of-pocket coinsurance and deductibles paid by an average Medicare beneficiary). Medicaid would pay the premium for dually eligible patients. This premium was eliminated shortly after end stage renal disease (ESRD) demonstration startup.
Prescription Drug Benefit	No copay and no annual maximum.	No copay for prescription drugs and dialysis-related non-prescription drugs.	Up to $780 per year; $10 copay per prescription (copay was eliminated shortly after demonstration startup).
Nutritional Supplements	All renal-related vitamins, phosphate binders, iron supplementation and oral nutritional supplements provided free of charge; IDPN covered with approval for medical necessity.	Provided free of charge in the dialysis unit.	Selected nutritional supplements provided free of charge, delivered to dialysis unit or nephrologist's office.
Dental and Vision Care	Routine dental cleaning and exam twice a year at no charge, routine eye care with $60 eye glass frame allowance (lenses free of charge), no copay.	Not offered.	Not offered.
Transportation Benefit	Not offered.	Transport to and from dialysis if needed, as determined by the social worker and case manager.	Unlimited transportation to and from dialysis center and nephrologists' office, based on demonstrated need.
Health Education	Group and peer counseling, special health education classes, wellness programs specific to the ESRD population, provided free of charge.	Programs available on a wide variety of topics: diet, social support, renal disease management, care of vascular access, care of peritoneal access, diabetes management, and hypertension management.	Educational seminars and videotapes.
Rehabilitation Program	Not offered.	Participation in a program of exercise, occupational therapy, neurological rehabilitation, amputee rehabilitation, and referral to a renal employment program.	Not offered.

Refer to footnotes at end of the table.

Table 3—Continued

Services and Benefits Covered Beyond Medicare for the ESRD Managed Care Demonstration Sites: 1998-2001

Service/Benefit	Kaiser[1]	HOI[2]	Xantus[3]
Home Health Services	Nothing above Medicare covered services.	Made available for post-surgical followup for new or revised access sites, exit site catheter care, diabetic wound care, and other services as needed.	Home visits made available.
Out-of-Area Coverage [4]	Covered for up to 60 days per year out of plan.	Up to 30 days per year at an approved facility.	Full coverage of the benefits package when outside of the service area, subject to the health plan's and CMS' definitions of emergency and urgently needed services.

[1] Kaiser Permanente Southern California Region, Los Angeles, California.

[2] Health Options, Inc., a subsidiary of Blue Cross® /Blue Shield®, based in Miami, Florida.

[3] Xantus Health Care Corporation, based in Nashville, Tennessee.

[4] During the time period of the demonstration, coverage for out-of-area dialysis became a benefit that Medicare-risk plans were required to provide.

NOTES: ESRD is end stage renal disease. IDPN is intradialytic parenteral nutrition. CMS is Centers for Medicare & Medicaid Services.

SOURCES: Oppenheimer, C. C., and Gaylin, D.S., National Opinion Research Center, Shapiro, J. R., Centers for Medicare & Medicaid Services, Beronja, N., The Lewin Group, Dykstra, D. M., and Held, P.J., University Renal Research and Education Association, and Rubin, R. J., Georgetown University School of Medicine, 2003.

Table 4

Selected Characteristics for a Sample of Kaiser Permanente Southern California Region ESRD Managed Care Demonstration Patients: 1999

Characteristic	Peritoneal Dialysis	Transplant	Hemodialysis Rollover	Hemodialysis Active
Sample Size	82	62	211	470
Mean Age (Years)	49.4	47.6	61.6	56.2
			Percent	
Other than White	48.8	31.1	41.4	38.0
Hispanic or Latino	17.1	30.6	20.9	29.8
Male	52.4	48.4	57.3	64.4
Cause of ESRD				
Diabetes	24.4	22.6	39.8	39.1
Glomerulonephritis	18.3	17.7	8.1	11.1
Hypertension	22.0	27.4	22.7	23.8
Other	12.2	9.7	8.1	11.5
Unknown/Missing	23.4	22.6	21.3	14.5

NOTES: ESRD is end stage renal disease. Hemodialysis Rollover patients were receiving care from Kaiser prior to the demonstration. Hemodialysis Active patients were newly enrolled in the Kaiser program.

SOURCES: Oppenheimer, C. C., and Gaylin, D.S., National Opinion Research Center, Shapiro, J. R., Centers for Medicare & Medicaid Services, Beronja, N., The Lewin Group, Dykstra, D. M., and Held, P.J., University Renal Research and Education Association, and Rubin, R. J., Georgetown University School of Medicine, 2003.

HOI Enrollment and Marketing

HOI selected the target areas of Dade, Broward, and Palm Beach counties because of the size of the patient population in these counties, as well as the population's racial and socioeconomic diversity. HOI's marketing approach was based on educating nephrologists in the area about the potential benefits of the demonstration, and it was hoped that nephrologists, in turn, would encourage their patients to enroll. HOI utilized a dedicated sales force to market the demonstration to providers and patients in the service area. This educational outreach was based on networking among physicians, direct mailing to providers, and in-person meetings with groups of providers. In addition to efforts aimed at nephrologists, HOI launched educational meetings with potential patients and marketed the program through the Florida ESRD patient newsletter.

At the start of the demonstration, HOI modeled its enrollment processes for the demonstration on its existing programs. Specifically, enrollment was handled by HOI's telemarketing unit, which was experienced in managed care. Additional training was provided to staff to ensure that they were prepared to handle demonstration-related issues.

HOI developed three mailings to send to all ESRD beneficiaries residing in the service area. The primary enrollment collection instruments were an enrollment form and a toll-free enrollment line. The enrollment process was highly focused on providing personal attention; for instance, followup calls were provided even after a patient enrolled.

HOI changed its enrollment process to counter problems that arose and to make the process run more smoothly. At the start of the demonstration, outdated criteria used by CMS to determine patient eligibility resulted in the initial rejection of many eligible patients who wanted to enroll in the demonstration. HOI responded to this problem by working with CMS' regional and national offices on streamlining the eligibility determination process, which, although successful in terms of streamlining the enrollment process, caused HOI to expend more resources than had expected.

At the beginning of the demonstration, HOI enrolled patients based on self-reported Medicare eligibility. However, they found that some of these patients were determined by CMS to be ineligible for the program. In order to minimize financial

Table 5

Selected Characteristics for a Sample of Health Options, Inc., ESRD Managed Care Demonstration Patients: 1999

Characteristic	Peritoneal Dialysis	Transplant	Hemodialysis
Sample Size	27	13	594
Mean Age (Years)	51.9	45.3	60.4
		Percent	
Other than White	29.6	45.5	48.1
Hispanic or Latino	11.1	7.7	24.8
Male	48.1	84.6	62.5
Cause of ESRD			
Diabetes	14.8	15.4	31.6
Glomerulonephritis	11.1	15.4	10.6
Hypertension	25.9	15.4	24.8
Other	7.4	7.7	8.2
Unknown/Missing	40.7	46.2	24.8

NOTE: ESRD is end stage renal disease.

SOURCES: Oppenheimer, C. C., and Gaylin, D.S., National Opinion Research Center, Shapiro, J. R., Centers for Medicare & Medicaid Services, Beronja, N., The Lewin Group, Dykstra, D. M., and Held, P.J., University Renal Research and Education Association, and Rubin, R. J., Georgetown University School of Medicine, 2003.

risk, HOI began enrolling patients only after their eligibility status had been verified through Medicare and the patient was determined to be in the CMS data system.

Similar to Kaiser, initial enrollment at HOI was also slower than anticipated. Patients cited the following reasons for not wanting to join the demonstration: (1) not wanting to change physician or dialysis unit, (2) fear of managed care and participating in a demonstration project, (3) physicians' active discouragement against joining, (4) concern about giving up supplemental health insurance, and (5) questions about insurance coverage after the demonstration ended. HOI addressed some of these patient concerns early in the enrollment process. For instance, they addressed questions about supplemental insurance by telling patients to keep their supplemental insurance for a few months in case they did not like the demonstration and wanted to disenroll. HOI also worked on options to guarantee supplemental insurance through Florida Blue Cross®/Blue Shield® for patients who disenrolled at the end of the demonstration.

In response to patient concerns about the distance to the transplant center in Jacksonville, HOI implemented a program to have the hospital transplant surgeon regularly visit the Miami region. The care managers also discussed patients' concerns about what was to happen at the end of the demonstration and assured patients that they would be able to enroll in HOI after the demonstration concluded.

In November 2000, HOI closed its enrollment period for new patients as part of the wind-down process of the demonstration. They enrolled 967 patients in the demonstration program, 118 (12 percent) of whom disenrolled (including patients that moved out of the service area), and another 170 died while in the demonstration. Table 5 provides demographic characteristics by modality for the sample of HOI enrollees included in the data collection for the evaluation.

Xantus Enrollment and Marketing

Initially, Xantus marketed the demonstration program through multiple direct mailings to eligible patients. In addition, Xantus representatives set up information booths at dialysis centers to promote enrollment in the demonstration. Xantus began service delivery in September 1998. In the first 8 months of the program, Xantus enrolled a total of 26 patients in the restricted five-county service area. Although

demonstration managers were optimistic about expanding into a larger service area, they experienced significant delays in obtaining an expanded Medicare-risk contract. In order to increase enrollment, the demonstration site eliminated the $70 monthly premium and the copayments for prescriptions. The site believed that these changes positively affected enrollment levels. By the time enrollment at the Xantus demonstration site was frozen in November 1999, a total of 50 patients had enrolled in the program.

IMPLICATIONS FOR FUTURE ESRD MANAGED CARE PROGRAMS

In assessing what can be learned from the demonstration experiences, in terms of operational outcomes, that may be relevant for future organizations, three questions can be explored:

- Can MCOs create relationships with nephrologists and dialysis facilities that are clinically, fiscally, and logistically feasible and enticing?
- Is managed care attractive to ESRD patients?
- Can the MCOs succeed financially?

Each of the demonstration sites faced challenges contracting with providers, and the underlying issues are likely to be faced again should MCOs be allowed to develop managed care programs for ESRD patients in the near future. Kaiser faced negative attitudes initially about the demonstration by community physicians and dialysis facilities, and HOI and Xantus experienced difficult, and ultimately unresolvable, negotiations with the providers they expected to contract with for significant service lines.

Kaiser Demonstration Challenge

Relationship with Providers

During the initial stages of the demonstration, reaction to the demonstration program from the non-Kaiser provider community, including both physicians and dialysis units, was fairly negative. Both nephrologists and facilities were concerned that Kaiser would use the demonstration to expand its market share resulting in a loss in revenue for both categories of providers. At the time of demonstration startup, the non-Kaiser dialysis units were particularly concerned because of Kaiser's partnership with Fresenius in which Kaiser opened new dialysis facilities. Non-Kaiser nephrologists were also concerned about disruptions in the continuity of care due to difficulty communicating routine patient updates with Kaiser nephrologists.

Nevertheless, both nephrologists and facilities acknowledged to the evaluation team Kaiser's reputation for providing high-quality care and reported that they would maintain a neutral stance about the demonstration when asked by their patients for advice about participating in the demonstration. However, according to Pifer et al. (2003), compared to HOI, a lower proportion of Kaiser patients reported that they enrolled in the demonstration on the recommendation of their physician.

Over time, community nephrologists and contract dialysis units exhibited a more positive attitude toward the demonstration. In interviews conducted by the evaluation team, providers reported that Kaiser made substantial efforts in their communications with community providers,

including involving community providers in demonstration service delivery-related issues through special committees and the provision of quality monitoring reports. Kaiser care managers also made efforts to strengthen relationships with the community providers. Further, comfort with Kaiser increased on the part of contracted providers when providers did not experience a substantial decline in patient volume due to enrollment in the demonstration.

HOI Demonstration Challenge

Contracting with a Transplant Provider

At the time that HOI submitted its proposal to CMS for the demonstration, the HMO had a tentative agreement with Jackson Memorial Hospital in Miami to provide transplant services. However, subsequent contract negotiations, which lasted more than a year, proved exceedingly difficult and ultimately the two organizations could not come to a financial agreement. The failure to contract with the only transplant center local to the demonstration counties forced HOI to contract with Jacksonville Methodist Hospital, 300 miles away.[8] Nephrologists expressed concern that most patients would not be willing to travel to Jacksonville for a transplant.

To address the issue of distance between the contracted transplant center and demonstration enrollees, halfway through the demonstration HOI arranged for the transplant surgeon to spend time each month in Miami to conduct pre-transplant workups. The clinical consequences of this arrangement are currently being analyzed. It is reasonable to assume that this aspect of the demonstration program affected HOI's patient recruitment to the demonstration, and possibly patient satisfaction as well. HOI experienced a larger number of disenrollees from the demonstration than did Kaiser. Many metropolitan areas have a single transplant center, which may put some MCPs at a disadvantage in negotiating for services that meet geographic proximity requirements.

[8] HOI's contract with Jacksonville Methodist Hospital to provide transplant services required approval by CMS. Future analyses will investigate access to transplantation in the demonstration.

Xantus Demonstration Challenge

Contracting with Nephrologists

The Xantus demonstration plan as proposed to CMS was based on a partnership with and model of care institutionalized by the largest single nephrology practice in the region representing more than 60 percent of patients and 75 percent of nephrologists. Shortly after winning the demonstration contract, difficult negotiations resulted in dissolution of the partnership between the two groups. This change required Xantus to remodel their demonstration program.

One key change was that Xantus established contracts with all nephrologists in the service region instead of just nephrologists in the large nephrology group practice. Thus, the program looked more like a network model than originally anticipated (the original plan looked more like a hybrid between staff model for nephrology, case management, and primary care services, and network model for other services). Another change was that Xantus hired case managers (originally it was planned that the case managers would be hired, managed, and compensated by the large nephrology group practice). This arrangement failed to create the hoped-for close, day-to-day working relationship between the case manager and nephrologists. It was also originally planned that the group practice would hire social workers and dieticians; instead, demonstration

patients were required to access such services in the traditional manner through their dialysis facility. Finally, with the loss of the partnership with the large group practice, the site lost much of its management-level ESRD expertise and its primary planned referral source (the group practice had over 600 patients and Xantus assumed that most of these patients would enroll at the encouragement of their physician).

Two additional issues significantly affected Xantus' ability to maintain a demonstration program. The first was the requirement that Xantus obtain a Medicare-risk contract, and the second was the financial health of the larger Xantus Corporation. Xantus won the demonstration contract prior to obtaining a Medicare-risk contract. Only after the award was made and the contract was signed did CMS clarify that Xantus needed to acquire such a contract in order to provide demonstration services. Therefore, before Xantus could begin providing demonstration services, it was necessary for the plan to invest considerable resources and time into obtaining the Medicare-risk contract. One outcome of this effort was that Xantus was able to obtain their risk contract for a service region of only five counties as opposed to the 40 county region proposed for the demonstration. Thus, the demonstration was also limited to operating in the five-county area. This change reduced the estimated eligible number of demonstration patients from 1,400 to 842.

The Xantus demonstration program was able to develop a new network of physicians and succeeded in obtaining the required Medicare-risk contract, however, due to financial difficulties in the organization's other business lines, Tennessee placed Xantus, as a whole, under receivership, and CMS placed a freeze on ESRD demonstration enrollment effective November 1, 1999. By mutual agreement between Xantus and CMS, the demonstration at this site was discontinued as of April 1, 2000. The residual 44 demonstration enrollees were notified March 1, 2000, and received assistance from Xantus staff, dialysis facility social workers, State Department of Commerce and Insurance staff, the ESRD network, and the CMS regional office in obtaining secondary coverage to supplement Medicare.

WILL ESRD PATIENTS ENROLL IN MANAGED CARE?

One goal in conducting the demonstration evaluation was to determine whether ESRD patients are willing to participate in managed care and whether enrolling patients are representative of the underlying population. The two sites that completed the demonstration proved that ESRD patients are indeed willing to trade some freedom of choice in health care for increased access to pharmaceuticals and reduced copayments. For a separate presentation and discussion of the patient characteristics willing to enroll in the demonstration, refer to Shapiro et al.(2003). As shown, patients who enrolled in this demonstration were not representative of the typical ESRD patient; they tended to be younger and healthier. Additionally, demonstration disenrollees spent more time in the hospital during the program compared to continuous enrollees, indicating that selection effects continued to appear even after initial enrollment. Another evaluation finding was that patient satisfaction with the demonstration was generally quite high (Pifer et al., 2003). It is worth noting that HOI, using the network model, appeared to have an easier time recruiting patients than Kaiser during the early days of the demonstration, which

may have been related to the level of encouragement patients in each location received from their providers (Pifer, 2003).

While Xantus' limited enrollment of patients was due to numerous factors, one factor that was seen to influence enrollment was the preponderance of dually-eligible patients (i.e., eligible for both Medicaid and Medicare) in the region (estimated by Xantus to be about 50 percent of ESRD patients). TennCare (Tennessee Medicaid Program) benefits were quite comprehensive—TennCare beneficiaries with ESRD received unlimited prescription benefits; were able to apply for a transportation benefit; and were not required to pay copayments. Thus, many eligible patients lacked any real incentive for joining the program.

LESSONS LEARNED

This demonstration can be considered a success in that two sites were able to implement managed care programs for ESRD patients. Although Xantus faced significant hurdles developing its demonstration program, it was ultimately undone by factors unrelated to the demonstration, and thus its failure should not diminish the accomplishments of CMS, Kaiser, and HOI in executing this initiative. In generalizing Kaiser's and HOI's experiences, it should be noted that if managed care becomes an option in the Medicare ESRD program, then there are far more network model HMOs than there are closed group models. HOI's program of managed care for ESRD patients was created specifically for the demonstration. Thus, HOI's approach and experiences are possibly more relevant to other potential programs than the program at Kaiser.

Many aspects of the service package were similar between the sites. In other ways, the programs were structured in very different ways. Again, the most notable difference is that Kaiser is a group model HMO with a closed delivery system, while HOI was a network model HMO. This distinction had implications beyond the way providers were paid—it likely affected the degree of control that the HMOs exercised over provider practices. Kaiser tried to actively influence provider practices, thereby instituting what might be called a disease management program. Examples include Kaiser's move to subcutaneous EPO, its aggressive vascular access program, and its protocol for primary care physician nephrologists and other caregivers to perform quarterly preventive checkups for all patients. In contrast, HOI exerted little effort to influence provider practices. Although HOI's structure certainly did not prohibit it from pursuing such management approaches, it is likely that due to the exclusive relationship between Kaiser and its nephrologists, Kaiser had an easier time influencing behavior change among providers.

Other factors unrelated to the demonstration program structure also shaped the demonstration plans' experiences. These include the sites' previous experience with ESRD patients, relative size, and their relationships with providers.

A major criterion by which to evaluate the feasibility of implementing a managed care option in Medicare ESRD is whether providing such care is financially feasible for the sponsoring organization. From the perspective of the demonstration sites, the initiative did not produce a financial windfall for either Kaiser or HOI. The capitation revenues received by HOI did not cover

total demonstration expenses in any year of the demonstration. Kaiser experienced a net loss during the first year of the program and very modest net income (2 percent or less) in the final 2 years of the demonstration (Dykstra et al., 2003). The demonstration differs significantly from what might occur if the barrier to managed care for ESRD patients is lifted in that they would likely be integrated into traditional Medicare+Choice programs rather than enroll in stand-alone ESRD managed care programs, thus reducing the financial impact of this population on a given HMO. Nevertheless, some stand-alone ESRD disease management programs have been developed. We raise the issue here to acknowledge the importance of the financial outcomes from the plans' perspectives on the future of manage care in the ESRD market. However, it is worth noting that both Kaiser and HOI received authorization from CMS to receive a capitated payment for demonstration patients based on the demonstration rates. This arrangement allows both sites to continue providing most of the demonstration benefits to enrollees and is intended to serve as a bridge to the new BIPA-mandated ESRD risk-adjusted capitation rates (Centers for Medicare & Medicaid Services, 2003b).

Developing and implementing a demonstration program of this magnitude requires a great deal of resources and commitment on the part of the demonstrations sites and the sponsoring organization. The demonstration outcomes, viewed in the context of the structural and operational arrangements described in this article, provide a strong foundation for CMS, Congress, and the broader ESRD community to rely upon as they consider the full range of policy options regarding ESRD patient (and provider) participation in managed care programs.

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