Final Report on the Evaluation of CMS's ESRD Managed Care Demonstration

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EXECUTIVE SUMMARY

Introduction and Background

Overview of Medicare's End-Stage Renal Disease Program

Individuals experience end-stage renal disease (ESRD), or total kidney failure, if both kidneys stop functioning. Because the kidneys perform so many critical functions, people whose kidneys fail face a life-threatening condition. Kidney failure means that the body can no longer rid itself of certain toxins and cannot properly regulate blood pressure and critical nutrients. Unless those experiencing kidney failure are treated, they can die within days due to the build-up of toxins and fluid in their blood. Treatment options are generally limited to dialysis, which artificially replaces the functions of the kidney, or kidney transplantation. Almost two-thirds (63 percent) of ESRD patients utilize in-center hemodialysis for therapy.[1] Even on dialysis, the health status of ESRD patients is diminished: the average hemodialysis patient spends approximately 14 days in the hospital and is prescribed about 8 medications per year.

The Medicare ESRD program was begun in 1972 with the goal of providing short-term life-saving treatment for a small number of critically ill patients. All persons with ESRD, subject to minimal social security requirements, are eligible for Medicare regardless of age. From an initial count of about 7,000 patients in the first year to 340,261 in 1999[2], the ESRD program exceeded expectations in terms of program size and budget. The economic consequences of this growing population are significant. For example, year-at-risk spending* on hemodialysis and associated care is more than $65,000 per patient annually.[3]

Purpose of the Demonstration and Evaluation

Under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Medicare ESRD beneficiaries are not permitted to enroll in HMOs unless they were enrolled in an HMO prior to the onset of ESRD. The Omnibus Budget Reconciliation Act of 1993, as one of the modifications in the Social HMO (SHMO) section, required the Centers for Medicare and Medicaid Services (CMS—then the Health Care Financing Administration) to conduct a managed care Demonstration project for end-stage renal disease patients. In 1996 CMS launched the ESRD Managed Care Demonstration to study the experience of offering a managed care option to ESRD patients. The intent was to see whether extension of an integrated system of care to ESRD beneficiaries was operationally feasible, efficient, and able to produce outcomes comparable to the current, fee-for-service (FFS) system.

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.

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* Includes spending by Medicare as well as other payors.

- 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 fee-for-service and the current capitation payment for ESRD patients in HMOs (see below for details on payment under the Demonstration).

Simultaneously, an evaluation of the program was undertaken to assess the efficacy and cost of HMO participation for Medicare beneficiaries with ESRD, with a comparison of the structure, process, and outcomes for patients enrolled in the Demonstration sites, with a similar set of ESRD patients in the fee-for-service sector. The evaluation addressed a wide range of research questions, including:

- Are there differences in baseline patient characteristics, including health status, between ESRD beneficiaries who choose to enroll into the Demonstration and those who do not enroll?
- Do mortality rates for the Demonstration enrollees differ from those of other ESRD beneficiaries in the fee-for-service sector?
- Do hospitalization rates differ for Demonstration enrollees and fee-for-service beneficiaries with ESRD?
- Are there differences in transplantation rates between the Demonstration enrollees and other ESRD beneficiaries?
- How do vascular access[†] outcomes differ between the Demonstration enrollees and fee-for-service beneficiaries?
- How do Demonstration enrollees and fee-for-service beneficiaries differ with respect to nutritional status, patient satisfaction, functional and health status, and quality of life?
- How do Demonstration enrollees and non-Demonstration managed care beneficiaries differ with respect to patient satisfaction and quality of life?
- To what extent do the HMOs provide care that is consistent with accepted standards of practice, such as meeting dialysis adequacy targets?

Payment Under the Demonstration

Traditional payments to Medicare risk contractors for ESRD patients differ from other Medicare capitation rates paid to Medicare risk contractors. Because ESRD beneficiaries comprise less than one percent of the Medicare population, individual cell sizes are too small to permit ESRD

[†] Vascular access is the site on the body where blood is removed and returned during dialysis.

rates to be set on a county-specific basis. Further, the flat, state-wide ESRD capitation rates are not risk-adjusted for age, sex, severity, or any other factor.

Like the traditional ESRD payment rates, Demonstration payment rates were based on state-wide average costs for ESRD patients (although costs of patients with Medicare as secondary payor were excluded since patients with a primary payor other than Medicare were not eligible to enroll in the Demonstration). However, because research has shown that there is significant heterogeneity in ESRD beneficiaries' health status, a key component of the Demonstration was to test the impact of risk-adjusted ESRD capitation rates versus the historic *single* state-specific capitation rate.

Under the Demonstration, costs for ESRD beneficiaries were partitioned into three discrete treatment status categories (due to the variation in costs associated with each mode of treatment):

- Medicare costs during a period of maintenance dialysis;
- Medicare costs associated with a transplant episode (defined as the month prior to, the month of, and the month following the transplant); or
- Medicare costs during a post-transplant period in which the beneficiary had a functioning kidney allograft.

A separate transplant rate cell was established because the up-front costs of transplantation are very high, and it takes a number of years for the transplant to "pay for itself" in lower functioning graft costs. Thus, there was some concern that a single, unadjusted payment rate might provide a disincentive for HMOs to provide transplants. The temporary, three-month transplant rate cell was intended to make the transplantation payment revenue neutral from the perspective of the managed care organization.

For the dialysis and functioning graft cells, rates were further adjusted for three age categories (under 20, 20-64, and 65 and over) and whether or not diabetes was the primary cause of the renal disease, as these are key drivers of expenditures in ESRD. The transplant rate cell was not so adjusted, since age and diabetes were not thought to be predictive of transplant costs.

Finally, because the ESRD managed care Demonstration was authorized through inclusion in the SHMO legislation, the development of the initial capitation rates under the Demonstration was based on 100 percent of the ESRD state-wide rates, rather than 95 percent of fee-for-service costs that had historically been paid to Medicare risk contractors. The Demonstration sites were required to provide additional services to justify the extra 5 percent payment. Subsequently, the Demonstration rates were updated annually based on the Medicare+Choice update factors (typically about 2 percent).

The Demonstration Sites

The Medicare ESRD Demonstration project was begun at three sites across the country: Health Options, Inc. (HOI), a subsidiary of Blue Cross/Blue Shield of Florida, based in Miami; Kaiser Permanente Southern California Region (Kaiser), based in Los Angeles; and Xantus Health Care Corporation, based in Nashville, Tennessee. The Demonstration was initiated in September

1996 and the sites began enrolling patients in 1998. Only the Kaiser (California) and HOI (Florida) sites remained operational for the duration of the Demonstration, which stopped enrolling new patients in early 2001. By that time, Kaiser had enrolled a total of 1,649 beneficiaries and HOI had enrolled a total of 967 beneficiaries (including, for both sites, those who later disenrolled or died). Xantus (Tennessee) terminated its Demonstration program in early 2000 due to financial difficulties experienced in its other operating units, having enrolled only 50 ESRD beneficiaries.

The two remaining Demonstration plans offered distinct models of care (Exhibit ES-1). The Florida site had primarily fee-based contracts with the majority of their providers, with the exception of capitation arrangements made with primary care nephrologists and select specialists. The Kaiser Demonstration plan was a closed-practice plan for specialist and inpatient care, with the majority of outpatient dialysis services provided under fee-based provider contracts (although over the course of the Demonstration, Kaiser "internalized" much of their dialysis care). In addition, while the Florida site had very few ESRD patients in their health plan prior to the Demonstration, the California site had about 2,000 ESRD patients in their regular Medicare risk plan at the outset. Kaiser was able to "rollover" some of their existing ESRD patients into their Demonstration program.‡

The plans offered similar benefit packages to patients. Both plans offered outpatient medications included in their formulary at no cost to patients, and provided all medical care with no patient co-insurance obligations. Co-payments were waived as part of the "extra benefits" offered, over and above the benefits offered in the standard Medicare Risk HMO, which were intended to equal the additional 5 percent of the AAPCC that the Demonstration health plans were reimbursed under the SHMO legislation. In contrast, standard FFS Medicare does not generally cover outpatient medications and typically has a 20 percent patient obligation for nearly all outpatient medical services and a substantial deductible for hospitalization services.

The Demonstration sites were required by CMS to have year-round open enrollment for eligible ESRD patients who were served in the fee-for-service system, including both dialysis patients and those with functioning grafts who were still ESRD-eligible (i.e., within three years of transplant). The Demonstration sites were also required to undertake active efforts to publicize the potential for Demonstration enrollment to all ESRD patients in the service area and were required to attempt to enroll at least 600 patients. Essential components of the Demonstration included: service integration, case management, use of clinical protocols, and provision of extra benefits. Exhibit ES-1 summarizes key structural and operational characteristics of the three Demonstration programs, Kaiser Permanente, Health Options, Inc., and Xantus HealthCare.

The remainder of this Executive Summary presents methods, results, and a discussion of the evaluation of the ESRD Managed Care Demonstration project.

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‡ CMS allowed Kaiser to offer the Demonstration to these current Kaiser patients at a rate of 2 new patients to 1 rollover patient.

Exhibit ES-1: Summary of Key Demonstration Characteristics

Feature	Kaiser Permanente	HOI	Xantus
Primary HMO Model	*Group HMO*	*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*
Premium and Co-pay Amounts	*None*	*None*	*$70 monthly premium and $10 co-pays (both eliminated shortly after start-up).*
Outpatient Dialysis Treatments and Ancillaries	*Mostly contracted facilities. Negotiated fee-for-service: Kaiser and contracted facilities.*	*All contracted facilities. FFS comparable to 100% of Medicare allowable charge.*	*All contracted facilities. All-inclusive per treatment rate comparable to 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 nephrologist in unit, Kaiser nephrologist 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 nephrologist on salary, risk adj. cap rates for contract nephrologist*	*One capitated rate for out and inpatient care.*	*Comprehensive capitation.*
Use of Case Managers & Team make-up	*Case Managers: Yes. Team: MD, RN, MSW, RD, Pharmacist, specialists.*	*Case Managers: Yes. Team: MD, RN, MSW, RD, Pharmacist, specialists.*	*Case Managers: Yes. Team: MD, RN, MSW, RD.*
Outpatient Drugs	*Formulary covered at Kaiser pharmacies.*	*Formulary covered at participating pharmacies.*	*Up to $780 per year, $10 co-pay per prescription.*
"Extra 5 %" beyond services covered for regular Medicare risk enrollees	*Nutritional supplements, no co-pays (on visits & drugs), dental, counseling.*	*Nutritional supplements, no co-pays, dental, transportation, rehab, expanded formulary.*	*Nutritional supplements, preventive services, transportation.*
Other Services	*Durable medical equipment w/ no co-pay, vision, out-of-area coverage.*	*Home health services, dialysis in nursing home, home dialysis, out of network dialysis, health education.*	*Home visits, educational seminars, educational videotapes.*
End Date of Data Collection	*August 2000 (manual); September 2001 (electronic)*	*August 2000 (manual); September 2001 (electronic)*	*January 2000 (manual)*

Evaluation Methods

A summary of evaluation methods is described here. A more detailed exposition of methods, comparison samples, and analytic techniques can be found in the Methods Appendix and in individual chapters of this report.

The evaluation entailed collection of patient-level clinical, outcomes, and quality-of-life data as well as plan-level financial data. Of key importance in this type of evaluation is to define appropriate comparison groups. In this case, we endeavored to compare the experiences of Demonstration patients with the experiences of the general, underlying ESRD population to identify any differences that could be attributed to the Demonstration. This comparison served two purposes: first, it enabled us to determine whether the group of patients who chose to enroll in the Demonstration were representative of the general ESRD population. Secondly, as a result, we were able to account for these differences in our analyses and thus more accurately interpret other evaluation findings, such as those on mortality or hospitalization. Thus, three separate patient populations were compared to the Demonstration patients. These included a nationally representative sample of hemodialysis patients from the Dialysis Outcomes and Practice Patterns Study (DOPPS)[4], and two matched samples of comparison patients:

Nationally Representative DOPPS Patients. Demonstration hemodialysis patients were compared to a nationally representative sample of US in-center adult hemodialysis patients from the Dialysis Outcomes and Practice Patterns Study. To increase sample size for focused geographic comparison analyses we broadened our selection of DOPPS patients from the Demo service areas to include those residing anywhere within CA or FL.

Matched Geographic Comparison Patients. In addition to the DOPPS, matched samples of fee-for-service and non-Demonstration Managed Care (NDMC) (i.e., Medicare Risk HMO) patients were also randomly selected from Demonstration service area dialysis facilities for comparison to the Demonstration patients. The FFS and NDMC patients were matched to the Demonstration patients according to their distributions of age, race, and time since onset of ESRD in order to optimize statistical power for a smaller sample of patients. These two matched comparison patient groups were compared to the Demonstration patients with respect to their baseline characteristics, quality of life, satisfaction with care, and other specific factors.

All comparative analyses presented within this report include hemodialysis patients from the Demonstration exclusively, for the purpose of comparison to other representative patient samples. The vast majority of Demonstration enrollees at both sites were hemodialysis patients (Exhibit ES-2).

Exhibit ES-2: Demonstration Enrollees by HMO Site and Modality at Time of Enrollment

Modality	Kaiser Permanente (%)	HOI (%)
Hemodialysis	82	93
Peritoneal Dialysis	10	5
Functioning Transplant	8	2

Data collection strategies included medical record abstractions, in-person interviews, and electronic data transfers from the Demonstration organizations. Three data collection instruments were developed by the evaluators, which borrowed liberally from the questionnaires developed for the DOPPS. Included were a clinical assessment form (CAF) for recording data from the medical record, a patient questionnaire (PQ) for assessing patient satisfaction and quality of life, and a termination form (TF) for recording the date and reason for departure from the Demonstration. The CAF and PQ were also obtained from the matched FFS and NDMC comparison patients. These instruments were used to collect both baseline and longitudinal data. Additionally, utilization and financial data from both Demonstration sites were received electronically on a periodic basis. Data for the analysis on access to transplant were obtained from the Organ Procurement and Transplantation Network (Health Resources and Services Administration, DHHS).

A wide variety of statistical analysis techniques were used to analyze the data, including multivariable regression models to control for differences in case mix between the Demonstration enrollees and comparison groups. All statistical analyses were performed with SAS version 8.0.[5] Unless specified, all results presented are statistically significant at the $p<0.05$ level.

Results

This section presents findings from the evaluation of the ESRD Managed Care Demonstration. Our presentation of the results is organized by topic area:

- **Enrollment Experience**
  - *Managed Care Penetration Rates and Trends.* HMO penetration rates (enrollees divided by eligibles) indicate the uptake of the managed care option, and if traced over time, can indicate potential growth of the market for HMO services. We calculated penetration rates for each Demonstration site overall and by age, race, sex, modality, and income level.
  - *Patient Selection.* Analyses on patient selection investigated the degree to which patients who chose to join the Demonstration were representative of the ESRD population as a whole.
- **Clinical Outcomes and Indicators**
  - *Mortality*. Almost one quarter of hemodialysis patients in the U.S. die each year.[6] Research is continually being done to determine which factors are associated with this large mortality rate. Analyses on mortality conducted as part of this evaluation compared the mortality of patients enrolled in the Demonstration to the experience of patients in the fee-for-service system.
  - *Hospitalization.* Hospitalization is a major source of patient morbidity and economic costs, with inpatient costs comprising nearly 40 percent of total spending for dialysis patients.[7] A major question for the evaluation was whether Demonstration patient hospitalization after one-year follow-up was similar to their pre-Demonstration

hospitalization experiences, and how the hospitalization rates for these patients compared to those of a nationally representative comparison sample.

- *Anemia Management and Dialysis Adequacy.* Healthy kidneys produce a hormone called erythropoietin, or EPO, which stimulates the bone marrow to make red blood cells, needed to carry oxygen (O_2) throughout the body. Anemia, which results when patients experience a deficiency in red blood cells, is therefore common among patients with kidney disease. Anemia management is an important issue for hemodialysis patients because patients with hematocrit levels (a direct measure of anemia) of less than 30 percent have significantly higher risks of mortality (cardiac death, death due to infectious disease, or death from any cause)[8] and hospitalization.[9] Inadequate dialysis dose is also associated with higher risk of mortality. Both issues were investigated as part of this evaluation by comparing patients enrolled in the Demonstration to the experience of patients in the fee-for-service system.

- *Vascular Access.* Vascular access is the site on the body where blood is removed and returned during dialysis. Vascular access-related complications are an important cause of hospitalizations in patients undergoing maintenance hemodialysis. It has been estimated that 16 to 23 percent of dialysis patient hospitalizations are related to vascular access-related complications.[10] The most common problems associated with vascular access are stenosis (narrowing of graft/blood vessel), infection, and thrombosis (clotting). Outcomes such as access survival and the costs associated with care are affected by the choice of permanent vascular access.[11] (Two primary methods of access exist: an arteriovenous fistula, which directly connects an artery to a vein, and a graft, which uses a synthetic tube implanted under the skin.) For example, a properly formed fistula is less likely than other kinds of vascular access (e.g., grafts) to form clots or get infected. Also, fistulas tend to last many years, longer than any other kind of vascular access. We compared patients in the Demonstration to comparison samples of other hemodialysis patients with respect to vascular access outcomes.

- *Quality of Life.* In addition to its usefulness as a stand alone indicator, patient quality of life (QoL), as measured by the SF-36®, has been shown to predict morbidity, hospitalization, and mortality in dialysis patients.[12] We evaluated patient QoL in the Demonstration by: 1) comparing baseline QoL to a sample of representative hemodialysis patients from DOPPS and to matched Medicare FFS and Medicare managed care patients not enrolled in the Demonstration; and 2) assessing changes in QoL among Demonstration patients over time.

- *Transplant Access.* A fundamental issue for chronic dialysis patients is timely access to transplantation. A transplanted kidney, called a functioning graft, can provide patients with increased independence, a longer life, and substantially improve their overall quality of life. A major question regarding the Medicare Demonstration is whether patients who enrolled in the Demonstration had access to kidney transplantation that was comparable to other dialysis patients in the same geographic locations.

- *Patient Satisfaction with Access to Care and Plan Benefits.* It has been postulated that a managed care health plan can provide better and more comprehensive health care at a

lower cost.[13] However, it has also been stated that the main disadvantage of managed care plans can be the restrictive nature of their health care management approaches. Patients may be confined to a specific group of health care providers and a predetermined set of medical services. An important aspect of the evaluation was to assess patient satisfaction with the benefits and services provided by the Demonstration plans by comparing Demonstration patients to matched samples of Medicare fee-for-service and Medicare managed care patients not enrolled in the Demonstration.

- **Financial Analyses**
  - *Federal Spending under the Demonstration Compared to FFS*. We conducted analyses to assess how much CMS would have spent for Medicare services for Demonstration patients had they remained in FFS. We also assessed Federal Medicaid cost impacts, as well as the net Federal cost impact of the Demonstration.
  - *Financial Issues from the Patient Perspective.* The financial benefits to patients resulting from the Demonstration plans' coverage of Medicare co-insurance and deductibles and of outpatient drugs were the top two reasons patients reported for enrolling in the Demonstration. As part of our financial analysis of the Demonstration, we estimated the savings that accrued to patients as the result of such coverage.
  - *Financial Viability from Sites' Perspectives.* We investigated the degree to which the Demonstration sites experienced financial gains or losses under this program. Financial viability, or success, from the sites' perspectives may indicate whether managed care plans would be interested in participating with future Medicare managed care programs for ESRD patients.

Highlights of results for each topic area are summarized below.

Enrollment Experience

Managed Care Penetration Rates and Trends

HMO penetration rates (enrollees divided by eligibles) indicate the uptake of the managed care option, and, if traced over time, can indicate potential growth of the market for HMO services. To assess penetration rates and patterns under the Demo, we calculated penetration rates for each Demonstration site overall and by age, race, sex, modality, and income level. Kaiser Permanente achieved a penetration rate of 5.2% at the end of Year 2 if rollover patients are included in our calculation or 3.0% if rollover patients are excluded. Rollover patients are those patients who were Kaiser ESRD patients prior to the start of the Demo and who were later converted to the Demo. In contrast, without the benefit of any existing rollover enrollees, HOI achieved a penetration rate of 11.1% at the end of Year 2. Both Demonstration sites appear to have achieved rates at the end of Year 2 that are higher than regular Medicare managed care plans achieved after two years in an untapped market (i.e., no previous experience with managed care). Based on a county-level analysis of Medicare managed care penetration between 1993 and 1998 conducted by The Lewin Group, after one year counties with previously

untapped markets had penetration rates of about 0.4%. After two years these counties had rates of about 0.7%.

A review of penetration rates by age, race, sex, modality, and income level subgroups reveals numerous areas in which Demonstration enrollment was disproportionate to the distribution of characteristics among the eligible population. For instance, at the HOI Demonstration site, the penetration rate among hemodialysis patients was 15.5% whereas among peritoneal dialysis patients the rate was 9.2% and among functioning graft patients the rate was only 1.1%. Analyses also revealed that Demonstration penetration at both sites was somewhat higher in high-income areas; this may be partly explained by the comprehensiveness of Medicaid benefits available to low-income beneficiaries. Beneficiaries who were eligible for both Medicaid and Medicare would have had little financial incentive to join the Demo.

Patient Selection

This Demonstration, like many demonstrations, did not randomly assign patients to participate in the program; patients chose whether or not to enroll with one of the participating health plans. Consequently, a major evaluation task was to identify whether the set of patients who chose to enroll in the Demonstration were different from the general ESRD population in terms of demographics and co-morbid conditions that are associated with patient outcomes. In addition, the evaluation quantified how these differences affected clinical outcomes of the Demonstration. This Demonstration confirmed the expected result that patients who elected to participate in the program were not a random subset of all ESRD patients (Exhibit ES-3).

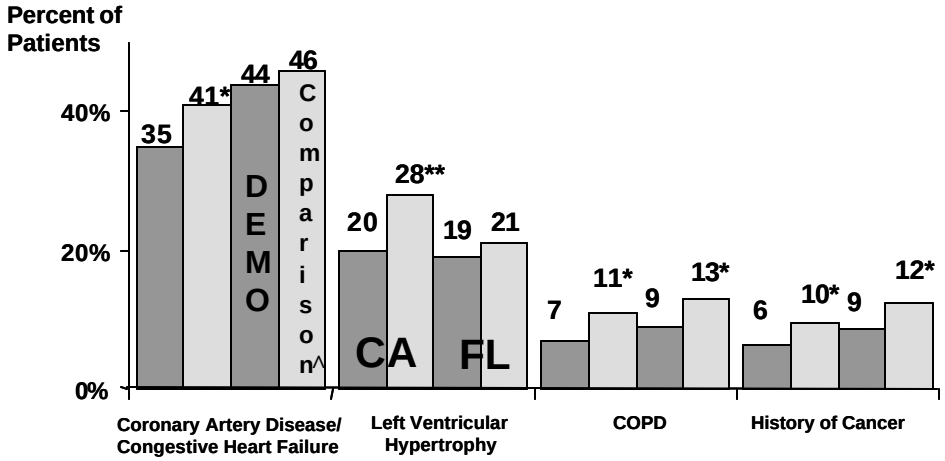
Exhibit ES-3: Example Demonstration and Comparison Group Demographic Characteristics

	California		Florida		All	Matched Comparisons*	
	Demo	DOPPS	Demo	DOPPS	Demo	FFS	NDMC
Mean age (years)	57.9	61.4‡	60.4	63.4‡	59.1	59.3	61.6†
Non-white race (%)	39.4	36.7	48.1	36.1‡	43.4	46.0	40.3
Hispanic (%)	27.0	28.9	24.8	8.6‡	26.0	34.4†	29.2
Male (%)	62.2	55.2†	62.5	57.7†	62.3	54.3†	54.6†
Less than 12 yrs educ. (%)	18.9	24.3†	34.2	30.4	25.9	39.1‡	31.4

* Compared to the combined demo group
‡ $p < 0.001$ versus demo, † $p < 0.05$ versus demo

The patients who joined the Demonstration were relatively healthier and younger, with substantially lower levels of co-morbidities (illnesses and conditions such as coronary artery disease and cancer, shown in Exhibit ES-4) that predispose patients to mortality and adverse outcomes, than the patients who did not choose to join.

Exhibit ES-4: Example Demonstration and Comparison Group (DOPPS) Co-morbid Condition Rates



** p<0.001; * p<0.05
^ DOPPS

Using information on demographics and co-morbidities, we developed a model to predict expected mortality differences between Demonstration patients and representative comparison patients. The expected mortality of the Demonstration patients in California was at least 32 percent lower than the comparison group of California fee-for-service patients and 43 percent lower in the Florida Demonstration compared to a group of Florida fee-for-service patients. Because of the measurable difference in risk factors for the Demonstration patients, we would expect to see lower absolute mortality rates and more favorable health-related outcomes when compared to average patients in the hemodialysis population. Analyses of all outcomes measured for this evaluation took into account these marked differences in baseline health.

Clinical Outcomes and Indicators

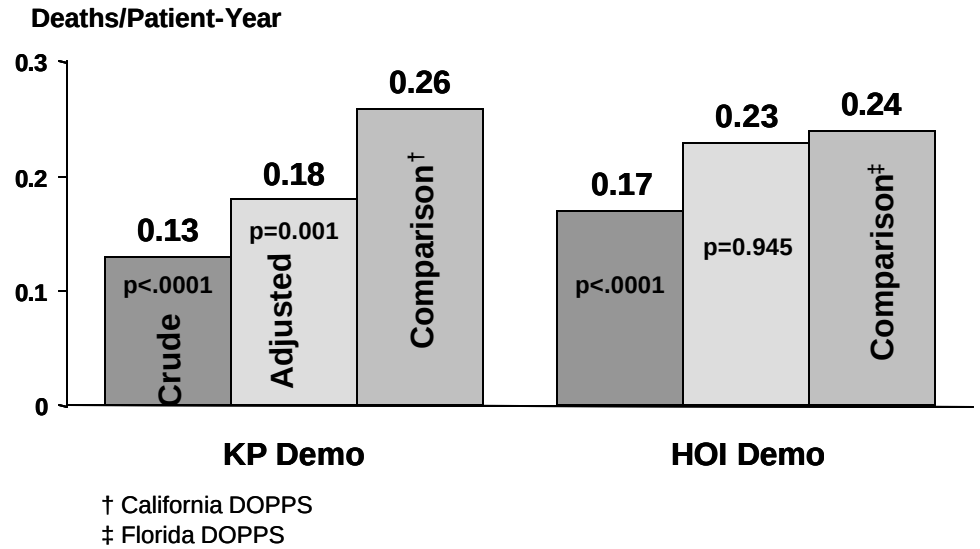
Mortality

The mortality analyses compared the mortality experience of patients enrolled in the Demonstration to the experience of patients from a nationally representative sample from the DOPPS, a largely fee-for-service sample. Our analyses indicate that patients at both Kaiser and HOI had favorable mortality experiences. As shown in Exhibit ES-5, the Demonstration sites experienced 0.13 deaths (Kaiser) and 0.17 deaths (HOI) per patient-year[§] compared to the same-state DOPPS comparison groups, which experienced 0.26 deaths (CA) and 0.24 deaths (FL). However, a large portion of this difference in death rates can be explained by differences in demographic and co-morbid factors between the Demonstration, with younger and healthier patients, and the comparison patients. After adjustment for these factors, deaths per patient-year narrowed between the two sets of patients to 0.18 deaths for Kaiser (versus 0.26 for

[§] Deaths per patient-year accounts for the fact that some patients may die early in a year whereas others may live almost a full year before dying.

California DOPPS, p=0.0008) and 0.23 deaths for HOI (compared to the Florida DOPPS reference of 0.24 deaths per patient-year). These adjusted mortality estimates for HOI were not statistically different than Florida DOPPS; however, the Kaiser mortality risk remained statistically significantly lower than the mortality risk for the California DOPPS patients, and demonstrates a reduction in mortality of 31 percent.

Exhibit ES-5: Crude and Adjusted Death Rates (Through May 2001) – Demonstration versus Comparison



† California DOPPS
‡ Florida DOPPS

Hospitalization

A major question for the evaluation is whether Demonstration patient hospitalization during the Demonstration was similar to the pre-Demonstration experience reported, and how the hospitalization rates for these patients compare to same-state comparison samples (DOPPS).

The unadjusted rate of days spent in the hospital per year-at-risk increased after one year in the Demonstration, compared to baseline measures for the pre-Demonstration period, as shown in Exhibit ES-6. The magnitude of the increase in hospital days that occurred from baseline (pre-Demonstration) to one year was greater for HOI than for KP. Relative to comparison patients in CA and FL, the unadjusted rates for Demonstration patients were lower, both during the pre-Demonstration period and the first year following enrollment.

Exhibit ES-6: Inpatient Hospital Days per Patient Year at Risk (PPY) (unadjusted)

Demo Group	Pre-Demo (6 months) Inpatient Days PPY	Demo (1 year) Inpatient Days PPY	Same-state Comparison^ Inpatient Days PPY
KP	6.29	7.61	9.60 (CA)
HOI	6.52	9.08	10.14 (FL)

^ Same-state DOPPS

The less frequent hospitalization of patients during the six months prior to joining compared to those who did not join the Demonstration is one indication that the Demonstration patients were healthier at the time of enrollment relative to comparison patients.

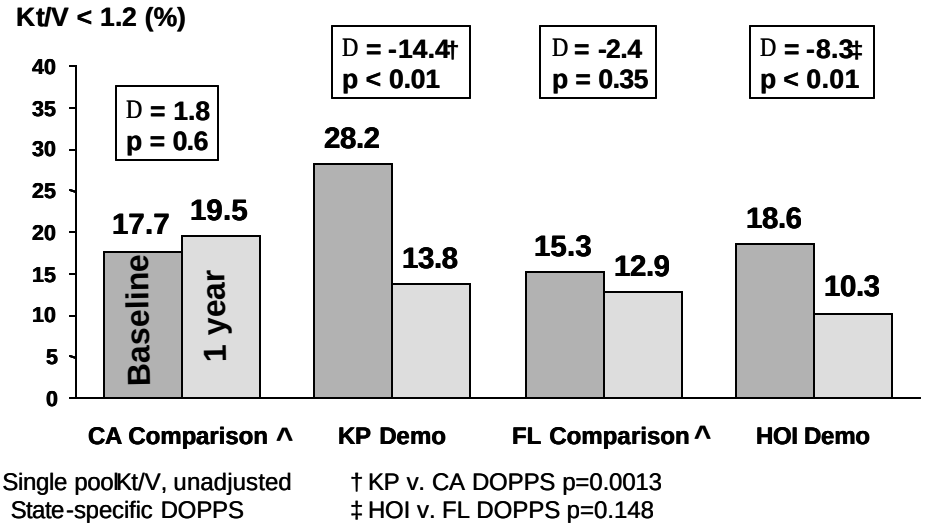
In order to determine whether Demonstration patient hospitalization during the year following enrollment was lower than comparison patients, even after accounting for the known differences in patient characteristics, the relative rate of hospitalization was calculated with adjustment for important patient factors. The adjusted relative rate of hospitalization for Demonstration patients compared to same-state comparisons was not found to be statistically different at the p=0.05 level for either HOI or KP.

Anemia Management and Dialysis Adequacy

We compared several anemia, anemia treatment, and dialysis dose characteristics, including hematocrit (HCT) levels (an indicator of anemia) and single pool (SP) Kt/V (a measure of dialysis dose). Comparing baseline to follow-up scores indicates that HCT levels of both Demonstration and comparison (DOPPS) patients increased over time (a positive trend). Comparison patients experienced greater increases than did Demonstration patients, but Demonstration patients had higher HCT levels at both baseline and follow-up. The average hematocrit level of Demonstration patients at both sites remained well within the Dialysis Outcomes and Quality Indicator (DOQI) guidelines (standard of care widely recognized by the nephrology community) of 33 percent to 36 percent for target HCT.

Demonstration patients at both sites received an adequate dose of dialysis, as defined by the DOQI guidelines, which state that the minimum dialysis dose (Kt/V) target should be 1.2. At follow-up, 90 percent of HOI patients and 86 percent of Kaiser patients met this guideline. Both Demonstration sites improved the average level of Kt/V and raised the distribution of Kt/V among enrolled patients (Exhibit ES-7). Kaiser reduced the proportion of patients below 1.2 Kt/V from 28.2 percent to 13.8 percent; HOI reduced this proportion from 18.6 percent to 10.3 percent. These changes are both statistically significant. Compared to same-state DOPPS patients, the change in the proportion of Kaiser patients not meeting the DOQI guideline is statistically significant at $p < 0.01$ (i.e., a decline of 14.4 percent at Kaiser compared to an increase of 1.8 percent of patients receiving a Kt/V of less that 1.2 in California DOPPS is statistically significant). The change in Kt/V distribution at HOI was not statistically different from Florida DOPPS patients.

Exhibit ES-7: Percent of Patients with Kt/V < 1.2: Baseline v. Follow-up*



Vascular Access

Vascular access complications are known to contribute significantly to hemodialysis patient morbidity and cost of care. The most common problems are stenosis (narrowing of graft/blood vessel), infection, and thrombosis (clotting). One of the major practice options available for vascular access is to choose a fistula versus a graft to achieve reliable permanent vascular access needed for regular hemodialysis. Fistulas are surgically created by connecting a patient's own artery and vein, usually in the forearm. Fistulas have the lowest rate of complications, but take from several weeks to several months to mature, heal, and develop in size. Fistulas, while not possible for all patients, are possible for the great majority of patients. Grafts are also created surgically, but use a synthetic blood vessel to connect the vein and artery. Grafts require shorter times (if any) to heal before they can be used, but tend to have more incidents of stenosis and thrombosis than fistulas. Additionally, compared to fistulas, grafts are more costly to maintain.[14] To assess vascular access treatment patterns among Demonstration patients, surveys were developed and electronic data were collected on a variety of measures, including counts of procedures performed and recorded vascular access events (e.g., date of first clotting or access failure).

While the changes observed after one year in the selection of vascular access type across both Demonstration sites were relatively small, there were some differences worth noting. For Kaiser patients the use of fistulas among hemodialysis patients increased by nearly 14 percent. The change in fistula use was most dramatic among *new* Demonstration patients at Kaiser (i.e., patients not "rolled over" from Kaiser's existing program), where the fraction of fistulas increased from 28.6 to 34.7 percent (p=0.145). While not statistically significant, this change suggests an upward trend in fistula use. For HOI patients, the use of fistulas stayed relatively constant after one year (33.8 v. 34.1 percent). However, since most of the Demonstration enrollees on hemodialysis were not new to ESRD and already had permanent accesses at the time of enrollment (92 and 85 percent for Kaiser and HOI respectively), the sites had less

opportunity to influence the choice of access type than they would have had among patients new to ESRD.

Unadjusted vascular access initial failure rates per patient year at risk (PPY) are given for Demonstration patients in Exhibit ES-8 below. Patients enrolled in the Kaiser Demonstration plan had a lower risk of fistula failure when compared to the DOPPS sample (relative risk of failure (RR)=0.38, p=0.003), while graft patency (i.e., risk of failure) was similar for both Kaiser and comparison patients. Conversely, fistula survival was similar for HOI and DOPPS patients, but HOI patients experienced better graft patency (i.e. lower risk of failure) than patients enrolled in DOPPS (HOI v. FL DOPPS, RR=0.67, p=0.013).

Exhibit ES-8: Unadjusted Vascular Access Failure Rates Per Patient Year (PPY)

Demo Site	Fistula Failures PPY	Graft Failures PPY
Kaiser	0.118	0.547
California DOPPS	0.225	0.331
HOI	0.241	0.405
Florida DOPPS	0.209	0.580

Quality of Life

In addition to its usefulness as a stand alone indicator, patient quality of life (QoL), as measured by the SF-36®, has been shown to predict morbidity, hospitalization, and mortality in dialysis patients.[15] We evaluated patient QoL in the Demonstration by: 1) comparing QoL to a sample of representative hemodialysis patients from DOPPS and to matched Medicare FFS and Medicare managed care patients not enrolled in the Demonstration; and 2) assessing changes in QoL among Demonstration patients over time.

After adjustment for the variation among the Demonstration and DOPPS patients due to differences in health factors, QoL at the time of Demonstration enrollment (baseline) was similar between Demonstration and DOPPS patients. Likewise, analyses comparing baseline QoL scores between Demonstration patients and matched comparison samples (Medicare fee-for-service and non-Demonstration managed care patients) also indicated similar baseline quality of life.

Analyses assessing changes in QoL scores among Demonstration patients between baseline and a one-year follow-up (i.e., changes in the same patients over time) show that nearly every component score of the Physical Component Summary (PCS) and Mental Component Summary (MCS) either improved or stayed approximately the same (Exhibit ES-9). For three of these components – bodily pain, mental health, and role emotional – the improvement was statistically significant. The overall MCS also showed a statistically significant increase.

Exhibit ES-9: Pre-Demonstration and Demonstration Quality of Life Measures

QoL measure	Baseline Mean	One Year Follow-up Mean	QoL*	p-value from paired t-test
Physical Functioning	49.9	49.4	-0.5	0.7059
Role Physical	39.7	43.0	+3.3	0.1283
Bodily Pain	66.3	69.5	+3.2	*0.0390*
General Health	48.3	48.3	+0.0	0.9954
PCS	**36.6**	**36.4**	***-0.2***	**0.6126**
Mental Health	71.2	74.7	+3.5	*0.0004*
Role Emotional	60.0	68.2	+8.2	*0.0004*
Social Functioning	67.2	67.8	+0.6	0.6592
Vitality	46.5	47.4	+0.9	0.3912
MCS	**48.3**	**50.2**	***+1.9***	***0.0006***

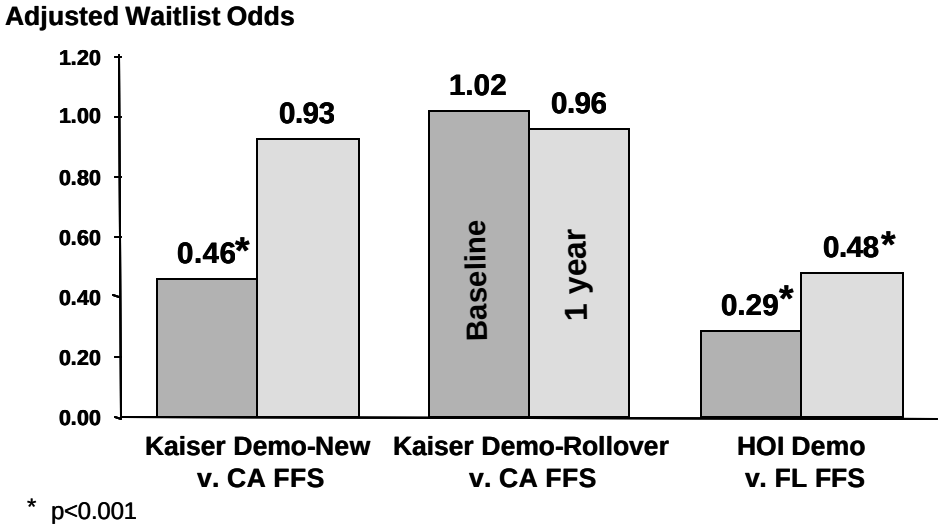
* A positive change indicates an improvement in the QoL indicator after one year of enrollment in the Demonstration.

These results are striking because ESRD patients, due to the chronic nature of their illness, typically exhibit deteriorating quality of life over time. Indeed, when we examined a sample of DOPPS patients over a one-year period of time, we observed that the PCS, as well as the component measures of physical functioning, bodily pain, social functioning, and vitality, were all statistically significantly lower after one year ($p<0.05$).

Transplant Access

Access to kidney transplantation was evaluated by analyzing the rate of waitlisting and the time to transplantation for Demonstration patients versus FFS patients. The percent of Demonstration patients on a kidney transplant waiting list was calculated both at enrollment and one year after and compared to California and Florida FFS patients during the same time periods. At baseline, 24 percent of Kaiser patients were waitlisted, compared to 36 percent among California FFS patients. After spending one year in the Demonstration, patients enrolled in the Kaiser plan had similar access to transplant waitlists as their FFS counterparts (adjusted waitlist odds are presented in Exhibit ES-10). Only ten percent of HOI patients were on a waitlist when they joined the Demonstration, whereas the percent among Florida FFS patients was 26 percent. Although at HOI the percent of patients waitlisted increased substantially from 10 to 15 percent, HOI patients were only one-half as likely as Florida FFS patients to be on a waitlist after one year, which may indicate that the distance to the only Demonstration-contracted transplant center (over 300 miles away in Jacksonville) was a deterrent.

Exhibit ES-10: Adjusted Transplant Waitlist Odds (AOR) at Baseline and One-year: Demonstration versus California and Florida FFS Patients (All Dialysis)



We also analyzed time to transplant among patients who were waitlisted during the Demonstration period. Time between waitlisting and transplant depends in part on the availability of organs, which varies between Organ Procurement Organization (OPO) service areas. Results show that HOI patients were significantly disadvantaged by moving from a Miami area center (where they would have been listed had they remained in FFS and opted to be put on the nearest transplant center waitlist) to a Jacksonville center, as indicated by a 48 percent lower rate of transplant for Jacksonville's OPO versus Miami's OPO. Additionally, HOI patients on the waiting list were less likely to receive a transplant than other patients listed in the Jacksonville area during the same period (RR=0.41, $p<0.001$). They exhibited a 68 percent lower adjusted relative rate of transplant versus other Miami-area patients on the Miami waitlist. Kaiser patients who were waitlisted with one of the three contracting transplant centers during the Demonstration were found to have similar rates of transplant to waitlisted patients within the same area. Post transplant outcomes were not analyzed due to the small number of patients who received transplants and the limited amount of follow-up time to capture graft failures or deaths.

Patient Satisfaction

We examined patient satisfaction with services provided by their dialysis facility, dialysis staff, and primary care physicians under the Demonstration health plan. We also assessed patient satisfaction with the benefits provided by the Demonstration plans and the reasons why patients chose to enroll into the Demonstration health plan. Our approach to conducting these analyses included: 1) comparison of Demonstration patients' satisfaction levels at time of enrollment versus one year later, and 2) comparison of Demonstration patients' satisfaction levels one year following enrollment versus matched fee-for-service and non-Demonstration managed care patients. Due to the size of the matched comparison samples, data for Florida and California are combined.

Overall, Demonstration and comparison patients appeared to be highly satisfied with their health care providers. Additionally, there were few differences between Demonstration patient satisfaction with their providers at baseline and after one year, which was not surprising given that many of the Demonstration patients did not change dialysis facilities and some also did not change other health care providers after enrolling in the Demonstration. However, there were some large and significant differences between the Demonstration and FFS patients in terms of satisfaction with staff support and encouragement, ease in obtaining appointments with primary care doctors and referrals to specialists, availability of social workers and dietitians, and transportation to and from dialysis facilities. While satisfaction among Demonstration patients was reasonably high, the FFS patients reported even higher satisfaction compared to Demonstration patients with respect to these services (e.g., 94% of FFS patients compared with 88% of Demonstration patients reported satisfaction in terms of ease in obtaining referral to a specialist ($p<0.05$)).

Although FFS patients reported higher satisfaction with health care providers and services, at one year following enrollment Demonstration patients reported significantly more satisfaction with the financial benefits and nutritional supplements provided under the Demonstration plan (Exhibit ES-11). Demonstration patients also were more satisfied with these areas compared to non-Demonstration managed care patients. These areas were also the most important reasons listed by the Demonstration patients for enrolling and / or staying in the Demonstration plan. In assessing changes in satisfaction levels among Demonstration patients over time, we found that between baseline and follow-up HOI patients experienced increased satisfaction with medical care costs ($p<0.0001$) and ability to obtain nutritional supplements ($p<0.01$); Kaiser patients reported increased satisfaction after one year with medical care and prescription drug costs ($p<0.0001$).

Exhibit ES-11: Satisfaction with Plan Benefits

Measure of Satisfaction	Demo (Follow-up)	Matched FFS	Matched Non-Demo Managed Care
	(% Agreeing with Statement)		
Co-payment/patient costs for my medical care is especially burdensome[§]	9.6	52.7 ‡	34.5‡
Cost to my family for medications is a large burden[§]	9.9	52.4 ‡	35.6‡
Ability to obtain nutritional supplements is easy and beneficial under this health plan^	87.2	67.7 ‡	67.8 ‡

[§] A lower number indicates greater satisfaction.
^ A higher number indicates greater satisfaction.
* p<0.01 †p<0.001 ‡p<0.0001 vs. Demonstration

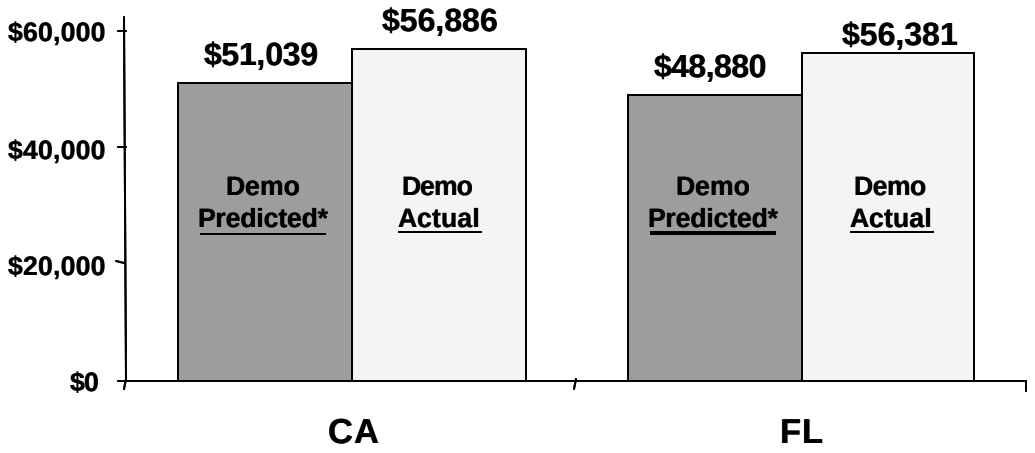
Financial Analyses

Medicare and Medicaid Spending Impacts

A statistical model was developed to assess how much CMS would have spent for Medicare services for Demonstration patients had they remained in FFS. Because Demonstration

enrollees were healthier than the FFS ESRD population at baseline, their pre-Demonstration costs and their predicted costs were significantly lower than the FFS population and, in turn, considerably lower than the capitation rates paid by CMS. Specifically, we found that predicted FFS costs for Demonstration patients in California and Florida were 10.3 percent and 13.3 percent lower on average, respectively, compared to actual Demonstration payments. Therefore, CMS's costs for the Demonstration enrollees appear to have been greater under the Demonstration than they would have been if these enrollees had remained in the FFS system (Exhibit ES-12).

Exhibit ES-12: Predicted versus Actual Average Medicare Spending per Patient Year, 1998-1999



* Adjusting for age, sex, race, modality, covered months, BMI, death, time with ESRD and 20 comorbid conditions

We also assessed the impact on Medicaid spending that resulted from the enrollment of dually-eligible ESRD patients in the Demonstration. Had these patients remained in FFS Medicare, Medicaid would have incurred costs associated with covering the patients' Medicare co-insurance and deductibles. For dual eligibles for whom the full package of Medicaid services is offered[**,16], Medicaid also typically incurs expenses for certain non-Medicare-covered services, most notably prescription drugs. Thus, the Demonstration's coverage of prescription drugs also contributed to reduced Federal Medicaid expenditures for the dually-eligible enrollees.

The Federal Medicaid savings associated with the Demonstration, however, do not outweigh the added costs to Medicare. We estimate that total annual Medicaid savings (including Federal and state shares) were approximately $10,000 per dual eligible enrollee. Since only about 16 percent of Demonstration enrollees were dual eligibles, this is about $1,600 per enrollee overall. With Federal Medical Assistance Percentages (FMAP) close to 50 percent in both California and Florida, the Federal Medicaid savings were at most approximately $800 per enrollee per year, which represents an offset to Medicare spending of about 1.5 percent. That is, the federal government did not save money under the Demonstration, whether one considers only the direct impact on Medicare spending or the combined impacts on Medicare and Medicaid.

** According to a Kaiser Family Foundation report, in 1995 88 percent of dual eligibles received full Medicaid benefits.

Financial Issues from the Patient Perspective

Our assessment of the financial impact of the Demonstration on patient out-of-pocket health care costs focused on two key additional benefits, over and above regular Medicare benefits, offered by the Demonstration sites: (a) prescription drug coverage and (b) absence of patient co-pays.

According to a recent study by the National Institute for Health Care Management, the average retail price per prescription is now more than $45; for the Demonstration patient, who averages about eight prescriptions per month, this translates to a prescription drug cost of $360 per month. Similarly, the lack of the Medicare Part A deductible and Medicare Part B co-insurance under the Demonstration provided a financial benefit to enrolled ESRD patients. For the average ESRD patient in traditional Medicare, on the other hand, cost-share responsibilities are generally close to $500 per month, according to CMS's Office of the Actuary. (For the healthier Demonstration enrollees, cost-share responsibilities would likely be 10-15 percent lower.)

Thus, those Demonstration enrollees who had no secondary coverage prior to the Demonstration may have saved, on average, more than $9,000 annually in out-of-pocket expenses ($4,000 in prescription drug expenses and at least $5,000 in Medicare cost-sharing) under the Demonstration. For those with secondary coverage prior to the Demonstration, similar savings likely accrued in part to those who had purchased the secondary coverage on the patients' behalf (either the patients themselves or, in come cases, their previous employers) and in part to private Medigap insurers.

Financial Viability from Sites' Perspectives

If, as discussed above, one assumes that the FFS Medicare costs of the Demonstration enrollees would have been 10 percent to 13 percent less than the CMS payments to the sites (which averaged approximately $56,700 per year in 1998-1999), the Demonstration sites received payments that exceeded the expected costs of Medicare-covered services by approximately $6,500 per enrollee annually. Thus, even if the Demonstration sites were unable to achieve any cost savings through more effective case management, utilization management, and price management, the sites still had some "built-in" savings to expend on additional services. For each of calendar years 1998, 1999, and 2000, Demonstration capitation revenues received by Kaiser and HOI were compared to their Demonstration program expenditures. For both Kaiser and HOI, capitation revenues for calendar year 1998 did not cover total Demonstration expenses (including medical and administrative costs) incurred in 1998. HOI's 1998 net loss of 14.79 percent was significantly higher than Kaiser's net loss of 3.3 percent. By calendar year 1999, the financial picture had improved for both plans' Demonstration programs, with HOI's loss decreasing to 3.6 percent and Kaiser showing a positive net income of 1.9 percent. HOI's net loss grew again in 2000 to 8.6 percent, while Kaiser continued to show a positive, though somewhat lower gain at 0.7 percent net income.

The costs to the sites of covering the Medicare deductible and co-insurance alone may well have exceeded $5,000 to $6,000 per enrollee per year. Add to this the significant costs of the prescription drug benefit (easily $2,000 to $4,000 per enrollee annually), the costs of other additional benefits offered, and the sites' administrative costs (including the costs of designing

and implementing a new and complex organizational plan), it is not surprising that the sites experienced financial losses or only very modest gains in their Demonstration line of business.

Concluding Summary

In summary, the evaluation of CMS's ESRD Managed Care Demonstration found that, in general, Demonstration patients fared as well as, or in some cases better than, a representative sample of fee-for-service comparison patients. Specifically:

- Medicare ESRD beneficiaries who chose to enroll in the Demonstration were younger and healthier than fee-for-service patients.
- The mortality experience of Demonstration patients was the same as or better than comparison patients even after adjustment for Demonstration patients' healthier status (although some unmeasured differences in health status may still exist).
- Hospitalization experiences after adjustment for patient differences were similar across the Demonstration and comparison groups.
- Clinical indicators, such as anemia management, dialysis adequacy, and vascular access rates, were the same as or better than comparison patients.
- Satisfaction levels with providers were high among patients in both groups, but Demonstration patients indicated higher satisfaction with health plan benefits.
- When contrasted with patients in the comparison groups, Demonstration patients experienced some improvement in quality of life, particularly with regard to mental well being.

Additionally, this evaluation had access to strong and credible comparison groups, thereby strengthening the trustworthiness of the above results.

While these results indicate the generally positive experiences of the ESRD patients in this Managed Care Demonstration, there are some important caveats that must be considered in interpreting the evaluation findings.

- Results may not be generalizable since only two HMOs participated. Furthermore, plan benefits currently offered by Medicare+Choice plans are far less generous than offered five years ago.
- As with all closely monitored programs, there was most likely a "Hawthorne effect," meaning that the Demonstration sites may have performed better than would have been the case had they not been carefully scrutinized by the evaluators and CMS.
- Access to transplantation (as defined by being listed on a transplant waiting list and by likelihood of receiving a transplant) among beneficiaries at the HOI Demonstration site was substantially lower than such access among fee-for-service comparison patients in Florida.
- Government expenditures for Demonstration patients were higher than expenditures would have been if these patients had remained in fee-for-service Medicare. The reason for this result is that beneficiaries who self-selected into the Demonstration were, on average,

younger and healthier than the general ESRD population, yet the capitation rates were based on the general population.

- Finally, despite the increased payment by the government, the Demonstration sites experienced financial losses (HOI) or only small gains (Kaiser) which brings into question the long-term financial viability of such a program from the sites' perspectives.

Nevertheless, while these limitations are important, the overall experience of the ESRD Managed Care Demonstration was that beneficiaries exhibited positive clinical and quality of life outcomes and were highly satisfied with their care.

CHAPTER I: EXPERIENCES OF THE ESRD MANAGED CARE DEMONSTRATION SITES

A. Introduction/Background

In 1998 the Centers for Medicare and Medicaid Services (CMS), (formerly the Health Care Financing Administration (HCFA)), launched the ESRD Managed Care Demonstration to provide an opportunity to study the experience of placing ESRD patients in managed care. Simultaneously, an evaluation of the program was undertaken to evaluate the efficacy and cost of HMO participation for Medicare beneficiaries with ESRD, with a comparison of the structure, process, and outcomes for patients enrolled in the Demonstration sites, with a similar set of ESRD patients in the fee-for-service sector. The clinical outcomes of patients enrolled in the Demo are being presented in the chapters that follow. The purpose of this chapter is to describe the structure of the Demonstration sites and detail the experiences of the sites while participating in the Demo.

A thorough understanding of the structure of the managed care programs involved in the Demo will provide context for the clinical outcomes and serve as a baseline for future program development. The experiences of the sites are instructive in terms of understanding the perspective of participating in a Demonstration project, as well as to illuminate critical organizational issues relevant to the ESRD community.

1. Background on the ESRD Population

The Medicare ESRD program was begun in 1972 with the goal of providing short-term life-saving treatment for a small number of critically ill patients. From an initial count of about 7,000 patients in the first year to 344,094 in 1999[17], the ESRD program exceeded expectations in terms of program size and budget. Incidence has risen in recent years with 89,252 newly diagnosed patients in 1998[18], and with obesity and diabetes reaching epidemic levels in the United States, it is likely that the incidence of ESRD will continue to grow in the coming years.

In addition to the personal burden of ESRD, the economic consequences of this growing population are significant.[19] Currently, year-at-risk spending* on hemodialysis and associated care is more than $65,000 per patient annually; spending for a peritoneal dialysis patient is $57,000 per year-at-risk. Year-at-risk spending on transplant patients, including the initial transplant procedure and related care within the first year, is about $149,000. Annual follow-up care for transplant patients, however, is much less costly than dialysis, averaging about $20,000 per year-at-risk.

In recent years, the ESRD program has consumed an increasingly larger share of the Medicare budget, and program costs have continued to rise beyond policymakers' expectations. Between 1994 and 1999, Medicare ESRD expenditures increased at an average annual rate of more than 7%. In 1999 alone, Medicare expenditures for ESRD amounted to $12.7 billion, representing 71% of total U.S. ESRD costs ($17.9 billion). The total Medicare ESRD program cost is projected

* Includes spending by Medicare as well as other payors.

to more than double in the next 10 years, surpassing $28 billion by the year 2010. Notably, however, per capita patient spending has shown little change over the past five years.

Growth in program costs has largely been a function of increased numbers of ESRD patients and a disproportionate increase in the number of costlier patients (e.g., elderly patients or those with co-morbidities). The expansion of Medicare benefits to include up to three years of immunosuppressive drugs required by transplant recipients to avoid graft rejection, and routine erythropoietin (EPO) therapy for dialysis patients, have also contributed to rising costs.

To control costs in the ESRD program, Congress has implemented a number of cost-saving measures. Among the most potent initiatives has been the development of bundled, or semi-capitated, payment models for physician and dialysis facility services. These payment strategies are designed to shift financial risk to renal providers, and to thereby encourage them to monitor their own costs. In addition to revising reimbursement methodologies, Medicare has also achieved cost savings by encouraging patients to use less costly treatment modalities and allowing dialysis providers to reuse their dialyzers (the artificial kidneys used to filter the blood).

In recent decades, the health care system in general has seen the rapid diffusion of managed care as the country has struggled to contain medical costs and achieve high quality care. To a large degree, the public sector has embraced managed care. For instance, CMS contracts with providers to provide capitated care for older Americans enrolled in the Medicare program. However, current law prevents ESRD beneficiaries from enrolling in Medicare managed care programs (ESRD patients are permitted to *stay* in a managed care organization if they develop ESRD after enrollment and the managed care organization has a Medicare risk contract). Originally put in place because HMOs feared the expense of ESRD enrollees, the bar is intended to protect ESRD patients because concern exists over the potential incentives under managed care to under-treat patients with a chronic disease. In the past several 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. 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 access to choose a managed care plan, Congress mandated a Demonstration project in 1993 to test whether ESRD patients could be successfully treated in a managed care setting.

2. The ESRD Managed Care Demonstration

The Omnibus Budget Reconciliation Act of 1993 required CMS (then HCFA) to conduct a Social HMO (SHMO) Demonstration project for end stage renal disease patients. SHMO 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 extension of an integrated system of care to ESRD beneficiaries was operationally feasible, efficient, and able to improve patient outcomes compared to the current fee-for-service system. Congress became interested in determining 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 fee-for-service and the current capitation payment for ESRD patients in HMOs (see below for details on payment under the Demonstration).

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 Demo. Under current law, employer group health plans and certain other insurers are primary payer for the first 30 months of ESRD eligibility and Medicare is secondary payer.

a. CMS's Requirements for Demonstration Sites

The Demonstration sites were required to have year-round open enrollment for eligible ESRD patients who were served in the fee-for-service system, including both dialysis patients and those with functioning grafts who were still ESRD-eligible (e.g., within three 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. Certain marketing practices, such as marketing to subgroups of patients, were prohibited. The Demonstration sites were required to attempt to enroll at least 600 patients.

Other essential components of the Demonstration included the following:

- ***Service Integration.*** 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.

- ***Case Management***. This component was considered by CMS to be an important aspect of a fully integrated, comprehensive, multidisciplinary continuum of service provision. Case managers could have been physicians, nurses, or other allied health professionals who follow patients through some or all settings in which ESRD patients receive care, and coordinate the acute, chronic, clinical, and social needs of patients. Case managers could have been coordinators only, or providers of care as well as coordinators. According to

CMS, basic functions of case managers include initial screening, assessment, care planning, service provision and/or referral, monitoring, and reassessment. CMS suggested that care planning could be guided by clinical protocols.

- ***Clinical Protocols.*** CMS required that the Demonstration sites 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 Medicare covered services plus additional, more comprehensive benefits. 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 these additional benefits were covered by higher payments from Medicare than were paid to HMO risk contractors outside of the Demo (i.e., organizations received 100% rather than 95% of the ESRD statewide rates that had historically been paid to Medicare risk contractors[†]).

- ***Submission of No-pay Claims.*** As part of its contract with CMS for the Demo, the sites were required to submit to the Agency "no-pay claims." No-pay claims are encounter-level data submitted through the regular Medicare fee-for-service claims process but without expectation of reimbursement.

  Section 1853(a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under Section 1876 of the Social Security Act, to submit such encounter data. The purpose of the law as it affects all Medicare+Choice organizations is to provide data to serve as the basis for plan level estimates of risk-adjusted payments.

  For the ESRD Demonstration, the purpose of the no-pay claims requirement was to provide data to support an evaluation of the financial aspects of the Demonstration program. Specifically, CMS wanted to compare its costs under the Demonstration program in contrast to what the Agency would have spent on the Demonstration patients should they have remained in fee-for-service Medicare.

b. Payment Under the Demonstration

Traditional payments to Medicare risk contractors for ESRD patients differ from other Medicare capitation rates paid to Medicare risk contractors. Because ESRD beneficiaries comprise less than one percent of the Medicare population, individual cell sizes are too small to permit ESRD rates to be set on a county-specific basis. Further, the flat, state-wide ESRD capitation rates are not risk-adjusted for age, sex, severity, or any other factor.

[†] Chapter 11 of this report discusses our analysis of the actual value of the extra benefits provided. It is worth noting that at the time the Demo sites submitted their applications, CMS had informed the sites that any benefits provided beyond Medicare covered services could be deemed "extra." Later, CMS reconsidered and ruled that benefits could only be deemed "extra" if the services were not already provided to regular Medicare-risk patients at the Demo site HMOs.

Like the traditional ESRD payment rates, Demonstration payment rates were based on state-wide average costs for ESRD patients (although costs of patients with Medicare as secondary payor were excluded since patients with a primary payor other than Medicare were not eligible to enroll in the Demonstration). However, because research has shown that there is significant heterogeneity in ESRD beneficiaries' health status, a key component of the Demonstration was to test the impact of risk-adjusted ESRD capitation rates versus the historic *single* state-specific capitation rate.

Under the Demonstration, costs for ESRD beneficiaries were partitioned into three discrete treatment status categories (due to the variation in costs associated with each mode of treatment):

- Medicare costs during a period of maintenance dialysis;
- Medicare costs associated with a transplant episode (defined as the month prior to, the month of, and the month following the transplant); or
- Medicare costs during a post-transplant period in which the beneficiary had a functioning kidney allograft (transplant).

A separate transplant rate cell was established because the up-front costs of transplantation are very high, and it takes a number of years for the transplant to "pay for itself" in lower functioning graft costs. Thus, there was some concern that a single, unadjusted payment rate might provide a disincentive for HMOs to provide transplants. The temporary, three-month transplant rate cell was intended to make the transplantation payment revenue neutral from the perspective of the managed care organization.

For the dialysis and functioning graft cells, rates were further adjusted for three age categories (under 20, 20-64, and 65 and over) and whether or not diabetes was the primary cause of the renal disease, as these are key drivers of expenditures in ESRD. The transplant rate cell was not so adjusted, since age and diabetes were not thought to be predictive of transplant costs.

Finally, the development of the initial capitation rates under the Demonstration was based on 100 percent of the ESRD state-wide rates, rather than 95 percent of fee-for-service costs that had historically been paid to Medicare risk contractors; the Demonstration sites were required to provide additional services to justify the extra 5 percent payment. Subsequently, the Demonstration rates were updated annually based on the Medicare+Choice update factors (typically about 2 percent).

c. Demonstration Sites

The Medicare ESRD Demonstration project was begun at three sites across the country: Health Options, Inc. (HOI), a subsidiary of Blue Cross/Blue Shield of Florida, based in Miami; Kaiser Permanente Southern California Region (Kaiser), based in Los Angeles; and Xantus Health Care Corporation, based in Nashville, Tennessee. Each program developed its own unique structure, though there were some similarities. The Demo was initiated in September 1996 and the sites began enrolling patients in 1998.

3. Evaluation of the ESRD Managed Care Demonstration

The evaluation of the Demo began in August 1997. Its goals were to determine how well the Demo worked and to offer guidance on how to proceed in structuring 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 fee-for-service ESRD patients. It also sought to determine if the additional covered services 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 lower cost, higher quality care.

Much of the evaluation entailed collection of patient-level clinical, outcomes, and quality-of-life data as well as plan-level financial data. However, we also captured qualitative information on the structure and operations of the Demonstration sites. The purpose of this chapter is to provide descriptions of: a) how the participating sites structured their programs; and b) the sites' experiences in operationalizing the Demo.

B. Methods

The information on Demonstration site experiences presented in this chapter was obtained primarily through site visits made by The Lewin Group and University Renal Research and Education Association. Information in this paper is supplemented with documentation from and personal communications with the Demonstration sites and CMS. Between October 1997 and February 2001, we conducted a total of 14 site visits to the three Demonstration sites, Kaiser Permanente, Health Options, and Xantus. Nine of these site visits were conducted at the Demonstration sites; the remainder were conducted by telephone. Although not technically "site visits" as we did not travel to the Demonstration programs, the telephone-based site visits were identically structured to the in-person visits. The purpose of conducting some of the site visits by telephone was to enable us to expand data collection efforts in the most cost-effective fashion.

For each Demonstration site, Exhibit 1-1 presents the dates on which the 14 site visits took place and the nature of the visit (i.e., in-person or telephone-based).

Exhibit 1-1: Site Visit Schedule

Kaiser Permanente (California)	Health Options, Inc. (Florida)	Xantus (Tennessee)
October 22, 1997 (in-person)	January 12, 1998 (in-person)	July 13, 1998 (in-person)
May 14, 1998 (in-person)	July 20, 1998 (in-person)	April 12, 1999 (telephone)
December 16, 1998 (telephone)	February 16, 1999 (telephone)	
July 21, 1999 (in-person)	September 30, 1999 (in-person)	
April 4, 2000 (telephone)	June 14, 2000 (telephone)	
November 9, 2000 (in-person)	February 6, 2001 (in-person)	

Prior to conducting each site visit we developed a detailed site visit protocol. The protocols all covered the following topics:

- Marketing and Enrollment
- Financial Issues and Provision of 5% Extra Benefits
- Information Systems
- Service Delivery and Care Coordination
- Patient Satisfaction and Outcomes
- Provider Arrangements

Individual questions within each topic were tailored for each of the sites and modified over time to reflect the sites' previous activities. The visits were structured such that we met or spoke with the most appropriate set of individuals from the Demonstration sites for each topic area. For example, during the discussion on marketing and enrollment we typically met with the Director of Marketing and his or her staff. During the discussion on information systems we met with the individuals responsible for implementing and maintaining data systems. During discussions on service delivery and care coordination we spoke with the program's medical director as well as participating clinicians.

Although the sites' program directors were typically present for all topics, we asked that all Demonstration employees and staff not be present in two cases on each visit. First, we met privately with physicians and other clinicians. We wanted to ensure that these individuals had an opportunity to speak freely.

Second, we spoke privately with groups of patients who were enrolled in the Demo. Discussions with patients were typically conducted by telephone as we did not want to burden patients by asking them to travel to meet with us. Topics covered with patients included:

- Overall satisfaction with the Demonstration
- Enrollment
- Quality of care
- Pre-Demonstration status
- Pre-Demonstration versus Demonstration comparison

Below we present the experiences of the Demonstration sites. We first present experiences of the Kaiser Permanente site, followed by Health Options, Inc., and Xantus. We conclude with a brief discussion of the Demonstration site experiences.

C. Results

1. Experience of the Kaiser Permanente Demonstration Site

a. Proposed Structure of the Demonstration Program

Of the three sites selected for participation in the Demo, Kaiser Permanente had the most well established managed care program with experience treating ESRD patients. In seeking participation in the Demo, Kaiser suggested that "nationally, the HMO and provider industries are not yet sufficiently prepared, nor are the chronically ill sufficiently receptive, to expect market forces to prompt significant managed care growth for these populations." Kaiser sought to contribute to knowledge surrounding care management for the chronically ill. Specifically, the goals for its Demonstration program included:

- "Promote informed decision-making among ESRD patients." Kaiser anticipated getting routine feedback from enrollees regarding their thoughts and preferences of the Demonstration program as well as patients' help-seeking behavior in general.

- "Innovation in service delivery and financing." Kaiser developed a care model based on a multidisciplinary team and provider contracting arrangements that included financial incentives for quality outcomes. Reimbursement to physicians was linked to continuous quality improvement efforts and credentialling, and contracts with facilities were linked to performance on dialysis facility report cards. In addition to relying on Kaiser staff physicians, Kaiser sought to contract with high quality nephrology IPAs to facilitate enrollment of patients while minimizing the need for new enrollees to switch providers.

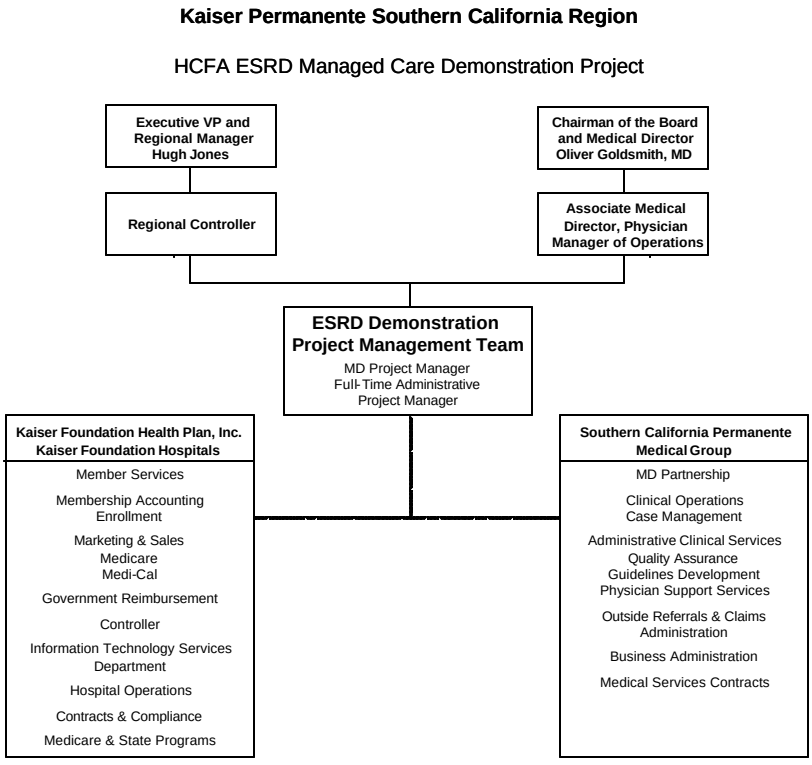
- "Data for accountability and evaluation." Kaiser expected to support the overarching goals of the Demonstration by assuring availability of data to support assessment of the interventions of the program. Kaiser created an Integrated ESRD Tracking System and wanted to utilize data to examine provider performance, patient outcomes, care management, and research.

1) Organizational Structure

The Kaiser Permanente Southern California Region (KPSCR) is a large closed-system managed care organization. A not-for-profit group-practice HMO, the organization operates through a Medical Service Agreement partnership between Kaiser Foundation Health Plans (KFHP), Kaiser Foundation Hospitals (KFH), and the Southern California Permanente Medical Group (SCPMG). When the Demo began, total Kaiser Permanente enrollment was well over 6 million covered lives, with more than 2 million enrollees being part of KPSCR. Of the 2 million, 168,000 enrollees were Medicare beneficiaries of whom about 2,000 had ESRD. KPSCR had been operating a Medicare risk plan, the "Senior Advantage" program, since 1987. It is worth noting that Kaiser's membership size and strong financial status translated into the capacity to bear risk for the program; the organization does not hold either reinsurance or insolvency insurance because of the financial strength of its assets.

Kaiser's Demonstration program was designed to utilize resources from both KFHP/KFH, and SCPMG with a management team serving as the bridge (see Exhibit 1-2). Many of the administrative aspects of the Demonstration were developed using expertise from the KFHP/KFH and the program relied on the SCPMG for clinical expertise, including case management and quality assurance aspects.

Exhibit 1-2: Kaiser Permanente Demonstration Organizational Structure



2) Provider Contracting and Reimbursement

As a closed system managed care organization, Kaiser owns and operates the large majority of medical services related to providing care under the Demo. At the time of application, KPSCR operated ten medical centers and more than 90 medical offices through the Southern California region. 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 (UCLA, Loma Linda University, UC Irvine, University of Southern California and UCSD). Kaiser operates its own medical laboratory, as well as over 130 pharmacies throughout the region.

Kaiser employed 25 nephrologists and operated one hemodialysis facility and six peritoneal dialysis facilities at the start of the Demonstration. Additional staff included ten ESRD nurse case managers as well as renal social workers and dieticians. To supplement this internal network, Kaiser had in place contractual arrangements with 112 dialysis centers and 120 nephrologists. Transplant services were provided through contractual arrangements with

UCLA, UCSD, and Loma Linda University using a case rate based on whether the procedure involved a cadaver or living related donor.

Prior to the Demo, Kaiser had typical payment contracts in place with community providers with one exception. One of Kaiser's contracts relied on a two-tiered reimbursement system that offered financial rewards as a higher portion of the provider's patient population achieved improvement in dialysis adequacy, anemia, and nutrition. For the Demo, Kaiser proposed to implement contractual arrangements with dialysis facilities and nephrology groups that included some risk sharing. For community providers, a capitation model was developed with adjustment for age, diabetes, and graft status. Additional incentives were developed based on dialysis adequacy, patient satisfaction, and facility report cards. Kaiser expected to develop an "Integrated Dialysis Provider" approach with some providers that would include payment for both nephrologists and dialysis-related services, capitating for the range of needed services with the exception of transplant and vascular access admissions.

3) Provider Roles

Kaiser developed its Demonstration program based on the pre-ESRD and ESRD care it was 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 comprised of a nephrologist, an ESRD case manager, a renal social worker, dietitian, and a pharmacist. Depending on patient need, a team might also have included other relevant providers such as a cardiologist or mental health professional. The care management team met at least quarterly to review patients' care plans. Additionally, all multidisciplinary care teams used a standardized care plan template. A single form for each Demonstration patient, the Dialysis Patient Quality Outcomes Assessment Tool, was continually updated and shared across members of each patient's team. The purpose of the form was to help the many members of the care team coordinate their efforts.

Each Demonstration patient assigned a Kaiser nephrologist to serve as the clinical director of the management team, sometimes in addition to the patient's contract nephrologist. In most cases, the Kaiser nephrologist also served as the patient's primary care provider. The Kaiser nephrologist was supposed to see all 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:

- Monitor ESRD patient care and promote quality improvement
- Coordinate and manage patient needs
- Provide early intervention, patient education, and encourage prevention
- Collect data on ESRD patient population and conduct analyses
- Manage the care and cost of ESRD patients

Caseloads of managers were adjusted for acuity levels of the patients. On average the ratios were about 1:125 for maintenance level patients, 1:35 for intermediate level patients, and 1:25 for intensive level patients. In addition to team meetings, all ESRD case managers were to meet bimonthly to share insights and develop best practices.

4) Service Package

In addition to the case management services described above, Kaiser proposed to offer several services beyond Medicare fee-for-service benefits. Exhibit 1-3 outlines the major services.

Exhibit 1-3: Kaiser "Extra" Benefits

Service/Benefit	Description
Co-insurance and Deductibles	$0 co-pay 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
Prescription and Over-the-counter Drug Benefit	$0 co-pay and no annual maximum; unlimited prescription drugs for immunosuppressive therapy
Durable Medical Equipment	Provided with no co-pay, assuming product meets Medicare and Kaiser guidelines
Nutritional Supplementation	All renal-related vitamins, phosphate binders, iron supplementation and oral nutritional supplements provided free of charge; IDPN covered with approval for medical necessity
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 co-pay
Health Education and Family Supportive Services	Group and peer counseling, special health education classes, wellness programs specific to the ESRD population, provided free of charge
Out-of-area Coverage[‡]	Covered for up to 60 days per year out of plan

5) Clinical Protocols, Quality Assessment, and Performance Improvement

Kaiser planned to utilize the ESRD Quality Management Plan (QMP), operational among the Senior Advantage program, to form the basis of their quality assurance activities in the Demo. The QMP included several clinical goals expected to minimize the complications of dialysis:

- Adequacy of Dialysis: 1.4 Kt/V for non-diabetic patients, 1.6 Kt/V for diabetic patients, and 1.8 Kt/V weekly for PD patients;
- Target rates for serum albumin, calcium, phosphorous, and hematocrit; and
- Hypertension and fluid control.

Prior to the Demonstration, Kaiser had invested resources to develop an assessment tool to facilitate the "credentialling" of dialysis providers, both internal and external facilities. The tool measured more than 400 aspects of care and assessed performance relative to known standards, as well as other facilities in the Kaiser program. It was Kaiser's intent to credential every unit before establishing a service contract, and biannually thereafter. In addition to credentialing the

[‡] Coverage for out-of-area services became a Medicare benefit during the time period of the Demo.

unit, Kaiser developed the "Dialysis Center & Provider Report Card" to be completed monthly to monitor select variables on patients, dialysis units, and attending nephrologists. Finally, Kaiser intended to use the Rand Corporation's Kidney Disease Quality of Life instrument to periodically monitor patient satisfaction.

6) Marketing Plan

In preparation for the Demonstration, Kaiser surveyed dialysis patients (both Kaiser enrollees and non-Kaiser patients) to identify factors related to plan selection. Using the data gathered from that survey, Kaiser developed a marketing approach based on three elements: 1) outreach and informing; 2) enhanced benefits and services; and 3) expanded provider contracting arrangements. Kaiser anticipated using existing marketing resources to conduct outreach to potential enrollees. It was also expected that the benefits of the Demo, notably the care management approach and financial aspects of the program, would be attractive to new enrollees. Finally, Kaiser anticipated that it might be necessary to expand the network of nephrology providers it contracted with, thus expanding the pool of beneficiaries who would be eligible to enroll.

b. Kaiser's Experience During the Demonstration

In this section we describe Kaiser's actual experiences in implementing and running the managed care Demonstration. Our description is focused on those areas where: 1) Kaiser's processes elucidate or inform key Demonstration activities; and / or 2) the program's experiences diverged from its plans or expectations as described in the original proposal to CMS. The reader should assume that, unless otherwise expounded upon, structural and operational features of the Demo as discussed above were implemented and carried out as planned.

1) Marketing and Enrollment

Marketing

Kaiser developed a range of marketing materials and approaches, including brochures, letters, open houses, and videos. Their marketing plan consisted of the following three separate initiatives: 1) internal marketing to Kaiser staff; 2) marketing to the ESRD provider community; and 3) marketing to ESRD patients.

Most of Kaiser's marketing was focused on patients. Kaiser administrators felt that their marketing approach was somewhat limited, however, by CMS's marketing restrictions, particularly restrictions on targeted marketing to sub-groups of patients. For example, Kaiser could not develop and distribute marketing materials exclusively to Hispanic patients or other groups.

Kaiser's choice to focus its marketing efforts on patients reflects, in part, the provider community's ambivalence toward the Demo (see Provider Arrangements and Relationships, below). Kaiser hoped to preclude hostile responses to the Demo among the provider community in order to prevent providers from actively dissuading their patients from enrolling in the Demo. Given the financial benefits of the Demo for ESRD patients, Kaiser hoped that

their patient-focused marketing approach would convince at least a few patients in every nephrologist's office and dialysis facility to join the Demo.

Kaiser's marketing to dialysis facilities was relatively successful. At the outset of the Demo, they had signed Demonstration contracts with 39 individual nephrologists and 20 nephrology groups, many of whom were already contracting with Kaiser. At this point, Kaiser had contracted with approximately 80% of the dialysis facilities in the Demonstration service delivery area (a total of 115 facilities), including eight individual facilities and nine dialysis chains. Throughout the Demonstration program, however, there remained a select number of dialysis centers that did not want their patients to join the Demo. Thus, Kaiser's marketing to patients was seen as essential in order to counteract a negative reaction by the provider community. As a result of this intense marketing, marketing costs for the Demo were significantly higher than anticipated. Kaiser's marketing to physicians, however, was relatively unsuccessful, and tensions with the non-participating provider community remained throughout the Demo (see Provider Arrangements and Relationships, below).

Enrollment Process

Kaiser's enrollment process was fairly well developed at the outset of the Demo. Kaiser had six marketing counselors who were well-educated about the Demonstration program and who, in the year before the Demo began, had worked exclusively with ESRD patients. To facilitate enrollment and data collection, Kaiser had put into place a fairly comprehensive enrollment tracking database system to track the types of enrollment issues that influenced ESRD patients' willingness and ability to participate in the Demo. Some of the data collected by this system included:

- Personal information (e.g., SSN, DOB, address, phone, insurance, current dialysis modality, transplant waiting list, dialysis facility, community nephrologist, willingness of patient to switch doctors, dialysis facility or transplant waiting list, dates of mailings)
- ESRD data (e.g., treatment location, first dialysis date, modality, date of transplant)
- Reasons for ineligibility, when applicable (e.g., out-of-area zip code, no Medicare A and B, non-contracting dialysis unit, or non-contracting nephrologist)

Exhibit 1-4 describes Kaiser's enrollment process at the outset of the Demo.

Exhibit 1-4: Enrollment Process at the Kaiser Demonstration Site (Selected Steps)

1. CMS mailings were sent to all Part A and B-eligible Medicare ESRD patients. These mailings included a business reply card and telephone number for obtaining additional information.
2. An outside telemarketing vendor called all patients who mailed back the reply card to collect preliminary qualification data.
3. Kaiser's sales team made follow-up calls to all patients who sent back the reply card.
4. Eligible patients who were interested received an "Additional Information" package and an "Enrollment" package.
5. The Nurse Case Manager met individually with patients to review their education and prior health history assessments and to orient the patient with Kaiser facilities and nephrology services.
6. Kaiser contacted all nephrologists whose patients expressed an interest in the Demo to see if the provider would participate. Short-term, temporary contracts were issued with community nephrologists for the duration of the Demo once the nephrologists passed Kaiser's credentialing process.
7. Patients who were not being treated at a participating dialysis facility were required to switch facilities. All newly contracted dialysis facilities received inspection from a Case Manager.

Kaiser reported that there was a 45- to 60-day gap between the submission of the enrollment application and the start of service delivery. One difficulty was that Kaiser found the process of eligibility screening difficult as it was hard to determine when patients did not pay their Part B premiums and therefore lost Medicare coverage.

Enrollment of "rollover patients" (i.e., ESRD patients already enrolled in Kaiser's existing managed care plan who were otherwise eligible for the Demo) occurred once a CMS-set minimum number of fee-for-service patients had enrolled. Kaiser sent a letter to existing Kaiser ESRD patients explaining the rollover process.

Kaiser administration reported the impression that patients enrolled in the Demo primarily for financial reasons. Kaiser found that patients without supplemental insurance and those who had recently lost their insurance were likely to enroll in the Demo. MediCal patients who had a cost share also saw some cost savings by joining the Demo, although MediCal patients with no cost-share tended not to enroll. As the Demo proceeded, Kaiser reported that a reputation for high quality of care became a factor in patients' reported decisions to enroll.

Reasons for enrollment into the Demo collected by the evaluators are presented in Exhibit 1-5.

Exhibit 1-5: Reasons for Enrollment in the Kaiser Demonstration

Reason for enrolling in the Demonstration (%)[1]	HD Active	HD RO[2]	PD	TX
Cost of Outpatient Drugs	68.0	69.2	67.8	71.4
Cost of Co-payments	63.4	65.8	60.4	71.4
Recommendation of Doctor	13.0	9.4	20.8	7.1
Other	22.5	29.1	24.5	31.0

[1] columns do not add to 100 because respondents could select up to two answers

[2] RO= Rollover

Enrollment Levels and Activities to Increase Enrollment

Initially, enrollment in the Demo remained lower than expected for both new and rollover patients, although Kaiser staff anticipated that that they would not have a problem meeting CMS's target total enrollment of 600 new patients. In addition to these 600 new patients, Kaiser planned to enroll a minimum of 300 rollover patients.

Kaiser postulated that enrollment initially remained low for new patients because of patient concerns about switching providers, patient concerns about what would happen at the end of the Demo, patient concerns about managed care, and a lack of knowledge about the Demo among providers.

In order to validate its perception of patient concerns with the Demo and further explain the low enrollment numbers, Kaiser held focus groups with patients who had recently enrolled in the Demo. The primary concern expressed by new patients was apprehension about what would happen once the Demo ended. Another concern was raised around the cost of medications; it appeared that although there were no co-payments in the Demo, patients did not adequately understand this benefit. Some patients also expressed concern about having to switch physicians (nephrologists, radiologists, and surgeons) or dialysis facilities. Patients in focus groups stated that Kaiser personnel adequately addressed each of their concerns prior to enrollment. Kaiser's response to patient concerns in this regard was likely integral to its ultimate enrollment success.

To more fully address patient concerns and boost enrollment, Kaiser implemented several steps to increase enrollment in the Demo. These steps included:

- Contracting with additional nephrologists. Kaiser signed a number of limited temporary Demonstration contracts with nephrologists in order to allow patients to enroll in the Demo without switching physicians[§];
- Paying CMS to send out additional mailings and re-designing the brochure for these mailings;
- Distributing informational materials to dialysis units. Kaiser had made Demonstration materials available in dialysis units and provided information to dialysis facility staff. However, as some of the staff at dialysis facilities were hostile toward the Demo, these materials were not always readily available;
- Working with facility social workers to encourage Demonstration referrals;
- Speeding up the contacting of rollover patients through using electronic files to keep track of enrollment, as the process of contacting rollover patients had become administratively burdensome and time-consuming;
- Developing a locally-based marketing campaign in San Diego. This campaign included presentations at community agencies, churches, senior citizen organizations, and other

[§] A "limited" Demo contract allowed the non-contracting physicians to be the Demo nephrologist only for their existing patients who expressed a desire to enroll in the Demo. These physicians were not listed as participating Demo physicians in the marketing literature.

organizations where ESRD patients were likely to receive services. The campaign also included print media coverage in local newspapers and a Public Service Announcement.

These initiatives to boost enrollment appeared to have a positive impact on the enrollment process. Many referrals to the Demo came through social workers at contracted and non-contracted dialysis units. Enrollment in the San Diego area increased 115% in the six months following the Public Service Announcement. Although Kaiser response rates for the first few CMS mailings declined with each subsequent mailing, response rates increased significantly in the final two mailings, an increase which Kaiser attributes, in part, to the newly designed brochure used in the final mailings.

Kaiser made some alterations to the enrollment process. Specifically, Kaiser ceased contracting with the outside organization that had operated the 1-800 number for information on the Demo and Demonstration enrollment. As the volume of calls was lower than anticipated, Kaiser realized that it could handle the 1-800 number internally, and that such a move would likely increase the quality of information presented to the potential enrollee.

By January 1999, enrollment was in line with expectations for both new and rollover patients, and showed significant progress from the previously lower-than expected numbers. Demonstration enrollment further increased 180% from the end of June 1999 until the beginning of April 2000. Kaiser attributed the increase in enrollment, in part, to the activities of its service associate and sales executives who sent informational brochures to all contracted dialysis units in November of 1999 and visited the units to speak directly with social workers and case managers.

By the end of the Demo open enrollment, Kaiser had enrolled 1,649 patients in the Demonstration program in all. They disenrolled 293 patients, including those patients (approximately 83% of all disenrollees) who died during the Demo.

Exhibit 1-6 presents Kaiser Demonstration enrollment figures over the course of the program.

Exhibit 1-6: Kaiser Demonstration Enrollment Experience

Date	Net Enrollment*	Total (Gross) Enrollment	Total Disenrollments**	Total Deaths
Aug. 1, 1998	253	263	3	7
Feb. 1, 1999	551	605	9	45
Aug. 1, 1999	736	845	17	92
Feb. 1, 2000	1077	1279	30	172
Aug. 1, 2000	1304	1587	49	234
Feb. 1, 2001	1356	1649	53	240

* Does not include patients who have disenrolled or died
** Does not include deaths

Exhibit 1-7 provides demographic characteristics by modality for the sample of Kaiser's enrollees included in the data collection effort for evaluation.

Exhibit 1-7: Selected Characteristics for Kaiser Demonstration Patients

	PD	TX	HD RO	HD Active
Sample Size (n)	82	62	211	470
Mean Age (years)	49.4	47.6	61.6	56.2
Non-white race (%)	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

2) Provider Arrangements and Relationships

Provider Arrangements

As described above, Kaiser Permanente Southern California Region (KPSCR) is a non-profit group-practice health maintenance organization (HMO). Its arrangements with providers for the Demo stemmed from its traditional structure.

Initially Kaiser had some difficulties in signing community provider contracts for the Demo. An initial RFP process was abandoned, as were quality-based incentives originally included in Demonstration provider contracts. Instead, Kaiser adopted "process-based" incentives in the amount of $40 per member per month (PMPM) for nephrologists to compensate for additional care provided to Demonstration patients and to encourage provider participation in the Demo. At the time of the first site visit, shortly before the Demo began operating, Kaiser had signed contracts with 29 individual nephrologists and 26 nephrology groups. In order to encourage enrollment of patients into the Demo, Kaiser instituted a policy to offer a temporary contract (i.e., would expire at the end of the Demo) to any nephrologist whose patient wanted to enroll in the program. Kaiser established several dozen such contracts over time.

Similar to the incentives offered to nephrologists, dialysis facilities received incentive payments of $20 PMPM for their participation in the Demo. Over time, Kaiser moved to "internalize" dialysis services. Through a partnership with Fresenius, Kaiser opened their own dialysis units, believing that care coordination is improved when all of the patient's care is provided internally by Kaiser. Existing patients were not required to switch to one of the Kaiser-owned facilities, but new patients were asked to select one of these facilities in which to receive dialysis.

Kaiser provided medical directorship for the internal, Fresenius facilities. Physicians received monetary incentives based on adequacy / quality assurance, albumin and laboratory data, and

reductions in hospitalization rates. Kaiser found that the biggest obstacle to internalizing dialysis was geographic location (i.e., distance some patients had to travel to the center).

Provider arrangements were structured slightly differently in the San Diego region. From the time that the Demo was operationalized in San Diego, all Demonstration patients were required to receive care from one of three Total Renal Care (TRC) dialysis facilities.

Relationships with Providers

Demonstration Start-up

During the initial stages of the Demo, reaction to the Demonstration program from the provider community, including both physicians and dialysis units, was fairly negative. The provider community was concerned about the Demo, primarily because providers believed that Kaiser had an unfair competitive advantage. Since community nephrologists were responsible for outpatient hemodialysis services only, they were concerned about losing revenue generated from patient hospitalizations. They were also concerned about continuity of care due to poor communications with Kaiser nephrologists. According to these providers, Kaiser provided very little patient data or quality improvement information.

At the time of Demonstration start-up, the dialysis units were particularly concerned because Kaiser had recently entered into a joint venture with Fresenius/BMA. They believed that once the Demo was over, Kaiser would begin contracting exclusively with Fresenius. Like the nephrologists, the dialysis facilities believed that Kaiser had an unfair competitive advantage that would allow Kaiser to increase patient enrollment during the Demo. After the Demo, the units believed that Kaiser would establish its own dialysis units and cease contracting with other units.

Nevertheless, both nephrologists and facilities acknowledged Kaiser's reputation for providing high quality care and reported that they would maintain a neutral stance about the Demo vis-à-vis their patients.

Over Time

Over time, community nephrologists and contract dialysis units exhibited a more positive attitude toward the Demo. 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. The primary reason for increased comfort on the part of contract providers was that these providers did not experience a substantial decline in patient volume due to enrollment in the Demo. We did not learn of any providers who terminated their contract.

Overall contract provider impressions of the Demonstration are provided in Exhibit 1-8.

Exhibit 1-8: Contract Provider Impressions of the Demonstration

Demonstration Benefits	Demonstration Threats
Demo saves patients money Care manager is a valuable resource Routine quality reports are useful Kaiser has more coordination on an inpatient basis Few patients from any single nephrologist or dialysis unit enrolled in the Demo (limited reduction in revenue)	Negative impact on referral network (prevents referrals) Kaiser would have an unfair competitive advantage post-Demo Kaiser does not offer transportation benefits, which are often needed by patients

In contrast to the more positive attitudes of contract providers, community providers without Demonstration contracts continued to maintain somewhat negative attitudes toward the Demo.

3) Service Delivery and Care Coordination

Below we summarize service delivery and care coordination processes under Kaiser's Demonstration program. Importantly, there were no differences in service delivery or care coordination between Demonstration and non-Demonstration Kaiser ESRD patients.

Clinician Roles

As discussed previously, in addition to the internal interdisciplinary team, external community nephrologists also played a critical role in providing patient care at dialysis clinics. At the time of Demonstration start-up, communication between multidisciplinary care teams and external nephrologists was informal and erratic. Perceived lapses in communication were, in part, responsible for the initially negative attitudes of contract providers. As the Demo progressed, Kaiser focused considerable attention on improving communication between care teams and community nephrologists. Procedures implemented to improve communication between internal and external providers included the following:

- Case managers faxed write-ups and recommendations from each patient's quarterly visit to the patient's dialysis center. Write-ups from the nephrologist visits were also provided.
- The case manager contacted the dialysis unit and community nephrologist by phone for urgent issues.
- In conjunction with community nephrologists, Kaiser developed a hospital discharge report. This report helped ensure that community nephrologists were aware any time their patients were hospitalized.
- Community nephrologists received Renal Quality Management reports.

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 follow-up.

Quality Improvement Program

Kaiser had a pre-existing quality improvement program that was continued under the Demo. Key components of the program included physician and facility report cards, facility site inspections, a quality of life questionnaire, a quality outcomes assessment tool, and a vascular access tracking tool. Outcomes were regularly monitored against established standards. Kaiser implemented the following additional steps for ESRD patients during the Demo:

- Using report card data, Kaiser identified any outliers. The list of outliers was sent to the appropriate case managers for review.
- The case manager assessed the situation to determine what the quality issues were, for example, whether there was a problem internal to Kaiser or with an external provider.
- The case manager sent a Plan of Action to the regional QM committee. The QM committee sent letters to the appropriate providers requesting corrective action.

Additionally, routine meetings among and across multidisciplinary teams were held to help disseminate information among providers.

Kaiser also implemented several drug- or disease-specific quality initiatives.

- For example, the plan implemented a review system to monitor the usage of Epogen (EPO) for the Demonstration patients as they had noticed that some units were using 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 successfully shifted administration of Epogen from IV to subcutaneous with a reported subcutaneous administration rate of 67% in 2000.
- Under another quality improvement initiative, Kaiser reviewed problems associated with transplant hyperlipidemia.
- Kaiser had an aggressive program to ensure that fistulas were patients' primary access sites. 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% among new accesses placed.

4) Experience with No-pay Claims

Consistent with the experiences of Medicare+Choice programs at large, Kaiser faced significant challenges in submitting no-pay claims. Challenges included:

- Developing systems for capturing encounter data. As a group model HMO, Kaiser did not have a system in place for capturing such data. It was necessary for Kaiser to implement an entirely new system to do so.
- Constructing an interface to translate claims. Using data from the new encounter system, Kaiser needed to translate the information into data that were readable by a CMS format.

Much of the data needed to be translated by hand (i.e., there was no automated way to translate the information).

- Lack of technical assistance available. Kaiser experienced difficulties in identifying individuals at CMS and at the carriers and fiscal intermediary to assist the plan in developing the no-pay claims interface.

- Readiness of fiscal intermediary (FI). The fiscal intermediary (i.e., the organization through which Kaiser was to submit its inpatient no-pay claims) experienced delays in their ability to accept no-pay claims. Ultimately, one FI was never able to process no-pay claims. Mid-way through the Demo, Kaiser had to begin working with a different fiscal intermediary.

- Assignment to multiple carriers (for outpatient claims submission). Complicating the process was that Kaiser was assigned to multiple carriers (i.e., carrier was dependent on geographic region). Thus, it was necessary for Kaiser to address technical problems with more than one carrier simultaneously.

Because of the difficulties with no-pay claims submission despite years of hard work and considerable expense, in the Spring of 2000 CMS announced that plans for no-pay claims submission for the Demo were cancelled. The evaluators worked individually with the Demonstration sites to obtain data so that financial analyses could still be conducted (see Chapter 11).

5) Patient Satisfaction

During the course of the Demo, we conducted focus groups with 14 Kaiser Demonstration patients, including eight hemodialysis patients, two peritoneal dialysis patients, and four functioning graft patients. Results from these focus groups are summarized below.

- ***Overall satisfaction.*** Despite some individual complaints, all 15 patients reported a high level of satisfaction with the services and care provided in the Demo. Components that patients mentioned as being particularly satisfactory included convenience of having all services in a centralized location; having a wide range of professionals available to them; preventive care aspect; and financial benefits. Concerns mentioned included having to switch dialysis facilities; having to switch nephrologists; referral process; worries about what would happen after the Demo ended; and not having enough time with their doctors.

- ***Enrollment.*** Without exception, all 15 patients reported that their primary motivation for enrolling in the Demo was the financial benefits offered by the Demo.

- ***Concerns prior to enrollment.*** The Demonstration patients discussed some concerns they experienced prior to enrolling in the program. Concerns included cost of medications (the patient was assured there was no medication co-pay); the possibility of needing to switch facilities or physicians; having heard negative comments about Kaiser in general; locations of facilities; and discouragement of enrollment by the patient's pre-Demonstration physician. The patients reported that Kaiser was very reassuring in responding to and discussing their concerns. For example, in two cases the patients' pre-Demonstration

nephrologists were invited to join the Demo so that the patients would not need to switch physicians.

- ***Low enrollment levels.*** Patients were queried as to why they thought other ESRD patients had not decided to enroll in the Demo. The majority of focus group participants agreed that it was probably the case that many ESRD patients did not know about the Demo. Other reasons mentioned were: patients did not want to undergo change; they did not want to switch facilities or doctors; patients may live a considerable distance from participating facilities; patients may have been told by their physician not to enroll; and perhaps patients had heard negative things about Kaiser in general.

- ***Quality of care.*** In general, focus group participants reported being satisfied with the quality of care received under the Demo. A majority of patients felt that their case manager was a valuable component of the program, although a couple patients did not know who their case manager was. Most patients reported positive experiences during hospitalizations or ER visits, although one patient was concerned that the treating physician was not especially familiar with the patient's case due to a lack of coordination. Several patients complained about the referral process, but most patients did not have a problem obtaining referrals to specialists. One PD patient would have liked his lab results to be more accessible.

- ***Pre-Demonstration versus Demonstration Comparison.*** Patients overwhelmingly reported preferring the care provided under the Demo to care under FFS Medicare. Reasons mentioned for preferring care under the Demo included centralization of services; better care coordination; more services; and, most importantly, less financial burden (reported by all focus group participants). One patient noted that better transportation services under the Demo would have been appreciated and two patients felt that their care had been better coordinated under FFS.

2. Experience of the HOI/ARO Demonstration Site

a. Proposed Structure of the Demonstration Program

In contrast to Kaiser's group-model managed care structure, the ARO / HOI site is a wholly owned for-profit subsidiary of Blue Cross and Blue Shield of Florida that relies on contracts with an independent network of providers to provide patient care. The entity had been operational for 11 years at the time of the Demonstration application; however, HOI did not have an established ESRD program prior to the Demo. In designing its approach to the Demo, HOI utilized a "Continuous Quality Improvement approach" to create an "integrated delivery of care." HOI's stated goals for participating in the Demonstration program include:

- "Enhance patients' health status which should reduce the need for high-cost medical services." HOI anticipated using preventive services, medications, and case management to improve the health status of patients, identify problems for earlier (less expensive) treatment, and reduce the need for some costly care.

- "Provide for improved patient well-being and enhanced lifestyle." The intention was that educational, psychosocial, and rehabilitation programs were going to supplement clinical care enrollees received and have a positive effect on patients well being.

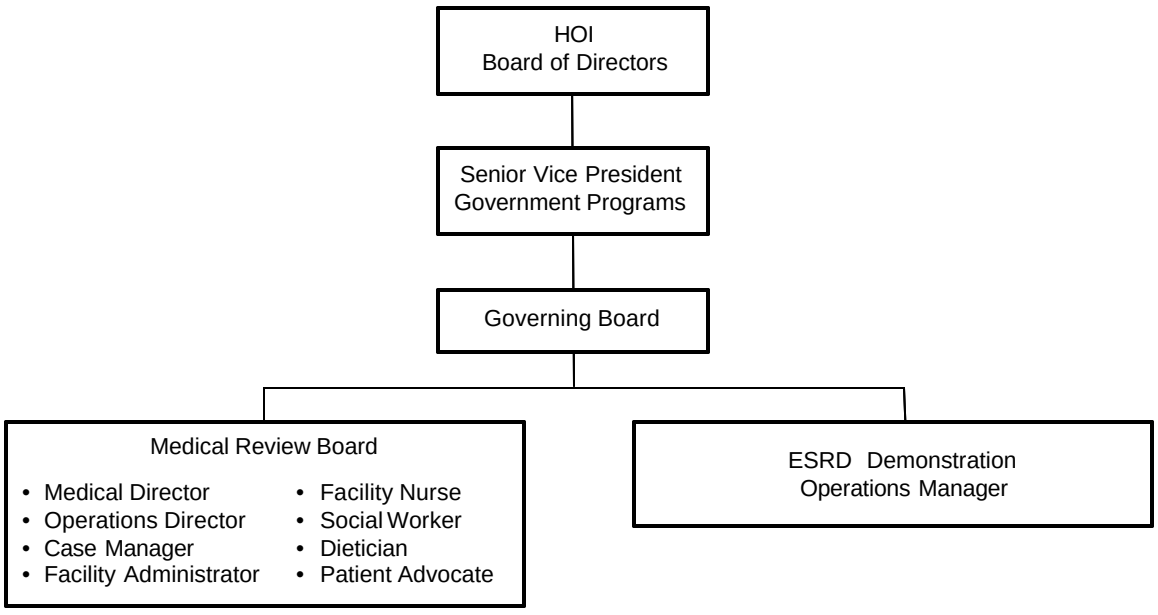
- "Provide more efficient utilization of health care resources." HOI planned to use a payment system that offered financial incentives for facilities that achieved documented improvements in patient outcomes. Additionally, the Demo sought to use nurse practitioners with nephrologists to assess patient care needs and to work with the case manager on coordinating care.

1) Organizational Structure

Advanced Renal Options (ARO) was the Demonstration program run by HOI operating in Dade, Broward, and Palm Beach counties in Florida. HOI operates throughout Florida, but limited the Demonstration operations to these counties. Providers are paid based on capitation, fee-for-service, DRGs, and per-diem rates. At the time the Demo was initiated, HOI was the second largest HMO in the Broward, Dade, and Palm Beach county area with total enrollment nearing 300,000 covered lives.

ARO was designed to operate as a separate program within HOI's organization and with a mixture of administrative staff being dedicated to the Demo and drawing on HOI staff in some instances (e.g., marketing staff). HOI established a Governing Board of senior management to oversee the project. An Operations Manager was designated to oversee day-to-day activities, and a Medical Review Board was created to oversee the development of medical policies and protocols for the Demo, as well as to handle grievances. The Medical Review Board was comprised of a Medical Director (a physician), the operations manager, a case manager, a facility administrator, a facility nurse, a social worker, a dietitian, and a consumer / patient advocate. See Exhibit 1-9 for an overview of HOI's structure.

Exhibit 1-9: Structure of HOI Demonstration Site



2) Provider Contracting and Reimbursement

When HOI applied for the Demo, its network of more than 2,800 physicians included 77 nephrologists. HOI developed a contract with one network of nephrologists to provide Demo-related care and anticipated adding more if needed. Access to care of other needed specialists (e.g., vascular surgeons, cardiologists, etc.) would be gained through HOI's established network of providers.

Compensation, in the form of a global capitation rate, to nephrologists was going to be based on primary care services delivered in both the inpatient and outpatient setting, renal care and management of dialysis in both settings, referral to other specialties, and the hiring of additional nurse practitioners. It was also expected that an incentive program would be developed based on 10% to 15% of a provider's per member capitation rate. To be eligible for the incentive payments, the provider had to achieve:

- 75% of patients receiving appropriate preventive services;
- 60% of patients participating in educational programs;
- 40% of patients participating in a rehabilitation program;
- hospitalizations meet "target rate"; and,
- stable or improvements in patient satisfaction.

HOI had preexisting relationships with 51 dialysis units in the target area and anticipated establishing Demo-specific contracts with at least 30 of the dialysis facilities, relying on a contract with one of the major national chains to secure the services of about 20 units. Dialysis units were to be paid a negotiated composite rate inclusive of equipment, supplies, labor, selected drugs, and medications. The payment was to be based on the Medicare composite rate, with additional payments for the enhanced services. The facility incentive program was to be approximately 3% to 5% of the total payment based on meeting and maintaining standards in:

- Kt / V
- Albumin
- Anemia
- Blood Pressure Control
- Reuse standards

HOI expected to contract with Jackson Memorial Hospital, in Miami, to provide transplant services, and intended to use established contracts with the 36 hospitals in the area to provide needed care for Demonstration patients. These contracts were based on per diem rates.

Beyond this traditional set of providers, HOI sought to include additional services with the program: transportation for dialysis patients, rehabilitation services in the form of physical and occupational therapy, and home and nursing home dialysis.

3) Provider Roles

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

The nephrologists were to serve as the primary care physician and provide appropriate referrals, authorizations, and arrangements for specialty and hospital care. The nephrologist was to be responsible for coordinating the team to establish a plan of care for all patients; assessing transplant candidacy; determining modality, and access type (when appropriate); working with the patient to identify an appropriate rehabilitation plan; and determining dietary, nutritional, and pharmaceutical prescriptions.

The nurse practitioner's role was to work with the nephrologist and serve as the primary care giver for both renal and non-renal services. It was anticipated that the nurse practitioner would "be in a position to identify potential problems and treat them early on, frequently avoiding an inpatient admission." It was expected that the nurse practitioner would see patients on a weekly basis.

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 to be 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 was to focus the plan of care for each patient to "continually improve the quality of renal patient care." It was anticipated that case managers would provide patient and dialysis staff educational seminars to encourage greater patient participation in decision-making. The HOI program anticipated using one case manager for up to 170 patients, one nephrologist for 100 patients, and one nurse practitioner for 50 to 60 patients.

4) Service Package

In addition to the case management services described above, HOI proposed to provide several benefits beyond the typical Medicare covered services.

It is worth noting that HOI anticipated funding these extra benefits through a combination of the additional five percent of AAPCC and expected savings in medical costs.

Exhibit 1-10: "Extra" Benefits Offered by HOI

Service/Benefit	Description
Co-insurance and Deductibles	$0 co-pay for physician services (including annual physical and access to preventive services)
Prescription Drug Benefit, Vitamins	$0 co-pay for prescription drugs and dialysis-related non prescription drugs
Nutritional Supplements	Provided free of charge in the dialysis unit
Transportation Benefit	Transport to and from dialysis for those who have need, determined by the social worker and case manager
Rehabilitation Program	Participation in a program of exercise, occupational therapy, neurological rehabilitation, amputee rehabilitation and referral to a renal employment program
Home Health Services	Made available for post-surgical follow-up for new or revised access sites, exit site catheter care, diabetic wound care and other services as needed
Out of Network Dialysis**	Up to 30 days per year at an approved facility
Health Education	Programs would be available on a wide variety of topics: diet, social support, renal disease management, care of vascular access, care of peritoneal access, diabetes management, hypertension management

5) Clinical Protocols, Quality Assessment, and Performance Improvement

HOI anticipated using algorithms for common clinical events to guide patient care and ensure consistency across sites. The Medical Review Board would serve to review and revise clinical protocols. In the Demonstration application, HOI referred to several aspects of care that would be assessed with protocols: Kt/V, anemia standards, vascular access management, transplants, preventive services, and rehabilitative services. Goals for dialysis adequacy were set at 1.3 for nondiabetic hemodialysis patients, 1.4 for diabetic hemodialysis patients, and 1.8 for weekly Kt/V for peritoneal dialysis patients. Only the access management protocol was described in detail with steps including:

- Ongoing screening by the nurse practitioner;
- Clinical indicators of stenosis leading to Doppler study or A/V fistulagram or A/V fistulagram with angioplasty;
- If significant stenosis is present, referral to a radiologist for care will be made, followed by a vascular surgeon if necessary.

HOI proposed to use several quality indicators to "proactively, objectively, and systematically monitor, evaluate, and improve the quality of care and service provided to the enrollee." The

** Coverage for out-of-area services became a Medicare benefit during the time period of the Demo.

indicators included the following: adequacy of dialysis and nutrition – minimum Kt/V and serum albumin; access management; functional status; referral for transplantation; quality of life; patient satisfaction; hospitalizations; infection rates; access to services; blood pressure control; anemia; preventative health measures; intradialytic symptoms; uremic symptoms; intradialytic hypotension; emergency room visits; modality of treatment; and mortality.

In addition to the quality indicators listed above, HOI intended to use data from the Demonstration to develop an ESRD simulation model to study the relationships between treatment methods, outcomes, and costs.

HOI intended to use the KDQoL biannually and a monthly patient satisfaction survey to assess patients' quality of life and satisfaction with the program.

6) Marketing Plan

HOI selected the target area of Dade, Broward, and Palm Beach counties because of its size and racial and socioeconomic diversity in patient population. HOI's marketing approach was based on educating the nephrologists in the target area regarding the potential benefits of the Demo; it was hoped that nephrologists, in turn, would encourage their patients to enroll. This educational outreach was based on networking among physicians in the target area, direct mailing to providers, and in-person meetings with groups of providers in the area. To overcome concerns about losing patients among the providers not selected to participate in the initial Demo, HOI planned to encourage these providers to potentially participate in future expansions of the program. In addition to efforts aimed at nephrologists, HOI planned to launch educational meetings with potential patients and to market the program through the Florida ESRD patient newsletter.

b. HOI's Experience During the Demonstration

In this section, we describe HOI's actual experiences in implementing and running the managed care Demo. Our description is focused on those areas where: 1) HOI's processes elucidate or inform key Demonstration activities; and/or 2) the program's experiences diverged from its plans or expectations as described in the original proposal to CMS. The reader should assume that, unless otherwise expounded upon, structural and operational features of the Demo as discussed above were implemented and carried out as planned.

1) Marketing and Enrollment

Enrollment and Marketing Process

At the time of Demonstration initiation, HOI modeled its enrollment processes for the Demo on their 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 Demo-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 1-800 enrollment

line. The enrollment process was highly focused on providing personal attention; for instance, follow-up calls were provided even after a patient enrolled.

HOI made changes to its enrollment process to counter problems that arose and to make the process run more smoothly. First, outdated eligibility criteria used by CMS to determine patient eligibility resulted in the initial rejection of many eligible patients who wanted to enroll in the Demo. HOI responded to this problem by working with CMS's regional and national offices on streamlining the eligibility determination process of potential Demonstration enrollees (this effort caused HOI to expend more resources than had been projected).

The BBA provision requiring all patients who enroll in a Medicare HMO to become active on the first day of the month following enrollment also caused a problem for the Demonstration enrollment, as HOI's enrollment system erroneously applied the BBA provision to Demonstration patients. As a result, 37 patients who enrolled in the Demo in late December 1998 were informed that the Demonstration services would be available as of January 1, 1999. HOI worked with the CMS regional office to enroll these patients on an "emergency basis" and then moved to rectify this problem. Furthermore, at the beginning of the Demo, ARO enrolled patients based on their self-report of Medicare eligibility. As the Demo proceeded, ARO changed this system of enrollment in order to minimize their financial risk. Consequently, ARO 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.

Finally, by July 1, 1999, HOI had centered its enrollment process around a dedicated sales force of four individuals. The dedicated sales force staff were selected based on the retention of their enrollees and a proven track record. The responsibilities of the sales force were distributed by county (one individual was responsible for one of the three county); the fourth member was bilingual and worked across multiple counties. These individuals underwent extensive training. The sales force provided and solicited a great deal of information in their conversations with patients and then conducted an in-person meeting with patients who met the eligibility criteria. The sales force staff also ensured that the patients and their family members understood the program in complete detail. According to ARO, the dedicated sales force helped facilitate more coordination and contact among members and an overall stronger relationship between the programs and enrollees in most instances. However, due to the actions of one salesperson, CMS precluded ARO representatives from marketing the Demo to patients during a dialysis session.

Patients who joined the Demo reported that they did not encounter any difficulties in the enrollment process.

Enrollment Levels and Activities to Increase Enrollment

By October 1, 1999 gross enrollment had surpassed 600, the minimum patient target set by CMS. Reasons for enrollment into the Demo collected by the evaluators are presented in Exhibit 1-11.

Exhibit 1-11: Reasons for Enrollment in the HOI Demonstration

Reason for Enrolling in Demonstration[1]	HD	PD	TX
Cost of Outpatient Drugs	50.8	82.4	40.0
Cost of Co-payments	41.6	70.6	0
Recommendation of Doctor	44.1	23.5	40.0
Other	16.6	11.8	20.0

[1] columns do not add to 100 because respondents could select up to two answers

While enrollment remained steady at a rate of 30-40 new enrollees per month through June 2000, gross enrollment was lower than initially expected. Some of the initial problems with enrollment discussed above might have contributed to the initial lower-than-expected enrollment. Other potential reasons for the lower-than-expected enrollment were the limited proactive marketing that took place through HOI's internal telemarketing unit because of the size of the Demo compared to other products for which the telemarketing unit was responsible. HOI also noted that educating physicians about the Demo took longer than expected.

By July of 1998, HOI had implemented some steps to increase enrollment in the Demo. For example, HOI hosted a luncheon for social workers in dialysis units to discuss the Demo so that these social workers could then explain the Demo fully to their patients. HOI posted Spanish language posters in some dialysis units in order to reach Spanish-speaking patients. HOI also tried to leverage the support of dialysis units and nephrologists by discussing the Demo with these individuals at routine meetings.

In order to encourage enrollment by addressing the concerns of patients who did not want to join the Demo, HOI conducted patient focus groups early in the enrollment process. Patients cited the following issues as their primary concerns and reasons for not wanting to join the Demo:

- Did not want to change physician or dialysis unit
- Did not like managed care / had a fear of managed care
- Afraid of participating in a "Demonstration" project
- Discouraged against joining the Demo by physicians
- Worried about giving up their supplemental health insurance
- Unsure about insurance coverage after the Demo ended

Other focus groups revealed additional reasons as to why patients might not have enrolled in the Demo including the lack of bilingual materials and the fact that many patients did not want to travel to Jacksonville for transplant services (see Provider Arrangement, below). Additionally, some dually covered by Medicare and Medicaid patients were hesitant to enroll in the Demo because they believed that HOI, unlike Medicaid, would not provide transportation to the dialysis facilities. Many diabetics are in wheelchairs and rely on this

transportation service. They would not join the Demo if it meant losing this benefit. (Note: In actuality, patients probably would not have lost this benefit. If they were already getting it under Medicaid, they would continue to do so. However, this arrangement was probably misunderstood by patients.)

HOI addressed some patient concerns early in the enrollment process. For instance, they addressed patients' questions about supplemental insurance by telling patients to keep their supplemental insurance for a few months in case they did not like the Demo 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 Demo. In response to patient concerns about the distance to the transplant center, ARO implemented a program to have the hospital transplant surgeon regularly visit the Miami region (see Provider Arrangements, Incentive Program, and Relationships for additional detail). The care managers also discussed patients' concerns about what was to happen at the end of the Demo and assured patients that they would be able to enroll in HOI after the Demo concluded.

As of November 2000, HOI had closed their enrollment period for new patients as part of the wind-down process of the Demo. They enrolled 967 patients in the Demonstration program in all. They disenrolled 288 patients, including those patients (approximately 59% of disenrollees) who died during the Demo.

Exhibit 1-12 presents HOI Demo enrollment figures over the course of the program.

Exhibit 1-12: HOI Demonstration Enrollment Figures

Date	Net Enrollment*	Total (Gross) Enrollment	Total Disenrollments**	Total Deaths
Dec. 1, 1998	350	390	23	17
June 1, 1999	484	594	48	62
Dec. 1, 1999	565	751	80	106
June 1, 2000	649	913	111	153
Dec. 1, 2000	679	967	119	169

* Does not include patients who have disenrolled or died
** Does not include deaths

Exhibit 1-13 provides demographic characteristics by modality for those HOI enrollees included in the data collection for the evaluation.

Exhibit 1-13: Selected Characteristics for HOI Demonstration Patients

	PD	TX	HD
Sample Size (n)	27	13	594
Mean Age (years)	51.9	45.3	60.4
Non-white Race (%)	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

2) Provider Arrangements, Incentive Program, and Relationships

Provider Arrangements

As described previously, Health Options, Inc. is a network-model health maintenance organization. Like Kaiser, HOI's provider arrangements and contracting for the Demo were consistent with its traditional structure.

The Advanced Renal Options (ARO) network of participating nephrologists consisted primarily of those nephrologists with whom HOI contracted prior to the Demo. After winning the Demonstration grant, HOI experienced an overwhelming number of requests from providers who were interested in participating in the Demo. However, administrators decided to limit the Demonstration provider network to allow for greater control over utilization and outcomes.

Similarly, HOI generally limited their network of dialysis facilities to those with which the plan had existing contracts. Dialysis facilities were selected based on where the nephrologists practice. The number of facilities included in the network expanded throughout the course of the Demo.

At the time that HOI submitted their proposal to CMS for the Demo, the HMO had a tentative agreement with Jackson Memorial Hospital in Miami to provide transplant services. However, contract negotiations, which lasted more than a year, subsequently proved exceedingly difficult and ultimately the two organizations could not come to a financial agreement.

Instead, HOI contracted with Jacksonville Methodist Hospital, a transplant center located in Jacksonville, a considerable distance (300 miles) from most Demonstration patients. Providers expressed concerns 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, mid-way through the Demonstration HOI arranged for the transplant surgeon to spend time each month in Miami to conduct pre-transplant workups.

Some specialists in ARO's network were paid on a capitated basis while others were paid on a fee-for-service basis. Individual hospitals, already part of the HOI network, were contracted for the Demo. Additionally, part way through the Demo, HOI contracted with free standing clinics to provide routine vascular access services. HOI believed that providing patients access to these clinics was responsible for a drop in hospitalizations.

Incentive Program

HOI developed incentive programs for nephrologists and dialysis facilities. The nephrologist incentive program was structured to involve all of the Demonstration nephrologists and represented up to 20% of their base salaries. There were to be five components to the program:

- Hospital days (30%),
- URR (20%),
- Albumin (20%),
- Hemoglobin (20%), and
- Patient satisfaction (10%).

The program was structured such that providers who met the criteria got the full amount of the bonus component, and providers who did not meet the criteria would not receive any portion of that bonus component (a "pass/fail" system). The incentives were to be based on six months of data. A solo practitioner would need a minimum of 15 Demonstration patients to be eligible for the incentive program and group practices needed to have at least 25 Demonstration enrollees.

The dialysis unit incentive program was limited, representing only up to 3% of the dialysis unit base payment rate. There were no enrollment minimums for dialysis unit participation in the incentive program.

Ultimately, incentive payments were made to six out of 18 eligible practices for the first six months of the program. However, in 1999 CMS determined that the incentive plan was not in compliance with their regulations due to the potential negative impact on patients' hospitalization and HOI was required to suspend the incentive plan. Additionally, HOI determined the original incentive plan encouraged physicians to increase EPO doses. HOI developed a second incentive plan that was approved by CMS. The plan included the requirement that the medical loss ratio had to be 90% before HOI would make physician payments. This financial point was never reached, effectively eliminating HOI's incentive program.

Relationship with Provider Community

Overall, HOI had a good reputation in the provider community, and the Demonstration providers were enthusiastic about participating in the Demo. The participating providers (both

dialysis units and nephrologists) reported to us that they believe managed care to be inevitable, and looked at the Demo as a way to define an optimal managed care service delivery structure for ESRD patients. Nephrologists were also drawn by the opportunity to serve as both primary care physician and provider of dialysis services, and were pleased by the inclusion of the care manager and other extra benefits in the program. Dialysis units were enthusiastic about the prospect of incentive payments based on meeting quality goals.

All of the providers from our site visits reported being comfortable with HOI's service delivery structure and payment rates. However, they believed that the ARO provider network should be expanded. In particular, dialysis chain representatives noted that the chains had some units that were participating and some that had been shut out of the Demo. Furthermore, the providers believed that a main reason for patients *not* to join the Demo would be having to switch providers.

To enhance their relationship with providers, HOI hosted quarterly meetings and provided physicians with summaries of their own patient data. The data were well received and helped heighten physician awareness. HOI noticed changes in physician behavior as a result. Physicians reported being very satisfied with the work of HOI care managers.

There were some isolated cases in which providers voiced their opposition to the Demo. For instance, three providers were dropped from the HOI network after they refused to sign a new contract in protest of the Demo. No provider with a Demonstration contract withdrew from the program, although several nephrologists were terminated due to concerns over quality.

3) Service Delivery and Care Coordination

Below we summarize service delivery and care coordination processes under HOI's Demonstration program.

Clinician Roles

For each individual patient, the care management process was initiated upon enrollment. Within the first few days following a member's enrollment in the ESRD Demonstration, the case managers made initial telephone contact with the member. At that time, the case manager conducted a patient assessment using a questionnaire. The case manager then:

- Visited with the patient at the dialysis facility.
- Collaborated with the patient, family, and members of the health care team to develop the plan of care.
- Held quarterly meetings with nephrologists.
- Participated in monthly facility care management meetings at the dialysis facility.
- On an ongoing basis, facilitated information flow and services among nephrologists, dialysis unit staff, and specialists and provided monitoring, follow-up, and feedback. For instance, the care manager analyzed patient outcome and cost data for nephrology care and initiated continuous improvement as appropriate. They also interviewed hospitalized patients and reported this information back to dialysis unit staff.

- On an ongoing basis, met regularly with patients and their families. The schedule of meetings was dependent on the severity classification of the patient. Meetings ranged from monthly to as often as weekly.
- Coordinated pre- and post-transplant care.
- Attended quarterly social worker meetings.

Case managers worked closely with one another. Each care manager was hired due to a particular area of expertise. Case managers held weekly, and sometimes daily, staff meetings. On average, each case manager handled 50 patients. Toward the end of the Demo, when resources were strained, case managers' case loads increased to approximately 70 patients.

Another key difference between Demonstration and non-Demonstration service delivery is that the Demonstration enrollees' nephrologists functioned also as the primary care physician (PCP). The nephrologists were responsible for providing preventive and primary care services and for referring and authorizing specialty and hospital care, as well as for developing the ESRD care plan and providing nephrology services.

Demonstration patients accessed dieticians and social workers through their dialysis facility (i.e., these were not HOI positions).

Quality Improvement and Guidelines Use

HOI implemented guidelines as initially planned. However, HOI did not implement quality improvement initiatives as described in their proposal.

Utilization of services

According to HOI, patient utilization of health services did not differ significantly from original expectations. HOI reported expected levels of utilization of referral services, extra benefits, after-hours services, urgent care, and emergency services. However, utilization of skilled nursing facilities was about 50% of original expectations. Drug use, in contrast, was high.

In addition, dialysis-related costs were slightly elevated due to high utilization of EPO in specific practices. After an investigation into EPO use and implementation of a new initiative, ARO was able to decrease utilization to more normal levels. Specifically, the new initiative was a review system for every instance that a physician prescribed more than 6,000 units per treatment. The review used clinical guidelines to determine whether 6,000 units were actually warranted, approving it for those extreme cases. However, if the high dose prescription was determined to be unnecessary, the clinic was responsible for the cost of the high dose.

4) Experience with No-pay Claims

Like Kaiser, HOI experienced considerable challenges with the no-pay claims process for the Demo (see Kaiser's experience with no-pay claims, above, for background information). Challenges faced by HOI included:

- Translation of encounter data. Encounter data had to be translated to accommodate three separate claims systems (fiscal intermediary, carriers, DMERCs). A great deal of this effort was completed by hand.

- Submission of incomplete claims. Because HOI is an HMO, the plan does not receive the same data items from providers as would be submitted under Medicare fee-for-service. No-pay claims could be rejected if certain fields were blank or incomplete. HOI tried to work with the FI and carrier to code "dummy" information, but the system still tended to reject claims. Capturing the additional data from providers also proved to be difficult.

As described previously, CMS ultimately cancelled plans for the Demonstration sites to submit no-pay claims data.

5) Patient Satisfaction

Patient Focus Groups

During the course of the Demo, we conducted focus groups with 12 HOI / ARO Demonstration patients, including seven hemodialysis patients, four peritoneal dialysis patients, and one transplant patient (i.e., received a transplant during the Demo). Results from these focus groups are summarized below.

- ***Overall satisfaction.*** All 12 patients reported being very satisfied with care received under the Demonstration program. In particular, focus group participants mentioned drug coverage and coordination of care as important benefits of the Demo. The only negative comment on overall satisfaction was that the Demo offers limited flexibility in selecting non-nephrologist physicians.

- ***Enrollment.*** Focus group participants offered a variety of reasons for enrolling in the Demo. Reasons included the financial benefits offered (i.e., prescription drug coverage), coordination of care, convenience of services offered, good organization of the program, continuity of care, ability to keep the same doctors, and less travel time.

- ***Concerns prior to enrollment.*** Prior to enrollment patients only experienced minor concerns about the Demo. These concerns included worries over what would happen to their coverage once the Demo concluded and some overall concerns with managed care in general.

- ***Low enrollment levels.*** Patients were queried as to reasons why other ESRD patients may not be joining the Demo. Possibilities mentioned by the focus group participants included: the lack of bilingual marketing materials; fear of managed care and fear of change; not wanting to travel to Jacksonville for transplant services; and the perceived lack of a transportation benefit (note: there was a limited transportation benefit offered but it was not well understood).

- ***Quality of care.*** Overall, the focus group participants were satisfied with the quality of care provided under the Demo. Patients felt that HOI takes care of all their clinical needs and they praised the care managers and primary care nephrologists. While some patients

were complimentary of the referral process, others experienced difficulty in obtaining referrals. A few areas for improvement were mentioned (e.g., one patient experienced a long wait for dental appointment; patients objected to the prescription drug formulary (several patients had to pay out-of-pocket for one of their prescriptions); one patient had trouble getting an eye exam; and there was no coverage of transportation to Jacksonville for family members of transplantation patients.) All patients with hospitalizations under the Demo were satisfied with the care provided.

- ***Pre-Demonstration versus Demonstration Comparison.*** In general, patients in the focus groups appeared to prefer care under the Demo compared to their previous care. Patients greatly appreciated the coordination of care provided and the prescription drug benefit. They were also pleased that they did not need to switch dialysis units or physicians to participate.

HOI Efforts to Measure Patient Satisfaction

Despite reporting in their proposal that they would do so, HOI did not conduct any surveys to measure patient satisfaction. According to HOI administrators, the program did not receive any widespread complaints from enrollees.

3. Experience of the Xantus Site

a. Proposed Structure

Xantus Corporation (formerly Phoenix Health Care) located in Nashville, Tennessee was one of the original Demonstration sites. A private, for-profit corporation chartered by the State of Tennessee, Xantus was an HMO dedicated to serving the state's Medicaid population. In its application to CMS, Xantus put forth the following goals for its Demonstration program:

- "Show that a superior ESRD program can be built." The Xantus site was distinguished from the other sites in that it did not treat Medicare or ESRD patients prior to the Demo.

- "Prove the effectiveness of smaller scale contractors." The Xantus site offered CMS the opportunity to determine whether a focused, local initiative could achieve equal or better results than those that occur on a larger scale.

- "Comprehensive care coordination using nephrologists." The Demo proposed to rely heavily on a 14-member group of nephrologists. This group planned to hire and oversee comprehensive case management teams that included nurses, dieticians, and social workers. The nephrologists would oversee and be accountable for the case management activities.

- "Demonstrate that discounts and penalties aren't needed for financial success." Xantus's proposed financial arrangements did not involve discounts or extensive risk-shifting. They believed that there existed ample room to save money, especially through inpatient usage reductions and by motivating physicians to raise health status and manage care.

Other stated goals included:

- Improvement and maintenance of objective standards of adequacy of dialysis
- Improvement in and maintenance of patient rehabilitation and quality of life
- Development of innovative protocols in the treatment and monitoring of ESRD patients
- Improving primary and preventive care for ESRD patients
- Prospective management of vascular access to enhance patency and minimize complications and hospitalization requirements
- Application of case management to improve utilization and outcome
- Provision of services and support to patients not available under the current reimbursement method

1) Organizational Structure

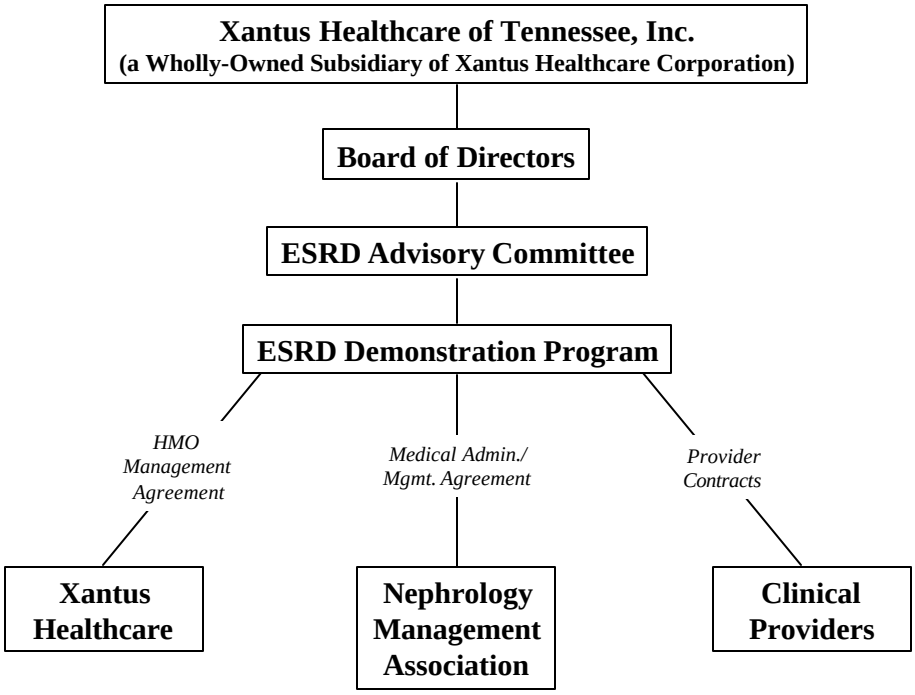
The proposed organizational structure (Exhibit 1-14) encompassed a joint effort between two organizations: Xantus Healthcare and Nephrology Associates. Xantus Corporation, headquartered in Nashville, Tennessee, was organized as a minority-owned, private for-profit corporation chartered by the State of Tennessee to operate a state-licensed health maintenance organization. Xantus Healthcare of Tennessee, Inc. was a health maintenance organization created to provide coordinated care under the TennCare program and was a wholly owned subsidiary of Xantus Healthcare Corporation.

Nephrology Associates was a single-specialty physician practice. The practice included 14 physicians and 14 regional offices. Through its outreach efforts to rural hospitals, the practice had developed a regional, integrated network, bringing renal care to previously underserved areas.

As a state-licensed HMO that met State requirements in regard to risk-bearing, Xantus Healthcare of Tennessee was planned to serve as the lead component of the organization and to receive and disburse the capitation payment from CMS. The governing board of Xantus would have had ultimate responsibility for all aspects of the Demonstration program. An ESRD Advisory Committee was planned that would provide recommendations and guidance throughout the planning and development phase of the program. After the program became operational, the Committee would continue to meet at least quarterly to assess the effectiveness of the program and to make recommendations for its continual improvement. The composition of the Committee was to include physician, nursing, social work, consumer / patient, ancillary provider, and health plan representation.

For the Demonstration program, all HMO management services (e.g., marketing, claims processing, utilization management office function) would be provided by Xantus Healthcare Corporation. Medical administrative management, including case management, supervision of utilization management, and medical information systems management, were to be provided by Nephrology Management Associates (a subsidiary of Nephrology Associates).

Exhibit 1-14: Xantus's Demonstration Organizational Structure



2) Provider Contracting

Xantus Healthcare was a for-profit network/IPA model HMO licensed to operate throughout the entire state of Tennessee. It operated though individual contracts with providers. For the Demo, Xantus planned to contract with two dialysis chains, representing 18 facilities, for the provision of outpatient dialysis services and dialysis home training. Each of the facilities was served by at least two physicians from Nephrology Associates, who were responsible for medical direction, supervision, and quality assurance within the facility.

The hospitals contracted for the Demo were to be those hospitals in the Demonstration service area with existing Xantus Healthcare contracts. Similarly, physicians to be contracted for the Demo were also among those with current Xantus Healthcare contracts. For the most part, Demonstration contracts were to be focused on subspecialists rather than on "traditional" primary care physicians, as it was planned that the Nephrology Associates nephrologists would function as the ESRD patient's primary care physician. In addition, these core Nephrology Associates physicians were to play a hands-on role in coordinating and managing all aspects of the members' health care needs.

Xantus Healthcare 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.

The core of service delivery under the Demonstration proposal was based on Nephrology Associates structure: a single group of integrated physicians, practicing within a well-defined

geographic region, utilizing a single medical information system, and a central management organization.

3) Provider Roles

It was planned that each nephrologist would coordinate care for approximately 60 ESRD patients enrolled in the Demonstration project. Nephrologists were to be supported in their efforts by a case management team of nurse case managers, dieticians, and social workers. These staff were to be employed by Nephrology Associates.

Case managers, who were to be assigned by the PCP nephrologists to individual patients, were going to be required to have daily discussions with the nephrologists whose patients they served. They were also to meet monthly with other case managers within the project to provide a forum for education. Planned functions of the case manager included:

- Conducting a home assessment
- Coordinating and procuring services and resources needed by the patient/family
- Ensuring and facilitating the attainment of quality/cost outcomes
- Intervening at key points for individual patients
- Addressing and resolving patterns which have a negative quality/cost impact
- Creating opportunities and systems to enhance outcomes

The entire care team planned to meet monthly to monitor indicators of quality care, including adequacy of dialysis, vascular access, nutrition, socioeconomic needs, hospitalization rates, transplantation needs, and rehabilitation conditions.

Additional case management was planned to be provided to the "high-risk enrollee," defined as a patient with diabetes mellitus; age 65 or older; with HIV positive status; with pre-existing atherosclerotic disease; and/or with a pre-existing malignancy. The program planned to hire at least one dedicated high-risk enrollee case manager to address the unique management of these patients.

4) Service Package

Exhibit 1-15 outlines the services/benefits that were originally planned as part of Xantus' Demonstration program.

Exhibit 1-15: Benefits Under Xantus's Demonstration Program

Service/Benefit	Description
Co-insurance and Deductibles	$70 premium* (roughly equivalent to the monthly out-of-pocket co-insurance and deductibles paid by an "average" Medicare beneficiary). Medicaid would pay the premium for dually eligible patients
Prescription and Over-the-counter Drug Benefit	Up to $780 per year; $10 co-pay per prescription*
Transportation	Eligibility for unlimited transportation to and from their dialysis center and nephrologist's office, based on demonstrated need
Nutritional Supplementation	Provision of selected nutritional supplements at no charge delivered to dialysis unit or nephrologists' office
Preventive Services	1) Physical examination; 2) Diagnostic procedures; 3) Counseling/education; 4) Immunizations
Care Coordination	1) Home visits; 2) Educational seminars; 3) Educational videotapes
Out-of-Area Coverage[††]	Full coverage of the benefits package when outside of the service area, subject to the health plan's and CMS's definitions of emergency and urgently needed services

* The $70 monthly premium and $10 Rx co-pays were eliminated shortly after Demonstration start-up.

5) Clinical Protocols, Quality Assessment, and Performance Improvement

Xantus planned to implement a variety of clinical protocols, including those for: maintenance of dialysis graft patency; prevention of complications from diabetes mellitus; control of hypertension; control of hyperlipidemia; maintenance of adequate nutrition; prevention of metabolic bone disease; provision of superior dialysis; prevention of anemia; rehabilitation of the ESRD patient; and screening for depression.

Xantus also identified a variety of quality indicators (e.g., hemodialysis Kt/V >= 1.4) along with related expected outcomes and interventions for each. Patient satisfaction surveys and quality of life assessments were also planned.

6) Provider Reimbursement

Exhibit 1-16 summarizes the reimbursement structure proposed under Xantus's Demonstration plan.

[††] Coverage for out-of-area services became a Medicare benefit during the time period of the Demo.

Exhibit 1-16: Xantus's Proposed Reimbursement Structure

Provider Type	Reimbursement Structure
Dialysis Clinics	All-inclusive flat rate per treatment
Nephrologists	Comprehensive capitation
Vascular surgeons	Capitation
Inpatient Hospital	Per Diem
Specialty Consultants	FFS
Transportation	Capitation
Radiology	FFS with goal to capitate
Laboratory	Capitation
Office Staff/Nurses	Salary

In addition to offering base reimbursement comparable to Medicare, Xantus also proposed a two-pronged provider bonus scheme: a budgeted bonus pool and a medical savings pool. The budgeted bonus pool would have been equal to a specified percentage of total negotiated nephrologist and dialysis center payments. Those entities would have received bonus payments regardless of whether or not overall medical cost savings were achieved provided they met specific quality criteria. Secondly, the program intended to distribute medical savings achieved, again provided quality targets were achieved.

7) Marketing Plan

Xantus and Nephrology Associates planned to market the Demonstration program primarily through one-on-one education and on information dissemination at the nephrologists' offices and dialysis clinics. The program also planned to use direct mail to all ESRD eligible participation; have a multimedia campaign; and show video tapes at dialysis clinics and nephrology offices.

b. Experience of the Xantus Demonstration Site

From the beginning, the Xantus Demonstration site faced a number of challenges that ultimately resulted in early closure of the Demonstration site. Below we briefly summarize the obstacles faced by the site and the limited progress the program made before its closure.

- ***Dissolution of the Xantus-Nephrology Associates partnership.*** As described above, the Xantus Demonstration plan as proposed to CMS was based on a partnership with and model of care institutionalized by Nephrology Associates, the largest nephrology practice in the region representing more than 60% of patients and 75% 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 Nephrology Associates group. 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 Nephrology Associates. As a result, the close, day-to-day working relationship between the case manager and nephrologist was not fully realized. It was also originally planned that Nephrology Associates 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 Nephrology Associates partnership, the site lost much of its management-level ESRD expertise.

- ***New Medicare risk contract requirement.*** Xantus won the Demonstration contract without already having a Medicare risk contract. Only after the award was made and the contract was signed did CMS decide 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 Demo. Thus, the Demo 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.

- ***Financial distress.*** Due to financial difficulties in the organization's other business lines, the State of Tennessee placed Xantus Corporation as a whole under receivership, and CMS placed a freeze on ESRD Demonstration enrollment effective November 1, 1999. By mutual agreement between Xantus Corporation and CMS, the Demo 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, staff in the State Department of Commerce and Insurance, the ESRD Network, and the Federal Regional Office in obtaining secondary coverage to supplement Medicare.

Despite these challenges, during its year of operation the Xantus Demonstration site did make considerable progress toward implementing and running the Demo.

- ***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 Demo. It is of interest that the dialysis facilities operated by Nephrology Associates physicians did not allow Xantus to market the Demo in those facilities.

- ***Enrollment.*** Xantus began service delivery in September 1998. In the first eight months of the Demo, 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 co-payments for prescriptions. The site believed that these changes positively affected enrollment levels.

Importantly, Xantus's original plan assumed that the vast majority of Nephrology Associates' 600+ Demonstration-eligible patients would enroll in the program due to the encouragement of their physician. With the deterioration of the relationship between Xantus and Nephrology Associates, these nephrologists were no longer a source of referral for the Demo.

Another 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. TennCare (the 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 co-payments. The only additional benefits available through the Demo were nutritional supplements and case management. Xantus estimated that about 50 percent of ESRD patients in the Demonstration service area were covered by TennCare. Thus, many eligible patients lacked any real incentive for joining the program.

By the time enrollment at the Xantus Demonstration site was frozen in November 1999, a total of 50 patients had enrolled in the program.

- ***Service Delivery and Care Coordination.*** Xantus hired two case managers for the program. These individuals visited newly enrolled patients at their homes and met with patients at least bi-monthly. Case managers were reported to facilitate communication between patients and nephrologists.

  With regard to the 5% extra benefits required under the Demo, the majority of patients in the program took advantage of the transportation benefit. Fewer than expected patients received nutritional supplements.

  Xantus reported that their relationships with non-Nephrology Associates physicians and dialysis units were positive. Xantus was able to establish Demonstration contracts with 100% of nephrologists in the area, including Nephrology Associates physicians.

D. Discussion

1. Summary of Key Demonstration Site Characteristics

Exhibit 1-17 summarizes key structural and operational characteristics of the three Demonstration programs, Kaiser Permanente, Health Options, Inc., and Xantus HealthCare. As is apparent from the table, a number of characteristics were similar across the three sites. For example, each had nephrologists act as primary care providers and each incorporated a form of case management. The sites also offered similar "extra" benefits, such as nutritional supplements.

In other ways, the programs were structured in starkly different ways. In particular, the structure of provider contracts distinguished the sites. Kaiser was a group model HMO, while

both HOI and Xantus were network model HMOs. This distinction has implications far beyond the way providers were paid – it may have affected the degree of control that the HMOs exercised over provider practices. Kaiser took it upon itself to try to actively influence provider practices, thereby instituting what might be called a disease management program. Examples include Kaiser's move to subcutaneous EPO, the site's aggressive vascular access program, and its protocol for PCP nephrologists and other care management team members to perform quarterly preventive check-ups for all patients. In contrast, HOI exerted little effort to influence provider practices. While HOI's structure certainly did not prohibit it from pursuing such management approaches, it is conceivable that Kaiser's structure actually facilitated some efforts and encouraged others.

Other characteristics, aside from those described in Exhibit 1-17, were also important in shaping the experiences of the Demonstration plans. These include their previous experience with ESRD patients, their relative sizes, and their relationships with providers.

The review of the Demonstration plans' structure and experiences presented in this chapter offers both a valuable historical record as well as a mechanism for highlighting issues for consideration as CMS considers its policy options and as additional plans consider entering the ESRD market.

2. Challenges

Perhaps not unexpectedly, each of the three Demonstration sites faced significant challenges to implementing their programs. Some of the challenges were related to the environment in which the sites were trying to operate, while others had to do with particular aspects of being part of a Demonstration project as a contractor with CMS.

a. Kaiser

At the start of the Demo, Kaiser faced challenges recruiting patients to the project due to the negative attitudes of community physicians who were unhappy about potentially losing patients to Kaiser. The result is that Kaiser spent more resources on patient recruitment than expected. The negative attitude of community physicians and the subsequent effect on enrollment of patients suggests that future efforts to recruit patients to a managed care program may be significantly affected by the attitude of the local provider community.

While Kaiser was aware of the no-pay claims regulations going into the Demo, operationalizing the no-pay claims process for Kaiser was extremely difficult given the structure of its administrative systems. The fact that CMS was steadfast in pushing Kaiser to comply with no-pay claims for three years before removing this aspect of the program was quite expensive for Kaiser – both in terms of financial and staffing resources. The burden of attempting to comply with the no-pay claims regulations likely affected the cost to conduct the Demonstration program for Kaiser, and ultimately the financial status of Kaiser's Demo program. The difficulty in complying with no-pay claims for a system such as Kaiser's is an issue that should be given more careful consideration by CMS in preparation for future Demonstration projects.

b. HOI

HOI's program of managed care for ESRD patients was created specifically for the Demo. HOI's structure and experience may be considered more relevant to other potential programs than the program at Kaiser. Two aspects of HOI's experience are particularly noteworthy.

First, despite expectations and several months in negotiations, HOI was unable to develop a contract with Jackson Memorial Hospital in Miami to perform transplants for Demonstration patients. As a consequence, HOI negotiated an agreement with Jacksonville Hospital, more than 300 miles away. The clinical consequences of this arrangement are examined elsewhere in this report; it is reasonable to conclude that this aspect of the Demonstration program affected HOI's patient recruitment to the Demonstration, and possibly satisfaction as well. Many metropolitan areas have a single transplant center which perhaps puts some managed care plans at a disadvantage in terms of negotiating for services that meet geographic proximity requirements. While restricted access to some services has long been a component of managed care plans, access to transplantation is a politically charged issue that may be a complicating factor for the development of other ESRD managed care programs.

A second aspect to HOI's program that may have affected their overall experience was their failure to implement a physician incentive program. HOI had intended to use financial incentives as a means to encourage changes in physician behavior. However, negotiations with CMS over the structure of HOI's incentive plan lasted several months into the Demo and ultimately broke down. During the negotiating period, it also became clear that the resources needed at HOI to implement a financial incentive were not available. By this point in the Demonstration, participating physicians had established patterns of treatment for Demonstration patients and HOI had fewer levers available to change clinician behavior.

c. Xantus

The Xantus experience with community providers illustrates the most serious consequences of a limited set of community providers available with whom they could contract for services. Xantus was unable to maintain a relationship with Nephrology Associates and lost access to patients, providers, and ESRD expertise when that relationship dissolved.

Finally, Xantus' financial situation was not as solid as it needed to be going into the demonstration. Further, Xantus was significantly hampered by CMS's requirement that Xantus be certified for a Medicare risk contract. This certification was not anticipated at the time of the Xantus application to the Demo, and the tremendous administrative effort required to achieve certification left Xantus less able to focus resources on the Demo.

Exhibit 1-17: Summary of Key Demonstration Characteristics

Feature	Kaiser Permanente	*HOI*	Xantus
Primary HMO Model	*Group HMO*	*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*
Premium and Co-pay Amounts	*None*	*None*	*$70 monthly premium and $10 co-pays (both eliminated shortly after start-up).*
Outpatient Dialysis Treatments and Ancillaries	*Mostly contracted facilities. Negotiated fee-for-service: Kaiser and contracted facilities.*	*All contracted facilities. FFS comparable to 100% of Medicare allowable charge.*	*All contracted facilities. All-inclusive per treatment rate comparable to 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 nephrologist in unit, Kaiser nephrologist 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 nephrologist on salary, risk adj. cap rates for contract nephrologist*	*One capitated rate for out and inpatient care.*	*Comprehensive capitation.*
Use of Case Managers & Team make-up	*Case Managers: Yes. Team: MD, RN, MSW, RD, Pharmacist, specialists.*	*Case Managers: Yes. Team: MD, RN, MSW, RD, Pharmacist, specialists.*	*Case Managers: Yes. Team: MD, RN, MSW, RD.*
Outpatient Drugs	*Formulary covered at Kaiser pharmacies.*	*Formulary covered at participating pharmacies.*	*Up to $780 per year, $10 co-pay per prescription.*
"Extra 5 %" beyond services covered for regular Medicare risk enrollees	*Nutritional supplements, no co-pays (on visits & drugs), dental, counseling.*	*Nutritional supplements, no co-pays, dental, transportation, rehab, expanded formulary.*	*Nutritional supplements, preventive services, transportation.*
Other Services	*Durable medical equipment w/ no co-pay, vision, out-of-area coverage.*	*Home health services, dialysis in nursing home, home dialysis, out of network dialysis, health education.*	*Home visits, educational seminars, educational videotapes.*
End Date of Data Collection	*August 2000 (manual); September 2001 (electronic)*	August 2000 (manual); September 2001 (electronic)	*January 2000 (manual)*

CHAPTER II: ESRD MANAGED CARE DEMONSTRATION ENROLLMENT PENETRATION RATES AND PATTERNS

A. Introduction

As described previously, the ESRD Managed Care Demonstration (Demo) run by the Centers for Medicare and Medicaid Services (CMS) sought to enroll patients with end stage renal disease into health maintenance organizations (HMOs). Under current law, ESRD patients are prohibited from enrolling in managed care plans. The purpose of the Demonstration was to test whether extension of an integrated system of care to ESRD beneficiaries was operationally feasible, efficient, and able to improve patient outcomes compared to the current, fee-for-service system. The Demonstration took place at two HMO sites: Kaiser Permanente (Kaiser) in Southern California, and Health Options, Inc. (HOI), a subsidiary of Blue Cross/Blue Shield, in the Miami area of Florida. The service area for Kaiser included Los Angeles, Orange, Riverside, San Bernardino, San Diego, and Ventura counties. HOI's service area was smaller: Broward, Dade, and Palm Beach counties.

In extrapolating experiences from the Demo to predict what may occur should the law change to allow ESRD patients to enroll in managed care plans, one potentially instructive aspect of the Demonstration experience is enrollment penetration rates. HMO penetration rates (enrollees divided by eligibles) indicate the uptake of the managed care option, and if traced over time, can indicate potential growth of the market for HMO services.

To assess penetration rates and patterns under the Demonstration, we calculated penetration rates for each Demonstration site overall and by age, race, sex, modality, and income level. Methods and results are presented below.

B. Methods

Penetration rates were calculated by taking the number of plan enrollees and dividing that number by the number of eligible persons (i.e., the total number of individuals who had the option of enrolling, whether they chose to do so or not).

Two primary data sources were used for this analysis, with additional data sources providing supplemental information. As part of the evaluation of the Demonstration, we collected from the Demonstration sites detailed information on each beneficiary enrolling into the Demonstration plans, including age, sex, race, modality (i.e., hemodialysis, peritoneal dialysis, or functioning graft), and zip code. Over the course of the Demo, we also collected dates of disenrollment from the Demo or death. These data were used to identify the number of enrollees in the Demonstration plans at a specific point in time.

The second data source was the Medicare Enrollment Database (EDB), which is a dataset compiled by CMS. This dataset identifies all Medicare-eligible beneficiaries, and includes data such as ESRD status, age, sex, race, modality, and zip code. In order to identify the number of Medicare beneficiaries who were eligible for the Demonstration, we queried the EDB for the total number of ESRD beneficiaries in Florida and California on June 1, 1998 for whom

Medicare was the primary payer (secondary payer patients were not eligible for the Demo). Using zip codes, beneficiaries residing outside of the Demonstration service regions were excluded from the file.

A third, supplemental data source provided an indicator of income level by zip code. Data compiled by CACI, Inc. extrapolated from the 1990 U.S. Census enabled us to assign an income level indicator to each beneficiary. Zip codes were grouped by centile into five categories: low, low / medium, medium, medium / high, and high. For example, all zip codes with an average income in the lowest 20% of the state were noted as "low," zip codes with an average income in the highest 20% of the state were indicated as "high," etc. The Dialysis Outcomes and Practice Patterns Study (DOPPS) provided additional data that we used to estimate the number of Medicaid and Medicare dually-eligible beneficiaries in the two service regions. Specifically, DOPPS is a representative sample of hemodialysis patients. Based on DOPPS data specifying the percent of hemodialysis patients in each of California and Florida to be dually-eligible, we extrapolated the number of dually-eligible patients in the two Demonstration service regions. A final supplemental data source was 1999 county-level fee-for-service and managed care demographic data provided by CMS's Office of the Actuary. These data were used to calculate Medicare managed care penetration rates among the Medicare disabled population (under age 65, non-Medicaid) in the Demonstration service area counties.

Using these files, we calculated point-in-time penetration rates for the Demonstration. Penetration rates were calculated at two points in time: one year following the start of enrollment and two years following the start of enrollment. For Kaiser Permanente in California, those dates were February 1, 1999 and February 1, 2000. For Health Options Inc. in Florida, those dates were June 1, 1999 and June 1, 2000. To be included in the numerator, an individual must have enrolled in the Demo during the analysis period (i.e., prior to January 31, 1999 for the Kaiser Year 1 analysis or prior to January 31, 2000 for the Kaiser Year 2 analysis), and still be actively enrolled (having neither disenrolled nor died) at the end of the analysis period. In other words, the analysis included only beneficiaries who were actively enrolled *on the day* for which the calculation was performed.

Data for the denominator (all eligible Medicare ESRD beneficiaries in the service region) were based on one date only: June 1, 1998. It was assumed that there would be minimal variation in the total eligible population during the analysis period.

Penetration rates were calculated for each site overall as well as by age, race, sex, modality, and income level subgroups. Calculations were repeated for each county in the Demonstration service areas.

C. Results

As shown in Exhibit 2-1, after one year, the Kaiser site had achieved a penetration rate of 2.7% (i.e., 551 enrollees among 20,519 eligibles). At the end of Year 2, this site's penetration increased to 5.2%. After one year, the Health Options site had achieved a much higher penetration rate of 8.3% (i.e., 484 enrollees among 5,860 eligible). HOI's penetration rate increased to 11.1% at the end of Year 2.

Exhibit 2-1: Year-end 1 and Year-end 2 Overall Penetration Rates at Kaiser Permanente and Health Options, Inc.

	Kaiser Permanente		Health Options, Inc.	
	Year 1	Year 2	Year 1	Year 2
Enrollees	551	1077	484	649
Eligible population	20,519		5,860	
Penetration rate	2.7%	5.2%	8.3%	11.1%
Penetration rate – Excluding rollovers	1.9%	3.0%	*NC*	*NC*

NC = no change

In California, a sizeable portion of Kaiser Permanente's enrollees were "rollover" patients (i.e., ESRD patients in Kaiser's existing managed care plan who were converted to the Demonstration plan). Among new enrollees only, Kaiser's Year 1 penetration rate was 1.9% and its Year 2 penetration rate was 3.0%.

Exhibit 2-2, below, presents penetration rates at the end of Year 2 by age, race, sex, modality, and income level for each of the Demonstration sites. As indicated, when examined by age group penetration was highest for both sites among 40 – 64 year olds. At Kaiser, penetration was highest among the "Other" race category*; at HOI, it was highest among Blacks. At both sites penetration was higher among males compared to females. When examined by modality, Kaiser experienced equal penetration among both hemodialysis and peritoneal dialysis patients. In contrast, HOI experienced much higher penetration among hemodialysis patients. Both sites experienced relatively low penetration among functioning graft patients. Finally, both sites had substantially lower penetration among beneficiaries who were eligible for both Medicaid and Medicare compared to Medicare-only beneficiaries.

We conducted a supplemental penetration rate analysis in an effort to estimate penetration rates by income level. As income data were available to us at the zip code level only (as opposed to the data presented above for which we had beneficiary-level data), the results are not as precise as the other results presented in this chapter. Nevertheless, as shown in Exhibit 2-3, both sites appear to have encountered similar trends regarding penetration rates by income category. At both Kaiser Permanente and Health Options, Inc., penetration rates were approximately two percentage points higher among those beneficiaries living in high income zip codes as compared to those living in low income zip codes.

* The race of individuals with Hispanic ethnicity were typically classified as "White" or "Black." Thus, Hispanics do not account for the high penetration in the "Other Race" category.

Exhibit 2-2: Year-end 2 Penetration Rates by Age, Race, Sex, and Modality Level at Kaiser Permanente and Health Options, Inc.

	Kaiser Permanente Year 2 Penetration Rate		Health Options, Inc. Year 2 Penetration Rate
	Including Rollovers	Excluding Rollovers	
Age			
Under 21 years	0.7%	0.2%	1.2%
21-39 years	5.1%	3.1%	9.1%
40-64 years	6.3%	4.0%	13.1%
65-84 years	4.5%	1.9%	9.8%
85+ years	2.3%	0.9%	9.8%
Race*			
Asian	2.5%	1.2%	2.3%
Black	5.4%	2.5%	10.3%
White	5.1%	2.9%	7.0%
Other	10.3%	7.8%	6.8%
Sex			
Female	4.4%	2.2%	9.4%
Male	6.0%	3.7%	12.4%
Modality			
Hemodialysis	6.9%	4.0%	15.5%
Peritoneal Dialysis	7.0%	3.8%	9.2%
Functioning Graft	2.5%	1.2%	1.1%
Medicaid Eligibility			
Dually Eligible	1.7%	NA**	5.9%
Medicare Only	9.3%	NA**	13.3%

* Year 1 penetration for Florida; Year 2 race data for Florida was not available.
** Not Available.

Exhibit 2-3: Year-end 2 Penetration Rates by Income Category at Kaiser Permanente and Health Options, Inc.

	Kaiser Permanente Year 2 Penetration Rate		Health Options, Inc. Year 2 Penetration Rate
	Including Rollovers	Excluding Rollovers	
Income Level			
Low	3.6%	1.8%	10.5%
Low/Medium	5.0%	2.6%	11.0%
Medium	5.8%	3.4%	11.0%
Medium/High	6.0%	3.7%	10.4%
High	5.5%	3.4%	12.7%

Exhibit 2-4 provides another way of looking at the distribution of enrollees and eligibles by subgroup. Whereas Exhibits 2-2 and 2-3 showed penetration rates for individuals with each characteristic, Exhibit 2-4 shows the proportion of Demonstration enrollees versus the proportion of all eligibles with each characteristic.

Exhibit 2-4: Year-end 2 Distribution of Demonstration Enrollees and Eligible Population by Subgroup at Kaiser Permanente and Health Options, Inc.

	Kaiser Permanente Year 2 Population Distribution		Health Options, Inc. Year 2 Population Distribution	
	Demonstration Distribution*	Eligible Population Distribution	Demonstration Distribution	Eligible Population Distribution
Age				
Under 21 years	0.3%	2.1%	0.2%	1.4%
21-39 years	14.9%	15.4%	10.9%	13.3%
40-64 years	54.8%	45.7%	52.9%	44.6%
65-84 years	29.0%	34.2%	33.6%	37.9%
85+ years	1.1%	2.6%	2.5%	2.8%
Race**				
Asian	4.8%	10.1%	0.6%	2.2%
Black	23.2%	22.5%	44.8%	36.0%
White	60.0%	62.2%	50.6%	59.6%
Other	7.3%	3.7%	1.4%	1.8%
Sex				
Female	39.0%	46.7%	37.1%	44.0%
Male	61.0%	53.3%	62.9%	56.0%
Modality				
Hemodialysis	78.8%	60.0%	92.9%	66.5%
Peritoneal Dialysis	9.3%	7.0%	4.6%	5.5%
Functioning Graft	10.7%	22.7%	1.8%	18.8%
Income Level***				
Low	14.9%	21.5%	27.1%	28.7%
Low/Medium	22.7%	23.6%	17.3%	17.3%
Medium	26.4%	23.7%	19.0%	19.1%
Medium/High	21.4%	18.9%	18.0%	19.2%
High	12.1%	11.6%	18.0%	15.7%
Medicaid Eligibility				
Dually Eligible	17.4%	53.6%^	15.6%	29.6%^
Medicare Only	82.6%	46.4%^	84.4%	70.4%^

* Includes rollovers
** Year 1 data for Florida
*** Zip code level analysis, as described previously
^ State-wide data

Exhibit 2-5 presents overall Demonstration penetration rates at the end of Year 2 for each county in the Demonstration service areas. In California, Demonstration penetration rates by county ranged from a low of 3.9% in San Diego County to a high of 6.5% in Riverside County. In Florida, penetration rates in Dade and Palm Beach Counties (12.3% and 12.9%, respectively) were approximately four percentage points higher than penetration in Broward County. The table also reports non-Demonstration managed care penetration rates among the Medicare disabled population for each county.

Exhibit 2-5: Year-end 2 Overall Demonstration and Non-Demonstration Medicare Disabled Managed Care Penetration Rates by Demonstration County

County	Year 2 Penetration Rate	Overall Medicare Managed Care Penetration Rate (Disabled Population), 1999
Kaiser Permanente*		
Los Angeles County, CA	5.2%	45.9%
Orange County, CA	4.8%	36.5%
Riverside County, CA	6.5%	45.8%
San Bernardino, CA	5.9%	44.9%
San Diego County, CA	3.9%	40.3%
Ventura County, CA	4.9%	33.1%
Health Options, Inc.		
Broward County, FL	8.0%	55.8%
Dade County, FL	12.3%	53.2%
Palm Beach County, FL	12.9%	48.6%

* Kaiser penetration rates include rollover patients.

D. Discussion

Examination of the Demonstration penetration rates can be useful for a number of purposes. First, these figures may give some indication of potential penetration should managed care options be made available to ESRD patients in other regions. Second, examination of penetration rates by subgroup (e.g., sex, race, income, etc.) can reveal patterns in managed care enrollment that are obscured by raw numbers or percentages to the whole.

Because of the somewhat artificial constraints inherent in a "Demonstration," the penetration rates associated with the ESRD Managed Care Demonstration are unlikely to perfectly predict what may occur in the future. For instance, the sites were told by CMS that their minimum enrollment target would be 600 beneficiaries. Each site kept this target in mind as marketing approaches were formulated and implemented; it is unknown what targets each site would have set their sights on under real-world conditions. Additionally, managed care organizations today are in the midst of benefit cutbacks; any changes to benefit packages would likely have a substantial impact on enrollment. Nevertheless, these results are worthy of careful examination.

Results of the descriptive analyses presented previously show that Kaiser Permanente achieved a penetration rate of 5.2% at the end of Year 2 if rollover patients are included in our calculation or 3.0% if rollover patients are excluded. Rollover patients are those patients who were Kaiser ESRD patients prior to the start of the Demo and who were later converted to the Demo. CMS permitted one rollover patient for every two new patients who enrolled in the program. In contrast, without the benefit of any existing rollover enrollees, HOI achieved a penetration rate of 11.1% at the end of Year 2.

Both sites reported that their initial enrollment levels were lower than originally anticipated. In conducting background research for this chapter, we discovered that a large number of Demo-area Medicare ESRD beneficiaries at both sites, probably in the thousands, were not sent Demonstration marketing materials due to inaccuracies in the Medicare database that stores information on beneficiaries. Our calculations indicate that only about 46% of Kaiser Demo-area eligibles and 59% of HOI Demo-area eligibles may have received mailings. As direct mailings of these materials were the primary initial marketing approach used by both sites, this discovery may help explain the lower than expected initial enrollment.

Nevertheless, both Demonstration sites appear to have achieved rates at the end of Year 2 that are higher than regular Medicare managed care plans achieved after two years in an untapped market (i.e., no previous experience with managed care). Based on a county-level analysis of Medicare managed care penetration between 1993 and 1998 conducted by The Lewin Group[20], after one year counties with previously untapped markets had penetration rates of about 0.4%. After two years these counties had rates of about 0.7%. These figures are substantially lower than the 3% (excluding rollovers) to 11% achieved under the Demo. This finding is not entirely unexpected; the additional resources and focus on the Demo because it was a *demonstration* were likely partially responsible for the higher rates. Additionally, managed care is particularly pervasive in both California and Florida compared to other parts of the U.S. Because Demo-area beneficiaries were likely to have been exposed to the culture or idea of managed care in the past (even though it had not been an option for most of them), they may have been likely to more quickly assimilate the concept into their own lives.

A review of penetration rates by age, race, sex, modality, and income level subgroups reveals numerous areas in which Demonstration enrollment was disproportionate to the distribution of characteristics among the eligible population. For instance, at the HOI Demonstration site, the penetration rate among hemodialysis patients was 15.5% whereas among peritoneal dialysis patients the rate was 9.2% and among functioning graft patients the rate was only 1.1%. One hypothesis for the low penetration among peritoneal dialysis and functioning graft patients is that these patients were less likely to learn about the Demo through word of mouth, which Demonstration administrators believed was an important factor in increasing enrollment. Not only were the dialysis centers the main venue for "word of mouth marketing," but Kaiser in particular relied on staff in the dialysis centers to market the Demo.

Review of the subgroup penetration rates also reveals disproportionate enrollment by age. Both sites had higher penetration among beneficiaries aged 40-64. However, in every other age cohort in both states, the health plans enrolled disproportionately fewer persons versus the underlying FFS mix of ESRD patients. While Kaiser had similar penetration among both Blacks

and Whites, HOI experienced higher penetration among the Black population. Both sites had higher penetration among males compared to females.

An interesting finding is that penetration rates increased somewhat with higher income at both sites, peaking at the "medium/high" income level at Kaiser and at the "high" income level at HOI. Other evaluation results strongly indicate that the majority of beneficiaries joined the Demo for financial reasons. Therefore, we may have expected to see higher penetration in low-income areas. The finding that penetration was higher in high-income areas may be partly explained by the comprehensiveness of Medicaid benefits available to low-income beneficiaries. Beneficiaries who were eligible for both Medicaid and Medicare would have had little financial incentive to join the Demo. An examination of DOPPS and Demonstration evaluation data (see Methods Appendix) reveal that, in fact, a disproportionately low number of dually-eligible beneficiaries joined the Demo. Specifically, in California 17% of Demonstration enrollees were dually-eligible compared to 54% of all California ESRD patients; in Florida 16% of Demonstration enrollees were dually-eligible compared to 30% of ESRD patients state-wide. Nationally, 36% of ESRD patients are dually-eligible.

In summary, a review of the penetration rates and patterns achieved under the ESRD Managed Care Demonstration can be useful for setting expectations for future Demonstrations, for understanding enrollment patterns under managed care, and for assessing Medicare reimbursement policy. Managed care plans entering into new ESRD markets in the future should be cautious in using these figures to predict enrollment into their own programs. Enrollment is a function of a diverse and numerous set of factors, including premiums and benefit packages, competition, provider network, and the health plan's enthusiasm for the product and corresponding marketing investment. Nevertheless, plans may consider these results to represent the high-end limit of the type of penetration to expect in the early years should the bar prohibiting ESRD beneficiaries from enrolling in managed care be dropped.

CHAPTER III: PATIENT SELECTION

A. Introduction

At the start of enrollment for each Demonstration (Demo) site, adult chronic renal failure patients with Medicare primary insurance who were residents in the Demo service area counties were indirectly recruited through Demo health plan marketing materials mailed by CMS. Subsequently, the Demo sites were also given opportunities to market directly to ESRD patients and staff at local dialysis facilities. Patients who were already enrolled in the KP Medicare Risk HMO plan were listed and randomized by CMS and given the opportunity to join the Demo on a two-for-one basis (i.e., for every two new enrollees, KP could enroll one of their existing managed care (MC) patients into the Demo plan). These KP patients are referred to as "rollover" patients, or KP RO. Enrollment commenced in February and June 1998 for the California (CA) and Florida (FL) Demo sites, respectively. Active recruitment and intake were continuous for at least 12 months at both sites, with "passive" enrollment continuing until the end of the three-year Demonstration period.

Because of the Medicare-primary insurance eligibility requirements to join the Demo and the special financial incentives provided, it was not anticipated that those who elected to enroll would be representative of the general population of ESRD patients under Medicare fee-for-service (FFS). Patients who choose to change their health insurance may be different from those who do not, and the lack of random assignment of patients to the Demo prevents generalizing results to any other ESRD population under the existing (primarily FFS) Medicare payment structures. Rather, an assessment of the effectiveness of the MC Demo should be made by understanding in what ways and to what extent patients who joined the Demo may differ from the general ESRD population, in order to adjust the expectation of the outcomes for these patients accordingly. While these results will show that Demo patients do bear some resemblance to other MC patients in Medicare Risk HMOs with respect to age, race, and time with ESRD, they will also show that the Demo attracted a select group of patients who were younger and healthier than the FFS ESRD population at large.

B. Statistical Methods

A complete description of the samples used in these analyses can be found in the Methods Appendix. Due to the composition of the comparison samples used, all comparative analyses were restricted to hemodialysis (HD) patients only. Chi-square and *t* test statistics were used to detect differences in means or proportions. Statistical significance was interpreted at the 0.05 level for a two-tailed test. All statistical estimation was performed using SAS version 8.0.[21] Logistic regression models were used to estimate the odds of having a fistula for the primary vascular access at study start. Dialysis Outcomes and Practice Patterns Study (DOPPS) patients in FL and CA were used for comparison to the respective Demo sites in those states. Demo patients (HOI and KP combined) were also compared to matched samples of non-Demo managed care (NDMC) and FFS patients. Poisson regression models were used to estimate the difference in the relative risk of pre-study inpatient hospitalization rates.

Predicted differences in expected mortality, a statement of mortality risk based on an index of co-morbid factors[22], were based on proportional hazards[23] (Cox 1972) parameter estimates of relative mortality risks and the mean or proportion of patients in a subgroup with that characteristic. The product of parameter estimate times the mean (or proportion) for a subgroup characteristic, when summed over all characteristics, is the predicted mortality for a subgroup. Differences in these sums between the two subgroups being compared, when exponentiated, provided the expected difference in relative mortality for two subgroups.

Mortality risk parameter estimates were based on an analysis of the time to death (or censoring) for the nationally representative reference population of all DOPPS patients, including in the model a full set of demographic and co-morbid factors as covariates (Exhibits 3-3 and 3-4). Time at risk for each patient began on the study start date. Patients were removed from the analysis at death or departure from the study.

C. Results

A total of 2,616 patients had enrolled in the two Demo sites as of September 1, 2001 (see Exhibit 3-1). Of these, extensive baseline clinical data were obtained for a sample of 1,479 patients (Exhibit 3-2). The FL site enrolled fewer PD patients (in part due to fewer PD patients in general in south FL) and TX patients than the CA site.

Exhibit 3-1: All Demo Patients: Modality, by Site (as of September 2001)

Demo Site	Hemodialysis (HD) N (%)	Peritoneal Dialysis (PD) N (%)	Functioning Transplant (TX) N (%)	Total
HOI	900 (93.0)	48 (5.0)	19 (2.0)	967
KP	1,353 (82.1)	169 (10.3)	127 (7.7)	1,649
Total	**2,253 (86.1)**	**217 (8.3)**	**146 (5.6)**	**2,616**

Exhibit 3-2: Demo Patients Followed for Comprehensive Data Collection: Modality by Site and Rollover (RO) Status

Demo Site	Hemodialysis (HD) N (%)	Peritoneal Dialysis (PD) N (%)	Functioning Transplant (TX) N (%)	Total
HOI	604 (93.8)	27 (4.2)	13 (2.0)	644
KP	690 (82.6)	82 (9.8)	63 (7.5)	835
KP New	478 (85.4)	50 (8.9)	32 (5.7)	560
KP RO	212 (77.1)	32 (11.6)	31 (11.3)	275
Total	**1,294 (87.5)**	**109 (7.4)**	**76 (5.1)**	**1,479**

1. Reasons for Enrollment

When asked to indicate the top two reasons for choosing to enroll in the Demo, the most common responses indicated on the patient questionnaire (PQ) by patients in both FL and CA were outpatient drug costs (57 percent) and lack of co-payments (53 percent). Florida Demo patients (44 percent) also indicated provider recommendation as a primary reason for joining.

2. Comparison to DOPPS

Comparisons between the Demo and same-state DOPPS patients were made with respect to a number of demographic and co-morbid characteristics (Exhibits 3-3 and 3-4). (The subset of selected risk factors that were included in multivariate regression models to follow can be found listed in Exhibit 3-5.) Compared to the DOPPS patients, Demo patients from both sites were proportionately younger and more frequently of male gender. A higher proportion of Hispanic and non-white patients enrolled in FL. Enrollees in the KP Demo had higher average education levels than the CA DOPPS. Household income was reasonably similar for respondents in both the Demo and DOPPS groups. While the average count of co-morbidities was similar in California for MC and DOPPS patients, in general fewer Demo patients from both sites were reported to have serious complications, such as difficulty ambulating. Although Demo patients had somewhat higher instances of peripheral vascular disease (and congestive heart failure in CA), they had higher rates of hypertension (known to be protective), and were significantly less likely to be undernourished as indicated by physical assessment, serum albumin level, or body mass index than DOPPS patients. Time with ESRD was substantially higher for Demo patients than for DOPPS patients, as a result of the eligibility requirement that patients who enrolled in the Demo have primary Medicare insurance.

3. Comparison to Matched Subgroups

In a similar fashion to the comparisons made with the DOPPS samples, the Demo patients (HOI and KP combined) were also compared to matched samples of non-Demo managed care (NDMC) and FFS patients with respect to demographic and co-morbid characteristics (rightmost columns of Exhibits 3-3 and 3-4). Since these groups were not matched on a one-to-one basis (but rather by distribution), some significant differences were found (see Methods Appendix). In some respects, the matched FFS and NDMC patients who were selected based on their age, race, and time with ESRD were healthier than the Demo patients, having lower cardiac risk factors and vascular disease. Differences that still existed after matching were controlled for by adjusting for these factors in the statistical models comparing patients in the Demo to those in FFS and NDMC.

Exhibit 3-3: Baseline Demographic Characteristics for Demo v. Comparison HD Patients: DOPPS and Matched Comparison Samples of FFS and NDMC

Characteristics	California		Florida		All	Matched Comparisons[1]	
	Demo	DOPPS	Demo	DOPPS	Demo	FFS	NDMC
Sample Size (n)	678	771	594	1072	1,272	203	213
Mean age (years)	57.9	61.4‡	60.4	63.4‡	59.1	59.3	61.6†
Non-white race (%)	39.4	36.7	48.1	36.1‡	43.4	46.0	40.3
Hispanic (%)	27.0	28.9	24.8	8.6‡	26.0	34.4†	29.2
Male (%)	62.2	55.2†	62.5	57.7†	62.3	54.3†	54.6†
Less than 12 yrs educ. (%)	18.9	24.3†	34.2	30.4	25.9	39.1‡	31.4
Years of school (mean)	12.8	12.3‡	12.1	12.2	12.5	12.1†	12.5
Employment (age<60) (%)							
Employed	21.9	21.7	15.6	19.2	19.3	9.5†	20.7
Retired	12.8	7.4†	11.9	6.6†	12.2	14.3	18.5
Disabled	54.1	44.0†	65.0	30.5‡	58.8	56.2	46.7†
Other	11.1	26.9‡	7.4	43.7‡	9.7	20.0†	14.1
Employment (age>60) (%)							
Employed	9.1	12.0	5.0	7.7†	7.0	2.8†	6.4
Retired	67.1	55.2‡	65.0	52.6‡	65.9	49.5†	69.6
Disabled	20.1	16.6	26.0	12.9‡	23.2	34.6†	18.4
Other	3.8	16.2‡	4.1	26.8‡	3.9	13.1†	5.6
Occupation (%)							
Professional	19.6	9.4‡	11.5	15.9†	15.8	10.4†	16.8
Technical	22.6	13.1‡	20.9	12.3‡	21.9	14.1†	18.8
Labor	14.5	17.5	22.6	11.7‡	18.2	11.5†	9.9*
Other	43.4	60.0‡	45.1	60.1‡	44.1	64.1‡	54.5†
Household income (%)							
<=10,000	27	33	43	37†	34	51†	23†
10,001-40,000	62	48	48	49	56	39	65
>40,000	11	18	8	14	10	10	12

[1] Compared to the combined demo group
‡ $p < 0.001$ versus demo, † $p < 0.05$ versus demo

Exhibit 3-4: Baseline Co-morbidity and Other Characteristics for Demo v. Comparison Hemodialysis Patients: DOPPS and Matched Samples of FFS and NDMC

Characteristics	California		Florida		All	Matched Comparisons[1]	
	Demo	DOPPS	Demo	DOPPS	Demo	FFS	NDMC
Sample size (n)	678	771	594	1072	1,272	203	213
Coronary disease/CHF (%)	35.1	40.8†	43.5	45.5	39.0	40.3	34.0
Myocardial Infarction (%)	15.9	15.9	19.6	20.2	17.7	12.8	12.0†
Cardiac arrest (%)	2.1	2.7	1.2	2.3	1.7	1.5	0.5†
Left Ventricular Hypertrophy (%)	19.6	27.9‡	19.3	20.9	19.4	13.8†	16.7
Cardiac dysrhythmia (%)	26.2	19.5†	18.1	29.2‡	22.3	20.7	16.5†
Cardiomegaly by x-ray (%)	29.7	30.6	16.7	23.4†	24.1	13.7‡	12.5‡
Pericarditis (%)	5.6	2.3†	3.1	3.5	4.6	2.5	1.5†
CVD, CVA, TIA (%)	14.8	18.9†	15.3	18.2	14.9	12.4	12.7
Peripheral vascular disease (%)	23.7	20.3	29.4	25.2†	26.0	18.5†	20.5
Hypertension (%)	93.7	84.9‡	92.6	85.2‡	93.3	91.9	94.0
Diabetes (%)	48.4	51.7	45.9	47.4	47.3	53.2	47.6
On insulin (among diabetics) (%)	53.1	69.1‡	52.1	72.8‡	52.7	53.7	53.1
COPD (%)	7.0	11.3†	9.0	13.1†	7.8	4.9	5.9
Hx pulmonary edema (%)	30.0	21.3‡	13.1	21.8‡	22.6	12.4‡	17.1
Current smoker (%)	9.6	17.5‡	5.4	15.5‡	7.9	3.0‡	3.4†
Hx of cancer (%)	6.3	9.5†	8.6	12.4†	7.4	9.4	6.8
Appears undernourished (%)	3.0	14.8‡	2.1	8.8‡	2.6	1.0	1.5
Alcohol dependence (%)	3.2	6.4†	1.7	4.5†	2.8	2.0	1.5
Drug dependence (%)	2.5	6.9‡	1.9	2.9	2.4	3.0	0.5†
HIV positive (%)	0.6	0.9	1.4	1.0	1.0	3.5†	0.0†
AIDS (%)	0.6	0.8	0.4	0.7	0.5	2.5†	0.0†
Walks with assistance (%)	20.2	41.1‡	17.7	36.1‡	19.3	22.0	28.6†
Transfers with assistance (%)	9.1	22.1‡	3.8	17.0‡	6.8	4.5	6.9
Live in nursing home (%)	1.0	8.9‡	0.6	7.5‡	0.8	1.7	0.5
Avg. # of co-morbidities	3.9	4.2	3.4	4.4‡	3.7	3.3†	3.3†
Height (cm)*	169.2	167.2†	168.7	168.9†	169.0	166.0	167.3
Weight (kg)*	75.0	70.0‡	73.1	73.1	74.1	74.7	72.2
Body Mass Index	26.1	24.9‡	25.7	25.7	25.9	27.2†	25.8
Time on ESRD (years)	3.46	1.84‡	3.83	1.95‡	3.63	5.5	4.1
Serum Albumin(mean g/dl)	3.85	3.52‡	3.89	3.56‡	3.87	3.83	3.77‡

* Adjusted for patient gender.
[1] Compared to the combined demo group
‡ $p < 0.001$ versus demo, † $p < 0.05$ versus demo

4. Predicted Risk of Mortality

The mortality risk implications of these lower demographic and co-morbid risk factors among Demo patients relative to the same-state DOPPS samples can be summarized by the linear estimation model shown in Exhibit 3-5. The entire DOPPS sample was used to construct the Cox proportional hazards model, which produced the corresponding parameter estimates and risk ratios shown for each risk factor. This "index" of parameter estimates serves as a basis for calculating the risk associated with each factor and comparing these risks among subgroups. This is done by multiplying the subgroup mean or proportion of patients with each risk factor times the parameter estimate (=log RR) for that factor, and taking the difference of these products between two subgroups to get the log risk for one group versus the other (e.g., KP and CA DOPPS). The sum of these product differences will yield the predicted log relative risk (RR) of mortality (in this case, by category of Co-morbid or Demographic). For example, the proportion of KP patients with coronary disease is 35.1 percent, and for CA DOPPS is 40.8 percent (Exhibit 3-4). Multiplying each of these by the parameter estimate for the risk of mortality due to coronary disease (0.223) and taking the difference yields a calculated log RR of mortality of (0.08-0.09)=-0.01 for KP relative to CA DOPPS. Summing the log RR across all risk factors gives an overall log RR of -0.27, which, when exponentiated, yields an expected relative mortality of 0.76 for KP versus CA DOPPS (Exhibit 3-6).

Exhibit 3-5: Factors used to Predict Mortality Risk for Demo Patients

Co-morbid or Demographic	Risk Factor	Parameter Estimate (PE)	Relative Risk (RR)	Log Risk for KP v. CA DOPPS	Log Risk for HOI v. FL DOPPS
C	Coronary disease	0.223	1.25	-0.01	0.00
C	Congestive heart failure	0.259	1.29	0.02	-0.02
C	Other cardiac problems	0.161	1.17	0.02	-0.02
C	Hypertension	-0.270	0.76	-0.02	-0.02
C	Cerebrovascular disease	0.104	1.11	0.00	0.00
C	Peripheral vascular disease	0.210	1.23	0.01	0.01
C	Pulmonary disease	0.267	1.31	-0.01	-0.01
C	Cancer (other than skin)	0.064	1.07	0.00	0.00
C	Diabetes	0.040	1.04	0.00	0.00
C	Left ventricular hypertrophy	-0.031	0.97	0.00	0.00
D	Race other than Caucasian	-0.298	0.74	-0.01	-0.03
D	Hispanic ethnicity	-0.318	0.73	0.00	-0.05
D	Age	0.023	1.02	-0.09	-0.06
D	Male (v. female)	0.109	1.12	0.01	0.00
D	Log of body mass index	-0.792	0.45	-0.04	0.00
C	Serum Albumin	-0.397	0.67	-0.13	-0.13

Co-morbid or Demographic	Risk Factor	Parameter Estimate (PE)	Relative Risk (RR)	Log Risk for KP v. CA DOPPS	Log Risk for HOI v. FL DOPPS
D	Region: South Atlantic	0.024	1.02	0.00	0.00
D	Region: Pacific	0.217	1.24	0.00	0.00
C	Live in nursing home	0.220	1.25	-0.02	-0.01
C	Walk with assistance	0.355	1.43	-0.07	-0.06
C	Transfer with assistance	0.318	1.37	-0.04	-0.04
C	Time w/ESRD <1 yr.	-0.320	0.73	0.13	0.10
C	Time w/ESRD 1-3 yrs.	-0.092	0.91	-0.02	-0.01

In both Demo sites the MC patients were predicted to have lower mortality than the same-state DOPPS patients based on these risk factors. A predicted relative risk (or risk ratio) of mortality that is less than one is protective. To calculate the associated percent decrease in risk, (i.e., reverse the direction of the comparison between Demo and DOPPS) the risk ratio can be divided into 1.00. On average, Demo patients in FL are expected to have 25 percent lower mortality due to co-morbid differences alone (Exhibit 3-6), and 15 percent lower risk due to demographic factors (43 percent lower risk overall); in CA the composition was 16 percent lower risk for co-morbidity, and 13 percent for demographics, with 32 percent lower risk overall.

Exhibit 3-6: Expected Mortality Risk for Demo Patients v. Same-state DOPPS Comparison Patients

Risk Factor	Log RR KP v. CA DOPPS	Predicted Risk KP	Log RR HOI v. FL DOPPS	Predicted Risk HOI
Co-morbid (C)	-0.15	0.86 (16% lower)	-0.22	0.80 (25% lower)
Demographic (D)	-0.12	0.88 (13% lower)	-0.14	0.87 (15% lower)
Overall	-0.27	0.76 (32% lower)	-0.36	0.70 (43% lower)

5. Pre-Demo Hospitalization

Based on Clinical Assessment Form (CAF) data abstracted from patient medical charts, Demo patients in both CA and FL had a significantly lower rate of hospitalization in the six months prior to enrollment relative to the comparison patients, consistent with their lower risk factors. The total number of days spent in the hospital during the six months prior to enrollment was also collected on the Patient Questionnaire (PQ). Estimates using these measures of patient recall were significantly correlated with data from the CAF (Pearson R=0.53).

Exhibit 3-7: Prior Inpatient Hospital Days per Patient Year at Risk (PPY)

Patient Group	Pre-Demo (6 months) Unadjusted Inpatient Days PPY
KP	6.29
HOI	6.52
CA DOPPS	9.60
FL DOPPS	10.14
Matched FFS	10.41
Matched NDMC	7.40

After adjustment for the risk factors measured, differences in pre-study hospital rates for Demo versus DOPPS patients are no longer apparent (see Exhibit 3-8). Also of interest are comparisons between newly enrolled Demo patients and those who had been in the KP plan previously (KP RO). At baseline, hospital risk for new Demo patients was similar to NDMC (Exhibit 3-9). Kaiser RO patients experienced significantly less hospitalization than the patients newly enrolled in KP and HOI, while matched FFS patients were significantly more likely to be hospitalized (RR=1.62, $p<0.001$).

Exhibit 3-8: Relative Rate of Hospitalization for Six Months prior to Demo v. Same-state DOPPS Comparison

Comparison	Relative Rate (unadjusted)	P-value	Relative Rate (adjusted*)	P-value
HOI v. FL DOPPS	0.63	0.0002	0.94	0.603
KP v. CA DOPPS	0.65	0.0003	1.05	0.655

*Adjusted for standard set of covariates and deaths recorded in the DOPPS sample

Exhibit 3-9: Adjusted Relative Rate of Hospitalization in Prior Six Months, Demo v. FFS, NDMC and KP Rollover (RO)

Patient Group	Adjusted Relative Rate	P-value
New Demo	1.00	(ref.)
FFS	1.62	<0.001
NDMC	1.00	0.971
KP RO	0.54	0.001

6. Vascular Access at Study Start

Another measure of selection to the Demo is the type of vascular access HD patients had at enrollment. Patients with arterio-venous (AV) fistulas tend to experience better outcomes than those with synthetic or bovine grafts, and for this reason, fistulas are recommended over grafts for permanent vascular access by the Dialysis Outcomes Quality Initiatives (DOQI) guidelines.[24]

Exhibit 3-10: Percent of Patients with AV Fistulas at Enrollment

Patient Group	Fistula %
HOI (n=594)	31.8
KP (n=678)	33.5
DOPPS CA (n=771)	15.7
DOPPS FL (n=1072)	21.7
Matched FFS (n=203)	24.8
Matched NDMC (n=213)	42.5

The unadjusted percentage of patients who enrolled in either the DOPPS or Demo with an AV fistula is shown in Exhibit 3-10. The likelihood of having an AV fistula versus a graft was estimated among Demo and comparison patients using a logistic regression model, with adjustment for the standard set of covariates found in Exhibit 3-5. To account for potential trends in fistula use over time, we also adjusted for the year of study entry, since some of the DOPPS patients enrolled prior to the start of the Demo.[25] Demo patients in California were more than twice as likely to have a fistula than comparison patients (Exhibit 3-11). The increased odds for KP were somewhat driven by the existing KP rollover patients, who were 44 percent more likely (p=0.051) to have a fistula than the new KP Demo patients when they were rolled into the Demo. The Demo patients in FL were also more likely to have a fistula than their FL counterparts, however this difference was not statistically significant.

Exhibit 3-11: Adjusted Odds of Fistula Use: Demo v. Same-state DOPPS Comparison

Comparison	Adjusted Odds Ratio	P-value
HOI v. FL DOPPS	1.15	0.284
KP v. CA DOPPS	2.12	<0.001

In contrast to newly enrolled Demo patients, matched NDMC and KP RO patients were more likely to have a fistula at study start after adjustment for remaining demographic or co-morbid differences (Exhibit 3-12). New Demo patients were more likely to have a fistula than a matched sample of FFS patients, however this difference was not statistically significant.

Exhibit 3-12: Adjusted Odds of Fistula Use: Demo v. Matched Comparison Samples

Patient Group	Adjusted Relative Rate	P-value
New Demo	1.00	(ref.)
FFS	0.73	0.097
NDMC	1.96	<0.001
KP RO	1.50	0.017

D. Discussion

Patients who chose to join the Demo were found to be considerably healthier than a representative sample of DOPPS comparison patients. Understandably, patients who choose to change their health insurance are not likely to be among those patients experiencing an acute hospital episode or other serious condition. Opportunities to change fundamentals such as health insurance are not likely to receive much attention during such periods.

Patients indicated that economic considerations were very prominent in their deciding to join the Demo. There were also indications that physician recommendations played a larger role for FL patients than for CA patients.

Demo patients in both plans tended to be younger and male. A higher level of education on average was found among CA Demo patients, who were also more likely to have a professional or technical job history. The reason more young males chose a MC option may be related to other risk-taking behaviors not measured by this study.

The lower (unadjusted) pre-enrollment hospitalization among Demo patients was explained entirely by the differences in demographic and co-morbid risk factors. In other words, after adjusting for these factors, rates of hospitalization were similar for Demo and FFS. In addition to having fewer hospital episodes prior to enrollment, Demo patients were more likely than other FFS patients to have a functioning fistula when they enrolled in the Demo, even after accounting for various risk factor differences.

This better health profile for patients who joined the Demo leads to a lower expected mortality of 32 (KP) to 43 (HOI) percent, relative to a sample of same-state HD patients. We report "at least" a 32 and 43 percent lower mortality risk for KP and HOI respectively, because the nature of survey data of the type used here are likely to include errors in variables (i.e., reporting errors). Such data errors are known to lead to a bias of the estimate parameters toward zero (i.e., toward no effect). The associations of mortality with co-morbid conditions are therefore likely to be minimal estimates.[26]

Because of the measurable difference in risk factors for the Demo patients, we would expect to see lower absolute mortality rates and more favorable health-related outcomes when compared to average patients in the HD population. Analyses of all Demo patient outcomes, as reported in the remainder of this document, take into account these marked differences in baseline health indicating selection.

CHAPTER IV: ANEMIA MANAGEMENT AND DIALYSIS DOSE ADEQUACY

A. Introduction

We examined the issues of anemia, anemia management, and dialysis dose adequacy as part of our evaluation of outcomes for Demonstration patients. Anemia management is an important issue for hemodialysis patients because patients with hematocrit levels less than 30% have a significantly higher risk both of mortality (cardiac death, death due to infectious disease, or death from any cause) and of hospitalization even after adjusting for patient demographic and co-morbid conditions.[27,28] Finally, higher hematocrit levels are linked with lower Medicare expenditures, even after adjustment for co-morbid conditions and disease severity.[29] Inadequate dialysis dose is also associated with higher risk of mortality. The National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI) Guidelines suggest single-pool Daugirdas Kt/V (SP Kt/V) should be greater than 1.2 to ensure adequate dialysis.

The NKF DOQI Guidelines devote an entire volume to anemia management, stating that "Effective treatment of the anemia of Chronic Renal Failure (CRF) improves survival, decreases morbidity, and increases quality of life."[30] All of these previous findings lead us to believe that patient hematocrit levels and their management by dialysis facilities are in themselves important outcomes, and practice patterns that should be investigated in order to present a more complete comparison of managed care and fee-for-service programs.

B. Methods

All comparative analyses presented within this chapter include only hemodialysis (HD) patients from the Demo. The Demonstration patients came from participating facilities in California and Florida.

Demonstration HD patients are compared to a nationally representative sample of U.S. in-center adult HD patients from Dialysis Outcomes and Practice Patterns Study (DOPPS). The models in this chapter use the entire DOPPS sample, with indicators for state of residence. Thus, HOI patients are compared to Florida DOPPS patients and Kaiser patients are compared to California DOPPS patients. For more information on the DOPPS sample, see the Methods Appendix.

Two sets of analyses are included in this chapter. The first analysis compares anemia-related characteristics and dialysis dose at baseline for patients in the Demo and patients in DOPPS, without adjustment for differences in patient mix. The results of these models were used to evaluate patient selection to the Demo on the anemia status and treatment of the selected patients. The second analysis examines changes in the anemia characteristics and dialysis dose from baseline to follow-up (one year later), adjusted for patient characteristics, within each of the samples. These analyses were used to evaluate the change over time in anemia status, treatment, and dose adequacy among Demonstration patients.

Several anemia and anemia treatment characteristics were studied: HCT (both as a continuous variable and as a dichotomous indicator of ≥ 33 or < 33); EPO Use (yes or no); EPO Dose (units

prescribed per kg of body weight of the patient per week); EPO Mode of Administration (subcutaneous or IV); IV Iron (yes or no); and SP Kt/V (continuous). Simple means, paired t-tests, logistic regression for the dichotomous variables (analysis of IV Iron, Rx EPO, or EPO via subcutaneous administration) and ordinary least squares regression (for analysis of EPO units/kg/week and SP Kt/V) techniques were all employed to conduct these analyses. Explanatory variables included an indicator for whether a patient was in DOPPS or one of the Demonstration groups and a series of demographic and co-morbid factors including age, race, sex, cause of ESRD, and presence of several diseases. The demographic factors were used to control for the fact that the different mix of patients in each sample might exhibit different changes over time for the variables being analyzed (e.g., patients with more co-morbid factors might exhibit a greater drop in HCT than patients with fewer co-morbid factors). In analyses of follow-up measures, baseline values were also included (e.g., baseline EPO dose was used to predict follow-up EPO dose). All statistical analyses were performed using the SAS program.[31]

Only patients who had baseline values and values at one year were included in the analysis because the effects of being included in the Demo were best analyzed as a difference over time. Depending on the missing data for the anemia-related variables examined, there were from 456 to 570 Demonstration patients (223 to 269 from HOI and 233 to 301 from Kaiser) and 1,711 to 2,722 DOPPS patients from across the nation (of whom 333 to 393 are from Florida and 190 to 221 are from California) with both baseline and follow-up information available.

Measures on DOPPS patients were limited to those taken after 1998 in order to keep them more comparable with the Demonstration patients, who were first enrolled in February 1998. The first measurements available on DOPPS patients after January 1, 1998 were considered baseline measures for DOPPS.

1. Baseline Analyses

The baseline analyses used measurements from the Demonstration patients when they entered their study and from DOPPS patients after January 1, 1998. These baseline values were used to calculate the simple means of the anemia treatment variables, HCT, and dialysis dose from each of the samples. These means are presented in Exhibit 4-1 for patients who have survived for at least one year within the study (i.e., those patients who are also included in the analyses of variation over time). A second analysis compared baseline values between the Demonstration groups and the DOPPS samples while controlling for differences in patient mix by including covariates for each of the demographic and co-morbid factors previously mentioned.

2. Analyses of Differences Over One Year

The effects of being within the Demonstration program over time on the anemia treatment variables, HCT, and on dialysis dose were evaluated using baseline values and the values at (or within a couple of months of) one year after joining the study. First, the baseline values and the values at one year were compared using a paired t-test within DOPPS and within each of the Demonstration groups. This test evaluated whether the values of the anemia treatment variables and HCT had changed significantly over time.

The models were adjusted for the list of co-morbid and demographic conditions listed in the "Baseline Analyses" section, and the compound symmetry correlation structure is used to account for the fact that not all observations are independent.[32] It is expected that observations made on the same patient (baseline and one-year) will exhibit some degree of correlation with each other while observations taken from different patients will not. The use of compound symmetry correlation structure allows for model estimation in this situation.

C. Results

1. Among Baseline Values

For patients who survived at least one year within the studies and who had measurements both at baseline and at one year, the mean values or percentage of patients prescribed the given drugs at baseline and at one year are given in Exhibit 4-1.

Exhibit 4-1: Unadjusted Baseline Measures

Anemia or Dialysis Dose Variable	HOI Baseline	DOPPS-FL Baseline	Kaiser Baseline	DOPPS-CA Baseline
% Rx IV Iron	61.9	49.5	49.0	49.8
% Rx EPO	97.5	87.0	90.7	92.5
% EPO via SC (vs. IV)	0.9	9.5	6.7	8.7
EPO units/kg/week	236.2	219.9	188.1	198.6
HCT (%)	35.0	32.4	34.6	31.9
% HCT ≥ 33	74.2	46.5	68.3	41.0
Kt/V	1.43	1.41	1.38	1.44
% Kt/V < 1.2	18.6	15.3	28.2	17.7

As shown in Exhibit 4-1, in comparing Demo and DOPPS groups, a higher proportion of the Demonstration population was receiving IV iron and EPO in Florida, but not in California, at baseline. A small proportion of Demonstration patients in both locations were receiving EPO through subcutaneous administration, and the average dose of EPO for Kaiser patients was lower than the DOPPS sample when they entered the Demo. Demonstration patients in both locations had a higher average hematocrit at baseline. Kaiser patients had lower average Kt/V at baseline compared to the DOPPS sample and had a higher proportion of patients with Kt/V less than 1.2.

Exhibit 4-2 compares DOPPS patients with Demonstration patients at baseline, before the effects of participating in the Demo are likely to become apparent, adjusting for differences in the patient populations. The dichotomous variables for likelihood (presented as an odds ratio [OR]) of being prescribed IV iron, EPO, and EPO through subcutaneous administration, and Kt/V < 1.2 are presented, comparing Demonstration patients to DOPPS patients. The continuous outcome measures of the difference in EPO dose, HCT, and dialysis dose are given for Demonstration patients compared to DOPPS patients. Each analysis controls for demographic and co-morbid differences.

Results indicate that HOI patients were statistically significantly more likely to receive IV iron and EPO, but less likely to receive EPO via subcutaneous administration than the DOPPS comparison patients at baseline. Kaiser patients were not statistically significantly different from their DOPPS counterparts in these regards. Additionally, when adjusting for patient differences, there was not a significant difference in average dose of EPO in California, but HOI did have a significantly higher EPO dose than Florida DOPPS. The Demonstration patients had a significant and clinically meaningfully higher hematocrit (Δ = 1.82 in Florida and 2.05 in California) than DOPPS patients. Note that these are different from the unadjusted difference of 2.6 (= 35.0 - 32.4) in Florida and 2.7 (= 34.6 - 31.9) in California, because we adjusted for the fact that the Demonstration patients were younger and healthier. The Demonstration patients at baseline in both locations were also much more likely to exceed the DOQI guideline of 33% HCT than the DOPPS patients. In contrast to hematocrit findings, Demonstration patients in both locations were more likely to have adjusted dialysis dose below DOQI Kt/V guidelines of 1.2, although this finding is statistically significant at Kaiser only.

Exhibit 4-2: Adjusted Baseline Measures

Anemia or Dialysis Dose Variable	HOI versus FL DOPPS		Kaiser versus CA DOPPS	
	OR or D	p-value	OR or D	p-value
IV Iron (yes/no)	OR = 1.77	0.0013	OR = 1.16	0.4461
Rx EPO (yes/no)	OR = 4.66	0.0006	OR = 0.73	0.3473
EPO via SC (v. IV)	OR = 0.49	0.0036	OR = 0.87	0.7196
EPO Dose (units/kg/week)	Δ = 30.24	0.0450	Δ = -2.06	0.9065
HCT (%)	Δ = 1.82	<0.0001	Δ = 2.05	<0.0001
HCT $\geq$ 33 (v. < 33)	OR = 2.57	<0.0001	OR = 2.63	<0.0001
Kt/V (units)	Δ = 0.00	0.9940	Δ = -0.05	0.0899
Kt/V < 1.2 (v. Kt/V $\geq$ 1.2)	OR = 1.59	0.0756	OR = 1.81	0.0374

2. Analyses of Differences Over Time

We examined differences over time among DOPPS and Demonstration patients in their anemia treatment variables, HCT values, and dialysis dose variables. Exhibits 4-3 and 4-4 present these differences over time by comparing one-year measures to those at baseline. The p-values presented in each set of columns are the results of testing if the average baseline and the average one-year values are the same within each sample (HOI, Florida DOPPS, Kaiser, or California DOPPS), and does not take into account co-morbid and demographic differences between the Demo and DOPPS patients.

Exhibit 4-3: Unadjusted Differences Over Time: HOI and FL DOPPS

Anemia Variable	HOI			Florida DOPPS		
	Baseline	1 Year	p-value	Baseline	1 Year	p-value
% Rx IV Iron	61.9	50.4	0.01	49.5	59.2	0.004
% Rx EPO	97.5	94.2	0.05	87.0	90.5	0.11
% EPO via SC (vs. IV)	0.9	0.9	1.00	9.5	0.3	<0.001
EPO units/kg/week	236.2	234.8	0.92	219.9	223.9	0.75
HCT %	35.0	35.9	0.01	32.4	35.6	<0.001
% HCT ≥ 33	74.2	77.8	0.32	46.5	77.6	<0.001
Kt/V	1.43	1.52	<0.001	1.41	1.46	0.005
% Kt/V < 1.2	18.6	10.3	0.009	15.3	12.9	0.35

Exhibit 4-4: Unadjusted Differences Over Time: Kaiser and CA DOPPS

Anemia Variable	Kaiser			CA DOPPS		
	Baseline	1 Year	p-value	Baseline	1 Year	p-value
% Rx IV Iron	49.0	57.7	0.04	49.8	50.6	0.85
% Rx EPO	90.7	90.3	0.87	92.5	92.9	0.87
% EPO via SC (vs. IV)	6.7	37.3	<0.001	8.7	11.7	0.26
EPO units/kg/week	188.1	190.9	0.78	198.6	197.6	0.95
HCT %	34.6	36.0	<0.001	31.9	34.8	<0.001
% HCT ≥ 33	68.3	77.9	0.01	41.0	69.7	<0.001
Kt/V	1.38	1.47	<0.001	1.44	1.44	0.98
% Kt/V < 1.2	28.2	13.8	<0.001	17.7	19.5	0.60

In general, hematocrit levels increased in each patient group (for both Demo and DOPPS comparison patients in both sites). In addition, Kt/V rose for patients at HOI, Florida DOPPS, and Kaiser. These results suggest an improvement in clinical indicators among patients with differences in practice patterns by location. A statistically significant increase in the use of subcutaneous (SC) EPO was found among Kaiser patients; the percent of patients receiving this form of EPO therapy increased from 6.7 to 37.3 percent after one year (Exhibit 4-4).

Prior clinical research about EPO dosing would suggest that this increased use of SC at Kaiser should have led to either lower EPO doses or higher HCTs. While the average dose of EPO among patients receiving therapy via the subcutaneous route at Kaiser was lower (by 9 percent) compared to intravenous (IV) administration (183.7 vs 200.1 units/kg/week) at follow-up, the difference in dose was not statistically significant and quantitatively smaller than one would expect. In terms of outcomes, however, every patient group experienced statistically significant and clinically meaningful increases in HCT over this 1-year interval. If EPO dose did not decrease then one might expect a higher HCT. In fact, there was no statistically significant difference in hematocrit levels by route of administration (hematocrit was 35.3 percent for SC and 35.2 percent for IV at follow-up).

Another possible explanation of the failure to find either a lower EPO dose or higher HCT with SC administration was that the patients who shifted to SC were atypical. If, for example, the SC patients were generally heavier, then EPO dose measured as units per kilogram of body weight would not necessarily indicate higher doses. Tests of patient characteristics for SC and IV administration did not support the notion that SC patients were atypical. In conclusion, we are left without a good explanation of why the Kaiser shift to SC did not lead to either higher HCT or lower doses.

It is common knowledge that anemia therapy includes a mix of iron and EPO administration. The trend in the chances of receiving IV Iron among HOI patients was lower than the trend among DOPPS patients in Florida. Among HOI patients, the percentage receiving IV Iron dropped from 61.9 to 50.4 while among DOPPS patients during a similar period the percentage rose from 49.5 to 59.2. These trends suggest that the IV iron dosing among HOI and Florida DOPPS patients were similar.

In Florida, both HOI and the DOPPS patients had a significant increase in Kt/V during the year, while in California we observed an increase in Kt/V for Kaiser patients, but not for the DOPPS patients. The baseline Kt/V for Kaiser patients was the lowest of the four groups, which may explain the larger increase. Both Demonstration sites significantly reduced the proportion of patients receiving less than 1.2 Kt/V, the clinically accepted lower limit of an adequate dialysis dose.

3. Analysis of Change in Distributions of Kt/V

Both Florida and HOI included target Kt/V rates as part of their quality assurance processes. Kaiser intended to deliver a Kt/V of 1.4 for nondiabetic hemodialysis patients and 1.6 for diabetic hemodialysis patients. HOI intended to deliver a Kt/V of 1.3 for nondiabetic hemodialysis patients and 1.4 for diabetic hemodialysis patients. Exhibit 4-5 presents the proportion of each Demo site's patients that met the intended targets at baseline and follow-up. Because the Kt/V targets differed between the Demonstration sites, we calculated the portion meeting both its own target, as well as the target of the other Demonstration site.

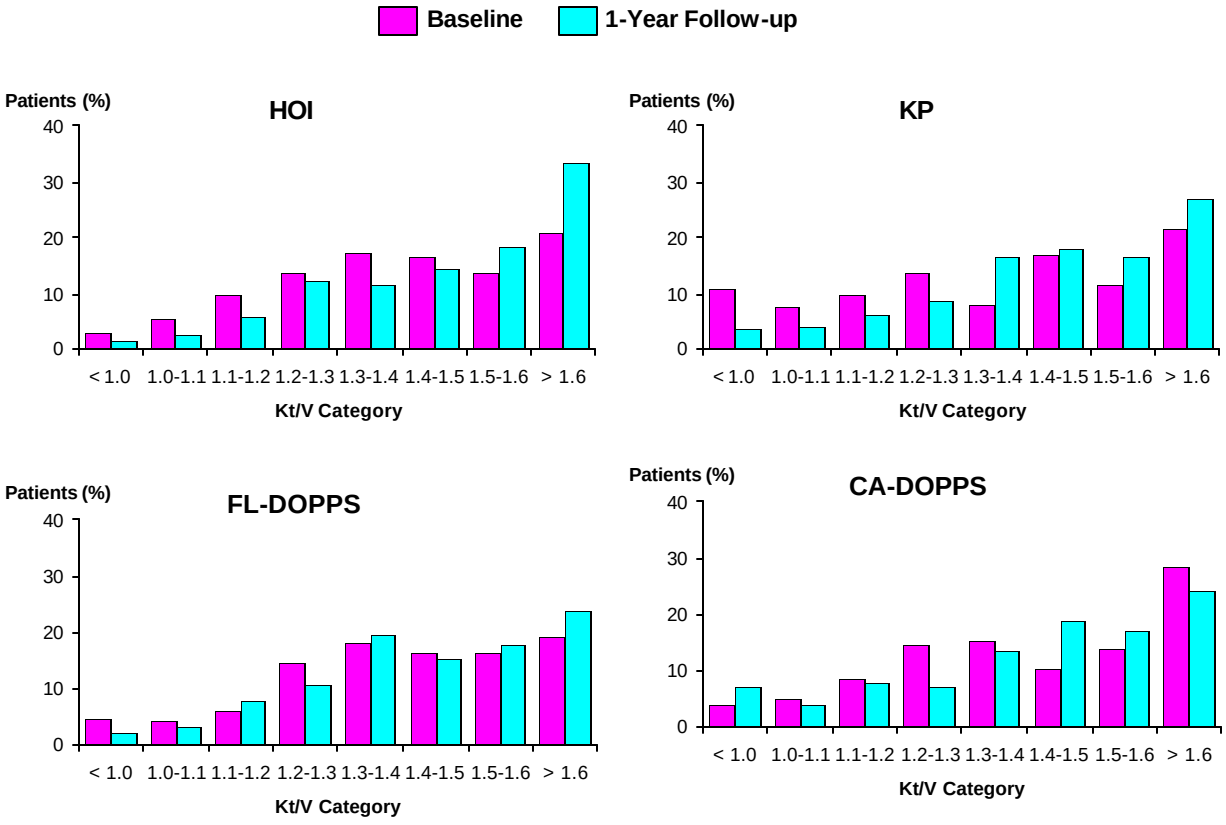
HOI achieved a higher proportion of its patients meeting the Kt/V targets it set for itself compared to Kaiser. At follow-up 74% of HOI patients were meeting the HOI target, compared with 51% of Kaiser patients meeting the Kaiser target. Interestingly, HOI had a larger proportion of its patients meeting the higher Kt/V targets defined by Kaiser than Kaiser had in meeting its own targets.

Exhibit 4-5: Proportion of Patients at Sites Meeting Kt/V Targets

	HOI (%)		Kaiser (%)	
	Baseline	Follow-up	Baseline	Follow-up
Proportion meeting HOI defined Kt/V target	66	74	55	72
Proportion meeting Kaiser defined Kt/V target	40	60	43	51

Exhibit 4-6 illustrates the distribution of Kt/V at baseline and follow-up by Demonstration site. At the start of the Demo, Kaiser had a greater proportion of patients in the lower Kt/V categories than any other site. Over the Demonstration period, Kaiser successfully improved the distribution of Kt/V. The distribution of patients at the lower Kt/V levels ($\leq$ 1.2) appears similar for HOI and Florida DOPPS patients at baseline. HOI also improved the distribution of patients' Kt/V levels, particularly at the higher end ($\geq$ 1.5).

Exhibit 4-6: Kt/V Distributions by Demonstration Site at Baseline and 1-Year



4. Components of Dialysis Dose at Baseline and Over Time

Exhibit 4-7 presents comparisons of dialysis dose components at baseline and follow-up. All sites had a low proportion of patients prescribed to receive dialysis twice a week. Both Kaiser and HOI had longer prescribed treatment times than California and Florida DOPPS, respectively, and both Demonstration sites significantly increased treatment times over the study period. Both Demo sites also had higher prescribed blood flows than their respective DOPPS counterparts. Both HOI and Florida prescribed higher blood flows at follow-up.

Exhibit 4-7: Component of Dialysis Dose at Baseline and Over Time

Treatment Aspect	HOI			DOPPS FL			KP			DOPPS CA		
	Base line	Follow-up	p-value	Base line	Follow-up	p-value	Base line	Follow-up	p-value	Base line	Follow-up	p-value
% Patients with 2 Sessions/Week	0.4	0.8	0.50	1.5	0.90	0.74	1.5	0.8	0.16	2.0	1.3	0.48
Prescribed Treatment Time (min)	218	224	< 0.001	210	212	0.05	207	213	<0.001	202	205	<0.001
Prescribed Blood Flow (ml/min)	426	430	0.20	411	424	<0.001	414	418	0.39	402	399	0.42

Exhibit 4-8 compares baseline dialysis dose components when adjusted for the differences in patient characteristics. HOI was statistically significantly more likely to prescribe longer dialysis treatment times by almost six minutes compared to Florida DOPPS. All other treatment characteristics were similar after adjustment.

Exhibit 4-8: Adjusted Baseline Dose Components

Treatment Aspect	HOI versus DOPPS-FL		Kaiser versus DOPPS-CA	
	OR or D	p-value	OR or D	p-value
% Patients with 2 Sessions per Week	OR = 2.20	0.21	OR = 2.80	0.54
Prescribed Treatment Time (min)	Δ = 5.9	0.04	Δ = 1.5	0.63
Prescribed Blood Flow (ml/min)	Δ = 4.5	0.42	Δ= 3.9	0.52

D. Discussion

Optimal treatment of anemia in hemodialysis patients may contribute significantly to better patient outcomes. In addition, anemia is a significant risk factor for left ventricular hypertrophy and independently correlates in observational studies with mortality and hospitalization. Quality of life and patient cognition have been shown to improve significantly with increased hematocrit.[33]

The examination of the baseline status of the two patient groups (i.e., Demonstration patients compared to DOPPS) allowed for comparison of the selection to these groups. At baseline, it would be too soon for any effects of managed care on anemia management to be observed. The differences at baseline probably reflect the fact that patients who choose to change their insurance tend to be younger and healthier, with fewer co-morbid factors (see Chapter 3). These differences (from Exhibits 3-3 and 3-4) included higher hematocrit levels in both Demonstration sites, and improved odds for HOI patients of receiving EPO and IV Iron.

The effects of any difference in care under the Demo would probably develop over time, rather than appearing immediately after patients joined the Demo. For this reason, anemia treatment

measures were repeated at one year to determine if Demonstration patients' anemia treatment and/or HCT changed over time. To assess how much of the change might have been due to enrollment in the Demonstration plan, the change over time for both the Demo and DOPPS patients was evaluated between baseline and one year using a paired t-test. While hematocrit levels of patients who had been in the Demo for a year did not increase as dramatically as for the DOPPS, their actual HCT levels at both baseline and follow-up were higher and their average hematocrit levels remained well within the DOQI guidelines of 33% to 36% for target HCT.[34] The fact that there was less of an improvement for the Demonstration patients could simply reflect the fact that there was less room for improvement due to high HCT levels at baseline.

In general, we found that Demonstration patients were managed effectively with respect to anemia while treated in the Demo. Differences in practice patterns were observed between the Demo and their DOPPS comparison groups; for example, at one year follow-up Kaiser patients were much more likely to receive subcutaneous EPO. Measures of anemia management showed better-than-adequate outcomes for Demonstration patients after one year. While the change in HCT levels over time was less dramatic than for DOPPS, it is clear that Demonstration practices successfully achieved DOQI standards and Kaiser made strides toward implementing the use of subcutaneous EPO. In contrast to expectation, Kaiser apparently did not reduce EPO dose when moving patients to SC administration. Further, the high dose of EPO among SC patients at Kaiser does not appear to have resulted in higher hematocrit outcomes. One possible reason for this comes from anecdotal reports that Kaiser experienced difficulty in maintaining patients on SC administration over time. If patients were routinely switched back and forth between IV and SC administration, the effects of SC may not be evident in the data with the IV group being influenced by time spent on SC and vice versa.

The majority of patients enrolled in the Demo received an adequate dose of dialysis, as defined by the DOQI guidelines. Both Demonstration sites improved the average level of Kt/V and both sites raised the distribution of Kt/V among enrolled patients. Importantly, the proportion of patients with a Kt/V prescription of less than 1.2 declined at both sites. However, neither Demonstration site achieved their own defined target Kt/V for all patients.

HOI achieved higher levels of delivered Kt/V than did Kaiser. While both Demonstration sites increased prescribed dialysis time over the Demonstration, HOI started out with longer prescribed treatment times and higher blood flows. HOI also started out with fewer patients with a baseline dialysis dose of <1.2. Potential differences in practice patterns (e.g., differences in size of dialyzer) may exist between the two sites. Changes over time among DOPPS patients show that Kt/V levels were increasing in Florida overall while remaining static in California, thereby suggesting that different practice patterns may exist across geographic regions.

CHAPTER V: HOSPITALIZATION

A. Introduction

Hospitalization is a major source of patient morbidity and economic costs, with inpatient costs comprising nearly 40 percent of total spending for dialysis patients.[35] Because of the high costs associated with hospitalization, managed care (MC) organizations have a strong incentive to minimize the number of days patients spend in the hospital. Since Kaiser Permanente (KP) is a closed-practice MC plan where hospitalization is internalized almost entirely, they could theoretically be better equipped to minimize hospital utilization than a MC organization such as Health Options Inc. (HOI), where hospitalization, although likely to be monitored and controlled, is contracted with outside providers and paid for at a per diem rate.

Previously discussed in this report was the topic of prior hospitalization for Demo patients as an indicator of health status at the time of enrollment (see Chapter 3). We found that patients who chose to enroll in the Demo were significantly less likely to have had an inpatient visit during the six-month period prior to Demo enrollment than comparison patients. When this result was adjusted for the healthier patient characteristics found in the Demo, no significant differences for Demo patients relative to DOPPS comparison patients were found. In other words, when Demo patient pre-Demo hospitalization rates are adjusted for these characteristics at baseline, the rates are not statistically different from comparison patients in the same state.

A major question for the evaluation is whether the Demo patient hospitalization during one year of follow-up differed from the pre-Demo experience reported, and how the hospitalization rates for these patients compare to those of a representative FFS comparison sample (DOPPS).

B. Methods

Longitudinal data were obtained for Demo patients using the evaluation clinical assessment form (CAF) to record the number of days spent in the hospital during the first year enrolled. The Demo CAF data were used in these analyses because they are directly comparable to the DOPPS data with respect to both the source and method of data collection (see Methods Appendix).

Unadjusted rates of hospital days per patient year at risk were calculated by summing the total inpatient days reported and dividing by the sum of the time at risk for each subgroup. Patients in both the Demo and DOPPS subgroups were followed for up to one year after enrollment (less if the patient died or departed from either study).

Poisson regression models were used to determine the relative rate of hospitalization for Demo patients versus DOPPS comparison patients, adjusting for baseline co-morbid and demographic factors. Whether or not the patient died during the one-year follow-up period was also accounted for in the regression models, since hospitalization is known to dramatically increase prior to death.

C. Results

The unadjusted rate of hospital days per patient year at risk increased after one year in the Demo compared to the pre-Demo period. The magnitude of the increase that occurred from baseline (pre-Demo) to one year later was greater for HOI than for KP (Exhibit 5-1). Compared to DOPPS patients in CA and FL, the unadjusted rates for both the pre-Demo and Demo periods were lower.

Exhibit 5-1: Inpatient Hospital Days per Patient Year at Risk (PPY) (unadjusted)

Demo Group	Pre-Demo (6 months) Inpatient Days PPY	Demo (1 year) Inpatient Days PPY	Same-state DOPPS Inpatient Days PPY
KP	6.29	7.61	9.71 (CA)
HOI	6.52	9.08	10.11 (FL)

To investigate whether the differences in hospitalization during one-year follow-up between Demo and DOPPS patients still existed after taking into consideration known differences in patient characteristics, the relative rate of hospitalization (total days spent in the hospital over time) for Demo versus DOPPS patients was calculated, both with and without statistical adjustment for patient differences. As shown in Exhibit 5-2, the unadjusted relative rate (RR) of hospitalization for Demo versus same-state DOPPS comparison patients was lower (also reflected by the crude rates shown in Exhibit 5-1). For KP, this rate difference was statistically significantly lower (RR=0.78, p=0.023). However, after adjustment, the risk of hospitalization appears to be the same for both KP versus CA DOPPS (RR=0.95, p=0.647) and HOI versus FL DOPPS (RR=1.04, p=0.685).

Exhibit 5-2: Relative Rate (RR) of Hospitalization (Total Days) Occurring Within First Year of Demo (1998-1999) v. Same-state DOPPS Comparison Patients

Comparison	Unadjusted RR	P-value	Adjusted RR	P-value
KP v. CA DOPPS	0.78	0.023	0.95	0.647
HOI v. FL DOPPS	0.90	0.288	1.04	0.685

D. Discussion

Patients who chose to enroll in the Demo had lower hospitalization during the pre-enrollment period, which is consistent with their being younger and healthier at enrollment. When patient differences were taken into account, there appeared to be no statistically significant differences between Demo patients and comparison patients, indicating that the differences in the crude rates of hospitalization were explained entirely by differences in demographic and co-morbid characteristics between the Demo and comparison patients.

We found that hospitalization increased for Demo patients during the first year of the Demo compared to the six months prior to enrollment. Assuming patients are more likely to switch

their health coverage at a point in time when they were not recently admitted to the hospital, it is conceivable that their hospital utilization might increase thereafter.

Comparing the hospitalization experience of Demo patients during their first year in the Demo to DOPPS comparison patients, we found that the lower hospitalization observed among Demo patients at both sites could be entirely attributed to patient mix.

The supposition that managed care plans may actively attempt to reduce hospitalization in order to lower costs was not supported by these results, since Demo patient hospitalization was the same as patients in fee-for-service Medicare. It is possible that if efforts were made by the Demo plans to minimize hospitalization through preventive care measures, a longer period of study would be needed in order to fully measure the impact of any preventive care. The value of the results presented here is that hospital rates for ESRD patients treated under managed care are shown to be the same in the short term as those under Medicare FFS.

CHAPTER VI: TRANSPLANTATION

A. Introduction

A fundamental issue for chronic dialysis patients is timely access to transplantation. A functioning graft can provide patients with increased independence and a longer life, as well as substantially improve their overall quality of life. A major question regarding the Medicare Demonstration (Demo) is whether patients who enrolled in the Demo had access to kidney transplantation that was comparable to other dialysis patients in the same geographic locations. Under fee-for-service (FFS), patients with Medicare insurance can choose to be listed at most any transplant facility. But under Managed Care (MC), the patient must choose from among the transplant providers with whom the MC organization has established financial relations and agreements for the provision of transplant services. We addressed this question by calculating the proportion of Demonstration patients on the kidney transplant waiting list relative to Medicare FFS dialysis patients in California and Florida. This analysis was performed at the start of the Demo and again at one year after enrollment.

For patients on a transplant waiting list, there is the subsequent issue of progressing to a transplant. Transplantation rates for waitlisted Demo patients were compared to rates for patients awaiting transplants within the same Organ Procurement Organization (OPO) regions. Because HOI contracted with one transplant center in Jacksonville located more than 300 miles away, it is important to evaluate the impact of this specific situation on transplant rates for HOI Demonstration patients. A direct comparison of Miami-area kidney transplant rates to Jacksonville-area transplant rates is of interest, since patients who joined the Demo in Florida were only offered the possibility of listing with the Jacksonville center. Had the Demo not taken place, patients who remained in FFS more than likely would have been listed with a Miami-area transplant center had they chosen to be listed.

B. Methods

1. Access to Transplant Waitlist

Kaiser and HOI dialysis patients who were enrolled from Demo start (February 1998 for Kaiser, June 1998 for HOI) through December 1, 1999 were compared to a cross-section of dialysis patients in California and Florida known to have Medicare primary FFS insurance on January 1, 1998 (see Methods Appendix for additional details). Logistic regression models with adjustment for the covariates of age, sex, race, ethnicity, and time with ESRD were used to compare the odds of being listed for Demo patients at baseline versus Medicare FFS patients in the same area. This analysis was repeated at one year after the date of enrollment. All dialysis patients 18 to 65 years of age were included in the comparisons.

2. Time to Transplant

Kidney waitlist data obtained from the Organ Procurement and Transplantation Network (OPTN) were used to identify transplant centers within the Demo areas and their associated OPOs, as well as several patient demographic and clinical measures at time of listing. The Demo sample for time-to-transplant analyses consisted of patients who were listed for a kidney-

only transplant during their enrollment in the Demo. For comparison patients in the same area, patients listed between February 1, 1998 and May 31, 2001 were included. All patient factors used for statistical adjustment in the models for these analyses were collected at the time the patient was listed with the transplant center. The comparison group for Kaiser waitlisted patients consisted of kidney transplant candidates listed with the Los Angeles and San Diego area transplant centers served by Southern CA OPOs. For HOI, the comparison group included all patients listed with Jacksonville area transplant centers during the study period. Exhibit 6-1 shows the comprehensive list of centers that were included in these analyses. Additionally, waiting times for kidney transplant candidates in the OPO serving Jacksonville were compared to waiting times for candidates in the Miami area OPO. This was done because of the unique situation affecting HOI patients, who would have most likely listed with a center in the Miami area, had they stayed in the FFS system and opted to be listed.

Exhibit 6-1: Demonstration Area Transplant Centers (Comparison Group)

(Demonstration transplant centers listed in italics)

Geographic Area	Organ Procurement Organizations (OPOs)	Transplant Centers
Southern California	Southern California Organ Procurement Center	Saint Bernardine Medical Center
		Children's Hospital Los Angeles
		Cedars Sinai Medical Center
		University of California Irvine Medical Center
		Harbor UCLA Medical Center
		St Mary Medical Center
		Loma Linda University Medical Center
		Riverside Community Hospital
		Arrowhead Regional Medical Center
		Saint Joseph Hospital
		Saint Vincent Medical Center
		University of California at Los Angeles Medical Center
		University of Southern California - University Hospital
		Western Medical Center
	Lifesharing Community Organ Donation	Scripps Green Hospital
		University of California San Diego Medical Center
		Sharp Memorial Hospital
Miami area	University of Miami Organ Procurement Organization	Cleveland Clinic Hospital Florida
		Jackson Memorial Hospital University of Miami School of Medicine
Jacksonville area	LifeQuest Organ Recovery Services	*Shands Jacksonville*
		St Lukes Hospital
		Shands Hospital at The University of Florida

Cox proportional hazards regression models were used to analyze time to transplant, adjusting for patient age, sex, race, ethnicity, time with ESRD, panel reactive antibody (expressed as percent PRA, the level of measured sensitivity to a standard panel of antibodies), blood type, year of listing, and transplant center clustering effects. Time at risk for patients started on the date of listing and ended at the earlier of the date of transplant or censoring. Patients were censored at the first occurrence of: the date of removal from the list, disenrollment from the Demo, death, or end of study (May 31, 2001). All analyses were performed using SAS software.[36]

C. Results

1. Access to Transplant Waitlist

Patients who joined the Demo were less likely to be on a waitlist at the time of enrollment than Medicare FFS dialysis patients in the same state. However, after one year, the percentage of dialysis patients who were waitlisted increased substantially for HOI and new (non-rollover) Kaiser patients. Exhibit 6-2 provides a comparison of the unadjusted proportion of waitlisted patients in these groups.

Exhibit 6-2: Baseline* and One-year Waitlist Percentages: Demonstration versus California and Florida FFS Patients (All Dialysis)

Patient Group	Sample Size (Baseline)	Percent on Waitlist at Baseline	Percent on Waitlist 1 Year after Baseline
California			
Kaiser New	388	19.1	32.1
Kaiser Rollover	144	36.1	35.1
CA FFS	19,739	36.1	-
Florida			
HOI	383	10.4	15.4
FL FFS	9,753	26.1	-

* Demonstration baseline is date of enrollment (enrollees through 12/99); for California and Florida FFS baseline was on 1/1/98.

The likelihood of new Demo patients to be waitlisted at time of enrollment was statistically significantly lower than FFS patients in the same geographic area, adjusting for patient differences that may affect listing status such as age, sex, race, ethnicity, and time with ESRD. After one year, the probability of listing improved substantially for new Kaiser patients, for whom waitlisting patterns were found to be similar to FFS patients in CA (AOR = 0.93,p = 0.596). Kaiser rollover patients were not found to be different from CA FFS at either baseline or one year later. For HOI Demo patients at follow-up, there was some improvement relative to likelihood of listing at Demo start, but after one year HOI dialysis patients were still over 50 percent less likely to be on a waitlist than FL FFS patients (AOR = 0.48, p<0.001, Exhibit 6-3).

Exhibit 6-3: Adjusted Waitlist Odds (AOR) at Baseline* and One-year: Demonstration versus California and Florida FFS Patients (All Dialysis)

Comparison	Baseline AOR	P-value	One-year AOR	P-value
Kaiser New v. CA FFS	0.46	<0.001	0.93	0.596
Kaiser Rollover v. CA FFS	1.02	0.915	0.96	0.849
HOI v. FL FFS	0.29	<.0001	0.48	<0.001

*Demonstration baseline is date of enrollment; for CA and FL FFS baseline was 1/1/98.

2. Time to Transplant

Unadjusted transplant rates during the study period were calculated for each patient group by dividing the number of transplant events by the total sum of patient-years on the waiting list. These results, shown in Exhibit 6-4, suggest that patients who joined the Demo from FFS were less likely to receive a transplant than those who remained in FFS. Similar rates of transplant were observed for new Demo patients at the California and Florida Demo sites, despite the apparent differences in the regional transplantation rates between California and Florida.

Exhibit 6-4: Kidney Transplantation Rates* (Feb. 1998 – May 2001) Demonstration Waitlisted Patients versus Waitlisted Patients in Same OPO Region

Patient Group	Sample Size	Total Transplants	Unadjusted Transplant Rate (per 100 patient-years)
Kaiser - New	266	45	6.8
Kaiser – Rollover	156	42	8.8
S. California (Comparison group)	7,253	1,770	12.0
HOI	92	11	6.3
Jacksonville area (Comparison group)	1,275	416	17.3
Miami area (Comparison group)	922	383	29.6

* Includes patients that were put on the waitlist prior to joining Demo, plus patients listed after enrollment.

Many factors are known to influence transplant rates, such as patient sex, race, blood type, and percent PRA.[37,38] Multivariable Cox regression models of time to transplant with adjustment for these and other factors provided evidence of lower transplant rates for new Demo patients in Florida, but not California. Comparisons of the relative rate (RR) of transplant are shown in Exhibit 6-5. New Kaiser patients were found to have rates similar to other patients listed in the same OPO region. Kaiser rollover patients appeared to have better transplant access than other waitlisted patients in Southern California, but this difference was not statistically significant (RR = 1.37, p = 0.436).

Significantly lower transplantation rates were found among HOI patients, even after adjustment for many patient factors known to be associated with transplant rates. The apparent disadvantage to HOI Demo patients that resulted from having their choice of centers limited to

Jacksonville was twofold: moving from a Miami area transplant center to Jacksonville reduced the chance of receiving a transplant by nearly 50% (RR = 0.52, p<0.001), and compared to other Jacksonville patients on the waitlist, HOI patients were disadvantaged another 60% (RR = 0.41, p<0.001). Compared to patients listed in Miami, HOI patients were only about one-third as likely to receive a transplant (RR=0.32, p<0.001).

Exhibit 6-5: Adjusted Relative Rate (RR) of Kidney Transplant: Demonstration Waitlisted Patients versus Waitlisted Patients in Same OPO Region

Comparison	Adjusted RR*	P-value
Kaiser New v. Southern CA OPOs	0.975	0.942
Kaiser Rollover v. Southern CA OPOs	1.368	0.436
Jacksonville v. Miami	0.52	<0.001
HOI v. Jacksonville OPO	0.41	<0.001
HOI v. Miami OPO	0.32	<0.001

*Adjusted for patient age, sex, race, ethnicity, time with ESRD, panel reactive antibody (% PRA), blood type, year of listing and transplant center clustering effects.

D. Discussion

1. Waitlist Access

Patients who joined the Demo were less likely to be on a waitlist at the time they enrolled at either site compared to FFS patients in the same geographic area. It could be speculated that patients already on a transplant center waitlist were less likely to change health plans. In the case of HOI, it is possible that the distance to Jacksonville was prohibitive to joining the Demo for patients with an interest in access to transplant (i.e., patients already waitlisted).

After spending one year in the Demo, patients enrolled in the Kaiser plan had similar access to transplant waitlists as their FFS counterparts. While HOI increased the proportion of patients on the waitlist, HOI patients were still only one-half as likely to be on a waitlist after one year, which may indicate that the distance to the Jacksonville center was a deterrent to patients getting on the waiting list.

2. Difference in Relative Transplant Rates: HOI versus Jacksonville

It is a matter of concern that patients who were already significantly disadvantaged by moving from a Miami area center to a Jacksonville center (where there was a 50% lower rate of transplant) were also put at a disadvantage relative to other patients listed in the Jacksonville area. One reason for this additional difference (60% lower rate of transplant for HOI versus Jacksonville) could be that the distance required to travel for transplant surgery was somehow prohibitive. (Note that HOI did pay for some of the costs associated with travel and accommodations for patients and their families.) Since the time that a donated cadaveric kidney can remain viable without a blood supply is short (best transplanted within 24 hours), time is a limiting factor. The several hours required for travel to the Jacksonville transplant

center may have contributed to HOI patients getting fewer organs, either because they were passed over for eleventh-hour organs, or perhaps due to their inability to make the lengthy trip on short notice.

Managed care plans, as well as some other forms of insurance, restrict the options of patients to choose transplant centers. In contrast, Medicare FFS patients can choose most any transplant center. In this Demo, Kaiser was able to contract with transplant centers in a manner that did not harm transplant access. Our analysis of the HOI experience suggests that limited transplant center options could potentially lead to lower levels of transplant access. Distance to a transplant center is also likely to have a large effect on transplant access. Looking beyond the Demo, transplant patients may find their options limited for a number of reasons: their HMO may choose to contract with only one of multiple co-located centers, there may be only one local center, or there may be no local center. Based on the June 30, 1999 OMB definitions of primary metropolitan statistical areas (PMSA), out of the 73 PMSAs, 37 have no kidney transplant program, 13 have only one local program, and 23 PMSAs have more than one local program. Thus, our findings may have wide-reaching policy implications beyond the current Demo.

CHAPTER VII: VASCULAR ACCESS

A. Introduction

Vascular access complications are known to contribute significantly to hemodialysis patient morbidity and cost of care. The most common problems are stenosis (narrowing of graft/blood vessel), infection, and thrombosis (clotting). One of the major practice options available for vascular access is to choose an arterio-venous fistula versus a synthetic or bovine graft to achieve reliable permanent vascular access needed for regular hemodialysis, as stated in the clinical practice guidelines for vascular access from the Dialysis Outcomes Quality Initiative (DOQI). Fistulas are surgically created by connecting a patient's own artery and vein, usually in the forearm. Fistulas have the lowest rate of complications, but take from several weeks to several months to mature, heal, and develop in size. While not possible for all patients, fistulas are possible for the great majority of patients. Grafts are also created surgically, but use a synthetic blood vessel to connect the vein and artery. Grafts require shorter times (if any) to heal before they can be used, but tend to have more episodes of stenosis and thrombosis than fistulas. Additionally, compared to fistulas, grafts are more costly to maintain.[39]

To assess vascular access treatment patterns among demonstration (Demo) patients, surveys were developed and electronic data were collected on a variety of measures, including counts of procedures performed and recorded vascular access events (e.g., date of first clotting or access failure). The primary goal was to use these various measures to analyze vascular access outcomes and the means by which they were achieved in the Demo.

Outcomes such as access survival and the costs associated with care are known to be affected by the choice of permanent vascular access (fistula or graft)[40], the setting in which the care is provided (since higher costs are associated with inpatient versus outpatient care), and the types of procedures performed (e.g., radiologic or surgical). We chose to examine each of these aspects of care, comparing the patients in the Demo to comparison samples of other HD patients with respect to both treatment patterns and outcomes.

B. Methods

At baseline and one year following enrollment (based upon each individual patient's enrollment date), the vascular access in use for each patient in the Demo sample was recorded in order to track possible trends in choice of access type. For comparison purposes, the types of vascular accesses in use among prevalent samples of same-state DOPPS patients and matched comparison patients in fee-for-service (FFS) and non-Demo managed care (NDMC) were also examined. (For a complete description of the sample and data collected, see the Methods Appendix.)

For any patient having a permanent access at Demo enrollment, the date of first observed access failure (i.e., clotting) during the one-year follow-up period was recorded for the purpose of analyzing access failure rates. Patients with less than one year of follow-up due to disenrollment or death were also included, with their time at risk censored at time of departure.

Permanent vascular access survival, defined as the time from study start to the first recorded vascular access failure, was modeled using Cox proportional hazards regression. Models included adjustment for the full set of demographic and co-morbid factors, as well as the number of prior permanent vascular accesses. Separate regression models were developed for each type of permanent access (fistula and graft).

Vascular access events captured by the Demo sites' data systems during 1999 and 2000 were obtained for the purpose of analyzing the rates of various types of procedures, as well as the setting of care (inpatient or outpatient). In addition, Medicare claims data for 1999 were queried from the CMS data system for selected comparison samples of Medicare-primary FFS patients (see Methods Appendix). The CMS Common Procedure Coding System (HCPCS) and International Classification of Diseases 9th Revision (ICD-9) codes for vascular access-related services were used to identify events in the Part A and B Medicare claims. A comprehensive list of these codes is shown in Exhibit 7-1.

Exhibit 7-1: ICD-9 and HCPCS Codes Indicating Vascular Access-Related Procedures

Type of Procedure	Associated ICD-9 Procedure Codes	Associated HCPCS Codes
Placement of a Permanent Access	3927, 3929	36821, 36825, 36830
Venogram		75790
Angioplasty		35475, 35476, 75978
Radiologic Salvage		36860, 36861, 37201, 75896
Thrombectomy/Revision	3942, 3943, 3949, 3953, 3959	34101, 34111, 34471, 34490, 35011, 35013, 35045, 35184, 35190, 36534, 35875, 35876, 36832, 36834
Creation of Temporary Catheter	3993, 3994, 3803	36489, 36491
Creation of cuffed catheter (Permcath)		36533

Due to some duplication of vascular access events that were recorded in both the Part A (institutional) and B (physician/supplier) claims, event data were grouped together as visits based on the dates of service. Rates of procedures per patient year at risk were calculated by summing the total number of procedures during the observation period and dividing the sum by the total number of patient years at risk for all HD patients (regardless of access type), censoring at the earlier of death, disenrollment, or end of study. Logistic regression methods were used to estimate the adjusted odds of inpatient versus outpatient vascular access-related procedures. Analyses were adjusted for patient age, race, ethnicity, sex, time with ESRD, congestive heart failure, coronary artery disease, cerebrovascular disease, diabetes, hypertension, pulmonary disease, peripheral vascular disease, difficulty ambulating, and body mass index. Only those patients in the FFS Medicare samples with co-morbidity data available from the CMS 2728 form were selected for comparison to the Demo patients (see Methods Appendix).

C. Results

1. Type Of Access Provided

We have shown previously (see Chapter 3) that a higher proportion of patients in both Demo groups had a fistula, in comparison to representative samples from the same geographic locations. The Demo group also had a higher percentage of fistulas than the matched sample of FFS patients (see Exhibits 7-2, 7-3). This was in sharp contrast to the matched NDMC patients, 42 percent of whom had fistulas, higher than the DOPPS, matched FFS, and Demo groups.

Exhibit 7-2: Vascular Access Type at Enrollment v. One Year Follow-up

Patient Group	Fistula %	Graft %	Perm/temp cath %
HOI (n=299)			
At enrollment	33.8	50.8	15.4
At one year	34.1	47.2	18.7
KP (all) (n=341)			
At enrollment	30.2	62.2	7.6
At one year	34.9	56.3	8.8
KP New only (no RO) (n=245)			
At enrollment	28.6	62.4	9.0
At one year	34.7	56.7	8.6

Exhibit 7-3: Vascular Access Type for Prevalent Samples of Comparison Patients, at Baseline

Comparison Group	Fistula %	Graft %	Perm/temp cath %
DOPPS CA	21.0	67.4	11.5
DOPPS FL	26.5	50.7	22.8
Matched CA and FL FFS	24.8	64.1	11.2
Matched CA and FL NDMC	42.4	46.7	10.8

While the changes observed after one year in the selection of vascular access type across both Demo sites were relatively small, there were some differences worth noting. For Kaiser patients, the use of fistulas among hemodialysis patients increased by nearly 14 percent. The change in fistula use was most dramatic among *new* Demo patients at Kaiser (i.e., patients not "rolled over" from Kaiser's existing program), where the fraction of fistulas increased from 28.6 to 34.7 percent (p=0.145). While not statistically significant, this change suggests an upward trend in fistula use. For HOI patients, the use of fistulas stayed relatively constant after one year (33.8 v. 34.1 percent). Since most of the Demo enrollees on hemodialysis were not new to ESRD, they were more likely to have had permanent accesses in place at the time of enrollment (92 and 85 percent for Kaiser and HOI respectively). Because of this, the sites had less opportunity to influence the choice of access type than they would have had among patients new to ESRD.

2. Vascular Access Procedures by Care Setting

The crude rates of the total vascular access procedures (including surveillance, prophylactic, and salvage procedures) were calculated for Demo patients using the utilization data provided by the Demo sites. We found that HOI had 2.05 procedures per patient year at risk (PPY), while Kaiser patients received 1.50 vascular access-related procedures PPY. Medicare FFS patients in CA and FL were found to have rates PPY of 2.92 and 2.73, respectively.

Although large differences in procedure rates for the different patient samples were apparent, these rates were not compared or tested among subgroups, given that the data were obtained from different sources for Demo and comparison patients (see Methods Appendix). Any under-reporting among these data sources could not be fully measured. We did assume, however, that none of the data sources were biased with respect to the place of service recorded. Therefore, we calculated the proportion of procedures performed on an inpatient basis as a percent of the total for each Demo site and compared these percentages to same-state FFS patients. The percent of inpatient procedures by type of procedure are shown in Exhibit 7-4. To gain further insight into the types of vascular access-related procedures performed, we calculated individual rates for the following: permanent vascular access creation, thrombectomy / revision, radiologic salvage, venogram (surveillance), angioplasty (prophylactic when done alone), temporary catheter, and permanent catheter placements. Exhibit 7-4 shows the calculated unadjusted rates by type of procedure for the Demo and same-state Medicare primary-insured FFS comparisons.

The adjusted odds of inpatient versus outpatient setting of care were calculated for each category of procedures shown in Exhibit 7-4, comparing each Demo site to the respective state's population of Medicare primary-insured ESRD patients. To address whether differences in the rate of inpatient procedures were due to differing patient characteristics among groups, these models were adjusted for demographic and co-morbid factors. As indicated by asterisks (*) in Exhibit 7-4, the relative number of procedures performed on an inpatient versus outpatient basis (% IP) was statistically significantly lower among Demo patients in both sites (versus same-state FFS) for many procedure categories. Creation of permanent and temporary accesses and all salvage procedures were less likely to be performed on an inpatient basis for Kaiser patients compared to patients in California FFS. HOI patients were less likely to have their permanent accesses created or venograms and angioplasties performed in the hospital than in an outpatient setting. Overall, vascular access procedures were significantly less likely to be performed in an inpatient versus outpatient setting for both Demo populations (Exhibit 7-4, right-most column), indicating that both Demo sites were disposed to treat vascular access on an outpatient basis.

Exhibit 7-4: Unadjusted Vascular Access (VA) Procedure Rates PPY: Inpatient (IP) v. Outpatient (OP)*

Patient group	Place of Service	Permanent VA creation	Thrombec-tomy/ revision	Radio-logic Salvage	Veno-gram	Angio-plasty	Temp cath Placement	Perm-cath Placement	Overall (all procs)
KP	OP	0.16	0.28	0.15	0.26	0.21	0.03	0.13	1.22
	IP	0.04	0.05	0.03	0.04	0.04	0.02	0.06	0.28
	Overall	0.19	0.33	0.18	0.3	0.25	0.05	0.19	1.50
	% IP	**21%***	**15%***	**17%***	**13%**	**16%**	**40%***	**32%***	**19%***
California FFS	OP	0.15	0.38	0.25	0.45	0.39	0.15	0.09	1.85
	IP	0.17	0.27	0.07	0.11	0.09	0.26	0.09	1.07
	Overall	0.31	0.65	0.33	0.56	0.48	0.41	0.18	2.92
	% IP	**55%**	**42%**	**21%**	**20%**	**19%**	**63%**	**50%**	**37%**
HOI	OP	0.21	0.15	0.13	0.43	0.37	0.14	0.17	1.6
	IP	0.05	0.06	0.03	0.05	0.05	0.11	0.09	0.45
	Overall	0.27	0.21	0.16	0.49	0.41	0.25	0.26	2.05
	% IP	**19%***	**29%**	**19%**	**10%***	**12%***	**44%**	**35%**	**22%***
Florida FFS	OP	0.12	0.31	0.17	0.40	0.33	0.22	0.14	1.69
	IP	0.15	0.26	0.05	0.11	0.08	0.26	0.13	1.04
	Overall	0.27	0.57	0.22	0.50	0.41	0.48	0.27	2.73
	% IP	**56%**	**46%**	**23%**	**22%**	**20%**	**54%**	**48%**	**38%**

*Adjusted comparison of the proportion of inpatient procedures for Demo site v. same-state FFS sample was statistically significant at the p<0.05 level. . For example, KP's rate of 21% of permanent VA creations occurring in an inpatient setting is statistically significantly different from the CA FFS rate of 55%.

3. Access Survival

The risk of failure (i.e., thrombosis) was compared for Demo patients with permanent vascular accesses versus DOPPS patients in California and Florida to determine whether Demo practices were associated with vascular access outcomes. Vascular access survival outcomes were assessed separately for grafts and fistulas (Exhibit 7-5). Kaiser HD Demo patients with a functioning fistula at Demo enrollment had significantly lower risk of failure than California DOPPS patients with fistulas (Exhibit 7-6). Kaiser HD patients who enrolled with a synthetic graft had a similar risk of initial access failure as the DOPPS patients. For HOI the exact reverse was observed. Patients with a fistula when they joined HOI had similar risk of failure to patients with a fistula in the Florida DOPPS sample; while the calculated relative risk (RR) was 0.77, the difference was not statistically significant (p=0.308). Conversely, HOI patients with a graft at the time of enrollment had a significantly lower risk of failure than Florida DOPPS patients with grafts (RR=0.67, p=0.013).

Exhibit 7-5: Unadjusted Failure for Fistulas and Grafts Among Demo Patients

Patient Group	Fistula Failures PPY	Graft Failures PPY
Kaiser	0.118	0.547
California DOPPS	0.225	0.331
HOI	0.241	0.405
Florida DOPPS	0.209	0.580

Exhibit 7-6: Relative Risk (RR) of Failure for Fistulas and Grafts, Adjusted for Demographic and Co-morbid Factors and Number of Prior Permanent Accesses

Comparison	RR Fistula Failure (p-value)	RR Graft Failure (p-value)
KP v. CA DOPPS	0.38 (0.003)	0.93 (0.541)
HOI v. FL DOPPS	0.77 (0.308)	0.67 (0.013)

D. Discussion

The majority of patients in the Demo already had a permanent access in place when they enrolled. This result was not surprising, given that patients were required to have Medicare-primary insurance in order to be eligible for Demo enrollment. The majority of Demo patients had ESRD for three or more years, which explains why we observed only a minor increase in fistula use at follow-up. However, the slight increase observed for Kaiser after one year does seem to indicate that they were choosing to place fistulas (rather than grafts) when it became necessary to replace existing accesses.

While the Demo sites were perhaps less able to influence the choice of permanent vascular access for the Demo patients, the Demo plans were able to affect vascular access outcomes by the type and frequency of procedures they performed. Dramatic differences are apparent between the Demo sites and Medicare FFS in terms of the setting in which vascular access procedures were performed (outpatient versus inpatient). After adjustment for patient differences, patients from both Demo sites were less likely than their same-state comparisons to have many of these types of procedures performed in an inpatient setting.

Shifting the setting of care from inpatient to outpatient does not appear to have had any adverse effect on permanent vascular access survival among Demo patients. Patients enrolled in the KP Demo plan had superior fistula outcomes compared to the DOPPS sample, while graft survival was similar for both KP and California DOPPS patients. Conversely, fistula survival was similar for HOI and DOPPS patients, but HOI patients experienced better graft survival than patients enrolled in Florida DOPPS.

Because of the independent and sizeable impact of both vascular access-related services and inpatient hospital care on HD patient costs[41], it is likely that the practice of shifting care of vascular access to outpatient settings could have substantial effects on the costs ultimately incurred by HD patients treated under managed care. Under traditional FFS, the cost of vascular access is not borne by the dialysis unit or the patient's physician. Managed care organizations, however, have strong financial incentives for managing vascular access costs. These results provide some insight into how vascular access is treated under a managed care system.

CHAPTER VIII: MORTALITY EXPERIENCES OF DEMONSTRATION SITES

A. Introduction

Almost one quarter of hemodialysis patients in the U.S. die each year.[42] Research is continually being done to determine which factors are associated with this high mortality rate. The purpose of the CMS Managed Care Demonstration (Demo) was to evaluate insurance practices and their effects on patient care and several outcomes, including mortality, hospitalization, quality of life, vascular access, and cost. The analysis presented in this chapter compares the mortality experience of patients from the Demo to patients from a nationally representative sample from the Dialysis Outcomes and Practice Patterns Study (DOPPS), a largely fee-for-service sample.

B. Methods

1. Sampling and Data Collection

Managed Care Demonstration patients were selected from participating facilities in California and Florida. The California facilities in the Demo were part of the Kaiser Permanente (Kaiser) network, and the Florida facilities were part of the Health Options Incorporated (HOI) network. For the purpose of comparison to other representative patient samples, all comparative analyses presented within this chapter include hemodialysis (HD) patients from the Demo exclusively. The vast majority of Demonstration enrollees were HD patients (see Chapter 3: Patient Selection).

The Demonstration HD patients are compared to a nationally representative sample of U.S. in-center adult HD patients from the Dialysis Outcomes and Practice Patterns Study (DOPPS)[43] (see Methods Appendix for additional details). Because DOPPS patients are representative of the entire U.S. and thus include only a few dialysis facilities that are located within the Demonstration service areas, the selection of DOPPS patients was widened to include those residing anywhere within California or Florida. The DOPPS sample is largely fee-for-service (FFS) (see Methods Appendix) and is a good contrast to the Demonstration sample.

2. Statistical Methods

Differences in survival between the DOPPS and Demonstration patients were evaluated using right-censored Cox[44] models of time to death from start of ESRD. Right censoring refers to patients who depart the study without dying. These patients contribute time at risk for the period that they are in the study, and stop contributing to this time when they leave. They are not considered to have "died" when they leave the study – they just stop contributing to the model (i.e., they are "censored" when they leave the study). Models of the mortality experience from start of ESRD were considered to be more meaningful than models starting from the time of patient entry into the study.

Statistical adjustment for patient years of ESRD prior to their entry into the study was made using left truncation.[45,46] This technique allows for estimation of Cox regression coefficients accounting for delayed entry into the "risk set." Patients who die prior to their entry into the

study cannot be included in the study, so the patient years of ESRD occurring prior to their entry into the study cannot be considered time "at risk." Left truncation allows for description of the survival experience beginning at the start of ESRD, and under this method patients only contribute to the risk set during times when they are actually at risk. All analyses were performed using SAS software.[47]

Analyses in this chapter are based on the subset of Demonstration patients for whom we collected extensive clinical and demographic data (n = 1,289) so that demographic and co-morbid adjustments could be made. Additionally, however, one supplemental analysis was conducted to calculate crude death rates for all Demonstration patients (n = 2,730); detailed demographic and co-morbid data were not required for this analysis.

3. Outcome and Predictor Variables

The primary outcomes in this investigation were mortality rates for each Demo site compared to the representative same-state DOPPS samples.

Mortality is influenced by many aspects of patient mix and treatment. This analysis controls for many of these factors through the use of 20 summary co-morbidity measures in an attempt to isolate differences in mortality experience to those not directly attributable to differences in the demographic mix between these two groups of patients. Please refer to Exhibits 3-3 and 3-4 in Chapter 3 for the comprehensive list of the demographic and co-morbid adjustment variables used in these analyses. In addition, delivered dialysis dose was included using the double-pool variable volume Kt/V, from the Daugirdas formula.[48] Patients positively identified as having HIV were excluded from the analyses. Missing co-morbid conditions were accounted for through the use of dummy variables to indicate missing/non-missing status. This technique allows for unbiased estimates of parameters and p values while still allowing patients with some missing data to contribute to the overall model. Patients were excluded if their age, race, or gender was missing.

C. Results

1. Expected Mortality

As presented previously in Chapter 3, because of their "healthier" mix of demographic and co-morbid conditions, patients at both Demo sites were predicted to have lower mortality than the same-state DOPPS patients based on these risk factors. On average, Demo patients in FL were expected to have 25 percent lower mortality due to co-morbid differences alone, and 15 percent lower risk due to demographic factors (43 percent lower risk overall); in CA the composition was 16 percent lower risk for co-morbidity, and 13 percent for demographics, with 32 percent lower risk overall.

Exhibit 8-1: Expected Mortality Risk for Demo Patients v. Same-state DOPPS Comparison Patients

Risk Factor	Log RR KP v. CA DOPPS	Predicted Risk KP	Log RR HOI v. FL DOPPS	Predicted Risk HOI
Co-morbid (C)	-0.15	0.86 (16% lower)	-0.22	0.80 (25% lower)
Demographic (D)	-0.12	0.88 (13% lower)	-0.14	0.87 (15% lower)
Overall	-0.27	0.76 (32% lower)	-0.36	0.70 (43% lower)

2. Crude Death Rates

As expected, crude mortality rates were lower for Demo patients compared to DOPPS (Exhibit 8-2). Due to the varying follow-up times, the death rate, shown in the last column, has been calculated in terms of the number of deaths divided by the number of observed patient years. The DOPPS sample had a much greater crude death rate than the Demo, for all comparisons. Specifically, as shown in Exhibit 8-2, the crude death rate at Kaiser for all patients was 0.13 (as opposed to 0.26 in DOPPS, $p<0.0001$) and the rate at HOI was 0.17 (compared to 0.24 in DOPPS, $p<0.0001$). These death rates translate into mortality rate differences of 50% at Kaiser and 29% at HOI (compared to DOPPS).

Exhibit 8-2: Crude Death Rates Demonstration vs. DOPPS

	N	Patient-years	Deaths	Death Rate (deaths/patient-years)
California				
California-DOPPS	792	1,255	324	0.26
Kaiser – Total	686	1,328	178	0.13*
Kaiser – New	474	908	116	0.13
Kaiser – Rollover	212	420	62	0.15
Florida				
Florida-DOPPS	1,130	1,670	402	0.24
HOI	603	1,081	187	0.17*

* $p<0.0001$ compared to same-state DOPPS

Crude death rates for all Demonstration patients (as opposed to the calculation above, which includes only the subset of patients for whom we collected extensive demographic and co-morbid data) can be seen in Exhibit 8-3. Exhibit 8-3 depicts these death rates for each group of patients. Due to the varying follow-up times, the death rate, shown in the last column, has been

calculated in terms of the number of deaths divided by the number of observed patient years. The crude death rates for this sample ranges from 0.11 to 0.16.*

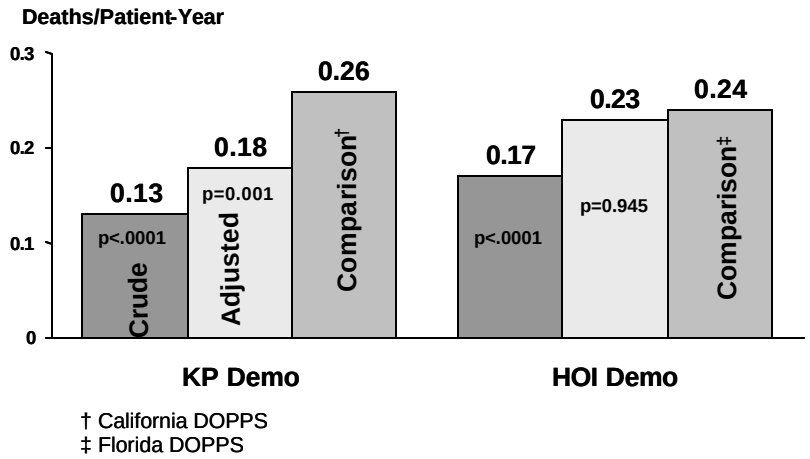
Exhibit 8-3: Crude Death Rates: All Demonstration Patients

	N	Patient-years	Deaths	Death Rate
California				
Kaiser – Total	1,739	2,607	293	0.11
Kaiser – New	1,045	1,547	178	0.12
Kaiser – Rollover	694	1,060	115	0.11
Florida				
HOI	991	1,539	251	0.16

3. Mortality Models

The Demonstration sample has a patient population with demographic and co-morbid characteristics that are commonly associated with reduced risk of mortality. For example, the Demonstration sample is about two years younger on average than the DOPPS sample and has lower incidence of most of the co-morbid factors examined. For more information on these differences, please see Chapter 3: Patient Selection. To account for the differences in case mix, Cox proportional hazards time-to-death models with adjustment for patient factors were employed (see Statistical Methods). Exhibit 8-4 shows the Demo crude mortality rates (from Exhibit 8-2), Demo adjusted mortality rates, and comparison population mortality rates for the patient groups of interest.

Exhibit 8-4: Crude and Adjusted Death Rates (Through May 2001) – Demonstration versus Comparison



* The lower crude death rates among the entire Demo population (ranging from 0.11 to 0.16) compared to the rates among the sample of patients with co-morbid and demographic data (ranging from 0.13 to 0.17) is most likely due to the late enrollment of newly diagnosed ESRD patients into Kaiser's Demo program. Toward the end of the Demo open enrollment period CMS made the decision to allow the practice of rolling over newly diagnosed patients. It would be expected for newly diagnosed patients to have lower crude death rates compared to most of the Demo patients who had had ESRD for at least 30 months.

After adjustment for the measurable case mix differences, mortality rates among patients at HOI were similar to DOPPS patients in Florida. However, patients at Kaiser continued to exhibit a statistically significantly lower mortality rate after adjustment for demographic and co-morbid factors.

D. Discussion

A key evaluation question of CMS's Managed Care Demonstration concerns the survival of patients under the managed care system. Does enrollment in managed care, as compared to receiving health services provided through traditional (i.e., FFS) mechanisms, impact the survival of ESRD patients?

Our analyses indicate that both HOI and Kaiser had favorable mortality experiences. The Demonstration sites experienced 0.13 deaths (Kaiser) and 0.17 deaths (HOI) per patient-year compared to the same-state DOPPS comparison groups, which experienced 0.26 deaths (CA) and 0.24 deaths (FL). However, a large portion of this difference in death rates can be explained by differences in demographic and co-morbid factors between the Demonstration, with younger and healthier patients, and the comparison patients. After adjustment for these factors, deaths per patient-year narrowed between the two sets of patients to 0.18 deaths for Kaiser (versus 0.26 for California DOPPS, p=0.0008) and 0.23 deaths for HOI (compared to the Florida DOPPS reference of 0.24 deaths per patient-year). These adjusted mortality estimates for HOI were not statistically different than Florida DOPPS; however, the Kaiser mortality risk remained statistically significantly lower than the mortality risk for the California DOPPS patients, and demonstrates a reduction in mortality of 31 percent.

From these mortality analyses it is clear that the Demonstration patients' survival is the same as, if not longer than, the representative DOPPS sample. While a large portion of this difference can be explained by the fact that Demonstration patients are younger and healthier, when controlling for these differences, the mortality rates for the Demonstration sites, particularly Kaiser, are favorable. There is still some remaining improvement in survival for Demonstration patients at Kaiser that is not explained by the differences in the patient mix.

CHAPTER IX: PATIENT SATISFACTION

A. Introduction

It has been postulated that a managed care (MC) health plan can provide better and more comprehensive health care at a lower cost.[49] However, it has also been stated that the main disadvantage of MC plans can be the restrictive nature of their healthcare management approaches.[50] For instance, patients are confined to a specific group of healthcare providers. This has often caused great dissatisfaction among patients who desire or need greater flexibility in their healthcare plan. An important aspect of the evaluation was to assess patient satisfaction with the benefits and services provided by a MC health plan.

This chapter focuses on patient satisfaction with services provided by their dialysis facility, dialysis staff, and primary care physicians under the Demo health plan. It also examines patient satisfaction with the benefits provided by the Demo plans and the reasons why patients chose to enroll or not enroll into the Demo.

B. Methods

1. Sampling and Data Collection

Baseline data were collected on 1,479 Demo patients and follow-up data were collected on 750 Demo patients one year after enrollment into the Demo. Data on two different comparison groups were collected in a similar fashion and in the same geographic areas as the Demo. The first comparison group consisted of 190 fee-for-service (FFS) patients and the second group was a sample of 190 MC patients not enrolled in the Demo (non-Demo Managed Care or NDMC). Both of these samples were matched to the Demo patients on age, race, and time since onset of ESRD. For more information on methods please see the Methods Appendix of this report

A Patient Questionnaire (PQ) was used to assess patient satisfaction and quality of life (see Chapter 10 for Quality of Life results). The PQ was administered in-person by trained data collectors to Demo patients usually while they were at the dialysis facility. PQ data were collected at baseline and one year after enrollment into the Demo. The response rates for the PQ were 85% for the Demo patients at baseline, 84% for the Demo patients after one year in the Demo, and 98% for the comparison groups (see the Methods Appendix for details).

2. Statistical Analysis

All analyses were restricted to hemodialysis patients in the Demo and both comparison groups. Chi-square statistics were used to test differences in proportions between (1) the Demo group at baseline versus one year follow-up and (2) the Demo group at follow-up vs. the FFS and NDMC groups. The Demo follow-up group was used in comparisons with the FFS and NDMC groups because the Demo patients would have a more accurate perception of their satisfaction with the Demo after one year rather than at baseline. Statistical significance was interpreted at the 0.05 level for a two-tailed test. All statistical estimation was performed using SAS version 8.0.[51]

3. Satisfaction Measures

Patient satisfaction measures from the PQ were grouped into three major categories:

1. Satisfaction with healthcare providers and services including:
   - dialysis staff
   - medical team (e.g., primary physician, social worker, dietitian, and transplant medical team)
   - dialysis facility
   - hospitals

2. Satisfaction with health plan benefits including:
   - Co-payment/cost requirements
   - Medication costs
   - Access to nutritional supplements

3. Reasons for joining the Demo health plan including:
   - Cost of outpatient drugs
   - Cost of co-payments
   - Recommendation of doctor

C. Results

1. Satisfaction with Healthcare Providers and Services

The Demo patients reported a high level of satisfaction with their dialysis staff in terms of friendliness and interest of dialysis staff, staff encouragement, and support. For both HOI and KP patients, there were no significant differences between patient satisfaction with dialysis staff at baseline and after one year in the Demo program.

Although the Demo and comparison patients all reported a high overall satisfaction with their dialysis staff, Exhibit 9-1 shows that a higher percentage of FFS patients (80.6%) vs. Demo patients (71.3%) reported that their dialysis staff encouraged them to be independent ($p<0.05$). Furthermore, a higher percentage of FFS and NDMC patients (89.0%, $p<0.05$ and 88.2%, $p<0.05$, respectively) were satisfied compared to the Demo patients (81.6%) in terms of staff support in coping with kidney disease.

While the differences between the Demo and comparison groups were significant for these two questions, it should be noted that there were also significant differences in terms of patients who reported "Don't know." In other words, more comparison patients may have reported satisfaction with staff encouragement and support, but that does not mean that more Demo patients reported *dissatisfaction* with these aspects of their healthcare; rather, more Demo patients reported that they did not have an opinion about these questions.

Exhibit 9-1: Patient Satisfaction with Dialysis Staff (Demo Follow-up vs. Comparison)

Patient Satisfaction Measure	Demo (Follow-up)	Matched FFS	Matched NDMC
Question 1:14 Friendliness and Interest of Dialysis Staff (%)			
Excellent	36.9	33.1	25.7*
Good	60.9	65.7	73.3*
Poor	2.2	1.1	1.0
Question 1:15a Staff Encourages Me to be Independent (%)			
True	71.3	80.6*	72.2
False	13.6	11.4	10.2
Don't know	15.1	8.0*	17.6
Question 1:15b Staff Supports Me in Coping with my Kidney Disease (%)			
True	81.6	89.0*	88.2*
False	8.6	8.7	7.5
Don't know	9.8	2.3*	4.3*

*p<0.05 vs. Demo

Overall, Demo patients at baseline and follow-up, as well as comparison patients, reported high satisfaction with care and services provided by their medical care team and dialysis facility. There were few significant differences in the Demo group from baseline to follow-up, which is to be expected since very few Demo patients switched to a new dialysis facility after enrolling in the Demo.

However, Exhibit 9-2 shows that FFS patients reported higher satisfaction compared to the Demo patients in terms of ease in obtaining appointments with a primary doctor ($p<0.01$), ease in obtaining referral to a specialist ($p<0.05$), and availability of a social worker or a dietitian ($p<0.05$). FFS patients also reported significantly higher satisfaction with their ability to get to and from their dialysis facility ($p<0.05$). On the other hand, FFS patients reported lower satisfaction with medical care when hospitalized ($p<0.05$).

Exhibit 9-2: Patient Satisfaction with Medical Team, Dialysis Facility, and Hospitals (Demo Follow-up vs. Comparison Groups)

Patient Satisfaction Measure§	Demo (Follow-up)	Matched FFS	Matched NDMC
Patient Satisfaction with Medical Team (% Agree)			
Medical care provided by primary doctor is excellent	86.8	91.0	81.3
Satisfied with the effort of my health care team in determining whether I could have a transplant	75.8	82.0	82.6
Overall care from my transplant medical team is excellent quality	78.3	71.6	68.1
Easy to obtain appointments with primary doctor	83.2	92.8†	80.6
Easy to obtain referral to a specialist	88.0	93.9*	84.8
Do not have to wait long to see my doctor for a scheduled appt.	84.3	80.2	74.9†
Social worker is usually available to see me when needed	89.4	94.8*	88.8
Dietitian is usually available to see me when needed	90.8	96.0*	92.6
Patient Satisfaction with Dialysis Facility (% Agree)			
Easy to get to and from dialysis at this facility	90.9	96.6*	89.6
Care I receive during dialysis is excellent	91.0	90.4	90.1
Usually able to obtain dialysis schedule I desire	91.3	94.3	94.5
Facility provides comfortable atmosphere and useful amenities	92.8	92.5	94.1
Patient Satisfaction with Hospitals (% Agree)			
Medical care when hospitalized is high quality	85.3	77.7*	81.7
Hospital choices are satisfactory	86.0	80.7	84.5

§ A higher number in the results columns indicates greater satisfaction
* $p<0.05$; † $p<0.01$ vs. Demo

There were few differences between the Demo and NDMC groups, with the exception of satisfaction with waiting time to see a doctor for a scheduled appointment. NDMC patients reported less satisfaction ($p<0.01$) with this measure compared to the Demo patients.

2. Satisfaction with Health Plan Benefits

There were significant differences between the Demo patients at baseline and follow-up and between the Demo and comparison groups in terms of three major benefits provided by the Demo plan: no co-payments, free medications, and free nutritional supplements. Within the Demo group, significantly fewer HOI and KP patients reported financial burdens at a year follow-up ($p<0.0001$) compared to baseline. At the one-year follow-up, HOI patients also reported greater ease ($p<0.01$) in obtaining nutritional supplements under the Demo health plan, which is in contrast to the KP patients who reported no difference.

A significantly smaller percentage of Demo patients reported financial burdens for co-payments and medications as compared to the FFS and NDMC patients ($p<0.0001$), while a significantly larger percentage of Demo patients reported ease in obtaining nutritional supplements ($p<0.0001$).

Exhibit 9-3: Satisfaction with Health Plan Benefits (% Patients Agree)

Measure of Satisfaction	HOI		KP			
	Baseline	Follow-up	New Baseline	New Follow-up	RO Baseline	RO Follow-up
Co-payment/patient costs for my medical care is especially burdensome§	31.0	14.4‡	27.6	6.7‡	22.9	3.3†
Cost to my family for medications is a large burden§	20.5	14.9	26.8	6.8‡	22.1	3.3†
Ability to obtain nutritional supplements easy and beneficial under this health plan^	69.0	84.4*	81.2	88.1	82.9	90.7

Measure of Satisfaction	Demo (Follow-up)	Matched FFS	Matched NDMC
Co-payment/patient costs for my medical care is especially burdensome§	9.6	52.7 ‡	34.5‡
Cost to my family for medications is a large burden§	9.9	52.4 ‡	35.6‡
Ability to obtain nutritional supplements easy and beneficial under this health plan^	87.2	67.7 ‡	67.8 ‡

§ A lower number indicated greater satisfaction.
^ A higher number indicates greater satisfaction.
* p<0.01 †p<0.001 ‡p<0.0001 vs. Demo

3. Reasons for Joining or Staying in the Demonstration

KP patients reported that the top two reasons for enrolling in the Demo MC plan and/or staying in the new plan after a year were the coverage of outpatient drugs and co-payments (see Exhibit 9-4). However, HOI patients reported that the top two reasons were coverage of outpatient drugs and recommendation of their doctor. Coverage of co-payments was still a major reason but seemed to be less of a factor than the recommendation of their doctor. The major "Other" reason reported by both HOI and KP patients for enrolling in the Demo was lack of other healthcare coverage.

Exhibit 9-4: Reasons for Changing to or Staying in Demo Health Plan (% Demo Patients at Baseline and Follow-up)

Reason for changing to or staying in Demo Plan	HOI		KP			
	Baseline	Follow-up	New Baseline	New Follow-up	RO Baseline	RO Follow-up
Cost of Outpatient Drugs	26.4	30.4	29.4	32.6	33.2	35.9
Cost of Co-payments	21.0	20.3	31.2	29.1	31.5	26.9
Recommendation of Doctor	23.7	25.3	7.0	5.8	6.4	2.1
Other	10.4	11.6	12.6	13.4	20.2	22.6

D. Discussion

1. Satisfaction with Healthcare Providers and Services

Patient satisfaction with their dialysis staff, medical team, and dialysis facility appeared to be very high among the Demo and comparison groups. The Demo patients reported few differences in satisfaction with their healthcare providers and their dialysis facility after one year of enrollment in the Demo. This is not surprising, as many of the Demo patients did not change dialysis facilities after enrolling in the Demo. Therefore, we did not expect any significant differences in satisfaction toward the healthcare team and/or dialysis facility from the Demo patients at the one-year follow-up.

In contrast, there were some very large and statistically significant differences in patient satisfaction with healthcare providers and services between the Demo and comparison groups, especially the FFS group. The matched FFS and NDMC patients reported significantly higher satisfaction with their dialysis staff compared to the Demo patients. It is uncertain why these comparison groups would report higher satisfaction with their dialysis staff, since they were recruited from mostly the same facilities as the Demo patients. It is unlikely that the dialysis staff would treat Demo patients differently from FFS or NDMC patients within the same facility. However, there was evidence of hostility towards KP in the Southern California area, which may have influenced staff attitudes and treatment toward patients enrolled in the KP Demo health plan.

Another significant difference was that, compared to Demo patients, FFS patients reported higher satisfaction with the ease in obtaining appointments with their primary care doctor and obtaining referrals to a specialist. This supports the commonly reported disadvantage of a MC health plan, namely, difficulty in gaining access to a primary care doctor and/or specialist.[52] In addition to higher satisfaction with access to their physicians, FFS patients also reported higher satisfaction with the availability of a social worker and dietitian. A possible explanation for this observation is that under a MC plan there may be the perception of restricted access (through referral requirements). FFS patients also reported greater satisfaction with the ability to get to and from their dialysis facility.

Although FFS patients reported higher satisfaction with their health care providers, they appeared to be less satisfied with their medical care when hospitalized compared to Demo patients. It is unclear why these differences would be observed, but it may be a reflection of more comprehensive hospitalization coverage under a MC health plan.

2. Satisfaction with Health Plan Benefits and Reasons for Joining/Staying in the Demo

We found significant differences in patient satisfaction with the financial incentives provided by the Demo plan. After one year of coverage, significantly fewer Demo patients reported financial burdens due to the benefit of free medications and no co-payments. These financial incentives were also the most important reasons listed by the Demo patients for enrolling and/or staying in the Demo plan.

When asked why they did not enroll in the Demo plan, 89.5% of the FFS and 88.4% of the NDMC patients reported that they were not offered the opportunity to join the Demo. This is surprising, since the comparison patients were selected from primarily the same facilities as the Demo patients and, therefore, would also have been informed about the Demo by the dialysis staff and/or received recruitment materials mailed from CMS. It is possible that they simply forgot they were offered the opportunity to enroll in the Demo due to a lag between the time the patients received recruitment materials and the time they were randomly selected for the comparison groups. However, there is some evidence that not all ESRD patients in the Demo regions received CMS mailings (see Chapter II: Market Penetration, Discussion).

Surprisingly, neither the HOI nor KP patients reported higher satisfaction with preventive care and wellness under the Demo plan. This is often one of the most frequently cited benefits of a MC health plan, but this does not appear to have been an important factor for the two Demo sites. A variety of explanations are possible. Patients may not have perceived a greater emphasis on preventive care. Alternatively, the patients may have valued this benefit less than the significant financial incentives of participating in the Demo. Another possibility is that patients considered coverage of preventive services to be a financial benefit (i.e., they received preventive services prior to the Demo but had to pay out-of-pocket for them).

CHAPTER X: QUALITY OF LIFE

A. Introduction and Background

Improving and maintaining patient Quality of Life (QoL) have become important treatment goals in End-Stage Renal Disease (ESRD).[53] Patient QoL, as measured by the SF-36®, has been shown to predict morbidity, hospitalization, and mortality in dialysis patients.[54] This investigation was concerned with evaluating patient QoL in the Managed Care (MC) Demonstration (Demo), by comparing Demo QoL (SF-36®) results to other representative comparison samples of Medicare fee-for-service (FFS) and Medicare managed care patients not enrolled in the Demo (non-Demo managed care or NDMC).

The SF-36® is a comprehensive short-form with only 36 questions. It yields an 8-scale health profile as well as summary measures of health-related quality of life. As documented in more than 2,000 publications, the SF-36® has proven useful in monitoring general and specific populations, comparing the burden of different diseases, differentiating the health benefits produced by different treatments, and in screening individual patients.[55] The two Summary Measures of the SF-36® are Physical Health and Mental Health. Each of these comprises four related scales: physical functioning, role-physical, bodily pain, and general health in the Physical Health Summary and vitality, social functioning, role-emotional, and mental health in the Mental Health Summary. This paper presents results for each subscale as well as the two summary measures.

B. Methods

1. Sampling and Data Collection

Three separate comparison samples were used for the quality of life analysis; the first was a nationally representative sample of hemodialysis (HD) patients in the US, taken from the Dialysis Outcomes and Practices Patterns Study (DOPPS).[56] Additionally, we compared the Demo patients to two samples selected from the Demo service areas who were matched to the MC demo patients by age, race, and time with ESRD. For more information concerning these samples, see the Methods Appendix of this report.

As part of the evaluation data collection, experienced local nephrology personnel who were not part of the patient's dialysis or transplant unit staff abstracted baseline medical record data and conducted in-person patient interviews on QoL. The patient questionnaire (PQ) used to collect this information contained the SF-36®. The baseline medical profiles and QoL data were collected in a similar fashion for the matched FFS and NDMC comparison patients.

For the DOPPS comparison sample, QoL data were taken from patient questionnaires collected for all DOPPS patients. These forms were similar to the Demo PQ and included the SF-36®. Data were obtained from approximately 60 percent of the eligible patients. The questionnaire was generally self-administered; therefore, healthier patients were more likely to complete the questionnaire, possibly introducing a bias toward healthier respondents for the DOPPS. However, a study of non-response showed no bias.[57] There was approximately an 85 percent response rate of surveyed patients from the Demo and the two matched comparison samples.

2. Outcome and Predictor Variables

Quality of life was scored using the SF-36® Health Survey according to Ware et al.[58] Unless otherwise noted, demographic and co-morbid factors were included in adjusted estimations. Please refer to Chapter 3 for a comprehensive list of adjustment factors.

3. Statistical Analysis

All analyses were restricted to HD patients in the MC Demo and comparison groups. *T* statistics were used to test differences in means for baseline QoL scores. Statistical significance was interpreted at the 0.05 level for a two-tailed test. All statistical estimation was performed using SAS version 8.0.[59]

Multiple linear regression analysis was used to detect differences in the adjusted QoL scores between the MC Demo and the DOPPS sample. These QoL models were adjusted for patient age and the co-morbid conditions listed in Chapter 3.

C. Results

1. Baseline Comparisons

a. DOPPS Comparison to Demo

As discussed in Chapter 3: Patient Selection, the MC Demo patients comprise a healthier group than most dialysis patients. Compared with a nationally representative sample (DOPPS), Demo patients have fewer co-morbidities, better mobility, and higher albumin on average. This better health is also reflected in their baseline QoL. Crude baseline Physical Component Summary (PCS) and Mental Component Summary (MCS) scores show the two Demo sites having significantly higher scores than the state-specific DOPPS comparisons (Exhibit 10-1).

After taking into account the variation due to differences in health factors between the Demo and DOPPS, the statistically significant differences at baseline disappear. Exhibit 10-1 shows the baseline scores after adjustments were made.

Exhibit 10-1: Baseline QoL Summary Scores, Demo vs. DOPPS

Sample	Sample Size (n)	PCS		MCS	
		Crude	Adjusted	Crude	Adjusted
KP Demo	523	34.9†	33.3	47.4†	46.7
CA-DOPPS	377	32.7	32.5	45.6	45.5
HOI Demo	386	35.3†	33.4	48.9†	47.4
FL-DOPPS	539	32.9	32.4	46.6	46.2

† Significantly different than same state DOPPS at $p < 0.055$

b. Matched FFS and NDMC Comparisons to Demo

The Demo patients reported similar QoL to the matched NDMC and FFS patients. As shown in Exhibit 10-2, the samples had generally similar unadjusted PCS and MCS scores at baseline.* No differences were seen in the mental QoL score for either comparison group, but the NDMC sample showed higher PCS scores.

Exhibit 10-2: Baseline QoL Scores: Demo vs. NDMC and FFS

Sample	Sample Size (n)	PCS	MCS
Demo	1,068	35.1	48.1
Matched NDMC Comparison	188	37.0†	48.1
Matched FFS Comparison	177	35.9	47.8

† Significantly different than the MC Demo at $p < 0.05$

2. Pre-Managed Care vs. Managed Care

One year following their enrollment in the Demo, patients were asked to report their QoL a second time. Exhibit 10-3 shows that QoL scores either stayed the same or increased for Demo patients. In particular, the mental health scores showed statistically significant increases. Although results are shown for both sites combined, the effect of improved mental scores was seen in both Demo populations independently.

Exhibit 10-3: QoL Pre-Demo and Demo

QoL measure	Baseline Mean	One Year Follow-up Mean	QoL	p-value from paired t-test
Physical Functioning	49.9	49.4	-0.5	0.7059
Role Physical	39.7	43.0	+3.3	0.1283
Bodily Pain	66.3	69.5	+3.2	*0.0390*
General Health	48.3	48.3	+0.0	0.9954
PCS	**36.6**	**36.4**	***-0.2***	**0.6126**
Mental Health	71.2	74.7	+3.5	*0.0004*
Role Emotional	60.0	68.2	+8.2	*0.0004*
Social Functioning	67.2	67.8	+0.6	0.6592
Vitality	46.5	47.4	+0.9	0.3912
MCS	**48.3**	**50.2**	***+1.9***	***0.0006***

In contrast to the Demo QoL scores increasing, Exhibit 10-4 illustrates that one-year changes in QoL for the nationally representative DOPPS sample showed some small, but statistically significant decreases.

* Because the samples were matched on age, race, and time with ESRD (variables on which adjustments would normally be made), unadjusted analyses are appropriate.

Exhibit 10-4: QoL DOPPS One-year Follow-up

QoL measure	Baseline Mean	One Year Follow-up Mean	QoL	p-value from paired t-test
Physical Functioning	42.8	41.0	***-1.8***	*0.0039*
Role Physical	33.3	32.4	-0.9	0.3894
Bodily Pain	60.5	58.9	***-1.6***	*0.0191*
General Health	41.9	41.0	-0.9	0.0503
PCS	**33.5**	**32.9**	*-0.6*	***0.0144***
Mental Health	69.8	69.2	-0.6	0.2037
Role Emotional	55.9	54.7	-1.2	0.3183
Social Functioning	64.9	62.9	***-2.0***	*0.0041*
Vitality	44.9	43.5	***-1.4***	*0.0059*
MCS	**48.1**	**47.7**	**-0.4**	**0.1215**

D. Discussion

Results from these QoL analyses address a key evaluation question of the Demo, namely: does enrollment in managed care as compared to receiving health services provided through traditional (i.e., FFS) mechanisms impact the quality of life experienced by ESRD patients? Quality of life measures are being increasingly recognized as important indicators of health.

The results presented here seek to explore several facets of QoL-related issues. First, these analyses assess whether or not baseline differences exist among those ESRD patients choosing to enroll in the Demo as compared to a nationally representative sample of patients. While the issue of patient self-selection into MC is discussed extensively in Chapter 3, the QoL analyses provide a new angle from which to examine this phenomenon.

Second, baseline QoL was compared between MC patients and the FFS and NDMC samples, which were matched on age, race, and time on ESRD. Assessment of baseline QoL differences between the Demo patients and these comparisons can indicate differences in QoL not due to characteristics matched upon. Finally, our results explore changes in QoL over time.

1. Quality of Life at Baseline

Results of the analyses comparing baseline QoL of HD Demo patients to that of DOPPS, a nationally representative sample, provide evidence that Demo patients in both California and Florida are "healthier" than a cross-section of all HD patients. At baseline, Demo patients have higher Physical Component Summary (PCS) and Mental Component Summary (MCS) QoL scores. Adjusted results indicate, however, that demographic and co-morbid factors (including age, sex, race, coronary artery disease, peripheral vascular disease, hypertension, among others) explain all of the difference in baseline QoL scores.

Baseline QoL comparisons were also conducted to compare PCS and MCS scores of Demo patients with the matched FFS and NDMC samples. With the exception of the PCS score among

the NDMC sample, there were no differences in QoL scores between Demo patients and the two matched comparison samples.

The higher PCS score among NDMC patients is important because it may indicate that patients who have been in managed care for some period of time (NDMC patients) may be healthier and have better physical quality of life than patients who self-select themselves into managed care at baseline. Further work would be necessary to determine whether the care received in managed care is responsible for these differences, or whether other self-selection factors are at play (i.e., even lower prevalence of co-morbid conditions). It is likely that the same type of self-selection would occur should all ESRD patients be given the opportunity to enroll in managed care plans, and public policy will need to carefully consider the financial and social implications of this phenomenon.

2. Changes in Quality of Life over Time

Longitudinal analyses that assess changes in quality of life and other health indicators over time are especially crucial for evaluating the success of managed care models for caring for ESRD patients. Presented in this chapter are results showing changes in QoL scores among Demo patients between baseline and at one year follow-up. Nearly every subscale component score of the PCS and MCS either improved or stayed approximately the same after one year (for three of these subscales – bodily pain, mental health, and role emotional – the improvement is statistically significant). The overall MCS also showed a statistically significant increase. These results are striking because ESRD patients, due to the chronic nature of their illness, typically exhibit deteriorating quality of life over time. Indeed, when we examined a sample of DOPPS patients over a one-year period of time, we observed a decrease in score among all of the subscale components as well as the two summary scores. Five of the scores (physical functioning, bodily pain, PCS, social functioning, and vitality) showed statistically significant declines. As quality of life indicators have been shown to predict morbidity, hospitalization, and mortality in dialysis patients, this is a result worthy of careful consideration. The strong quality of life results among Demo patients may indicate value inherent in managed care approaches to patient care and management for ESRD patients.

CHAPTER XI: DEMONSTRATION COST

A. Introduction

The Demonstration (Demo) evaluation cost analyses were designed to address a number of separate but related questions, which can be broadly summarized as follows:

Question 1: What were CMS's costs for the Demonstration enrollees compared to what they would have been without the Demo?

A statistical model was developed to assess how much CMS would have spent for Medicare services for Demonstration patients had they remained in FFS. We additionally examined the impact of Medicaid spending that resulted from the enrollment of dually-eligible ESRD patients in the Demonstration.

Question 2: Did the cost and value of the extra benefits received by Demonstration enrollees equal the five percent extra revenue the Demonstration sites received in the capitation rates?

CMS's payment to the Demonstration sites was based on 100% of fee-for-service costs for Demonstration-eligible enrollees, compared to the standard 95% of fee-for-service costs paid to regular Medicare risk contractors. In return for this higher payment level, Demonstration sites were expected to provide "extra benefits" equal to the 5% extra payment. Because virtually all Medicare risk contractors (including Kaiser and HOI) provide some additional, non-Medicare-covered benefits to their regular risk enrollees within the 95% payment level, CMS defined "extra benefits" for purposes of the Demo as benefits over and above what the sites offered to their regular Medicare risk enrollees. CMS further instructed that the extra benefits must consist of medical services and/or supplies; non-medical enrollee services generally included in an MCO's administrative expenses, such as case management services, were not to be counted toward the 5% extra benefits.

Question 3: Was the Demo financially viable from the Demonstration sites' perspective, i.e., what was actual Demonstration spending by the sites compared to capitation revenue overall, and within the risk-adjusted rate cells?

A key component of the Demonstration was the revised payment methodology, which was intended to improve upon the single capitation rate structure historically in place for HMOs serving enrollees who develop ESRD and remain enrolled. One way to test the soundness of the payment rate refinements and the effectiveness of the risk adjustments they embody is to assess how well the overall payments to the Demonstration sites, and the payments within each rate cell, reflected the sites' expenditures.

Question 4: What was the financial impact of the Demonstration from the patients' perspective?

The financial benefits to patients resulting from the Demonstration plans' coverage of Medicare co-insurance and deductibles and of outpatient drugs were the top two reasons patients

reported for enrolling in the Demonstration. As part of our financial analysis of the Demonstration, we estimated the savings that accrued to patients as the result of such coverage.

B. Methods

1. Medicare Spending Impacts

a. Background

The issue of how much is spent by Medicare for ESRD patients treated under Managed Care (MC) versus fee-for-service (FFS) is complex and somewhat difficult to address. Different services are provided under each type of medical coverage, with MC in some cases providing services not covered under traditional Medicare FFS (e.g., outpatient prescription drugs). One approach for estimating costs under the MC Demo was for the Demo sites to submit zero-charge Medicare FFS bills in order to simulate FFS billing practices. It was the intention that this would generate a data set of Medicare-reimbursable services for the Demo patients, to which we would attach Medicare-approved reimbursement dollars. The idea was that these "costs" would be directly comparable to the Medicare claims already captured in the CMS data system for FFS, and would therefore provide an estimate of what CMS would have paid if these patients had remained under FFS.

At the time of the initial proposal, we had expressed concerns about the comparability of these no-pay claims data to the FFS claims, given the uncertainty about whether no-pay claims would pass through the established data edits and the effect of the lack of incentives for the Demo sites to resubmit rejected claims. In addition, we were concerned that this approach to estimating what costs would have been under FFS would not capture potential differences in utilization of services between FFS systems and MC. That is, this approach would simply apply FFS *unit cost* assumptions to the services provided under MC. Total cost, however, is a function of both unit cost and usage. Thus, this approach would provide a reasonable estimate of what CMS would have paid for these patients under FFS only if MC had no impact on the utilization of services. Since managed care systems rely largely on utilization management techniques (such as case management, coverage of preventive services, and substitution of lower cost services for expensive hospitalization where possible) to deliver cost-effective care, the use of no-pay claims as the primary method of comparing MC costs to FFS costs was recognized to have inherent drawbacks.

When it became evident that the Demo sites were probably unable to submit these claims prior to the end of the Demo, an alternative proposal was submitted to CMS by the evaluators for assembling and analyzing cost data. Further methods for analyzing cost were developed as part of this alternative proposal, including the development of a statistical model not reliant upon the use of no-pay claims data. This model was employed to answer the question of how much CMS would have paid for Demo patient care had these beneficiaries remained in FFS. Comparisons of these cost estimates to actual Demo spending (both by CMS in the form of capitation payments made to the Demo sites and actual expenditures made by the Demo health plans) as well as previous Medicare spending for Demo patients prior to enrollment served as the primary basis for our analysis of Demo costs.

b. Pre-Demo Spending for Enrolled Patients

Pre-Demo spending rates for Demo enrollees were calculated using paid claims generated by these patients while covered under Medicare FFS. For Demo patients who had Medicare primary insurance prior to enrolling, up to one year of prior claims were summarized for calculating average cost rates during this period. Only claims through December 31, 1998 were available for this analysis, limiting our claims search to those patients who enrolled prior to December 1999. This resulted in patients having up to, but no more than, one year of data, with a possible gap (due to the cutoff being the end of 1998) of up to 11 months. It should also be noted that Kaiser rollover patients, having been in the Kaiser MC plan prior to enrollment, would not have generated FFS claims prior to the Demo and were thus excluded from any pre-Demo cost calculations. All patients on either hemodialysis (HD) or peritoneal dialysis (PD) that were enrolled in the Demo and met these criteria were included. For HOI, 461 patients were identified and for KP, 401 patients were included in this sample (total patient years are given in Exhibit 11-1, row 1). Patients were identified as being on dialysis and Medicare primary-insured using CMS's Enrollment Data Base (EDB) insurance status information, in conjunction with established minimum cut-points for monthly spending on dialysis.

c. Cost Comparison Sample

For the purpose of achieving comparison spending data for the Demo patients, total costs and costs by spending category for Medicare FFS patients in California and Florida were aggregated and averaged from 1998-1999 claims data. ESRD patients who were identified as receiving dialysis on January 1, 1998 and covered by Medicare primary insurance were included (see Methods Appendix). Patient time at risk was censored at the earlier of December 31, 1999 or date of death. For this model, censoring was not done for changes in dialysis, however, patients identified as not having FFS Medicare primary insurance coverage at any time during the 1998 calendar year were excluded.

d. Demo Patient Predicted Cost Models

To address the question of what the Demo patients would have cost Medicare had they remained in FFS, separate regression models for estimating spending in California and Florida were developed using 1998-99 Medicare FFS claims data from these two states. Medicare FFS spending was modeled (as the natural log of cost), varying according to age, sex, race, ethnicity, time with ESRD, modality (HD or PD), body mass index, follow-up time (in months), death, and the 20 co-morbidities listed on the CMS 2728 form. Using the parameter estimates resulting from these linear regression models, the Medicare total predicted FFS cost for each Demo patient was calculated by multiplying the individual patient values for each risk factor times the parameter estimates affecting cost. These predicted costs were standardized (per patient year at risk) by assigning each patient who survived through the year a total of 12 months of follow-up. Patients known to have died during the first year were given 6 months of follow-up (i.e., weighted to have one-half the contribution to cost per year) under the assumption that deaths were evenly distributed throughout the year. The average predicted total cost was calculated by exponentiating predicted log cost and taking the mean for all Demo patients.

The predictive value of each of the models was validated separately by comparing actual FFS costs per patient year in CA and FL to the model-predicted costs for the average dialysis patient

in each state. The confidence limits on these estimates were also calculated from the cost models in order to assess the degree of similarity between FFS actual and model-predicted costs in CA and FL.

2. Medicaid Spending Impacts

CMS's Waiver Cost Estimate for the ESRD Managed Care Demonstration included an analysis of Medicaid cost impacts in its discussion of Demonstration costs / savings. CMS's estimate of the amount typically paid by Medicaid for the dually-eligible ESRD patient was calculated by: (a) determining the 20% co-pay associated with the national Part B AAPCC for ESRD; (b) estimating the percentage of ESRD patients who accrue a Part A deductible during a year; and (c) translating the results into an actuarial equivalent value (i.e., per patient per month or per year amount). CMS then applied the yearly amount to an assumed number of person-years of enrollment of dually-entitled persons in the Demo. The assumption was that the distribution of Medicaid coverage among demonstration enrollees would be the same as among the catchment area population.

Our methodology for estimating Medicaid payments for Medicare cost-share responsibilities used two approaches. First, we applied the same methodology as described above, except that we were able to estimate more accurately the actual number of person-years of enrollment of dually-entitled persons in each Demonstration site. In addition, we estimated the 20% co-pay associated with Part B services using the California-specific and Florida-specific statewide Part B ESRD payment rates. Using this methodology, we estimated that Medicaid incurs, on behalf of dual eligibles, approximately $758 per eligible per month in Medicare cost-sharing expenses.* (It is important to note that states have some flexibility in complying with the requirement to pay Medicare cost-sharing for dual eligibles, i.e., they have the option to base their payments on the full Medicare-approved amount or on the amount the state pays for the same service on behalf of a Medicaid recipient not entitled to Medicare. Our estimates assume Medicaid payment of Medicare cost-sharing based on the full Medicare-approved amounts, and thus represent the *upper limit* of Medicaid spending for Medicare cost sharing and, in turn, Medicaid savings under the Demonstration.)

Additionally, we considered the estimate CMS's Office of the Actuary provided regarding average cost-share responsibilities for ESRD patients in traditional Medicare. We assume that the Office of the Actuary's estimate of $500 per month would be somewhat lower for the healthier Demonstration enrollees, perhaps 10-15% lower. Thus, we estimate that Medicaid incurs between $425 and $750 per dual eligible per month in Medicare cost-share expenses.

We also included pharmacy costs in our assessment of Medicaid savings. For dual eligibles for whom the full package of Medicaid services is offered†, Medicaid also typically incurs expenses for certain non-Medicare-covered services, most notably prescription drugs. Based on the

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* Calculated as follows:
The year 2000 Part B statewide ESRD payment rate was $2,897 and $2,816 per month ($34,767 and $33,792 per year) in California and Florida, respectively. The associated 20% co-pays were $8,692 and $8,448 per year. In addition, assuming that about two-thirds of ESRD patients are hospitalized at least once during a year, incurring a Part A deductible of about $800, the average ESRD patient in these states will accrue about $9,100 per year in deductibles and co-pays (about $758 per month).

† According to a Kaiser Family Foundation report, in 1995 88% of dual eligibles received full Medicaid benefits.

average retail price per prescription ($45, according to a recent study by the National Institute for Health Care Management), the average number of prescriptions per year for Demonstration patients (eight), and assumptions regarding Medicaid pharmacy discounts and rebates, we estimated that Medicaid typically incurs prescription drug costs of $200 to $300 per month for dually-eligible ESRD patients who receive the full Medicaid package of services.

3. Demonstration Reimbursement and Expenditures

To analyze questions 2 and 3, above, we requested annual statements of expenses and revenues related to the ESRD Demo only (as opposed to information on other HMO lines of business or the health plan as a whole) from each of the two Demonstration sites. In an effort to obtain reasonably consistent and comparable revenue and expense information, we developed report formats for the sites' use. Sites were asked to record CMS capitation revenue, medical expense information by major category of service, and administrative expenses for the overall Demonstration. In addition, medical expenses also were to be provided separately for the "treatment modality / cause of renal failure" categories that corresponded to the capitation rate cells, i.e., dialysis patients (diabetic nephropathy and other), functioning graft patients (diabetic nephropathy and other), and transplant patients (incorporating medical expenses during the three months surrounding the transplant). Reports in the requested format were to be submitted to the evaluation team five months after the end of each calendar year of the Demonstration, with all claims incurred during the previous calendar year and paid through the most recent month, included.

In general, HOI was able to comply with the requested report format. Kaiser, on the other hand – due to the historically enclosed health care delivery system inherent in its group-model structure – found it much more difficult to supply data in the requested formats. Its data systems have been developed to function primarily as transaction systems and are not equipped to measure visit intensity. Therefore, its reported medical costs in many categories of service represent an average for the medical center, based on department (or service category) costs and utilization, and do not adjust for age of patient or the actual intensity of any given service. For this reason, Kaiser felt it would be inappropriate and misleading to report data disaggregated into several rather small modality-specific categories, and instead provided the revenue and expense information for the Demo as a whole and for "all modalities, diabetic nephropathy" and "all modalities, other."

It should also be noted that, for both Kaiser and HOI, it is difficult to isolate administrative expenses related solely to the Demo. Both Kaiser and HOI have other lines of business, including commercial and Medicare risk products. Reported administrative expenses therefore are partially dependent upon how corporate overhead expenses are allocated to the Demo. We are unable to address and control for likely variations in the derivation of administrative expenses within the scope of this evaluation. We point them out as potential drawbacks of the cost analysis and as factors that must be considered when interpreting the analytic results.

C. Results

1. Medicare Spending Impacts

a. Pre-Demo Spending: A Measure of Selection

Based upon the sub-sample of Demo patients that had spending data available from 1997 and/or 1998, Medicare spending rates were calculated for the period during which they were Medicare primary insured preceding Demo enrollment. The rates per patient year (PPY) prior to Demo enrollment for HOI and KP patients are shown in Exhibit 11-1, line 1. These pre-Demo rates were 19.6 and 27.7 percent lower than those calculated for the Florida and California FFS comparison groups, respectively. Due to the better health of Demo patients at baseline, it is not surprising that these patients would have lower expenses prior to their enrollment in the Demo. Another contributory factor to the higher cost observed in the FFS group is the considerable cost associated with death. This added cost contributes to the higher overall spending PPY observed among FFS Medicare patients during 1998, since deaths in the FFS population were not excluded. In this way, the FFS population differed from the Demo sample, which was assured total survival during the pre-Demo period.

Also shown in Exhibit 11-1 are the actual revenue and expenditures for all dialysis patients (by site) who enrolled in the Demo in 1998 (lines 3 and 4). The composition of these costs, which were provided by the Demo sites on their annual financial statements, will be addressed later in this chapter. Note that the total expenditures shown here include administrative costs and spending for extra benefits not typically provided under regular Medicare risk plans.

Exhibit 11-1: Comparison of Actual Total Spending per Patient Year (PPY) (All Dialysis): Demo v. Medicare FFS, Unadjusted

Spending category	Florida		California	
	Total Patient Years	Total Spending PPY	Total Patient Years	Total Spending PPY
1. Actual Pre-**Demo** Medicare Payments (1997-98)	386	$ 46,430	315*	$ 43,709
2. Actual Medicare Payments for state-wide FFS **Comparison** Patients (1998)	8,094	$ 57,776	13,713	$ 60,469
3. Actual CMS **Demo** Payments (1998) **	156	$ 54,255	237	$ 58,130
4. Actual **Demo** Expenditures (1998)		$ 62,280		$ 60,080

* KP non-RO patients only were used for pre-Demo cost rates in California.
** As reported in the 1998 annual statements of expenses and revenues by HOI and KP

Patients who enrolled in the Demo cost CMS 6.1 percent less in FL and 3.9 percent less in CA than the average dialysis patient within the same state during 1998 (comparing line 3 to line 2); however, this comparison makes no adjustment for co-morbid differences between the Demo patients and FFS patients. In other words, we would expect these Demo patients to cost less for comparable coverage than the average comparison patient in CA and FL FFS as indicated by

their lower-than-average pre-Demo costs and healthier status at baseline. What we would predict these patients to have cost CMS during this initial period, had they remained in FFS, is discussed in the following section.

b. Predicted Demo Patient Costs

In order to estimate what Demo patients would have cost Medicare had they not chosen to enroll in the Demo, regression models to predict the (natural log of) cost were developed (as described in the above methods section) using actual CA and FL Medicare patient costs for 1998 and 1999. The cost models were validated by calculating predicted annualized costs for CA and FL that were based on the population averages within each group. The predictive value of each model was assessed by estimating 95 percent confidence limits based on the model standard errors. Exhibit 11-2 shows the predicted one-year costs for CA and FL and the corresponding confidence limits, which can be compared to actual average costs per patient year (PPY) calculated from 1998-1999 Medicare claims data for the same patients.

Exhibit 11-2: Cost Model Validation Results: Model Predicted Costs versus Actual Total Medicare Spending Per Patient Year (PPY) for CA and FL FFS Patients 1998-1999

Spending category	Florida		California	
	Total Spending PPY	95% Confidence Limits	Total Spending PPY	95% Confidence Limits
Predicted Medicare Payments for state-wide FFS **Comparison** Patients (1998-99)	$ 52,108	(51,243, 53,007)	$ 54,815	(53,974, 55,669)
Actual FFS Payments (1998-99)	*53,025*		*57,316*	
Predicted v. Actual (% difference)	-1.71%	(-0.03%, -3.36%)	-4.36%	(-2.87 %, -5.83%)

Both cost models were found to predict yearly costs that were slightly lower than actual PPY averages. Based on the 95 percent confidence limits shown in Exhibit 11-2, the predicted costs for Florida FFS patients were estimated to be as little as 0.03 percent or as much as 3.4 percent lower than the actual cost per patient year for the same patients. In California, the model predicted cost is estimated to be between 2.9 and 5.8 percent lower than the actual PPY cost.

Each Demo patient's costs were then predicted using the parameter estimates from the state-specific regression models. Exhibit 11-3 shows the average predicted costs PPY for Demo patients in each state, based on their demographic and co-morbid characteristics and estimated follow-up time. The standard deviation of the mean PPY cost is also shown to give a measure of the spread of the predicted patient costs within each Demo subgroup.

Exhibit 11-3: Model Predicted versus Actual Total Medicare Spending Per Patient Year (PPY): Demonstration Patients 1998-1999

Spending category	HOI of FL		Kaiser of CA	
	Mean Total Spending PPY	Standard Deviation (SD)	Mean Total Spending PPY	SD
Average Predicted* **Demo** Patient Costs to CMS as if under Medicare FFS (1998-99)	$ 48,880	12,157	$ 51,039	14,395
Actual CMS Demo payments (1998-99)	*$ 56,381*		*$ 56,886*	

* mean of expected costs for all patients (calculated using parameter estimates from the 1998-1999 FFS cost model of patient characteristics), where each patient living at the end of one year is assigned one year of time at risk and deaths are given 0.5 years.

When comparing predicted total costs to actual CMS costs for patients enrolled in the Demo during 1998 and 1999, we find that predicted costs for Demo patients in CA and FL are estimated to be **10.3** and **13.3** percent lower, respectively. However, these estimated differences should be viewed in light of the model validation results for the underlying FFS populations in CA and FL (see Exhibit 11-2). The validation results suggest that some fraction of the differences between the Demo predicted and Demo actual costs may be attributable to the tendency of the cost models to predict low (from 0 to 3.4% lower for FL, and 2.9 to 5.8% lower for CA).

2. Medicaid Spending Impacts

In CMS's Waiver Cost Estimate for the ESRD Managed Care Demonstration, CMS had estimated savings to Medicaid to be approximately twice the savings we calculated. There are two key reasons for this discrepancy. First, total enrollment in the Demo did not reach the levels CMS had predicted, partially due to the exit of Xantus from the Demo. Second, the distribution of dual eligibles in the enrolled population did not mirror the distribution in the underlying population. CMS had estimated that approximately 30% of the Medicare-entitled ESRD beneficiaries in the Demonstration service areas were also covered by Medicaid, and that this distribution would hold in the enrolled population. In fact, we found that approximately 54% of the California DOPPS population are dually-eligible, while only 17.4% of the Kaiser enrolled population were dual eligibles. In Florida, approximately 30% of the statewide DOPPS ESRD patients are dually-eligible, versus 15.6% of the HOI enrollees. This finding is consistent with our more general finding that patient selection into the Demo is not representative of the FFS ESRD population.

Based on our analysis, the estimated savings to Medicaid (including both federal and state shares) were, at the most, $10,000 per dual eligible enrollee per year. Since only about 16% of Demonstration enrollees were dual eligibles, this is about $1,600 per enrollee overall. With a Federal Medical Assistance Percentage (FMAP) close to 50% in both California and Florida, the Federal Medicaid savings were at most $800 per enrollee per year, which represents an offset to Medicare spending of about 1.5%. That is, the federal government did not save money under the Demonstration, whether one considers only the direct impact on Medicare spending or the combined impacts on Medicare and Medicaid.

3. Demonstration Site Reimbursement and Expenditures

a. Value of Extra Benefits Used by Enrollees

Both South Florida and Southern California are highly competitive Medicare managed care markets, and the Medicare+Choice payment rates in both areas are relatively high. As a result, Medicare risk contractors in these markets traditionally have offered rich benefit packages, including outpatient prescription drugs, often with no cost-sharing and at zero premium. Exhibit 11-4 shows the Demo extra benefits, over and above the regular Medicare risk program package of benefits, offered by Kaiser and HOI for calendar years 1998, 1999, and 2000, along with the per-member-per-month dollar value of these benefits and the percentage of capitation revenue they represent.

Exhibit 11-4: Value of Extra Benefits

Site	Extra Benefits	PMPM			Percent of Revenue		
		CY 98	*CY 99*	*CY 00*	*CY 98*	*CY 99*	*CY 00*
Kaiser	Nutritional Supplements	$10.16	$10.69	$11.11	0.21%	0.23%	0.24%
	No Co-pay for Outpatient Visits	$9.78	$39.49	$38.95	0.20%	0.85%	0.85%
	Total Extra Benefits	**$19.94**	**$50.18**	**$50.06**	**0.41%**	**1.08%**	**1.10%**
HOI	Nutritional Supplements	$6.23	$7.35	$5.66	0.14%	0.13%	0.12%
	Transportation	$2.60	$6.71	$1.27	0.06%	0.12%	0.03%
	Extra Pharmacy*	$12.46	$24.28	$27.09	0.28%	0.50%	0.57%
	Rehabilitation Services**		$73.32	$89.31		1.24%	1.87%
	Total Extra Benefits	**$20.77**	**$111.66**	**$123.33**	**0.46%**	**2.31%**	**2.58%**

* The HOI demonstration includes a formulary that is broader than the regular Medicare risk formulary. In addition, there is no annual or biannual cap on the demonstration pharmacy benefit, while there is on the regular Medicare risk pharmacy benefit.

** The rehabilitation service was not offered as an extra benefit during the first year of the Demo; phase-in of this benefit commenced in year 2.

It is worth noting that there were a number of benefits offered by the Demonstration sites that could not technically be counted as part of the 5% extra benefits, but that nevertheless may have been of significant value (either monetary or otherwise) to the Demonstration enrollees. It is thus important to consider and quantify these benefits in answering question #4 as stated in the Introduction to this chapter. For example:

- Prescription drug benefits are part of the regular Medicare risk product at both Kaiser and HOI, and therefore the majority of this benefit could not technically be counted as part of the 5% extra benefits under the Demo. The *value* of this benefit to the Demonstration enrollee, however, was significantly greater than the value of the benefit to the regular Medicare risk enrollee, as ESRD patients utilize prescription drugs at a much higher rate than the average Medicare beneficiary. For example, HOI's reported PMPM cost of the pharmacy benefit for Demonstration enrollees was approximately twice the PMPM cost for non-Demonstration, non-ESRD Medicare risk enrollees (about $180 PMPM vs. about $90 PMPM in calendar year 1999). This represented an extra cost to HOI equal to almost 2% of its capitation revenue. The extra *value* of the benefit to the Demonstration enrollee was likely significantly higher than $180 per month, as Medicare beneficiaries with no

prescription drug coverage generally pay significantly higher prices for their drugs than do bulk purchasers. According to a recent study by the National Institute for Health Care Management, the average retail price per prescription is now more than $45; for the Demonstration patient, who averaged about eight prescriptions per month, this translates to a prescription drug cost of $360 per month.

- Similarly, the lack of the Medicare Part A deductible and Medicare Part B co-insurance is an additional benefit offered by virtually all Medicare risk contractors. Again, however, the *value* of this benefit to Demonstration enrollees far exceeded its value to the average Medicare risk enrollee. As calculated by CMS, the average per capita actuarial value of the Medicare co-insurance and deductibles under traditional Medicare, based on Medicare beneficiaries nationally (the very large majority of whom are non-ESRD patients), has ranged from about $75 per member per month in 1998 to more than $100 per member per month in 2000. For the average ESRD patient in traditional Medicare, on the other hand, cost-share responsibilities are generally close to $500 per month, according to CMS's Office of the Actuary. (For the healthier Demonstration enrollees, cost-share responsibilities would likely be somewhat lower, perhaps 10-15 percent lower.)

Thus, those Demonstration enrollees who had no secondary coverage prior to the Demonstration may have saved, on average, more than $9,000 annually in out-of-pocket expenses ($4,000 in prescription drug expenses and at least $5,000 in Medicare cost-sharing) under the Demonstration. For those with secondary coverage prior to the Demonstration, similar savings likely accrued in part to those who had purchased the secondary coverage on the patients' behalf (either the patients themselves or, in come cases, their previous employers) and in part to private Medigap insurers.

In addition, the case management services offered by the Demonstration sites carried a cost. Kaiser offered its multidisciplinary care management approach to all of its ESRD patients, regardless of whether they were enrolled in the Demo, as well as to its pre-ESRD patients. Kaiser included the costs of the multi-disciplinary team on its calendar year 1998 statement of revenues and expenses, and these costs represented approximately 1.2% of the capitation revenue. The value of the sites' case management services, however, has not been quantified.

b. Financial Viability of the Demonstration from the Demonstration Sites' Perspective

1) Overall Viability of the Demonstration Line of Business

For each of calendar years 1998, 1999, and 2000, Demonstration capitation revenues received by Kaiser and HOI[‡] were compared to their Demonstration program expenditures (see Exhibit 11-5). For both Kaiser and HOI, capitation revenues for calendar year 1998 did not cover total Demonstration expenses (including medical and administrative costs) incurred in 1998. HOI's 1998 net loss of 14.79% (about $1.3 million) was significantly higher than Kaiser's net loss of 3.3% (about $463,000). By calendar year 1999, the financial picture had improved somewhat for both plans' Demonstration programs, with HOI's loss decreasing to 3.56% (about $1.1 million)

[‡] Capitation revenues include payments actually received from CMS for the months included in the reporting period, as well as payment expected from the sites but not yet received at the time of report submission. For instance, CMS payment of the transplant rate for the three months surrounding a transplant often lagged behind other payments.

and Kaiser showing a positive net income of 1.9% (about $799,000). HOI's net loss grew again in 2000 to 8.6% (about $3.3 million), while Kaiser continued to show a positive, though somewhat lower net income, at 0.7% (about $397,000).

2) Medical Loss Ratio

Aggregate costs of **medical services** (i.e., including all Medicare-covered services, outpatient prescription drugs, and "extra benefits") as a percentage of total revenue – referred to as the medical loss ratio – ranged from 93.6% to 99.1% across sites and years, as shown in Exhibit 11-5. In other words, both sites were able to deliver all Medicare-covered services and certain non-Medicare-covered preventive services, plus outpatient prescription drugs, plus the extra benefits not covered under the plans' regular Medicare risk products, for an amount less than the capitation revenue. As discussed previously, the capitation payment under the Demo is based on 100% of FFS for Medicare-covered services delivered to Demonstration-eligible Medicare beneficiaries.

In addition to analyzing overall medical costs, we also looked at two sub-categories of medical cost (see Exhibit 11-5): Medicare-covered services only, and services covered under the regular Medicare risk contract. Although the first sub-category closely approximates Medicare-covered services, it does include some services and costs that are not covered by Medicare, e.g., certain preventive services and the Medicare co-insurance and deductible. This category does not include the outpatient prescription drugs offered by the Demonstration sites, nor does it include the "extra benefits" offered. As shown in Exhibit 11-5, both Kaiser and HOI were able to deliver this category of services for, in most cases, less than 90% of the capitation revenue.

The addition of outpatient prescription drugs to the sub-category of medical costs described above essentially mirrors the package of services offered under the plans' regular Medicare risk products. Again, the experience across sites and years was similar, with medical costs in this category ranging from 91% to 96% of capitation revenue.

Exhibit 11-5: Service Components, PMPY Expenditures and as Percent of Capitation Revenue

Service Components	HOI			Kaiser		
	CY 98	CY 99	CY 00	CY 98	CY 99	CY 00
Capitation Revenue PMPY	$54,255	$58,112	$57,334	$58,130	$55,641	$54,750
Medical Services						
Medicare-Covered Services Only*						
PMPY Costs	$49,445	$51,169	$53,350	$49,969	$48,700	$47,884
Expenditures as % of Revenue	91.14%	88.05%	93.05%	85.96%	87.53%	87.46%
Services Covered Under Regular Medicare Risk **						
PMPY Costs	$50,934	$53,043	$55,362	$55,832	$51,827	$51,815
Expenditures as % of Revenue	93.88%	91.28%	96.56%	96.00%	93.15%	94.64%
All Medical Services (including "extra benefits")***						
PMPY Costs	$51,183	$54,383	$56,841	$56,746	$52,429	$52,416
Expenditures as % of Revenue	94.34%	93.58%	99.14%	97.62%	94.23%	95.74%
Administrative Services						
PMPY Costs	$11,096	$5,799	$5,448	$3,335	$2,144	$1,938
Expenditures as % of Revenue	20.45%	9.98%	9.50%	5.74%	3.85%	3.54%
Medical & Administration						
PMPY Costs	$62,280	$60,182	$62,291	$60,080	$54,573	$54,353
Expenditures as % of Revenue	114.79%	103.56%	108.64%	103.35%	98.08%	99.28%

* This category actually includes some services that are not Medicare-covered, e.g., certain preventive services. In addition, it includes the Medicare deductible and co-insurance that are the patient's responsibility in the FFS system. We were unable to isolate the costs of these services within the scope of the evaluation. Outpatient pharmacy services, however, are *not* included in this category.

** This category includes the services in the first category, *plus* outpatient prescription drugs that are covered under the sites' regular Medicare risk products.

*** This category includes all medical services covered under the Demo, and the percentages in this row are equivalent to the sites' total medical loss ratios.

Note: Because of the differences between the Kaiser and HOI service delivery models and the associated differences in the methodologies for capturing costs, it is inappropriate to compare HOI's financial results to Kaiser's financial results for specific services or categories of service. More general financial comparisons across the two sites (e.g., of total medical loss ratio and of total net income) are less problematic.

3) Administrative Costs

A comparison of administrative costs to total revenue (see Exhibit 11-5) revealed the following:

- In HOI's case, the significant overall improvement between 1998 and 1999 can largely be explained by the administrative economies of scale realized in 1999. That is, while Demonstration-related administrative expenditures increased between 1998 and 1999 (from approximately $1.8 million to approximately $3.0 million), member months increased more dramatically during this period (from 1,926 in 1998 to 6,260 in 1999). While capitation revenues and medical expenses are variable costs that are largely determined by number and mix of members, a large portion of administrative costs are fixed or semi-variable. As a result, administrative expenditures as a percent of revenue decreased from 20.5% in 1998 to 10.0% in 1999, after which they leveled out at 9.5%.

- Kaiser's Demonstration program experienced much lower administrative expenses (when expressed as a percent of revenue) – 5.7% in 1998, 3.9% in 1999, and 3.5% in 2000. Likely factors contributing to the difference between HOI and Kaiser are size of Demonstration membership (which affects per member per month direct administrative expenses); size of total health plan membership (which affects per member per month overhead administrative expenses); and differences in methodologies for allocating administrative expenses.

- Notwithstanding the differences between Kaiser and HOI relative to reported administrative expenses, both Kaiser and HOI experienced a considerable decrease in administrative expenses as a percentage of total revenue between the first and second years of the Demo, with a leveling off in the third year.

4) Spending within Rate Cells

As discussed, only HOI was able to report medical expenditures by capitation rate cell. Exhibit 11-6 displays medical loss ratios by rate cell for HOI, for calendar years 1998, 1999, and 2000. Number of member months in each rate cell is also shown.

For dialysis patients whose primary cause of renal failure was diabetic nephropathy, HOI was able to achieve a medical loss ratio below 90% during both 1998 and 1999, but experienced a medical loss ratio of almost 96% in 2000. For dialysis patients whose renal failure was due to other causes, the medical loss ratio was considerably higher in 1998 and 1999 (96.8% and 99.6%, respectively), and exceeded 101% in 2000. For both subgroups of dialysis patients, HOI had enrollees only in the 20-64 and the 65+ age groups, with no enrollees in the 0-19 age group. In both the "diabetic nephropathy" and "other" subgroups, the medical loss ratio in the 20-64 age group was higher than that in the 65+ age group.

The number of member months represented by functioning graft patients was significantly lower than for dialysis patients. Even the most populated rate cell ("Other," age 20-64, calendar year 2000) had only 195 member months, or on average 16 enrollees at any time during the year. It is understandable, then, that the medical loss ratios by rate cell for this group of patients varies widely across calendar years and age groups.

HOI had 22 member months represented in the transplant rate cell in calendar year 1999, which translates to approximately seven patients who had transplants that year, and 34 member months in calendar year 2000 (approximately 11 patients receiving transplants). The transplant rate is paid for the three months surrounding the transplant; one or more of the transplant recipients were not enrolled for the entire three-month period. HOI's medical loss ratio for this group was almost 99% in 1999 and about 68% in 2000.

Exhibit 11-6: Medical Loss Ratio by Rate Cell, HOI

	Member Months			Medical Loss Ratio		
	CY 98	CY 99	CY 00	CY 98	CY 99	CY 00
Total Demonstration	1,926	6,260	7,906	94.34%	93.58%	99.14%
Dialysis Patients						
Diabetic Nephropathy	484	2,097	2,811	88.31%	89.87%	95.83%
Age 0-19	0	0	0	N/A	N/A	N/A
Age 20-64	288	1,135	1,434	92.81%	96.75%	101.51%
Age 65+	196	962	1,377	82.50%	82.74%	90.57%
Other	1,392	3,947	4,817	96.77%	99.57%	101.19%
Age 0-19	0	0	0	N/A	N/A	N/A
Age 20-64	885	2,441	3,057	100.00%	100.63%	104.53%
Age 65+	507	1,506	1,760	92.05%	98.14%	96.45%
Functioning Graft Patients						
Diabetic Nephropathy	5	19	10	33.33%	48.72%	63.64%
Age 0-19	0	0	0	N/A	N/A	N/A
Age 20-64	4	8	2	28.57%	100.00%	110.14%
Age 65+	1	11	8	50.00%	16.67%	53.89%
Other	45	175	234	111.76%	157.62%	169.90%
Age 0-19	1	0	0	0.00%	N/A	N/A
Age 20-64	44	175	195	111.76%	157.62%	166.77%
Age 65+	0	0	39	N/A	N/A	180.07%
Transplant Patients	0	22	34	N/A	98.66%	67.69%

It is difficult to draw any preliminary conclusions from this analysis or even to hypothesize about what the findings might suggest, particularly for the functioning graft and transplant rate cells where the member months are so low. However, the analysis does surface the following areas for potential further exploration:

- ***The age 20-64 rate cells for both "diabetic nephropathy" and "other" categories of dialysis patients***. These rates cells both had significant numbers of member months represented, and the medical loss ratios in these rate cells showed relatively little variation between calendar year 1998 and calendar year 2000. HOI experienced high medical loss ratios in these rate cells (between 93% and 101%) which likely would be unsustainable for a managed care organization. Further research into the reasons for these high medical loss ratios might prove enlightening. Such research could focus, for instance, on: (a) whether any changes in treatment patterns for this age group have occurred since the development of the rates; and (b) whether further refinements in the age grouping (e.g., 20-44 and 45-64) might create better risk adjustments).

- ***The rate cells for functioning graft patients.*** Although the member months for these rate cells are very low, the medical loss ratio is consistently well over 100% in those rate cells

with the highest numbers of member months. Again, it is difficult to draw conclusions regarding the adequacy of the payment rates for these rate cells. However, questions have been raised, both by the Demonstration sites and by CMS officials, as to whether the payment rates for these cells might be understated. CMS has indicated that, historically, Medicare fee-for-service claims for immunosuppressive drugs – which would be an important component of cost for functioning graft patients – are incomplete. Further exploration of this issue may be warranted.

It should also be noted that our penetration analysis (see Chapter 2) indicated that HOI enrolled a disproportionately small number of peritoneal dialysis (PD) patients versus hemodialysis (HD) patients (compared to the underlying population). Studies indicate that PD patients are less expensive to treat than are HD patients.[§] Because the Demonstration sites received the same capitation rate regardless of dialysis modality, we assessed the degree to which the dialysis payment rate to HOI may have been understated as a result of HOI's mix of PD and HD patients being different than the mix assumed by the combined rate. We found that varying the payment rate by modality (HD vs. PD) would have resulted in a slightly higher payment to HOI in the dialysis rate cells of approximately 0.4%. Thus, such a risk adjustment would not "buy" much in terms of payment accuracy, and there are likely other appropriate adjustments that could be made that would actually decrease payment. For instance, if dual eligibles are, as is likely, more expensive than the Medicare-only population, a risk adjustment to account for that difference would have resulted in lower payments to the sites, since they enrolled substantially fewer dual eligibles compared to the proportion of dual eligibles assumed in the rates.

D. Discussion

Our findings can be summarized as follows:

- Our analyses have concluded that Demonstration enrollees were healthier than the FFS ESRD population at baseline. Thus, their pre-Demonstration costs and their predicted costs were significantly lower than the FFS population and, in turn, considerably lower than the capitation rates paid by CMS. That is, CMS's Medicare costs for the Demonstration enrollees appear to be greater under the Demo than they would have been if these enrollees had remained in the FFS system; for this reason, managed care did not "save" CMS money. This finding mirrors that of several studies focusing on Medicare risk contracting in general, which conclude that because Medicare risk enrollees are generally healthier than the general Medicare population, even within demographically adjusted rate cells, Medicare pays more for Medicare risk enrollees than they would have under FFS.[**] We supplemented the Medicare-spending analysis by assessing the cost impact on Medicaid resulting from the enrollment of dual eligibles into the Demo. We found that considerable

[§] In a 1999 Lewin Group / URREA study entitled, "Categorizing and Predicting ESRD Spending: Development of a Capitation Model," the authors reported average yearly spending for a PD patient to be 87.5% of the average yearly spending for an HD patient. USRDS's 2001 Annual Data Report shows the percentage to be approximately 85%.

[**] For example, Mathematica Policy Research, Inc., Biased Selection in the Medicare Risk Contract Program (Sept. 21, 1990); and Medicare: Changes to HMO Rate Setting Method are Needed to Reduce Program Costs (Chapter Report, 09 / 02 / 94), GAO / HEHS-94-119

savings do accrue to Medicaid, but that these savings do not outweigh the additional costs to Medicare.

- Interestingly, although the rates paid by CMS to the Demonstration sites were significantly greater than the predicted costs of Demonstration enrollees, the Demonstration sites did not experience anything resembling a "windfall." In fact, both sites experienced financial losses in the first year, while HOI continued with losses in Years 2 and 3, with Kaiser showing a small positive net income for both those years. There are a number of possible explanations for this. Certainly, the fact that the Demonstration sites provided additional benefits to Demonstration enrollees than are covered by Medicare contributes to their level of spending. Coverage of the Medicare deductible and co-insurance alone may well have cost the Demonstration sites an average of $5,000 to $6,000 per enrollee per year. HOI, in particular, paid the majority of its non-facility providers on the basis of 100% of Medicare allowable charges although the rates received from CMS were based on only 80% of allowable charges for Part B services. Thus, the sites would have had to achieve significant savings just to cover the additional costs associated with this benefit. Of course, the sites provided coverage of other non-Medicare covered services as well, and the costs of the prescription drug benefit were also significant (easily $2,000 to $4,000 per enrollee annually).

  It may also be true that Demonstration enrollees "catch up" on their care during early years of enrollment, seeking care that they had previously foregone due to financial constraints. In addition, some of the savings managed care organizations might be able to achieve due to more effective care coordination, for instance, may not be realized for a couple of years. Finally, the administrative costs associated with implementing case management and other tailored programs are likely to be significantly higher when dealing with a seriously and chronically ill population than when serving the general Medicare population.

- Providing "extra benefits" that equal 5% of capitation revenue appeared unrealistic for several reasons. First, doing so was not financially viable for the health plans. They were already covering significantly more services than are covered under Medicare, and the cost and value of these additional benefits – particularly the absence of Medicare co-insurance and deductibles, and the outpatient prescription drug benefits – are much greater for the ESRD population than for the average Medicare beneficiary. Second, in highly competitive markets where Medicare+Choice benefits are already quite rich, it is difficult to add benefits that meet CMS's definition of "additional benefits," and for which the value is easily quantifiable. (However, this second constraint is becoming less of a factor as an increasing number of Medicare managed care plans are reducing their benefits, particularly via increased co-pays and limits on drug coverage.)

- The risk adjustments embodied in the capitation cannot be evaluated fully, particularly in those instances where the member months in a given rate cell are very low. It appears, however, that the rates for 20-64 year-old dialysis patients may need to be revisited.

METHODS APPENDIX

Samples

Demonstration Samples

Initial data collection at the time of enrollment was completed for the first 1,292 enrollees (678 Kaiser and 594 HOI patients). Based on power calculations for determining the necessary sample sizes to detect differences in the outcomes analyses performed, only the first 750 Demonstration enrollees were selected for a second round of data collection at 12 months following enrollment.

All comparative analyses presented within this report include hemodialysis (HD) patients from the Demonstration exclusively, for the purpose of comparison to other representative patient samples, unless otherwise noted. Patients were classified based on their modality at enrollment. The vast majority of Demonstration enrollees in both states were HD patients (93, 5, and 2 percent of HOI and 82, 10, and 8 percent of Kaiser enrollees were HD, peritoneal dialysis (PD) and functioning graft, respectively). Too few PD and functioning graft patients were enrolled to make any meaningful comparisons or statistical inferences.

Several sources of data were available for the Demonstration patients, including electronic pre-Demonstration utilization data, data collected manually by the evaluators at enrollment and one-year follow-up, and utilization data that was provided by the participating Demonstration sites. Each source of data is described briefly below.

Pre-Demonstration Utilization Data

CMS Medicare claims from the Standard Analysis Files were queried for all Demonstration enrollees for a one-year period prior to Demonstration enrollment, with the exception of the Kaiser rollover patients, who were in an HMO prior to enrolling in the Demonstration and therefore did not generate any Medicare fee-for-service (FFS) claims. Since Medicare primary insurance was requisite for patients entering the Demonstration, only those periods where patients were known to have primary Medicare insurance were included in the assessment of pre-Demonstration utilization.

Baseline Data

Baseline information including demographic, clinical, and pre-enrollment information was collected for Demonstration patients through medical record abstractions, in-person interviews, and electronic data transfers from the Demonstration organizations. The medical record abstractions and in-person patient interviews were conducted by experienced local nephrology personnel hired and trained by the evaluators who were not part of the patient's dialysis or transplant unit staff. Three data collection instruments were developed by the evaluators. Included were a clinical assessment form (CAF) for recording data from the medical record, a patient questionnaire (PQ) for assessing patient satisfaction and quality of life, and a termination form (TF) for recording the date and reason for departure from the Demonstration.

Longitudinal Data

Manual Evaluation Data Collection

The CAF and PQ described above were repeated after one year among the patients selected for follow-up. Repeated lab measurements, vascular access events, hospitalization, and quality of life (QoL) data were collected. During this follow-up period, TFs were collected for patients who disenrolled in order to capture their reasons for leaving, as well as summary information on vascular access events and hospitalization during their time in the Demonstration. Thus comparisons of vascular access and hospital outcomes included not only patients that were still in the Demonstration after one year, but those who may have died or disenrolled as well. Mortality and disenrollment status were collected continuously throughout the Demonstration.

Demonstration Site Electronic Utilization Data

Utilization data from both Demonstration sites were received electronically on a periodic basis, roughly every six months. For HOI, this included a set of claims that were paid to contracted providers for services rendered to Demonstration patients. Similar to Medicare claims data, these included information on provider, date and place of service, and the type of service performed. Kaiser utilization data were combined from multiple sources, namely their vascular access tracking tool database and hospital mainframe system.

Comparison Samples

Nationally Representative DOPPS Patients

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is a prospective observational study involving a sample of hemodialysis patients randomly selected from nationally representative dialysis facilities in the US[60]. Facilities were stratified for random selection based on standardized measures of mortality and hospitalization outcomes. The acceptance rate among randomly selected US facilities was high (nearly 80 percent), minimizing the potential for a biased sample. State-specific comparison patient samples in California (N=771) and Florida DOPPS (N=1,072) were used for the Demonstration evaluation since the DOPPS enrolled a substantial percentage of randomly selected dialysis facilities in these states. The California DOPPS facilities comprise 5 percent of all California facilities, and 10 percent of total facilities in Florida were enrolled in DOPPS.* Of the 19 Florida and 15 California DOPPS facilities, roughly one-half of the California DOPPS facilities were in the Kaiser Demonstration area, while nearly one-third of Florida DOPPS facilities were in the HOI Demonstration service area. The data collection instruments used in DOPPS were the basis for the forms developed by the evaluation team in order to collect identical information for Demonstration patients. Furthermore, data for Demonstration and DOPPS patients were collected in a similar manner through medical chart abstraction completed by trained dialysis nurses. Another strength of the DOPPS sample is that it is largely Medicare FFS. Approximately 82 percent of DOPPS patients have Medicare primary FFS insurance. Among these patients, a small number (about 5 percent) are covered by Medicare Risk HMO plans. The remaining 18 percent are insured by private

* Based on hemodialysis facility totals from the 1998 CMS Annual Facility Survey.

health plans (of which, about 30 percent are non-Medicare managed care plans) or state Medicaid.

Matched Geographic Comparison Patients

In addition to the DOPPS, matched samples of FFS and non-Demonstration managed care (or NDMC, i.e., Medicare Risk HMO) patients were also randomly selected from Demonstration service area dialysis facilities for comparison to the Demonstration patients. The FFS and NDMC patients were matched to the Demonstration patients according to their distributions of age, race, and time since onset of ESRD. Due to slight oversampling, the total number of patients randomly selected for the NDMC and FFS comparison groups was 213 and 203, respectively (target=190 patients per group). These two matched comparison patient groups were compared to the Demonstration patients with respect to their baseline characteristics, quality of life, satisfaction with care, and other specific factors. With the intention that they would be geographically combined in order to achieve sufficient statistical power, these matched comparison samples were also selected to reflect the higher proportion of patients enrolled in the California Demonstration.

Managed Care Kaiser Rollover Patients

Patients who were "rollovers" (i.e., those already covered by the Kaiser HMO plan who were randomly selected to "roll over" into the Demonstration plan) were treated separately in many of the analyses, and are denoted as Kaiser RO. Kaiser was allowed to roll over one existing patient for every two patients who enrolled in the Demonstration from FFS. There were a total of 211 rollover patients in our selected sample. Because these patients were found to differ from those enrolling in the Demonstration program from FFS, in certain instances these patients are reported on separately from the new Kaiser Demonstration enrollees.

California and Florida Medicare FFS Patients

All ESRD patients residing in California and Florida who were on hemodialysis on January 1, 1998 and had Medicare as their primary insurer were identified using the Medicare Enrollment Database. Only patients with complete co-morbidity information from the CMS 2728 form were included in order to adjust for case mix when making comparisons to Demonstration patients. These data restrictions resulted in a sample of 6,348 FFS comparison patients in Florida and 11,042 patients in California. Claims data from the CMS Standard Analysis Files were queried for these patients and incorporated in the analysis of cost and utilization.

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