Evaluation Results for the ESRD Managed Care Demonstration

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Executive Summary

The two demonstrations described in the attached reports [the report on the SHMO demonstration is available at http://www.cms.hhs.gov/researchers/reports/2002/thompson.pdf] tested new approaches for providing care, under capitated payment models, to patients with special needs. These two managed care demonstrations provided targeted Medicare beneficiaries with additional services not routinely covered by Medicare HMOs. The second generation Social/Health Maintenance Organizations (S/HMO IIs) targeted frail, medically complex patients at risk of nursing home placement. The End-Stage Renal Disease (ESRD) demonstration enrolled patients with end-stage renal failure, who are currently prohibited from enrolling in managed care plans after the onset of kidney failure. Typical services in the S/HMO II demonstration include case management, personal attendant care, transportation, day care, prepared meals, respite care, and social services. The precise services provided to an individual patient in the S/HMO II demonstration were determined in an assessment of the patient's medical and social needs. In contrast, the ESRD demonstration sites offered benefits important to dialysis and transplant patients, such as no copayments on pharmaceuticals, nutritional supplements, free transportation to the dialysis facility, dental care, and rehabilitative and preventive care.

Legislative History

The Deficit Reduction Act of 1984 (P.L. 98-369, Section 2355) mandated a demonstration of the S/HMO concept and submission of the attached final report to Congress. Submission of the report was originally to be 45 months following the enactment of the Deficit Reduction Act. However, each of the pieces of legislation described below extended the life of the demonstration and deferred the submission of the final report.

A demonstration of a second generation (S/HMO II) model was authorized in the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508, Section 4207). The legislative guidelines for the second generation model were based on findings from the evaluation of the first generation S/HMO. The Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66, Section 5079) increased the enrollment limit of the S/HMO demonstration and allowed for a new demonstration under the S/HMO authority for beneficiaries with ESRD. The Balanced Budget Act of 1997 (P.L. 105-33, Section 4014) required a report, submitted to Congress on February 1, 2001, on integration and transition of the S/HMO into the Medicare + Choice (M+C) program. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (P.L. 106-113, Section 531) extended the demonstration and changed the submission for the attached reports to 21 months after the submission of the transition report. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Section 631) extended the demonstrations of both generations of social health maintenance organizations from 18 months to 30 months following the submission of the transition report.

The following discussion includes two self-contained sections on the S/HMO II and ESRD evaluations that can be read independently. While there is no explicit requirement of a report to Congress concerning the ESRD Demonstration, the demonstration is authorized in the section

relating to S/HMOs. Therefore, the results of the ESRD evaluation are being included as a separate section of the final S/HMO report to Congress.

PART 1: EVALUATION RESULTS FROM THE S/HMO II DEMONSTRATION

Background

Although not more than four additional projects were authorized by Congress, only one S/HMO II plan was actually implemented. Started in late 1996 by the Health Plan of Nevada (HPN), this plan, Senior Dimensions, is still in operation. The evaluation examined the effects of the S/HMO II on the health and functioning, service use, and quality of care of its members from July 1997 through April 1999.

The second generation S/HMO incorporated many features of the first generation model but added modifications suggested by findings from the evaluation of the first generation S/HMOs. Both models are designed to supplement the basic services of a Medicare HMO with additional services and benefits for selected enrollees. Under both models, beneficiaries receive systematic screening assessments at enrollment and every 12 months thereafter. Members who appear to be at medical risk undergo an additional, more extensive, in-person assessment by case managers to determine what, if any, extra services they require. Distinctions between first and second generation S/HMOs include differences in the payment design, in the method for targeting patients, and in the additional focus in S/HMO II on interdisciplinary teams to manage care.

The S/HMO II model also incorporates a more team-oriented geriatric approach to care compared to the first generation model. It brings together primary care physicians, specialists, pharmacists, dieticians, geriatricians, and nurse case managers in an interdisciplinary care coordination team to fully integrate acute and long-term care services. Examples include annual screening of members for risk factors, formulary restrictions that discourage use of drugs found harmful among older people, personal care, transportation, emergency response systems, respite care, and other services for at-risk members.

S/HMOs are capitated and accept risk for their members, just like Medicare risk plans. Payments are based on the Medicare county rate book amount for risk plans but without the implicit 5 percent discount that is built into the risk-plan rates. The augmented rate is intended to cover the expanded community care and care coordination S/HMOs provide.

Payments are risk-adjusted for both S/HMO I and S/HMO II plans but using different approaches. The S/HMO I plans receive higher payments for enrollees who are nursing home certifiable and lower payments for enrollees who are not. The resulting payments were 15 percent to 30 percent higher than standard Medicare HMO's would have received for the same enrollees. These higher payments are surprising in that there is little difference in case-mix between the S/HMO and local risk plans. This finding suggests that many of the enrollees classified as nursing home certifiable may not be highly impaired. Payments to the S/HMO II plan are based on a more complex risk adjustment formula that incorporates multiple variables derived from the health and functional status assessments of each enrollee. The S/HMO II

methodology resulted in payments that were only 5 percent higher than the payments that would have been made to a regular Medicare HMO, which is consistent with the project's payment structure.

This report evaluates the effect of the S/HMO II in terms of three basic measures of plan performance: (1) changes in enrollee health and functional status, (2) utilization of services, and (3) quality of care. In addition to these measures, the evaluation examined the extent to which enrollees in the S/HMO II plan received additional services and benefits that are not standard Medicare benefits.

Findings

S/HMO II effects on utilization were modest, except for a small high-risk group.

S/HMO II members used more physician care and were more likely to use skilled nursing facility and home health care than were members of the traditional risk plan. There was no clear evidence that the S/HMO II reduced the rate of hospitalization in the overall study population. There did appear to be a significant reduction in hospital admissions in a very small sub-group of patients with histories of multiple prior hospitalizations. The evaluation found no effect of the S/HMO II on the probability of admission to a custodial nursing home stay although the small number of such admissions in both groups made detection of an effect very difficult.

There was no consistent evidence that the S/HMO improved health or functional status relative to HPN's Medicare risk plan.

The evaluation used 39 measures of self-reported health and functional status, including impairment in activities of daily living and in instrumental activities of daily living. Generally, there were few statistically significant effects noted. Although there were some modest indications of positive S/HMO II effects on performance of certain IADL functions such as meal preparation, housework, and management of finances, these trends were far too weak to conclude that S/HMO II members were better off than they would have been had they not joined the S/HMO II. Moreover, findings suggestive of a positive impact were offset by indications that the S/HMO II may have performed less effectively than the comparison groups in other areas such as self-reported improvement in health.

The quality of care provided by the S/HMO II was not clearly superior to that provided to other beneficiaries in the Southwestern United States.

Quality of care was assessed by examining the provision of routine preventive care, frequency of physician visits for persons with specified chronic conditions, and rates of hospitalization for enrollees with potentially avoidable hospital conditions. Overall, there was no evidence that the quality of care provided to S/HMO II enrollees was consistently better than care received by enrollees in other Medicare HMO's or by Medicare beneficiaries using traditional Medicare fee-for-service coverage.

Conclusion

There was no convincing evidence that outcomes for S/HMO II enrollees overall were better or worse than they would have been had the enrollees not participated in the S/HMO II. The only clear evidence of a possible effect was a reduction in hospital utilization in a very small sub-group of high-risk enrollees who had been hospitalized more than once before enrollment in S/HMO II. While these findings suggest that the S/HMO II model was ineffective, other factors may have contributed to the lack of significant findings. For example, the evaluation period may have been too short to demonstrate positive effects. It is also possible that S/HMO II services were directed at too broad a population and were not sufficiently focused on Medicare enrollees who would have benefited most.

Finally, study of the S/HMO model at additional sites would have been helpful in demonstrating any effects of the S/HMO II program. Although the demonstration was designed for not more than four additional projects, only one of the plans that were selected to participate actually implemented the program. As a result, the evaluation was limited to a single plan, an insufficient basis for reliable inferences about the effectiveness of the S/HMO II model.

PART 2: EVALUATION RESULTS FROM THE ESRD MANAGED CARE DEMONSTRATION.

Background

ESRD, or total kidney failure is fatal, unless the person is treated by dialysis, which artificially replaces the functions of the kidney, or kidney transplantation. Even with treatment, the health status of ESRD patients is diminished: the average hemodialysis patient spends approximately 14 days in the hospital and is prescribed about eight medications per year. Year-at-risk spending for all medical care (not just Medicare covered services) is more than $65,000 per hemodialysis patient. In the 1972 Amendments to the Social Security Act (P.L. 92-603, Section 2991), Congress extended full Medicare coverage to persons with ESRD, subject to minimal Social Security requirements, regardless of their age.

Under the Tax Equity and Fiscal Responsibility Act of 1982, Medicare beneficiaries with ESRD 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 S/HMO section, required CMS 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 Medicare ESRD patients. The intent was to see whether extension of an integrated system of care to ESRD beneficiaries was operationally feasible, efficient, and, most importantly, able to produce health outcomes as good as 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;

- ESRD-focused case management, with particular emphasis on improved outcomes of care;
- Preventive and supportive interventions and more comprehensive benefit coverage for ESRD patients; and,
- An ESRD payment and risk adjustment method specific to ESRD patients that, among other factors, incorporated cause of renal failure and treatment modality (dialysis or transplant).

The evaluation of the demonstration assessed many quality of care indicators, process measures and final outcomes for patients with comparison groups from randomly selected facilities and patients in the same state. The findings in the Report to Congress are summarized below.

Findings

Enrollee Characteristics:

- Beneficiaries who enrolled in the demonstration were younger, more likely to be male, of white race and had fewer co-morbid conditions, especially cardiovascular diseases.

Quality of Care and Outcome Indicators:

- Demonstration patients' survival 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 levels, after adjustment for patient differences, were similar in the demonstration and comparison groups.
- Clinical indicators in the demonstration patients, such as anemia management, dialysis adequacy, and vascular access rates, were the same as or better than comparison patients.
- Access to transplantation (as defined by being listed on a transplant waiting list and by likelihood of receiving a transplant) among beneficiaries at the Florida demonstration site (where the contracted transplant provider was 300 miles away) was substantially lower than such access among fee-for-service patients. The California site, which contracted with three local transplant centers, had transplantation rates indistinguishable from the comparison patients.

Patient Satisfaction and Quality of Care:

- Satisfaction levels with providers were high among patients in both Demonstration and FFS groups. However, 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 in mental well being.

Costs:

- Government expenditures for demonstration patients were higher than expenditures would have been if they had remained in FFS Medicare. The demonstrations' risk adjustment formula did not adequately compensate for the younger and healthier enrollees.

- Demonstration sites experienced financial losses (HOI) or only small gains (Kaiser). This finding should be viewed in the context of the rich benefit packages available in 1995 that the sites maintained throughout the demonstration.
- Medicare beneficiaries who enrolled reported much lower out-of-pocket medical expenses than under traditional FFS Medicare.

Conclusions:

Qualitatively, compared to ESRD beneficiaries in traditional FFS Medicare, the evaluation suggests that enrolling ESRD beneficiaries in the demonstration plans produced results similar to those that other studies have found from enrolling aged or disabled beneficiaries in M+C plans. First, younger, more male, and healthier patients chose to enroll. Quality of care and patient outcomes were similar to, and occasionally better than, FFS comparison groups after adjustment for differences in demographic characteristics and health status factors. Medicare payments to both the demonstration and M+C plans were higher than payments to FFS providers would have been because the younger and healthier enrollees required less medical care than the average comparison group beneficiary. Finally, both demonstration and Medicare M+C enrollees report satisfaction with access to care and quality of care under their plan. Demonstration patients report lower out of pocket expenses than under traditional FFS Medicare.

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.[i] 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[ii], 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[1] on hemodialysis and associated care is more than $65,000 per patient annually. [iii]

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.
- 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?

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

- Are there differences in transplantation rates between the Demonstration enrollees and other ESRD beneficiaries?
- How do Demonstration enrollees differ with respect to patient satisfaction and quality of life compared to FFS and non-Demonstration managed care beneficiaries?

To what extent do the HMOs provide care that is consistent with accepted standards of practice, such as meeting dialysis adequacy targets?

CMS awarded a contract to The Lewin Group to conduct the evaluation. The University Renal Research and Education Association (URREA) and the National Opinion Research Center were subcontractors and conducted parts of the analysis, including much the data collection and analysis. This report is based primarily upon their results. When it refers to the "evaluators" it includes staff from all organizations.

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, statewide 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 statewide average costs for ESRD patients (although costs of patients with Medicare as secondary payer were excluded since patients with a primary payer 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 modality 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 predictors 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 statewide 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. No analysis was performed on the limited amount of Xantus data collected.

The two remaining Demonstration plans offered distinct models of care **(Exhibit 1)**. The Florida (HOI) 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 California (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 by standardizing treatment patterns and opening a few Kaiser-owned facilities). 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. The Kaiser plan in California was able to "rollover" some of their existing ESRD patients into their Demonstration program.[2]

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 coinsurance 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 plans finalized their benefit packages during 1995 and maintained them unchanged throughout the demonstration, 1996-2000.

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

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

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 1** summarizes key structural and operational characteristics of the three Demonstration programs, Kaiser Permanente, Health Options, Inc., and Xantus HealthCare. The remainder of this report presents methods, results, and a discussion of the evaluation of the ESRD Managed Care Demonstration project.

Exhibit 1: Summary of Key Demonstration Characteristics

FEATURE	KAISER PERMANENTE (SOUTHERN CALIFORNIA)	*HOI (Southern Florida)*	XANTUS (CENTRAL TENNESSE)
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-PAYMENT AMOUNTS	***NONE***	***NONE***	***$70 MONTHLY PREMIUM AND $10 COPAYS (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 COPAY PER PRESCRIPTION.***
"EXTRA 5% "BEYOND SERVICES COVERED FOR REGULAR MEDICARE RISK ENROLLEES	***NUTRITIONAL SUPPLEMENTS, NO COPAYMENTS (ON VISITS & DRUGS), DENTAL, COUNSELING.***	***NUTRITIONAL SUPPLEMENTS, NO COPAYS, DENTAL, TRANSPORTATION, REHAB, EXPANDED FORMULARY.***	***NUTRITIONAL SUPPLEMENTS, PREVENTIVE SERVICES, TRANSPORTATION.***
OTHER SERVICES	***DURABLE MEDICAL EQUIPMENT W/ NO COPAY, VISION, OUT-OF-AREA COVERAGE.***	Home health services, dialysis in nursing home, home dialysis, out of network dialysis, health	***HOME VISITS, EDUCATIONAL SEMINARS, EDUCATIONAL***

		education.	***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 Appendix to 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, the goal was 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, to determine whether the group of patients who chose to enroll in the Demonstration was representative of the general ESRD population, and secondly, to account for these differences in the 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)[iv], and two matched samples of comparison patients:

Nationally Representative DOPPS Patients. Demonstration hemodialysis patients are 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 are 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 2)**.

[**] The Dialysis Outcomes and Practice Patterns Study is an international comparison of hemodialysis patterns of care and patient outcomes. It is directed by URREA, one of the evaluation subcontractors, with funding from a for-profit biotechnology company.

Exhibit 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.[v] 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. The presentation of the results is organized by topic area:

- **Enrollment Experience**
  - 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 Quality of Care Indicators**
  - Mortality. *Almost one quarter of hemodialysis patients in the U.S. die each year.*[vi] *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. *Hospitalizations are an important index of patient morbidity and source of economic costs, with inpatient costs comprising nearly 40 percent of total spending for dialysis patients.*[vii] *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, 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)*[viii] *and hospitalization.*[ix] *Inadequate dialysis dose (measured by a formula designed to assess the amount of blood cleaning during a dialysis session relative to the patient's tissue mass) 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 hemodialysis. 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.*[x] *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.*[xi] *(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. Demonstration patients were compared to 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.*[xii] *Patient QoL in the Demonstration was evaluated by: 1) comparing baseline QoL to a sample of representative hemodialysis patients from DOPPS and to matched samples of 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. Economic factors may also affect plan or patient transplant decisions: the transplant itself requires an expensive hospitalization of at least several days, but there are long term cost savings, as long as the graft remains functioning. 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.*[xiii] *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. *Based on the characteristics of Demonstration enrollees, the evaluation estimated enrollees' Medicare and Medicaid costs had they remained in FFS.*
- Financial Issues from the Patient Perspective. *The Demonstration plans' coverage of Medicare coinsurance and deductibles and of outpatient drugs were the top two reasons patients reported for enrolling in the Demonstration and we estimated the savings that accrued to patients as the result of such coverage.*
- Financial Viability from Sites' Perspectives. *Using data supplied by the plans on enrollees' use of services, the evaluation projected the Demonstration sites' financial gains or losses under this program.*

Highlights of results for each topic area are summarized below.

Enrollment Experience: 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 comorbid 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 3)**.

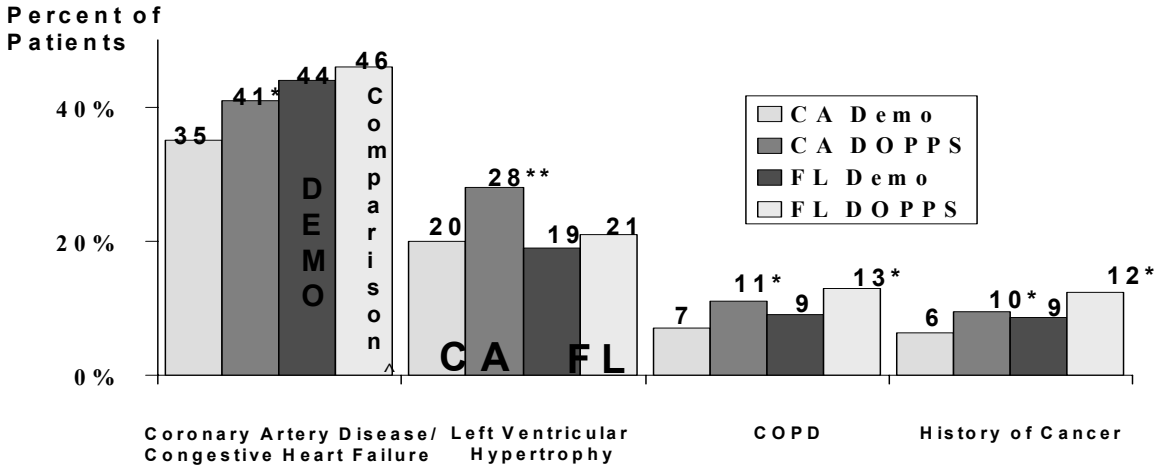
Exhibit 3: Example Demonstration and Comparison Group Demographic Characteristics

	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 education (%)	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 comorbidities (rates of illnesses and conditions such as coronary artery disease and cancer, shown in **Exhibit 4**) that predispose patients to mortality and adverse outcomes, than the patients who did not choose to join.

Exhibit 4: Example Demonstration and Comparison Group (DOPPS) Comorbid Condition Rates



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

Using information on demographics and comorbidities, a model was developed 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, one 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 (methods on the approach for accomplishing this can be found in the Appendix).

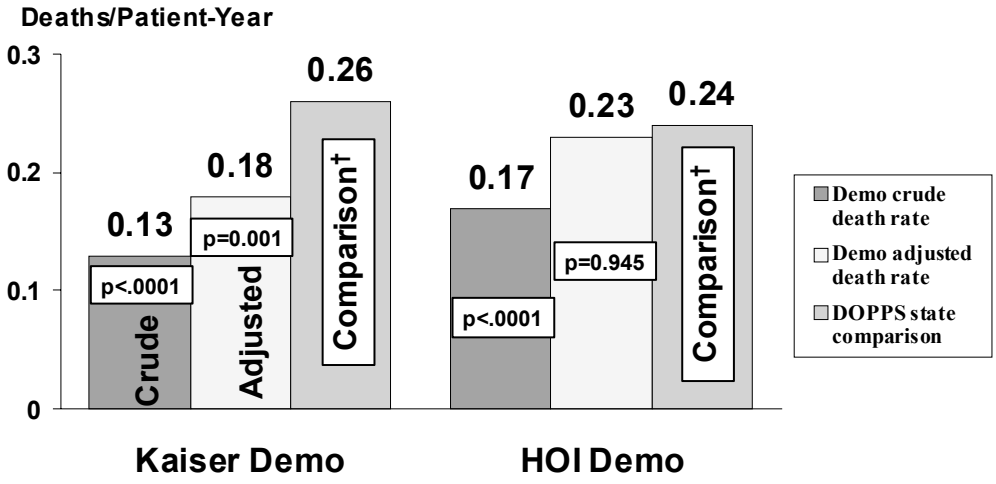
Clinical Outcomes and Quality of Care Indicators

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. The analyses indicate that patients at both Kaiser and HOI fared well on mortality measures. As shown in **Exhibit 5**, the Demonstration sites experienced 0.13 deaths (Kaiser) and 0.17 deaths (HOI) per patient-year[3] compared to the same-state DOPPS comparison groups, which experienced 0.26 deaths (CA) and 0.24 deaths (FL).

A large portion of this difference in death rates can be explained by differences in demographic and comorbid factors between the Demonstration, with younger and healthier patients, and the comparison patients (methods on adjustment to the crude rates can be found in the Appendix). 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.. The Kaiser enrollees adjusted mortality rate is .08 deaths per patient year at risk lower than the state-wide comparison sample, a reduction of 31 percent.

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



† The comparison for Kaiser is the California DOPPS sample and that for HOI is the 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).

[3] 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.

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 6**. The magnitude of the increase in hospital days that occurred from baseline (pre-Demonstration) to one year was greater for HOI (Florida) than for KP (California). 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 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 demonstration enrollee characteristics such as age, race, Hispanic ethnicity, congestive heart failure, hypertension, diabetes, and time with ESRD, 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 (methods on adjustment to the crude rates can be found in the Appendix).

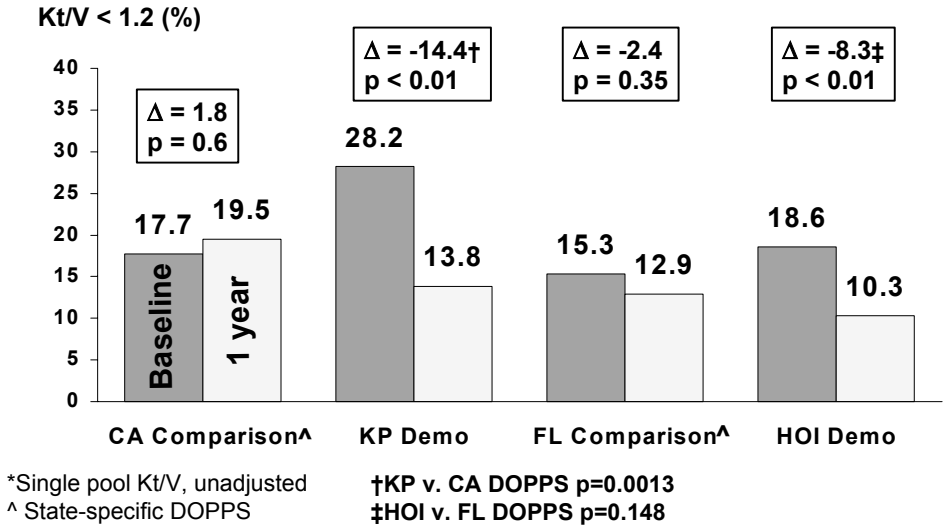
Anemia Management and Dialysis Adequacy

The evaluation 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. Demonstration patients at both sites had average HCT levels that remained well within the National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI) clinical practice guidelines (standard of care widely recognized by the nephrology community) of 33-36 percent target HCT for patients receiving Epoetin therapy.

Demonstration patients at both sites received an adequate dose of hemodialysis, as defined by the DOQI clinical practice 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 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 that of Florida DOPPS patients.

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



*Single pool Kt/V, unadjusted
^ State-specific DOPPS
†KP v. CA DOPPS p=0.0013
‡HOI v. FL DOPPS p=0.148

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.[xiv]
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 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 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.[xv] Patient QoL in the Demonstration was evaluated 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 (see the Appendix for details), 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 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 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***

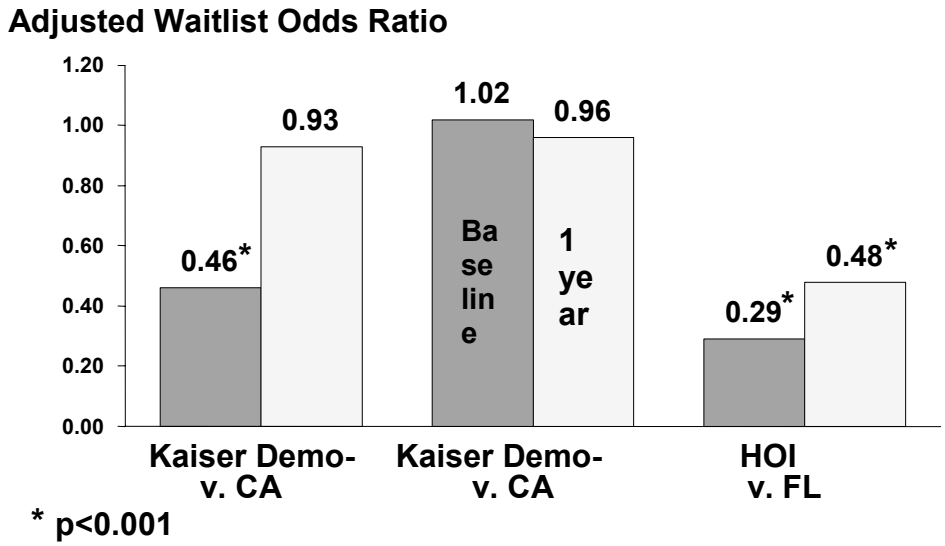
** A positive change indicates an improvement in the QoL indicator after one year of enrollment in the Demonstration.*

These results are striking because ESRD patients, due to the chronic nature of their illness, typically exhibit deteriorating quality of life over time. Indeed, in a sample of DOPPS patients, 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 10**). Only 10 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 10: Adjusted Transplant Waitlist Odds Ratio at Baseline and One-year: Demonstration versus California and Florida FFS Patients (All Dialysis)



The waiting time to transplant among patients who were waitlisted during the Demonstration period was analyzed. 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 40 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. Overall, HOI enrollees exhibited a 60 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

The evaluation examined patient satisfaction with services provided by their dialysis facility, dialysis staff, and primary care physicians under the Demonstration health plan. It 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. The 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 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 high, the FFS patients reported even higher satisfaction compared to Demonstration patients with respect to these services, e.g., 93.9% of FFS patients compared with 88.0% 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 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 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 11: Satisfaction with Plan Benefits

Measure of Satisfaction	Demo (Follow-up)	Matched FFS	Matched Non-Demo Managed Care
	(% Agreeing with Statement)		
Copayment/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 ‡

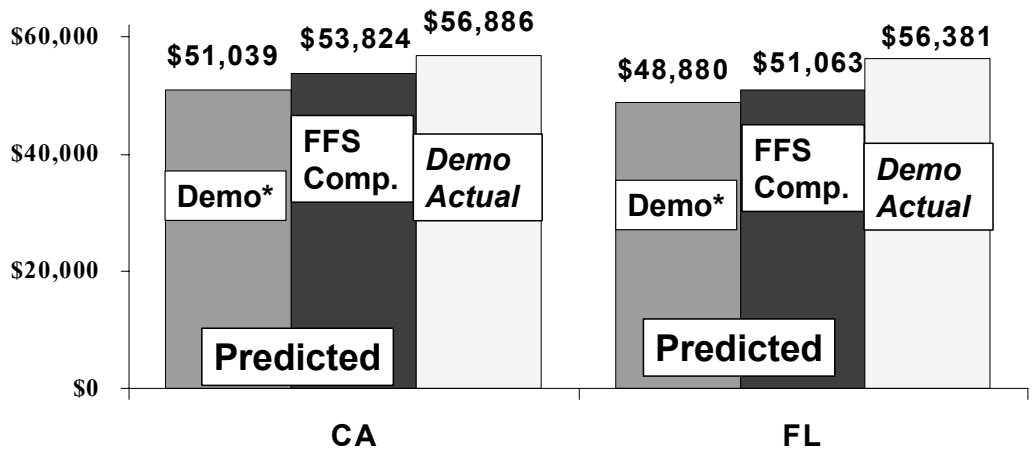
[§]A lower number indicates greater satisfaction.
^A higher number indicates greater satisfaction.
*p<0.01 †p<0.001 ‡p<0.0001 vs. Demonstration

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 (see the Appendix for methods). 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, the predicted Medicare payments for demonstration patients in California and Florida, had they remained in traditional Medicare, were 10.3 percent and 13.3 percent lower on average, respectively, compared to actual Medicare payments to the demonstration plans. 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 12)**.

Exhibit 12: <u>Predicted</u> versus Actual Average Medicare Spending per Patient Year: Demo v. Comparison, 1998-1999



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

There was also an impact on Medicaid spending resulting from the enrollment of dually-eligible ESRD patients in the Demonstration (see the Appendix for methods). Had these patients remained in FFS Medicare, Medicaid would have incurred costs associated with covering the patients' Medicare coinsurance and deductibles. For dual eligibles for whom the full package of Medicaid services is offered[4][xvi], 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. 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.

Financial Issues from the Patient Perspective

The 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 copayments.

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 coinsurance 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

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

enrollees, cost-share responsibilities would likely be 10-15 percent lower than for the average ESRD beneficiaries.)

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 in Section C.1 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 coinsurance 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, more male, 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.
- Access to transplantation (as defined by being listed on a transplant waiting list and by likelihood of receiving a transplant) among beneficiaries at the Florida Demonstration site (where the contracted transplant provider was 300 miles away) was substantially lower than such access among fee-for-service comparison patients. The California site, which contracted with three local transplant centers, had waitlisting and transplantation rates identical to the comparison patients.
- 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. This finding should be viewed in the context of the rich benefit packages (with low or zero patient copays or premiums) that were then offered by many Medicare Managed Care plans that are no longer available.

The 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, one predominantly a closed-practice HMO and the other a fee-based contracts plan.
- As with all closely monitored programs, there was most likely a "Hawthorne effect" that may have caused the Demonstration sites to perform better than if they had not been carefully scrutinized by the evaluators and CMS. The amount of this possible bias cannot be estimated.
- The Demonstration payment rates were designed to test a simple risk adjustment algorithm different from current or planned risk adjustment methods.
- Plan benefit packages currently offered by Medicare+Choice plans are far less generous than offered six years ago. The Demonstration plans charged neither copayments nor deductibles and included all outpatient prescription drugs.

- 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. This suggests that further testing of a capitated payment system for ESRD beneficiaries is warranted. Further testing of capitated

payment systems for ESRD beneficiaries could improve risk adjustment mechanisms for this population of vulnerable chronically ill patients.

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The findings can be simply summarized: Qualitatively, and in some cases quantitatively, the evaluation suggests that enrolling ESRD beneficiaries in the Demonstration plans produced results similar to those found by other studies of enrolling aged or disabled beneficiaries into M+C plans. First, younger, more male and healthier patients chose to enroll. Quality of care and patient outcomes were similar to, and occasionally better than, FFS comparison groups after adjustment for demographic and health status factors. Medicare payments to the Demonstration plans were higher than the expected payments would have been to FFS providers because the younger and healthier enrollees required less medical care than the average ESRD beneficiary. Finally, both Demonstration and Medicare M+C enrollees report satisfaction with access to care and quality of care under their plan, and, especially for the Demonstration patients, report lower out of pocket expenses than under traditional FFS Medicare.

APPENDIX: ANALYSIS SAMPLES AND METHODS

I. 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 were 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. The evaluators developed three data collection instruments. 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) 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[xvii]. 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[5]. 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 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

[5] Based on hemodialysis facility totals from the 1998 CMS Annual Facility Survey.

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 the 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 comorbidity 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.

Statistical Methods

Unless otherwise specified, hemodialysis patients enrolled in the Demonstration were compared to same-state DOPPS patients in California and Florida for all analyses. The full set of demographic and comorbid covariates adjusted for in many of the statistical models include: age, sex, race, Hispanic ethnicity, body mass index, coronary disease, congestive heart failure, other cardiac problems, hypertension, cerebrovascular disease, peripheral vascular disease, pulmonary disease, cancer (other than skin), diabetes, left ventricular hypertrophy, serum albumin, lives in nursing home, walks/transfers with assistance, and time with ESRD. All analyses were performed using SAS version 8.0[xviii].

Patient Selection

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. Predicted differences in expected mortality, a statement of mortality risk based on an index of comorbid factors[xix], were based on Cox proportional hazards[xx] 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), including in the model a full set of demographic and comorbid factors as covariates.

Mortality

Differences in survival between the DOPPS and Demonstration patients were evaluated using right-censored Cox models of time to death from start of ESRD. The right-censoring method removes patients at the end of follow-up or time of departure from the study if they did not have a death event. 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[xxi,xxii]. 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.

Hospitalization

Manually abstracted data were used in these analyses because of the comparability to the DOPPS data with respect to both the data source and method of data collection. Comparison to DOPPS patients is desirable because of the ability to adjust for demographic and comorbid factors. Unadjusted rates of hospital days per patient year at risk were calculated by summing the total inpatient days reported and dividing by the total time at risk for each subgroup. This was done at baseline and follow-up for Demonstration patients, and over the entire DOPPS study period for the DOPPS comparison patients. Poisson regression models were used to determine the relative rate of hospitalization at the time of follow-up for Demonstration patients versus DOPPS comparison patients, adjusting for the full set of baseline comorbid and demographic factors and death (since the risk of hospitalization dramatically increases prior to death).

Anemia Management and Dialysis Adequacy

Simple means, paired *t*-tests, logistic regression for the dichotomous variables and ordinary least squares regression 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 comorbid 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 comorbid factors might exhibit a greater drop in hematocrit than patients with fewer comorbid factors). In analyses of follow-up measures, baseline values were also included. Only patients who had baseline values and values at one year were included in the analysis because the effects of being included in the Demonstration were best analyzed as a difference over time. Measures on DOPPS patients were limited to those taken after 1998 in order to make them more comparable to the Demonstration patients, who began enrolling in February 1998.

Vascular Access

At time of enrollment and one year following, the vascular access in use for each patient in the Demonstration sample was recorded. The likelihood of fistula use was modeled using logistic regression methods. For any patient having a permanent access at Demonstration enrollment, the date of first observed access failure (i.e., clotting) during the one-year follow-up period was recorded. Data were collected in a similar manner for DOPPS comparison patients over time. Initial failure rates per patient year at risk were calculated by dividing the sum of the initial failures by the total time at risk and annualizing the result. Time at risk was defined as the earlier of the date of first failure or end of study period minus the enrollment date. Cox proportional hazards regression methods were used to calculate the relative risk of initial vascular access failure. Patients with less than one year of follow-up due to disenrollment or death were included in the time-to-first-failure analyses, having their time at risk censored at time of departure from the Demonstration.

Quality of Life

A Patient Questionnaire (PQ) containing the SF-36™ was administered to Demonstration patients at time of enrollment and one year later. A nearly 85 percent response rate among Demonstration enrollees was achieved. Differences in means for baseline QoL scores were tested using the *T* statistic. Statistical significance was interpreted at the 0.05 level for a two-tailed test. Multiple linear regression analysis was used to detect differences in the adjusted QoL scores between enrollment and one-year follow-up. Because patients were compared to themselves one year later, no additional adjustment factors were included in the regression models.

Transplant Access

Access to waitlist

Kaiser and HOI dialysis (hemo and peritoneal dialysis) patients who enrolled from Demonstration start through December 1, 1999 were compared to a cross-section of all dialysis patients in California and Florida known to have Medicare primary FFS insurance on January 1, 1998. 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 Demonstration patients at baseline versus Medicare FFS patients in the same state. This analysis was repeated at one year after the date of enrollment. Only patients 18 to 65 years of age were included in the comparisons.

Access to transplant

Kidney waitlist data obtained from the Organ Procurement and Transplantation Network (OPTN) were used to identify transplant centers within the Demonstration areas and their associated OPOs, as well as patient-level demographic and clinical measures at time of listing. The Demonstration sample for time-to-transplant analyses consisted of patients who were placed on a transplant waitlist at some point during their enrollment in the Demonstration. For comparison waitlisted patients in the same area, patients added to the waiting list on or after February 1, 1998 through May 31, 2001 were included. All patient factors used for statistical adjustment were collected at the time the patient was listed with the transplant center. More specifically, 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 California OPOs. For HOI, the comparison group included all patients listed with Jacksonville area transplant centers

during the study period. 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 chose to be listed for transplant.

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 Demonstration, death, or end of study (May 31, 2001).

Patient Satisfaction

A Patient Questionnaire (PQ) was used to assess patient satisfaction and quality of life. Because the DOPPS patients were not asked to report on patient satisfaction, a matched sample of non-Demonstration managed care (NDMC) and FFS patients were selected for comparison purposes (see detail on comparison samples above). The PQ was administered in-person by trained data collectors to Demonstration and matched comparison patients. The response rates for the PQ were 85 percent for the Demonstration patients at baseline, 84 percent for the Demonstration patients after one year in the Demonstration, and 98 percent for the comparison groups. Chi-square statistics were used to test differences in proportions between (1) the Demonstration group at baseline versus one-year follow-up and (2) the Demonstration group at follow-up vs. the matched FFS and NDMC groups. The Demonstration follow-up group was used in comparisons with the FFS and NDMC groups because the Demonstration patients would have a more accurate perception of their satisfaction with the Demonstration after one year rather than at baseline. Statistical significance was interpreted at the 0.05 level for a two-tailed test.

Financial Analyses

Pre-Demonstration spending rates for Demonstration enrollees on dialysis were calculated using paid claims generated by these patients while covered under Medicare FFS. For Demonstration 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. It should be noted that Kaiser rollover patients, having been in the Kaiser HMO prior to enrollment, would not have generated FFS claims prior to the Demonstration and were thus excluded from any pre-Demonstration cost calculations. Included in the comparison sample for Demonstration costs after enrollment were patients in California and Florida who were identified as being on dialysis and Medicare primary-insured on December 1, 1998 using CMS's Enrollment Data Base (EDB) insurance status information, in conjunction with established minimum cut-points for monthly spending on dialysis[xxiii]. Medicare FFS spending was modeled for these comparison patients (as the natural log of cost), varying according to age, sex, race, ethnicity, time with ESRD, modality (HD or PD), body mass index, time (in months), death, and the 20 comorbidities listed on the CMS 2728 form. Patient time at risk was censored at the earlier of December 31, 1998 or the date of death. Using the parameter

estimates given from these regression models, the predicted Medicare total FFS cost for each Demonstration patient was calculated by multiplying the individual patient values for each risk factor times the parameter estimates affecting cost. The average predicted total cost was calculated by exponentiating predicted log cost and taking the mean for all Demonstration patients. Predicted costs using the same model were also generated for the FFS comparison patients to validate the model as well as provide a more direct comparison to the predicted estimates for Demonstration patients.

The methodology for estimating Medicaid payments for Medicare cost-share responsibilities used two approaches. First, the actual number of person-years of enrollment of dually-entitled persons in each demonstration site was determined. In addition, the 20% copay associated with Part B services using the California-specific and Florida-specific statewide Part B ESRD payment rates was estimated. Using this methodology, it was estimated that Medicaid incurs, on behalf of dual eligibles, approximately $758 per eligible per month in Medicare cost-sharing expenses.[6] (It is important to note that states have some flexibility in how they comply 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 represent the *upper limit* of Medicaid spending for Medicare cost sharing and, in turn, Medicaid savings under the Demonstration.)

Additionally, CMS's Office of the Actuary provided an estimate of average cost-share responsibilities for ESRD patients in traditional Medicare. The Office of the Actuary's estimate of $500 per month was reduced 10 to 15 percent lower to account for the healthier status of the demonstration enrollees giving an estimate that Medicaid incurs between $425 and $750 per dual eligible per month in Medicare cost-share expenses.

Pharmacy costs were included in the assessment of Medicaid savings. For dual eligibles for whom the full package of Medicaid services is offered,[7] Medicaid also typically incurs expenses for certain non-Medicare-covered services, most notably prescription drugs. According to a recent study by the National Institute for Health Care Management, the average retail price per prescription is approximately $45. For the Demonstration patient, who averaged about eight prescriptions per month, this translates to a prescription drug cost of $360 per month. Certainly, the costs to Medicaid would be lower because of the discounts and rebates it receives from drug manufacturers; pharmacy costs to Medicaid of $200 to $300 per ESRD recipient per month were assumed.

Annual statements of expenses and revenues related to the ESRD Demonstration only (as opposed to information on other HMO lines of business or the health plan as a whole) were obtained from each of the two Demonstration sites. Sites were asked to record

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[6] 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% copayments 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 copayments (about $758 per month).

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

CMS capitation revenue, medical expense information by major category of service, and administrative expenses for the overall Demonstration.

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