NEFROLOGIA. Vol. XIX. Número 3. 1999

ARTICULO ESPECIAL

Medicare's end-stage renal disease program: current status and future prospects

A. R. Nissenson* and R. A. Rettig**

*Professor of medicine and director of the dialysis program at the University of California, Los Angeles. He recently completed service as a Robert Wood Johnson Health Policy Fellow of the Institute of Medicine (IOM) and is the president-elect of the Renal Physicians Association. ** Senior Social scientist at the RAND Corporation in Washington, D.C. He was a member of the professional staff at the IOM from 1987 to 1995 and was the study director for the IOM committee report, Kidney Failure and the Federal Government (National Academy Press, 1991).

On 30 october 1972 President Richard Nixon signed the Social Security Amendments of 1972, one provision of which extended Medicare coverage to persons with chronic renal failure. That amendment became effective 1 july 1973. The summer of 1998, therefore, marked a full quarter-century during which the U.S. government, through Medicare, has financed the treatment of nearly all Americans with permanent kidney failure through the end-stage renal disease (ESRD) program.

The criteria for eligibility for ESRD treatment under Medicare were that a person be «fully or currently insuded» under Social Security; have a diagnosis of chronic renal failure; and have applied for benefits or be the «spouse or dependent child» of such a person[1]. The original statute was written for those who «had not attained the age of 65», but the Social Security Administration (SSA) extended the benefit to chose age sixty-five and older, and a 1978 amendment removed any reference to age.

The ESRD entitlement is as close as anything in American medicine to a universal entitlement, with approximately 92-93 percent of the U.S. population eligible to receive it[2]. Congress justified this near-universal, disease-specific entitlement partly in the expectation that some form of national health insurance would be adopted in 1973-1974[3].

In this paper we summarize the major developments in the ESRD program over the past twenty-five years. We also describe and analyze the forces now acting on the program and indicate in what direction it is headed, if no changes take place. Finally, we discuss the challenges confronting the program and suggest some areas for consideration by policymakers that could strengthen it while constraining its costs.

Data sources. No single, reliable longitudinal data set exists for the entire twenty-five-year period of the ESRD program. From 1973 through 1978, when administrative responsibility for the program was divided between the SSA's Bureau of Health Insurance and the Public Health Service's Bureau of Quality Assurance, the data were generally poor[4]. ESRD data greatly improved in 1979, following the creation of the Health Care Financing Administration (HCFA), which has published a series of data reports more or less annually, the most recent in 1998[5].

The quantity of quality of data increased again after 1988, when the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD) established the U.S. Renal Data System (URSRD). This secod data system was estabiched to collect and analyze information on the incidence and prevalence of kidney failure and its associated morbidity and mortality, thus going beyond the HCFA data in scope and depth. The USRDS has published a series of annual data reports beginning in 1989 (the most recent in 1998), as well as a number of special studies[6]. ESRD data are arguably the best Medicare data that exist and include reimbursement, clinical and mortality data, which can be used for extensive analyses of both medical and economic questions.

Patient population. During the twenty-five years of the Medicare kidney entitlement, the ESRD patient population has increased more than twenty-fivefold, from approximately 10,000 persons in 1973 to nearly 284,000 at the end of calendar year 1996 (Exhibit I). In 1996 patients age sixty-five and older constituted one-third of all patients and nearly half of all new

Correspondencia: Richard A. Rettig Ph D
RAND Corporation
1333 Street NW
Washington DC
20005-4707

Exhibit I. Characteristics Of Medicare End-Stage Renal Disease (ESRD) Patients, By Age, Sex, Race and Primary Diagnosis, 1996

	Prevalence on 12/31/96			Incidence during 1996		
Characteristic[a]	**Count (n)[b]**	**Percent of total**	**Rate per milion[b]**	**Count (n)[b]**	**Percent of total**	**Rate per million[b]**
Age 0-19	5,180	1.8%	64	1,129	1.5%	13
Age 20-44	73,734	26.0	692	12,622	17.3	117
Age 45-64	109,834	38.7	2,280	25,417	34.8	542
Age 65-74	58,549	20.6	3,518	19,456	26.6	1,144
Age 75+	36,635	12.9	2,715	14,467	19,8	1,079
Female	130,551	46.0	883	33,835	46.3	225
Male	153,381	54.0	1,233	39,256	53.7	325
Asian/Pacific Islander	9,863	3.5	1,291	2,408	3.3	354
Black	91,580	32.3	3,404	21,808	29.8	829
Native American	4,504	1.6	2,761	1,279	1.7	817
White	173,443	61.1	754	46,102	63.1	199
Other/unknown	4,542	1.6	–[c]	1,494	2.0	–[c]
Diabetes	92,211	32.5	339	30,933	42.3	113
Hypertension	69,538	24.5	256	18,844	25.8	70
Glomerulonephritis	50,378	17.7	185	7,882	10.8	29
Cystic kidney disease	13,454	4.7	50	1,796	2.5	7
Total	283,932	100.0	1,041	73,091	100.0	268

Source: Reprinted from U.S. Renal Data System, *USRDS 1998 Annual Data Report* (Bethesda, Md: National Institutes of Health, National Institute of Diabetes and Kidney Diseases, 1998).
Note: Counts and rates do not include patients from Puerto Rico or U.S. territories.
[a]Patients with other or unknown race are excluded from rate analysis. Other urologic, other, unknown, and missing causes of ESRD are included in the total but are not shown.
[b]Rates are adjusted for age, sex, and race. Rates are computed relative to the corresponding population for age, sex and race results. Preliminary.
[c]Not available.

patients; a large proportion —In percent of all patients and 20 percent of new patients— were over age seventy-five. Black patients accounted for one-third of all patients and 30 percent of new patients; white patients, slightly more than 60 percent of the totals. The three primary diagnoses to which permanent renal failure is attributed are diabetes mellitus, hypertension and glomerulonephritis.

The ESRD patient population has changed considerably over time. It is characterized by increasing age, a much greater rate of kidney failure among African Americans than among whites, a marked increase in diabetes and hypertension as causes of renal failure, and medical comorbidities that are both more frequent and more severe. The annual rate of increase during 1989-1994 was 6 percent for new fifty-five-to sixty-four-year-old patients; 9 percent for sixty-five-to seventy-four-year-olds; and 12 percent for those age seventy-five and older[7]. The rate of new black ESRD patients in 1994 was 558 per million population, compared with 195 per million for whites. Diabetes mellitus was usually a contraindication to treatment in 1973; today it is the leading cause of ESRD, accounting for 38 percent of new patients. Although the 1989-1994 changes in rates of kidney failure have slowed somewhat compared with 1986-1991, they remain dramatic and relentless.

In-center hemodialysis continues to be the most prevalent mode of dialysis, with peritoneal dialysis performed at home accounting for 15-17 percent of dialysis patients. This is quite different from the situation in some countries, where peritoneal dialysis is used more extensively, primarily because of reimbursement policies[8]. Home hemodialysis has almost disappeared in the United States, although new technological developments may reverse this trend[9].

There are no direct measurements of ESRD patients' income, but the economic consequences of kidney failure are very severe. Moreover, a disproportionate share of ESRD patients are drawn from minority populations known to have a higher-than-average incidence of poverty. Michael Klag and colleagues reported recently that lower income is as great a risk factor for ESRD as high blood pressure is among African American male ESRD patients[10].

MEDICARE ESRD EXPENDITURES

ESRD patients, who constitute half of 1 percent of the Medicare beneficiary population, consume 5 percent of all Medicare expenditures (Exhibit II). Medicare-only expenditures for persons with ESRD rose from $5.7 billion in 1991 to $8.1 billion in 1995[11]. Total national ESRD expenditures were $13.1 billion in 1995 and $14.6 billion in 1996[12].

HCFA data indicate that dialysis patients accounted for nearly 80 percent of all Medicare ESRD expenditures in 1991. For dialysis patients, inpatient expenditures represented 40 percent of total costs for this patient group. Transplant patients accounted for just over 20 percent of all Medicare ESRD expenditures in 1991. For transplant patients, inpatient expenditures represented a much greater percentage of total costs for this group, because of the procedure-heavy nature of transplantation services. In aggregate, in-patient expenditures for all ESRD beneficiaries hovered around 45 percent of total program expenditures from 1986 to 1991[13]. Medicare spending per beneficiary per year ranged from $36,000 for those age twenty-four and younger to $51,000 for those age seventy-five and older; this reflects increasing disease severity and comorbidities among older patients and a correspondingly greater need for in-patient care. An additional $9,000-$13,000 per patient per year is paid for by other insurers or by patients themselves.

Exhibit II. End-Stage Renal Disease (ESRD) Medicare Beneficiaries And Program Expenditures, Millions Of Dollars, Fiscal Years 1974-1999

Fiscal year	Expenditures, Parts A and B	Number of beneficiaries, Part A only	Expenditures per person
1974	$229	15,993	$14,319
1975	361	22,674	15,921
1976	512	28,941	17,691
1977	641	35,889	17,861
1978	800	43,482	18,398
1979	1,010	52,636	19,188
1980	1,250	55,509	22,519
1981	1,472	61,930	23,769
1982	1,651	69,552	29,738
1983	1,994	78,642	25,355
1984	2,336	87,929	26,567
1985	2,824	97,200	29,053
1986	3,159	106,633	29,625
1987	3,475	116,937	29,717
1988	3,909	127,487	30,662
1989	4,601	139,132	33,069
1990	5,093	152,541	33,388
1991	5,654	164,354	34,401
1992	6,124	174,454	35,104
1993	6,662	184,257	36,156
1994	7,266	194,201	37,415
1995	7,960	204,310	38,960
1996	8,754	214,564	40,799
1997	9,617	224,926	42,756
1998	10,580	235,351	44,954
1999	11,657	245,806	47,424

Source: Office of the Actuary, Health Care Financing Administration, Department of Health and Human Services, for fiscal years 1979-1999. Reprinted from 1994 *Green Book,* Committee on Ways and Means, U.S. House of Representatives.
Notes: Estimates for 1979-1999 are subject to revision by the Office of the Actuary, Office of Medicare and Medicaid Cost Estimates. Projections for 1994-1999 are under the FY 1995 budget assumptions.

COST CONTAINMENT POLICIES

High spending for a relatively few ESRD beneficiaries, in the context of overall Medicare financing issues, guarantees that short-term cost containment pressures will remain severe in the ESTD program. The growth of the ESRD patient population has been the primary driver of increasing expenditures, and total ESRD program costs have been the main driver of policy. These facts highlight and inescapable dilemma for Medicare policymakers: The are obligated under the law to finance care at the same time that they must give constant attention to cost containment. These facts also suggest that the longer-term issue of limiting access to care cannot be avoided indefinitely[14].

Cost containment has been an integral part of the ESRD program since its inception. It was once hoped that kidney transplantation might contain costs by capturing an increasing proportion of new ESRD patients. Although U.S. transplant rates are among the highest in the world, the shortage of organs and the rapid growth in the number of new ESRD patients have long since eliminated that hope. In 1997 slightly fewer than 12,000 kidney transplants were performed, bur slightly more than 50,000 new ESRD patients enrolled in treatment[15]. The ESRD program in mainly a dialysis program.

«Component capitation». Medicare ESRD cost control has focused on a few basic strategies. The primary one might be called «component capitation». Payment for facility outpatient dialysis was capped at a uniform flat of $138 per treatment in 1973-1983 and from 1983 onward by a «composite rate», a blend of home and center dialysis rates adjusted for wage and area differences. The composite rate initially averaged $129 and then fell to $126. These rates have never been adjusted for inflation, unlike the rest of Medicare. Using a conservative deflator, the 1993 payment, for example, was roughly thirty

cents on the 1974 dollar [16]. Hospital-based outpatient dialysis was paid at an estimated $159 per treatment before 1983, much higher than in independent units. The differential fell when the composite rate was introduced.

Payment for physician outpatient dialysis services also has been capitated and only recently was placed in the Medicare resource-based relative value scale (RBRVS) system. Payment for inpatient physician services follows more traditional Medicare patterns but is scrutinized closely by HCFA. Since 1983 the hospital charge for inpatient dialysis has been included in the diagnosis-related group (DRG) billed, rather than being reimbursed separately.

Bundling. A second strategy used by HCFA over time has been to bundle once separately billable services (for example, electrocardiograms) into the composite rate. Thus, providers are forced to do more with fewer resources. As a consequence of ESRD cost-control efforts, dialysis facilities have been squeezed tremendously. Highly trained staff, such a registered nurses (RNs), are being replaced by less well trained persons at lower cost; reuse of dialysis filters is another economizing strategy adopted in response to capped payment; and old, outdated equipment is replaced only gradually[17]. The question, for which no easy answer exists, is the extent to which these Medicare strategies have, at the margin, provided incentives for efficiency or for shaving quality.

Cost shifting. A third strategy has involved shifting costs to the private sector. In the 1980s Congress amended the Medicare statute to require that employer-group health plans whose beneficiaries experienced kidney failure be the primary payer for the first twelve months of ESRD care. Implemented in the mid-1980s, this Medicare-as-secondary-payer (MSP) policy was extended to eighteen months in 1990. The Balanced Budget Act (BBA) of 1997 extended the MSP period to thirthy months. Both Congress and the administration have favored this cost-shifting policy.

The nephrology community has usually supported this MSP policy because private insurers generally have reimbursed dialysis at a higher rate than Medicare has, and the blended reimbursement from Medicare and private payers has been reported as the key to economic survival for many dialysis units. This cost-shifting strategy has worked largely because private insurers do not track expenditures for ESRD patients carefully, relying on traditional diagnosis and procedure codes for managing costs and paying limited attention to low-incidence diseases. However, the thirty-month extension of the MSP policy may change this as private payers are presented with a larger ESRD treatment bill. They may begin to resist paying more for dialysis services than Medicare does.

Focus on one cost element. Finally, HCFA has sought at times to control ESRD program costs by focusing on a rapidly growing element of the total cost structure, as it tried to do in 1997 with respect to erythropoietin (epoetin alfa). One of the most important clinical developments in the treatment of dialysis patients in the past decade has been the availability of recombinant human erythropoietin (rHuEPO), a bioengineered form of erythropoietin that improves the anemia that is present in the vast majority of dialysis patients. The naturally occurring form of this hormone normally is produced in the kidneys of healthy persons but is lacking in patients with kidney failure. In June 1989, rHuEPO, produced by Amgen, was approved by the Food and Drug Administration (FDA) for the treatment of anemia in dialysis patients and was approbed as a coverage drug by HCFA the following month[18]. Improvement of anemia by rHuEPO treatment has led to better survival, fewer hospitalizations, and an improved quality of life for dialysis patients[19]. However, it adds substantially to Medicare expenditures for ESRD patients. Facilities now receive direct reimbursement on a per unit administered basis, and the average dialysis patient receives about 16,500 units per week[20]. The current estimated annual cost to HCFA is close to $1 billion.

HCFA sought to limit expenditures for rHuEPO en 1997 by issuing a policy that denied payment when patient hematocrits (a measure of the percentage of red blood cells in total blood) exceeded 36.5 percent, based on a three-month rolling average. Moreover, the policy did not allow for appeals on medical justification grounds. So in pursuit of cost containment objectives, HCFA inserted itself into clinical practice[21]. Furthermore, it did so after the National Kidney Foundation (NKF) issued evidence-based guidelines that recommended a target hematocrit range of 33-36 percent. For the mean hematocrit in a population of patients at a dialysis facility to be in this target range, a significant humber of patients in any given month would exceed the trigger for nonpayment, merely because of the known biological variation in hematocrit values from to month. To avoid a nonpayment, patients were receiving lower doses of rHuEPO than they needed, and the number of patients reaching the desired target hematocrit began to fall. After analyzing its own data and being pressured by representatives of several renal community organizations and by concerned members of Congress, HCFA not only rescinded the 1997 regulation but issued new gui-

dance to intermediaries and carriers that endorsed the 33-36 percent target range and the NKF guideline; raised the audit triggering level to 37.5, based on a 90 percent rolling average reviewed after the fact (payment was no longer withheld); reinstated the rule that medical justification for a higher hematocrit was required if the higher hematocrit was to be maintained in a particular patient[22].

«Cruise control» of payments and costs —that is, setting a nominal payment rate and letting inflation erode its real dollar value over time— provides a strong incentive to efficiency, especially when reinforced by stable expectations of adherence to a steady course. When punctuated by real reductions in the payment rates, as occurred in 1982-1983 and was attempted in 1986, political considerations come to the fore. When more and more services are bundled into the basic rate, dialysis units are stretched severely in their capacity to respond. Cost shifting becomes attractive for the blended rate effect. Some may liken this phenomenon to the pricepower experience with computers, but it is worth remembering that dialysis treatment is a highly labor intensive service, not simply a technological product.

MANAGING AND MEASURING QUALITY

The fundamental problem created by Medicare's reimbursement policies and cost containment efforts is their impact on the quality of dialysis services. The dominant role of federal financing of ESRD care has resulted in continuing claims that reimbursement policies have jeopardized quality. A 1991 Institute of Medicine (IOM) report found a «suggestive but not conclusive» relationship between reduced reimbursement and increased mortality and hospitalization. It also documented a relationship between reduced reimbursement and changed unit staffing, especially the substitution of technicians for RNs. However, this association was not associated with increased mortality or hospitalization[23]. The difficulty of documenting the relationship between payment and quality has been reinforced by the absence of good measures of quality as well as by HCFA reimbursement officials' general indifference to this problem.

Although the conceptual bases for evaluating quality are clear —outcomes of care, processes affecting outcomes, patients' preferences and satisfaction, and cost— considerable uncertainty surrounds measurement in any given clinical setting, as well as how best to convey information about quality to providers, payers and patients. This uncertainty applies to the ESRD program as well, although progress has been made, as described below[24].

Mortality and morbidity. ESRD providers traditionally have defined quality in clinical measures. The outcomes of kidney transplantation, for example, have been almost exclusively patient survival and graft (that is, the transplanted kidney) survival. Although the literature shows that the quality of life of transplant patients, in general, is better than that of dialysis patients, such data are not systematically collected for transplant patients. So the result of research about some transplant patients has hardened into an unmeasured conviction about all such patients.

Quality measurement in dialysis has emphasized mortality and morbidity (usually measured by hospitalization). More recently, several biochemical markers related to morbidity and mortality have emerged as process or proximate outcome measures affecting patient outcomes, including delivered dose (or «adequacy») of dialysis, hematocrit (level of anemia), and albumin (nutritional status). The introduction of rHuEPO to treat anemia in dialysis patients was explicitly justified on quality-of-life grounds and was later shown to affect mortality and hospitalization.

Unadjusted dialysis mortality rates were stable during 1978-1982; they increased abruptly from 1982 to 1983 and continued upward during most of the 1980s. However, when HCFA data from 1983 onward were adjusted for age, race and sex, mortality rates were very stable[25]. The shift in unadjusted mortality coincided with a 1983 change in reimbursement policy and with publication of the results of the National Cooperative Dialysis Study (NCDS), which showed that patients with a lower time-averaged blood urea concentration had better outcomes than those with a higher value[26]. Although some providers argued that HCFA payment policy was driving mortality rates upward, it is now believed that misinterpretation of both the original NCDS findings and the subsequent mechanistic analysis of the NCDS resulted in changes in clinical practice that led to poorer patient outcomes[27].

Survival of ESRD patients has improved steadily in the 1990s. In 1995 the USRDS found «an overall decline in mortality since 1983 for all ESRD patients, for dialysis patients and for transplant patients», further documenting a trend it had reported in its 1993 and 1994 reports[28]. The most recent USRDS analysis documents a 17 percent overall decline in mortality for dialysis patients in 1997 compared with 1989[29]. This improvement in survival has occurred

amid a significant increase in older, sicker patients being placed on dialysis and continuing deterioration of the reimbursement rate[30].

The conflict between payment levels and quality continues. Certain biochemical markers are now known to predict poor outcomes in dialysis patients. These include a low dose of delivered dialysis, severe malnutrition as measured by serum albumin, and severe anemia. However, current reimbursement policy is not designed to assist clinicians in these areas. For example, there is no differential payment for longer dialysis treatment that might be required in some patients, since longer treatment is more costly to provide. Nor is there any reimbursement for nutritional supplements in ESRD patients, even though poor nutrition is a major risk factor for mortality in this population.

Evidence-based medicine in ESRD. Over time, measured quality of care within the ESRD program has improved, as indicated by the USRDS mortality data and by HCFA Core Indicators data. The latter includes information on hematocrit, albumin and dose of dialysis in a sample of dialysis patients; two of the three indicators (hematocrit and dose) have improved steadily over the time that the project has been collecting data. Further improvement in quality in the ESRD program is likely with the application of evidence-based medicine to the care of ESRD patients.

The nephrology community has also developed several clinical practice guidelines to assist clinicians who care for ESRD patients. The Renal Physicians Association (RPA) published the first such guideline on adequeacy of hemodialysis in 1993[31]. This was followed by the National Kidney Foundation-Dialysis Outcomes Quality Initiative (NFK-DOQI) project, which developed four practice guidelines on adequacy of hemodialysis, adequacy of peritoneal dialysis, vascular access management, and anemia treatment[32]. A fifth guideline on renal nutrition is currently being developed[33].

Furthermore, the BBA requires the secretary of health and human services (HHS) to develop a method to measure and report the quality of Medicare's renal dialysis services. HCFA is funding a project, awarded to ProWest, a peer review organization in Washington State, to develop a limited number of clinical performance measures from the NKF-DOQI guidelines[34]. The RPA and the American Society of Nephrology (ASN), working with other renal community organizations, recently published a plan to assist local practitioners to implement the NKF-DOQI clinical practice guidelines[35].

Quality of life. There have been extensive efforts in recent years to develop and promote health status measurement instruments for clinical use in dialysis. Several general quality-of-life instruments provided a base for these efforts, and clinical nephrologists have begun using them[36]. As experience grows, the criteria for assessing functional status results as a performance measure will be clarified, the limited clinical correlations with clinical outcomes already realized can be expected to increase and become accepted clinical knowledge, and the scope of ESRD patient assessment will routinely include patient-reported information because it is clinically useful.

The active promotion of ESRD patient rehabilitation has also occurred in the past five years with the knowledge but not the financial support of Medicare. These efforts have included an invitational competition for exemplary programs, a strong emphasis o physical exercise, and the development of health status-based measurement instruments of renal rehabilitation.

Community-driven quality improvement: ESRD Networks. Congress authorized ESRD Networks in 1978 to provide regional oversight for Medicare-approved dialysis and transplantation facilities. The initial thirty-four networks were later consolidated to eighteen and are now funded at $11 million annually[37]. The funds are derived by withholding fifty cents per treatment from the payment to the dialysis facility. Each network collects and manages data on Medicare ESRD patients that are provided through HCFA to the USRDS for its annual data report and special studies. The national Forum of ESRD Networks facilitates the exchange of information among the networks, renal community, and HCFA and promotes improved quality of care through education and data collection, analysis, and dissemination.

ESRD Networks also promote quality improvement in the nearly 3,300 U.S. dialysis facilities. In 1997-1998, for example, each network initiated a quality improvement project, with topics ranging from adequacy of dialysis to hepatitis B vaccination to managing anemia. Although hampered in the past by uncertain funding, lack of standardized information systems, and a continually changing scope of work, the networks have enhanced the ability of the nephrology community to monitor and improve the quality of its services.

The RPA, ASN and network forum are leading an effort to implement a quality improvement strategy in the ESRD program, with participation by the American Nephrology Nurses Association and the National Renal Administrators Association, with likely participation by the NKF, the American Association of Kidney Patients, and the American Kidney Fund[38]. This plan, based on the President's

Advisory Commission on Consumer Protection and Quality in the Health Care Industry, aims to decrease the burden of chronic renal disease while increasing the health and functional status of persons with ESRD. It will rely on an information infrastructure that expands and improves current quality measurement and reporting. To the extent possible, evidence-based clinical practice guidelines will inform the process. This plan, well suited to a public/private partnership, is now seeking funding. Finally, increasing emphasis is being placed on continuous quality improvement in dialysis facilities, in an attempt to improve outcomes. However, such programs are costly in staff time and resources, particularly computer systems, and no additional funds have been made available to the facilities to carry out these critical activities.

THE PRESENCE CONTEXT AND ITS IMPLICATIONS

Workforce issues. Current trends in recruiting and training new nephrologists, coupled with the projected growth in the ESRD patient population, indicate a critical shortage of nephrologists by 2010[39]. The current ratio of one nephrologist for every forty to sixty ESRD patients will increase to one nephrologist for up to 120 patients. A growing number of advanced practice nurses (nurse practitioners and clinical nurse specialists) are now being trained to help meet this shortage. Overall, the number of nurse practitioners has increased 47 percent since 1992, and nurse practicioners' roles are being developed in nephrology programs to help maintain high-quality care in ligh of nephrologists' increased patient loads[40].

Industry consolidation. The number of ESRD facilties in the United States continues to grow. Between 1996 and 1997 the number of treatment units grew by 341 to a total of 3,423 ESRD providers, including freestanding and hospital-based dialysis units, transplant centers providing dialysis services, and centers providing transplant care only (Exhibit III)[41]. As of june 1998 there were 3,470 ESRD providers[42]. HCFA has interpreted this growth as evidence that payment rates are adequate. A different interpretation is that rates are adequate only for those dialysis units that are affiliated with large for-profit chains.

This appears to be the case. The lion's share of outpatient dialysis is supplied by for-profit treatment units. At the end of 1993, 56 percent of freestanding facilities were for-profit ventures. At the end of 1997 the percentage was 65.1 percent. The number of hospital-based for-profit units increased only slightly, from 1.4 percent to 2.7 percent, reflecting slow growth in these units in general[43].

As the patient population has grown, the number of dialysis facilities also has increased, most being proprietary units that are part of large chains. Fresenius Medical Care, a vertically integrated company with its own manufacturing and clinical laboratory division, owns more than 700 treatment units worldwide and treats more than 20 percent of all U.S. dialysis patients. Total Renal Care recently merged with Renal Treatment Centers to become the largest «pure play» renal dialysis company, treating nearly 30,000 patients in approximately 420 facilites in thirty-three states[44]. Other major chains include Gambro Healthcare, Renal Care Group, and Dialysis Clinics Incorporated[45].

The continued profitability of large for-profit dialysis chains financed mainly from the public sector, which provides an attractive and stable return for investors, creates an understandable resistance among policymakers to increasing reimbursement rates. Clearly, however, the financial pressures on smaller chains and individually owned units make their continued profitability questionable. The escape hatch for smaller units remains to sell to the chains, at $25,000 to $40,000 per patient. U.S. payment policy thus may be driving dialysis providers into larger corporate entities. Although industry consolidation may allow for greater efficiencies in

Exhibit III. Increases In End-Stage Renal Disease (ESRD) Facilities, 1993-1997

Type of facility	1993	1994	1995	1996	1997
Total providers	2,506	2,640	2,863	3,082	3,423
Freestanding dialysis facilities	1,646	1,795	2,000	2,212	2,506
Hospital-based dialysis units	626	609	627	633	673
Hospitals providing					
Transplantation and dialysis services	170	168	163	156	160
Transplantation care only	64	68	73	81	84

Source: Reprinted from *Nephrology News and Issues* (July 1998), with permission.
Note: Figures are as of the end of each year shown.

service delivery and collection and analysis of outcomes data, the resulting trade-off may be reduced physician and patient choice and autonomy.

PROSPECTIVE COST CONTAINMENT STRATEGIES

Capitation. The capitation of all ESRD patient care, not just outpatient dialysis, is being evaluated now in a HCFA demonstration project required by the Omnibus Budget Reconciliation Act (OBRA) of 1993. In 1994 RAND published a report that discussed the important issues to consider when developing an ESRD capitation program and presented a basic methodology to determine a capitation payment[46]. Although criticized for a number of limitations, the RAND study became the basis for the current HCFA ESRD Global Capitation Demonstration Project[47]. The purpose of the demonstration is to determine if high-quality ESRD care can be delivered in a globally capitated payment system. HCFA will pay demonstration providers a capitated rate equal to 100 percent of the adjusted average per capita cost (AAPCC) (for ESRD patients), but awardees will be required to provide additional services not covered by Medicare, including health education, prescription drugs, nutritional supplements, and transportation. The demonstration sites are southern California (Kaiser Permanente), Nashville (Phoenix Healthcare), and southern Florida (Health Options). Enrollment has been extremely slow to date (slightly more than 400 patients enrolled), which calls into question the probable benefit of the demonstration[48]. Capitation could alter many of the dynamics of ESRD care, including patient flow, financial incentives to providers, access to care, and definition and monitoring of quality of services[49].

New approaches to coordinating care for ESRD patients are emerging rapidly in the private sector[50]. Several disease management organizations have formed and are seeking to contract with managed care organizations (MCOs) for the financial risk and clinical responsaiility for managing ESRD patients. Because nearly half of the cost of ESRD patients are attributable to inpactient care, the greatest opportunity for improving quality and constraining costs lies here: Vascular access complications, unexpected congestive heart failure of hyperkalemia, and uncontrolled diabetes account for most hospital days, and all can be minimized by careful, prospective care management.

Managed care. ESRD patients are the only Medicare beneficiaries now prohibited from joining a managed care plan. In spite of this, it is estimated that nearly 16,000 ESRD patients are enrolled in MCOs, who developed ESRD while in the plan or who belong to Medicare risk programs. It is likely that this number will continue to grow rapidly with extension of the MSP to thirty months and the continued rapid growth of Medicare risk programs. As experience with global capitation, managed care and disease management accumulates, there will be increasing pressure on Congress to allow ESRD patients to join managed care plans. Although legislators have expressed reluctance to act before the demonstration results are reported, private-sector experience will be available much sooner, will involve more patients, and may overcome this reluctance. If this occurs, however, the current structure of the ESRD AAPCC rates used to pay health maintenance organizations (HMOs) must be reexamined. Current rates include dialysis patients, transplant patients and MSP patients. The potential bases introduced by the inclusion of these categories in the ESRD AAPCC calculation could lead to significant underfunding of the true expenditures associated with dialysis patients in Medicare risk programs[51].

CONCLUSIONS AND RECOMMENDATIONS

The Medicare ESRD program has been a remarkable success from many perspectives. Countless lives have been saved, patients' quality of life has been enhanced, and many productive citizens who would have died of kidney failure twenty-five years ago have returned to the workforce and to their families. This has been acomplished despite a steady decline in inflation-adjusted payment to providers. However, several major policy dilemmas must be addressed within the next few years.

Incidence of ESRD. The continued growth of the ESRD patient population should ring alarm bells in the minds of all of those who are concerned with chronic care and its treatment. Primary kidney disease contributes only modestly to end-stage kidney failure. The two largest feeder streams to ESRD by far are diabetes (an endocrine disorder) and hypertension (a cardiovascular disease). It is projected that by 2002 two-thirds of all U.S. ESRD patients will have a diagnosis of hypertension or diabetes mellitus as the principal cause of their renal failure[52]. The early identification of at-risk patients and their improved medical management offers an opportunity to decrease the incidence of ESRD as well as to improve other aspects of health associated with great morbidity and cost. Many patients, however, will progress to ESRD despite early

identification and appropriate medical care. More careful selection of patients likely to benefit from dialysis will raise yet again the specter of rationing access to this life-saving treatment.

Reimbursement policy, cost control and quality of care. Additional improvements in quality could come from reimbursement policy changes that permit higher doses of dialysis and appropriate clinical use of nutritional supplements and rHuEPO[53]. To the extent that these improvements decrease hospitalization, they could save money for the overall program, bur this hypothesis needs to be tested. Highet-quality services, of course, will increase patient survival, a goal sought by patients and clinicians, but one that undoubtedly would increase total program costs.

Cost savings might be realized if all ESRD services were capitated, but this should be done cautiously with concurrent quality monitoring and with sensitivity to which entities are able to assume risk and provide the highest-quality services for a capitated price. In addition, if a capitated payment is dependent of the AAPc, the structure of this rate needs careful examination. Historically, however, the ESRD program has been squeezed by Medicare in ways quite unlike those in any other segment of medicine, and savings here are apt to be one-time only. Cost shifting may give providers short-term payment relief from the stringency of Medicare payment but may be costly in the long term as private payers become more sophisticated, and tight-fisted, in the purchase of ESRS services.

Kidney transplantation. Several prospects are on the horizon, including the use of cross-species organs (xenografts) and new immunological approaches to prevent organ rejection. The lack of human donors, however, remains the most important barrier to achieving a higher trans-plantation rate. A recent HCFA regulation may help to increase donation, especially as it draws on research focusing on important factors in the donation process that take place at the donating hospital[54]. In addition, the lack of payment for antirejection drugs after thirty-six months may adversely affect the length of transplant survival. Finally, there is no systematic approach to managing either costs or quality in transplantation.

Availability of data. There are some encouraging new developments in this area: For example, the BBA requires Medicare+ Choice plans to submit some clinical and financial information, and HCFA is working on a Standard Information Management System (SIMS) project that would permit electronic transfer of standardized information from facilities to networks to HCFA. Despite this, the high-water mark of data quality and quantity may have already been reached in the Medicare ESRD program. These data still are derived primarily from the Medicare fee-for-service system. Their continued availability and quality is potentially threatened by the extension of MSP and by the growth of managed care, since neither private insurers nor MCOs that treat ESRD patients are required to collect clinical and reimbursement data comparable to those collected by HCFA and used by the USRDS. Without such requirements, the implications for program management will be negative and considerable.

Quality of care. Recently HCFA and the nephrology community have worked together and succeeded in improving quality of care related to anemia management. This collaboration of patients, clinicians and policymakers will be even more important in the future as resource scarcity increases. Prospective development of ESRD policy by HCFA, in consultation with clinical experts and patients, will help to avoid policy-related medical error, as described in the report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry[55].

Patients with ESRD are among the most medically vulnerable in the Medicare program. Future projections suggest that this patient population will continue to grow in size and medical severity and that the number of available professionals to provide the care will not be adequate to meet the needs. Concomitant with these trends, and overall increase in total program consts can be anticipated. Policymakers must work closely with the renal professional, scientific and patient communities to assure that any new a-pproaches to delivering and financing this care are carefully considered and will enhance, rather than erode, the quality of services provided.

REFERENCES

1. P. L. 92-503, *Social Security Amendments of 1972,* sec. 2991, 30 october 1972.
2. A small number of ESRD patients are not covered by Medicare. See Institute of Medicine, *Kidney Failure and the Federal Government,* ed. R.A. Rettig and N. G. Levinsky (Washington: National Academy Press, 1991); and M. Thamer y cols., «Excluded from Universal Coverage: ESRD Patients Not Covered by Medicare», *Health Care financing Review 17,* no. 2. (1995): 123-146. The Medicare ESRD entitlement is a powerful example of the willingness and ability of providers to treat low-income minority populations when payment for such care is available. However, it is worth noting that Congress ignored an IOM recommendation in 1991 to create truly universal coverage by extending the entitlement from 92-93 percent of U.S. citizens and resident aliens to all such persons.

3. R.A. Rettig: «Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972», in *Decision Making in Science and Technology,* ed. K. Hanna (Washington: National Academy Press, 1991).
4. R. A. Rettig, *Implementing the End-Stage Renal Disease Program of Medicare* (Santa Monica, Calif.: RAND, september 1980).
5. Health Care Financing Administration, *Health Care Financing Research Report: End-Stage Renal Disease, 1993-95* (Baltimore, Md.: HCFA, 1998).
6. U. S. Renal Data System, *USRDS 1998 Annual Data Report* (Bethesda, Md.: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1998).
7. HCFA, *End-Stage Renal Disease.*
8. A. R. Nissenson y cols.: «Non-Medical Factors That Impact on ESRD Modality Selection», *Kidney International 40* (Supplement february 1993): S120-S127; and A. R. Nissenson y cols., «ESRD Modality Selection into the 21st Century: The Importance of Non-Medical Factors», *American Society of Artificial Internal Organs (ASAIO) Journal* (May/June 1997): 143-150.
9. C. R. Blagg and L. U. Mailloux, «The Case for Home Hemodialysis», *Advanced Renal Replacement Therapy* 3, no. 2 (1996): 96-98.
10. M. J. Klag y cols. «End-Stage Renal Disease in African-American and White Men». *Journal of the American Medical Association 277,* no. 16 (1997): 1293-1298.
11. U. S. Renal Data System, *USRDS 1997 Annual Data Report.*
12. USRDS, *1998 Annual Data Report.*
13. HCFA, *End-Stage Renal Disease.*
14. The Renal Physicians Association and the American Society of Nephrology have begun to address this issue by beginning work on a clinical practice guideline on initiation of and withdrawal from dialysis. William Haley, assistant professor of medicine, Mayo Medical School, Jacksonville, Florida, personal communication to Nissenson, june 1998.
15. USRDS, *1998 Annual Data Report.*
16. R. A. Rettig, «The Social Contract and the Treatment of Permanent Kidney Failure». *Journal of the American Medical Association 275,* no. 14 (1996): 1123-1126.
17. A. R. Nissenson and N. Hoffart: «The Future of ESRD Care: Nephrology Enters a New Millennium». *Advances in Renal Replacement Therapy 5,* no. 4 (1998):257-266; and Task Force on REuse ofDialyzers, National Kidney Foundation. «National Kidney Foundation Report on Dialyzer Reuse», *American Journal of Kidney Diseases 30,* no. 6 (1997): 589-871.
18. The development of rHuEPO was carried out in the private sector and most of the postmarketing research with this substance has been privately funded.
19. J. W. Eschbach,« Erythropietin: The Promise ad the Facts», *Kidney International 44* (Supplement january 1994): S70-S76.
20. Allan Collins, associate professor of medicine, University of Minnesota, personal communication, August 1998.
21. P. A. Abraham, «Health Care Payment Policies: Lessons from Erythropoietin», *American Journal of Kidney Diseases 22,* no. 4 (1993): 596-597; and N. R. Powe, P. W. Eggers and C. B. Johnson, «Early Adoption of Cyclosporine and Recombinant Human Erythropoietin: Clinical, Economic, and Policy Issues with Emergence of High-Cost Drugs», *American Journal of Kidney Diseases 24,* no. 1 (1994): 33-41.
22. DHHS, HCFA, Program Memorandum to Intermediaries/Carriers, Transmittal no. *AB-98-34* (July 1998), Change Request no. 555, *Modification of Medicare Policy of Erythropoietin (EPO).*
23. IOM, *Kidney Failure and the Federal Government.*
24. P. Kurtin and A. R. Nissenson, «Variations in End-Stage Renal Disease Patient Outcomes: What We Know, What Should We Know, and How Do We Find Out?» *Journal of the American Society of Nephrology 3,* no. 11 (1993): 1738-1747.
25. IOM, *Kidney Failure and the Federal Government.*
26. F. A. Gotch, «Kinetic Modeling in Hemodialysis», in *Clinical Dialysis,* ed. A. R. Nissenson, R. N. Fine, and D. E. Gentile (Norwalk, Con.: Appleton and Lange, 1995), 156-188.
27. F. A. Gotch and J. Sargent, «A Mechanistic Analysis of the National Cooperative Dialysis Study (NCDS)», *Kidney International* 28, no. 3 (1985): 526-530. Low blood urea can result from a high dose of dialysis or from poor nutrition. The latter possibility was not sufficiently stressed in the NCDS or the Gotch and Sargent paper, nor was it appreciated by many clinicians. Some clinicians reduced the dose of dialysis in patients with a low blood urea, many of whom were actually malnourished, an approach that aggravates malnutrition and increases mortality. The proper response, it is now recognized, would have been to increase the dialysis dose.
28. U. S. Renal Data System, *USRDS Annual Data Report* for 1993, 1994 and 1995.
29. Robert Wolfe, director, USRDS, personal communication, June 1998.
30. U. S. General Accounting Office, *Medicare: Enrollment Growth and Payment Practices for Kidney Dialysis Services* (Washington: GAO, november 1995).
31. Renal Physicians Association Clinical Practice Guideline Working Committee, *Clinical Practice Guideline on Adequacy of Hemodialysis,* Clinical Practice Guideline no. 1 (Dubuque, Iowa: Kendall Hunt Publishing, 1996).
32. NKF-DOQI Clinical Practice Guidelines, *American Journal of Kidney Diseases* 30, Supplement 2, 3 (1997): 30.
33. Gary Eknoyan, past-president, NKF, personal communication, april 1997.
34. Jonathan Sugarman, medical director, ProWest, personal communication, june 1998.
35. A. S. Kliger and W. E. Haley, «Clinical Practice Guidelines in End-Stage Renal Disease: A Strategy for Implementation», *Journal of the American Society of Nephrology* (forthcoming).
36. See K. N. Lojh, ed., *Medicare: A Strategy for Quality Assurance,* vols. 1 and 2 (Washington: National Academy Press, 1990); K. N. Lohr, ed., «Advances in Health Status Assessment: Conference Proceedings», *Medical Care 27* (Supplement march 1989); and K. N. Lohr, ed., «Advances in Health Status Assessment: Proceedings of a Conference», *Medical Care 30* (Supplement May 1992).
37. L. H. Diamond and D. Daly, «Forum of ESRD Networks role in Implementing the NKF-DOQI Clinical Practice Guidelines», *Advances in Renal Replacement Therapy* (forthcoming).
38. Ibid.
39. P. R. Kletke, «The Changing Supply of Renal Physicians», *American Journal of Kidney Diseases* 29 no. 5 (1997): 781-792.
40. Nissenson and Hoffart, «The Future of ESRD Care».
41. «Issues in Managed Care», *Nephrology News and Issues* (july 1998): 19.
42. Ibid.
43. Ibid.
44. Ibid.
45. These chains were severely criticized in the New York Times in late 1996, but the series contained glaring omissions and gross oversimplifications. K. Eichenwald, «Rivals Shown Little Mercy by Big Kidney-Clinic Chain», *New York Times,* 5 december 1996; and K. Eichenwald, «Making Incentives Work in Kidney Patient's Favor», *New York Times,* 6 december 1996.
46. D. O. Farley y cols.: *Designing a Capitation Payment Plan for Medicare End-Stage Renal Disease Services* (Santa Monica, Calif.: RAND, 1994).

47. R. J. Rubin y cols.: *ESRD in the Age of Managed Care: A Primer on Capitation* (Washington: Renal Physicians Association Research and Education Foundation, 1996); and B. S. Cooper, P. W. Eggers and B. M. Eddington, «Development of an End-Stage Renal Disease Managed Care Demonstration», *Advances in Renal Replacement Therapy* 4, no. 4 (1997): 332-339.
48. Paul Eggers, senior analyst, HCFA, personal communication, april 1998.
49. T. Steinman, «Managed Care, Capitation and the Furute of Nephrology», *Journal of the American Society of Nephrology* 8, no. 10 (1997): 1618-1623.
50. L. R. Coutts and M. E. Neumann, «Renal Disease Management and the Future of Nephrology», *Nephrology News and Issues* (Supplement 1998).
51. Collins, personal communication, september 1998.
52. Wolfe, personal communication, june 1998.
53. DHHS, *Modification of Medicare Policy of Erythropoietin (EPO).*
54. *63 Federal Register 33856* (22 june 1998). See S. L. Gortmaker y cols.: «Organ Fonor Potential and Performance: Size and Nature of the Organ Donor Shortfall», *Critical Care Medicine 24,* no. 3 (1996): 4432-4439; S. L. Gortmaker y cols.: «Increasing Consent to Organ Donation by Improving the Donation Request Made to Families», *Journal of Transplant Coordination* (forthcoming); M. J. Evanisko y cols.: «Readiness of Critical Care Physicians and Nurses to Handle Requests for Organ Donation», *Journal of Critical Care 7,* no. 1 (1998): 4-12; and C. L. Christiansen y cols.: *American Journal of Public Health 88*, no. 11 (1998): 1645-1650.
55. President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Quality First: Better Health Care for All Americans,* Final Report to the President of the United States (Washington: U. S. Government Printing Office, 1998).