THE POLITICS OF HEALTH COST CONTAINMENT: END-STAGE RENAL DISEASE*

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I SHALL briefly review certain efforts to control the costs of the End-Stage Renal Disease (ESRD) Program of Medicare, a program created by Section 2991 of Public Law 92-603, the Social Security Amendments of 1972. It extends Medicare coverage to those under 65 years of age, fully or currently insured, or entitled to monthly insurance benefits under the Social Security Act, and to their spouses or dependent children if they have chronic renal failure and require either dialysis or transplantation to live.[1]

The program was enacted to provide life-saving treatment beyond the means of practically everybody. Inequities of access had developed in the 1960s because of differential effects of the kidney program of the Veterans Administration, the research, demonstration, and capacity-building efforts of the Public Health Service, and varying responses of state governments.[2] The ESRD Program substituted a near-universal Medicare benefit program for the pre-existing hodge-podge of programs. Cost control was a derivative, not a primary objective. In this respect, the program is similar to the general problem of controlling the costs of medical care. Access was and is the primary objective.

BACKGROUND

Table I shows the ESRD patient population for the first five and one-half years of the program. With 11,000 beneficiaries at its inception, the program now has an estimated 50,000 beneficiaries. Projections of

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TABLE I. MEDICARE ESRD PATIENT POPULATION 1973-1978

End of calendar year	*Total number of patients*
7-1-1973*	11,000
1973	14,000
1974	23,000
1975	31,000
1976	38,000
1977	44,000
1978	50,000

*Inception of Program.
Source: Office of Financial and Actuarial Analysis, Division of Medicare Cost Estimates, Health Care Financing Administration, March 1979 (hereafter OFAA/HCFA.)

TABLE II. AVERAGE ANNUAL ENROLLMENT OF MEDICARE ESRD BENEFICIARIES BY BENEFIT CATEGORY 1974-1978

Calendar year	*Total*	*%*	*299I*	*%*	*Disabled renal*	*%*	*Aged renal*	*%*
1974	19,000	100	13,000	68	5,000	26	1,000	5
1975	27,000	100	16,000	59	8,000	30	3,000	11
1976	35,000*	100	18,000	51	10,000	29	6,000	17
1977	41,000	100	20,000	49	13,000	32	8,000	20
1978	47,000	100	21,000	45	17,000	36	9,000	19

*Total does not add due to rounding.
Source: OFFA/HCFA, March 1979.

TABLE III. ANNUAL BENEFIT PAYMENTS FOR MEDICARE ESRD BENEFICIARIES BY BENEFIT CATEGORY (INCURRED BASIS) 1974-1978 ($ millions)

Calendar year	*Total*	*%*	*299I*	*%*	*Disabled renal*	*%*	*Aged renal*	*%*
1974	$283	100	$170	60	$ 79	28	$ 34	12
1975	450	100	248	55	127	28	75	17
1976	598	100	309	52	172	29	117	20
1977	757	100	381	50	223	29	153	20
1978	947	100	464	49	284	30	199	21

Source: OFAA/HCFA, March 1979.

patients for 1980, 1985, 1990, and 1995, respectively, are 61,000, 79,000, 88,000, and 90,000. This population, therefore, begins to stabilize after perhaps 20 years but in any case is a relatively small proportion of the total American population.

In Table II patient population data are broken down according to benefit category—2991 only, disabled-renal, and aged-renal. The disabled-renal have increased from one quarter of the ESRD patient population in 1974 to more than one third in 1978, and the aged-renal now account for one fifth of all ESRD patients. Though Sec. 2991 had no legal bearing on benefits to the aged, it spotlighted a special benefit for the less-than-65 population which also had to be available for the aged. Though Medicare aged beneficiaries would probably have begun to claim renal benefits during the 1970s, it seems unreasonable to assume that growth would have equalled that actually witnessed. The impact of Sec. 2991 on the disabled-renal is more direct. The eligibility waiting period for disabled Medicare benefits is 24 months, long enough for many to die of kidney failure before becoming eligible. Sec. 2991, therefore, has been a "port-of-entry" to many disabled-renal beneficiaries.

Costs of renal dialysis and transplantation have always been high. In 1975, on the basis of 1972 data, the General Accounting Office reported an average annual charge of $30,500 for dialysis in 81 hospitals, $27,500 for nonhospital dialysis, and home dialysis charges of $14,000 in the first year and $7,000 for successive years. Transplantation charges in 24 hospitals ranged from $5,500 to $20,500, and averaged about $12,800.[3]

High costs of treatment mean high total costs for the ESRD program, despite the few beneficiaries. Total program costs and those for the three benefit categories are shown in Table III. Projected costs to 1980, 1985, 1990, and 1995, respectively, are $1.4 billion, $2.4 billion, $3.4 billion, and $4.6 billion!

Are ESRD program costs out of control? The answer to this question can be found in Table IV. Current unadjusted costs of the program (from Table III) are deflated to 1972 constant dollars using two indices—the Consumer Price Index (CPI) for all items and the CPI subindex for medical care. We assume that inflation has affected the ESRD program at least as much as the entire economy but not as much as medical care in general; if this is true, these two deflators set lower and upper limits to ESRD program inflation. The $947 million unadjusted program benefit payments for 1978, therefore, fall somewhere between $572 million and

TABLE IV. COMPARISON OF CURRENT AND CONSTANT DOLLAR ESRD PROGRAM BENEFIT PAYMENTS AND AVERAGE BENEFIT PAYMENTS PER PATIENT 1974-1978

		Annual ESRD benefit payments ($ million)			*Average benefit payments per patient*		
			Deflated by CPI index 1972 = 100			*Adjusted by CPI index*	
Calendar year	*Average annual enrollment*	*ESRD program unadjusted dollars*	*All items**	*Medical†*	*Unadjusted*	*All items*	*Medical*
1974	19,000	$283	$244	$254	$14,895	$12,842	$13,368
1975	27,000	450	354	354	16,667	13,111	13,111
1976	35,000	598	447	429	17,086	12,771	12,257
1977	41,000	757	535	495	18,463	13,049	12,073
1978	47,000	947	623	572	20,149	13,255	12,170

*Implicit price deflator, Gross National Product. *Economic Report of the President, 1979*, Table B-4, p. 188.

†Computed by setting 1967 CPI Medical Care subindex value for 1972 (132.5) equal to 100.

TABLE V. TOTAL MEDICARE BENEFIT PAYMENTS COMPARED TO ESRD BENEFIT PAYMENTS FOR PARTS A AND B (CASH BASIS)* 1974-1980 ($ millions)

	HI Trust Fund (Part A)			*SMI Trust Fund (Part B)*		
Calendar year	*Medicare benefit payments*	*ESRD benefit payments*	*ESRD as % Medicare*	*Medicare benefit payments*	*ESRD benefit payments*	*ESRD as % Medicare*
1974	$ 9,099	$ 69	0.7	$3,318	$143	4.3
1975	11,315	115	1.0	4,273	251	5.9
1976	13,340	143	1.1	5,080	373	7.3
1977	15,737	168	1.1	6,038	504	8.3
1978	17,682	210	1.2	7,252	643	8.9
1980 est.	24,267	314	1.3	9,967	936	9.4

*Cash basis figures are those actually paid out; they are lower than incurred basis figures due to the lag between incurred obligations and actual expenditures.

Sources: 1979 Annual Report of the Board of Trustees of the Federal Hospital Insurance Trust Fund, April 13, 1979, Table 6, p. 27; 1979 Annual Report of the Board of Trustees of the Federal Supplementary Medical Insurance Trust Fund, April 13, 1979, Table 6, p. 20; and OFAA/HCFA, March 1979.

$623 million 1972 dollars. Using both deflated cost stream and computing an average benefit payment per patient for 1974 through 1978, practically no cost growth has occurred! It appears, therefore, that total program cost increases are due almost entirely to inflation and an increased patient population. The ESRD program is costly, to be sure, but these costs are not out of control.

Moreover, the astronomical cost projects to 1995 are seen in a different

light if constant, rather than inflated, dollars are used. If we take the 1978 average benefit payment per patient of roughly $20,000, the projected program benefit payments for 1980, 1985, 1990, and 1995, respectively, are $1 billion, $1.6 billion, $1.8 billion, and $1.8 billion. These obviously high costs are not as overwhelming as the unadjusted projections suggest.

More significant, perhaps, than future year projections, is the impact of the ESRD Program on the entire Medicare Program. Table V compares total Medicare benefit payments to ESRD benefits payments for the Hospital Insurance Trust Fund (Part A) and the Supplementary Medical Insurance Trust Fund (Part B). Though ESRD benefit payments have risen gradually to 1.3% of the total Medicare Part A Payments, ESRD benefit payments have climbed steeply to nearly 10% of total Medicare Part B payments.[1] In other terms, 10% of the SMI benefit payments now go to 50,000 ESRD beneficiaries, and 90% go to the more than 23 million aged enrollees. Within Part B, moreover, for the year ending June 30, 1977, per capita incurred benefits were $218 for 22,605,000 aged enrollees, $214 for 2,233,000 disabled enrollees, and $13,355 for 31,000 ESRD enrollees.[4] The $947 million ESRD benefit payments for 1978 is one half of one percent of the national health expenditure of $192 billion for the same year.[5] Cost control, though a derivative objective of the ESRD Program, is clearly important.

Cost Containment Efforts

Kidney transplantation. Transplantation, both to treat end-stage renal disease and to contain costs, might well be regarded as the nonevent of the ESRD Program. The facts, certainly, have run counter to expectations.

The basic facts about transplantation are these. First, the proportion of cadaver kidney donors compared to parent and sibling living donors has shifted. According to the 12th Report of the Human Renal Transplant Registry, "Cadaveric sources of kidneys have increased from 56% of the grafts in 1967 to 70.4% in 1973."[6] Second, this has created a scarcity—far more individuals await a cadaver transplant than there are kidneys available for transplantation.

Third, *patient survival* for cadaver transplant patients has improved. Worldwide, one year post-transplant patient survival, according to the 13th Report of the Human Transplant Registry, increased from 59% in 1968 to 72% in 1974.[7] Starzl and his colleagues experienced markedly improved

patient survival for cadaver kidney recipients from 1968 onward: "Three-fourths or more of the recipients were alive at 1 year and from then until 4 or 5 years, the deaths were reduced. However, a different attitude about the primacy of the transplants was obvious. Now the grafts were being abandoned, and the patients were being treated by return to dialysis and aggressive retransplantation."[8] More recently, physicians in Boston report that the mortality of cadaver transplant recipients at the end of one year had been reduced to 5% through a number of modifications in patient management.[9]

But the fourth basic fact is that the *survival of the graft,* or the transplanted kidney, has declined over time. Worldwide data show that one year graft survival for cadaver transplant recipients was 46% in 1968, rising to 55% in 1970, and falling steadily back to 46% in 1974.[10] Terasaki and his colleagues reported, in 1976: "It now appears certain that there is a definite decline in the transplant survival (graft survival) rates with each succeeding year. This trend was reported by us for the first time in 1973 and has continued since."[11] They found a progressive decrease in graft survival rates for cadaver donor, parental donor, and HL-A-identical sibling donor transplants of approximately 2% per year.

What are the implications of these facts for cost containment? Stange and Sumner recently sought to predict future medical care costs and life expectancy for three treatments of end-stage renal disease—facility dialysis to home dialysis, facility dialysis to transplantation, and home dialysis to transplantation.[12] They first predict costs and expected life-years for a 1,000 patient cohort over a 10 year period for each treatment. They then develop the cumulative costs and life-years associated with each treatment for successive annual cohorts through the 10th year. For transplantation, they make a "low assumption" about the survival of both patients and grafts and a corresponding "high assumption."

Comparing transplantation to dialysis, both for single cohorts over a 10 year period and for multiple cohorts in the 10th year, they project lower costs for transplantation over both forms of dialysis but an accompanying reduction in life expectancy. For the "low assumption" projection, predicted costs are reduced 30 to 40% while predicted life expectancy is reduced 15 to 20%. The "high assumption"—higher patient and graft survival—predicted less reduction in life expectancy (6 to 10%) but a smaller cost savings (20 to 30%).

One problem with the Stange and Sumner paper, however, is that

survival of patients and transplanted kidneys is presumed to vary in direct relation to each other. In fact, as indicated above, patient survival has improved as graft survival declined. Patient survival improved from improved patient management but improved graft survival is not reported.

It is therefore realistic to expect average patient survival to increase, but it is prudent to expect no more than stability of graft survival. If these expectations prove true, the expected life-years of transplanted patients will go up. But the costs will as well, because an increasing proportion of transplant failures will return to dialysis. It is simply erroneous to assume, as did a recent report from the Center for Disease Control, that "cadaveric kidney transplantation is a *cost-effective* and desirable treatment alternative for many patients on chronic dialysis" (emphasis added).[13]

The real problem, however, with transplantation as a cost containment strategy is that there is practically nothing that the federal government can do in the short run to intervene in the situation. The underlying immunologic problems, we expect, will yield in time to scientific research. The clinical decisions reside entirely in the hands of physicians and surgeons and are not a province for government policy.

Institutional dialysis. Section 2991 created a near universal benefit for victims of end-stage renal disease, and thus eliminated the non-Medicare medical market as the basis for reimbursement levels paid by Medicare. Moreover, that market, such as it was before the ESRD Program, varied so widely in reimbursing both facilities and physicians as to provide practically no guide to the Social Security Administration's Bureau of Health Insurance. (One California study, for instance, showed physician charges ranging from $5.68 to $111.49 per dialysis session!)

Medicare policy reimbursed facilities by a screen on allowable charges for each dialysis treatment. The screen was initially represented as a permeable upper limit, which could be increased if supporting documentation were provided. In time, for all practical purposes, the screen became a ceiling. The basic screen was $150 per dialysis session where physicians were reimbursed by the facility, and routine laboratory tests were performed by the facility. Downward adjustments were made where physicians were paid directly on a monthly capitation basis and routine laboratory work was performed outside the facility; in such cases, the amount was $133 per dialysis session.[14]

One effect of the screen put strong pressure on hospital based outpatient dialysis centers with substantial hospital overhead in their cost structure.

This caused a shift from hospital based to nonhospital limited care dialysis centers, both nonprofit and proprietary. The cap on reimbursement, in short, forced maintenance dialysis into lower cost institutional settings.

In all likelihood, the rate and direction of technical change in dialysis treatment has been affected. When facilities are forced by a reimbursement limit to become efficient users of scarce resources, they transmit that fact to suppliers of dialysis equipment and supplies. The latter, in turn, respond by attempting to maintain or to increase market share through price competition by incremental cost-reducing technical change on individual items or by marketing products that substitute for labor. Regarding the latter, large surface dialyzers introduced during recent years permit faster dialysis. It is no longer necessary to dialyze 6 to 8 hours per session, but times of 3½ to 4½ hours are now possible for many patients. These faster times permit two patient shifts per nursing shift. When one realizes that institutional dialysis costs consist in large measure of professional costs, the cost saving possibilities are clear.

Two facts are worth noting. Constant dollar costs per patient for the ESRD Program have remained essentially unchanged for the first five years of the program, as indicated in Table IV, and screens established in 1973 and 1974 have remained unchanged to the present time despite substantial inflation during this period.[15] One implication of this is that some cost savings have come through technical change.

A second implication, more readily grasped by program administrators, is that the intial screens were too high. The initial intention of the Bureau of Health Insurance (BHI) was to collect data on experience with screens and revise them in light of such data. However, the efforts to secure cost data reveal numerous facets of the politics of health cost containment.

The screen was intended to apply to those facilities without prior experience when the ESRD program began. Nonhospital dialysis facilities operating during the 12 months prior to July 1, 1973 were to be reimbursed on the basis of the weighted average of all dialysis service reimbursements from all third parties, subject to the $150 limit. In many cases, however, Medicare intermediaries responsible for applying this formula did not bother to do so but simply set the initial reimbursement level at $150. In one notable case, however, that did not occur. The Queens Artificial Kidney Center, Jackson Heights, had treated Medicare patients since 1970, and had billed for its services through Group Health, Inc., New York, the Medicare carrier. Nonhospital billing under the ESRD program

was to be through intermediaries, not carriers, and a limited care facility was to bill through that intermediary which served the hospital with which it had its primary affiliation. Queens was affiliated with the Mount Sinai School of Medicine, one of a small number of institutions which had elected to bill Medicare directly through the Division of Direct Reimbursement of BHI, a government intermediary, not through the New York intermediary. The government intermediary, perhaps more conscientious than the New York intermediary, scrutinized the Queens situation carefully.

The Queens facility, during the year before the ESRD program became effective, had been reimbursed at $75 per treatment by New York State Medicaid and at $150 per treatment for Medicare patients by Group Health, Inc. Because the ESRD program was administered by Medicare, Dr. Eugene I. Schupak, proprietor and director of the Queens facility, assumed that the $150 treatment rate would prevail. But since the New York Medicaid patients accounted for 61% of the facility's patients, when the weighted average formula was applied the Medicare allowable charge was only $99.09.[16]

Schupak felt unfairly treated because the $75 rate had resulted from a long, complicated relation with New York Medicaid. He entered into lengthy negotiations with BHI, which offered to raise the Medicare allowable rate to $107.16 per treatment. This was unsatisfactory to him, since his facility and only three others in New York City were being reimbursed at less than the full screen. BHI invited Schupak to submit cost data demonstrating hardship and, if these were persuasive, an appropriate adjustment would be made. He refused to do so.

The reasons for refusal lie in an ESRD program effort then underway to collect cost data on outpatient dialysis, in the corporate nature of the Queens facility, and in the perceived risks to Queens of providing such data.

In December 1973 BHI distributed a renal dialysis questionnaire to provider and nonprovider facilities to secure data to permit intermediaries to evaluate a facility's charge or cost per dialysis and Medicare to evaluate reimbursement issues.[17] A follow-up intermediary letter in November 1974 noted that about half of the 600 dialysis facilities had not returned the questionnaire, stressed the importance of compliance, and asked for documentation of inability to respond.[18] Nonrespondents included many limited care dialysis facilities, both nonprofit and proprietary.

Schupak's facility was among the proprietary nonrespondents. In fact, the director of the Queens facility was also then president of National Medical Care, Inc., the nation's largest provider of limited care dialysis services, all under proprietary auspices.[19] None of the National Medical Care affiliated dialysis centers had returned the ESRD questionnaires or in any other way provided cost data. They reasoned that their data would permit the government to reduce charges in facilities which showed a profit; that they would be shared with others, including competitors; and that the government had no right to such data.

On July 11, 1975 Schupak filed suit against David Matthews, Secretary of Health, Education, and Welfare, in the U.S. District Court for the District of Columbia.[20] Schupak argued, essentially, that the reimbursement rate established by the interim regulations and intermediary letter, first, had been improperly issued in violation of the Administrative Procedures Act and, second, that it violated the Medicare act's requirement that reimbursement be based on reasonable charges. He asked the court for summary judgment.[21] The government responded that the plaintiff had not exhausted administrative remedies, that the court lacked jurisdiction in the matter, that the regulations and intermediary letter were not issued in violation of APA, and that the substance of the reimbursement rate represented a reasonable exercise of discretion by the secretary in the instance. It asked the Court to dismiss the plaintiff's motion and give a summary judgment.[22]

Judge William B. Bryant, in his opinion, held that the plaintiff had exhausted all administrative remedies, that the court did have jurisdiction, and that the government had not complied with the requirements of the APA. Specifically, on this last point the court pointed out that the intermediary letter

> contains that specific [reimbursement rate] formula itself. It directly controls the reimbursement to be paid to dialysis facilities, and has a substantial impact on the rights of those facilities. It is definitive, new, and controlling, and is precisely the sort of regulation required to be imposed only pursuant to the rulemaking requirements of the APA. Accordingly, the Court holds that such a rule may only be promulgated pursuant to these procedures, including the public participation and notice provisions of the APA.[23]

Bryant then ordered that the intermediary letter be "set aside as void and of no effect," but that the order be stayed until a regulation replacing the intermediary letter could be promulgated in accordance with the APA requirements.

The substance of the dispute was whether the Secretary had acted within his authority in establishing criteria to determine "reasonable charges" published in the interim regulations and, specifically, whether the estimated customary charge formula of the intermediary letter legally reimbursed reasonable charges in general and for the plaintiff. In Bryant's judgment:

> Given the Secretary's responsibilities under the new program, the complexity and novelty of the issues it raised, and the discretion in determination of reasonable charges delegated to him by Congress in this matter, the Court finds the regulation and formula adopted to be legal and reasonable.

The judge further upheld the government on all questions of substance, and the plaintiff's arguments were rejected as without merit.

The District Court judgment was filed on September 17, 1976. In response, HEW published a Notice of Proposed Rulemaking on November 9, 1976, which, among other things, republished the interim regulations, clarified criteria for reasonable charge determinations for nonprovider dialysis facilities, and required that nonprovider facilities submit cost information to *SSA/BHI.*[24]

Schupak appealed the District Court decision. On November 2, 1977 the Court of Appeals for the District of Columbia Circuit upheld Judge Bryant's decision,[25] but ordered that the stay imposed by the lower court should expire at the end of 60 days. HEW, under this pending court order, managed to publish final regulations on the determination of reasonable charges on December 30, 1977, the last available working day before expiration of the stay.[26] The Department had now fully established the basis for reimbursement of nonprovider dialysis facilities and the secretary's authority to request cost data from facilities.

Or so it would seem. BHI, in a May 1977 intermediary letter,[27] renewed its request to dialysis facilities for cost and statistical data and cited authority provided by final regulations issued in 1976. The pertinent section of these regulations required dialysis facilities as a condition of approval to furnish data and information "in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs." A follow-up intermediary letter in September 1977 noted that submission dates, not specified in May, were to be within 90 days of the end of the facility's fiscal year or the date of issuance of the intermediary letter, whichever was later. If noncompliance persisted, BHI threatened, "the Medicare Regional Office may take action to terminate the coverage of the facility as a provider of renal services."

Noncompliance did persist. In response, Medicare issued an intermediary letter in March 1978,[28] "requesting that all renal dialysis facilities report their costs and statistical information to the Health Care Financing Administration."[29] Citing final regulations issued December 30, 1977, as well as those issued in 1976, the initial cost questionnaire was to be submitted no later than March 31, 1978. Sanctions were indicated: "Any nonprovider renal dialysis facility failing to submit the requested costs information within the specified time period will be subject to a suspension of its Medicare reimbursement." If a facility failed to submit data by March 31, the intermediary was instructed to initiate steps leading to suspension of payment of all bills from it received after April 30.

Schupak filed for a preliminary injunction in the U.S. District Court for the Eastern District of New York, enjoining the HEW Secretary from enforcing the intermediary letter and challenging the legal validity of the December 30, 1977 regulations. The government asked the Court to dismiss the complaint, or to transfer the case to the District of Columbia Court. Judge Jacob Mishler, after reviewing procedural irregularities in the earlier District of Columbia case, found Judge Bryant's decision "sound and well-reasoned," and refused to depart from it, concluded that the reimbursement rate and the authority of the Secretary to set it were "in full conformity with the mandates of the Social Security Act and the expectations of Congress when it enacted the ESRD program," held that the secretary's resort to cost as a factor in determining reasonable charges was "clearly consistent" with his responsibility to the nearly 25 million beneficiaries whose voluntary contributions accounted for nearly half of the Part B Trust Fund, and found the intermediary letters exempt from the Administrative Procedures Act rule-making requirements.[30] He granted the HEW request to dismiss Schupak's complaint.

This final confrontation was a high-tension episode. Schupak, who treated 250 patients in his Queens facility, the second largest one in the country, reportedly had threatened to close the facility if Medicare payments were suspended.[31] Since no National Medical Care facilities had yet complied with the cost data request, and since Schupak was president, there was a good deal of anxiety among Washington officials about the seriousness of the threat and how many facilities might join Queens if the threat materialized. Soon after Judge Mishler's decision, however. Schupak informed the Health Care Financing Administration that he would comply with the request for data. It had been an "eyeball-to-eyeball" confrontation and "the other fellow just blinked."

Surrey has noted the well-developed role of the Tax Court in the implementation of tax law.[32] The five year process definitively to establish the secretary's authority to reimburse nonprovider dialysis facilities on the basis of charges related to cost and to require the submission of cost data from such facilities points to the clear though less developed role of the courts in the implementation of health-financing legislation.

Home dialysis. Dialysis at home first occurred in Boston in 1964 and soon thereafter in Seattle. It was in Seattle, however, that Dr. Belding H. Scribner pioneered the extensive use of home dialysis. In Washington State, for instance, the proportion of total dialysis patients on home dialysis has consistently exceeded 75% since 1969.[33] Indiana, to take another example, has averaged 60% or more for many years. For the Veterans Administration dialysis population, more than 45% was either at home or in home training in early 1973.[34] At the national level, the home dialysis proportion of total patients was 40% and 36% respectively, on January 1, 1972 and January 1, 1973.[35] Home dialysis is attractive to many policy officials, in part because home patients generally do better than center patients.[36] Also attractive is the fact that home dialysis is the least costly dialysis treatment.[37]

It was with some distress, therefore, that a number of physicians realized soon after publication of the interim regulations that the Medicare program had created a number of disincentives to home dialysis. Distress deepened into sustained disappointment as the proportion of dialysis patients in the home setting dropped steadily to less than 15% in 1978 from inadvertent policy decisions by the government.

In the fall of 1973 nine physicians analyzed the obstacles to home dialysis created by the interim regulations.[38] Five problems were identified: equipment, operational costs, physician fees, dialysis helper costs, and the entitlement waiting period. For fixed equipment, home-dialysis patients had to pay the 20% Medicare copayment and then enter a monthly lease arrangement for the remaining 80%; no provision was made for equipment maintenance. Under operational costs, home patients were more likely than center patients to have to pay the 20% copayment for supplies:[39] home patients were usually billed directly by suppliers, who were normally unwilling to make the next delivery without full payment; center-dialysis patients, by contrast, did not deal with suppliers, but with facilities providing treatment; facilities, in turn, often absorbed the supply copayment requirement in their own expenses rather than pass it on to the patient. Moreover, some supplies covered in center dialysis were not covered for

use in the home setting. Physician-fee arrangements were especially adverse to home dialysis. Where center physicians could receive a portion of the facility "overhead" for general patient supervision, no matter how distasteful the arrangement, physicians with home patients were deprived of even this compensation; only if a home patient became sick, was hospitalized, or had a routine checkup could physicians be paid for their services. And no physician fee was provided for home-dialysis training. Home-dialysis helpers, moreover, could not be reimbursed, though reimbursement of highly trained nursing and technical personnel occurred in centers. Finally, the three-month waiting period for patients to become eligible for Medicare ESRD benefits meant that home-dialysis training, to be reimbursed, had to be deferred until that period was over.

The recommendations of these physicians included 100% reimbursement of initial equipment, home supplies, and all Part B covered services. Some means for reimbursing physicians caring for home patients was recommended, as was a flat physician's fee for home training. Also recommended was reimbursing home helpers, shortening the waiting time to permit home training to begin early, and increasing the home training fee to the training center.

So, all the ways in which ESRD reimbursement procedures created disincentives to home dialysis and incentives to center dialysis for both patients and physicians were identified very soon after the program began, but policy responses were much slower in coming.

BHI did move to eliminate the inequity between home and center on covered supplies. It identified syringes, alcohol wipes, adhesive tape, bandages, alcohol, Betadine, and underpads as "generally uncovered items" for home-dialysis patients which, nevertheless, were reimbursed for treatment in centers. Covered supplies include dialyzers, venous and arterial sets, dialysate, saline solutions, administration sets, fistula needles, and heparin. Difference in coverage was based on the distinction between those items required for "the effective operation of a home dialysis machine" and those that were not. The following solution was found: "However, if such noncovered items were included in a package with covered items the reasonable charge for Medicare reimbursement purposes will be the lesser of the total of individual reasonable charges for all covered items in the package when purchased separately in comparable quantities, or the package charge."[40] In short, inclusion in a "package" permitted reimbursement.

The ESRD Program also communicated to fiscal carriers and regional offices that any delay in reimbursing claims for home-dialysis supplies "can cause significant financial hardship for the patient." Instructions were given, in the fall of 1973, for temporary special procedures "to preclude unnecessary hardship" as part of the special procedures then being adopted for the program. Later instructions allowed interest and carrying charges to be added by suppliers reimbursed on a monthly rather than lump-sum basis as before the program.[41] Installation and delivery charges for home-dialysis equipment were also allowed.

Not until April 1974, however, was the physician-fee problem resolved by the Secretary's "Final Policies" and a following intermediary letter. The "Final Policies" briefly noted that "since it is primarily a physician decision as to the mode and setting of therapy for the patient..., any incentive to the physician to preclude self-dialysis and home dialysis should be corrected."[42] Henceforth, physicians supervising home patients would also be entitled to a comprehensive monthly retainer fee. Further, a flat fee for physician services for home-dialysis training was to be established.

It remained for the intermediary letter to spell out the details.[43] The monthly payment to physicians was limited to a charge of not less than $8 nor more than $12, multiplied by a "conversion factor" which "reflects not only the frequency of services which are customarily provided to maintenance dialysis patients but also the complexity of the specialized care rendered by nephrologists." The conversion factor was to be 14 for physicians treating home patients and 20 for physicians treating patients in centers. The monthly retainer, then, ranged from $112 to $168 for the former and from $160 to $240 for the latter. The lower conversion factor was justified because "self-dialysis patients usually do not receive or require as extensive services as patients in facilities who are not on self-dialysis." For physicians supervising self or home dialysis training, the intermediary letter provided a flat fee of $500.

Thus, one year after the program began, HEW had removed some to home dialysis. But, since some of the other disincentives derived from the Medicare statute, legislation was necessary to correct them.

Concerned physicians focused on the Senate Finance Committee, where the professional staff were sympathetic listeners. The Renal Physicians Association president, Dr. John H. Sadler, wrote Senator Russell Long on December 13, 1974 urging the following legislative changes to encourage

home dialysis: entitlement at the time home training begins;[44] 100% coverage of equipment and supplies, including those supplies needed to use the equipment; and permission for direct purchase, lease, or rental of home equipment based on economic considerations.

These discussions resulted in the introduction by Senator Long of S. 1492 on April 21, 1975, a bill "to provide incentives and otherwise to encourage the utilization of home-dialysis and to encourage early kidney transplantation." The bill proposed that entitlement begin in the month when a patient began an approved self-dialysis training program, and that entitlement continue 36 months after receipt of a transplant rather than 12 months as under existing law. For individuals in approved self-dialysis training programs or "self-dialyzing at home or in an approved self-dialysis facility" the proposed language called for

> payment with respect to medically necessary items, services, or supplies in connection with self-dialysis (including physician's services...) covered under part A or part B of Title XVIII shall be made for 100 percentum of the reasonable cost or reasonable charge for such...; and the provisions of such part A or part B relating to deductibles and coinsurance shall not apply to such items, services, or supplies....[45]

No hearings were held on this bill and no further action was forthcoming in the Senate.

In the House, however, 1975 was the year in which Representative Wilbur Mills relinquished the chairmanship of the Ways and Means Committee. Under the new chairman, Representative Al Ullman, subcommittees were established for the first time. Representative Charles A. Vanik, chairman of the Subcommittee on Oversight, began an inquiry into the ESRD program, which produced a background document, a set of hearings, and a subcommittee report.[46] A good deal of subcommittee attention focused on how to arrest the declining proportion of home-dialysis patients, and Vanik introduced a bill on February 19, 1976 to help accomplish this. H. R. 12012 was longer, more comprehensive, and different in important respects from Senator Long's bill. The deductible and copayment provisions of Part B would be retained in the reimbursement of home-dialysis equipment and supplies, but all such expenses were now to be covered. The secretary was to survey the country to determine the accessibility of home-dialysis training facilities. He was then to develop a program to insure that such training was accessible, and that "at least 50 percent of all individuals in the area...suffering from end-stage renal

disease and [who] require renal dialysis will actually be undergoing home dialysis or receiving home dialysis training."

No further legislative action occurred in the 94th Congress, but the spadework had been done for the 95th Congress, which convened in 1977. On February 3, 1977 Representative Dan Rostenkowski, chairman of the Health Subcommittee of the Committee on Ways and Means, with Representative Vanik, introduced H. R. 3112. The new bill extended the provision of the earlier one that 50% of renal patients be on home dialysis or in self-dialysis training. Renal disease networks were proposed, having medical review boards which, among other functions, were to encourage "the use of self-care dialysis settings." The secretary, on the basis of data from networks, was to establish the appropriate proportion for self-dialysis and self-dialysis training for each network on the basis of the following:

> With respect to all networks, such proportion shall be equal to 40 percentum by October 1, 1978, 50 percentum by October 1, 1980, and such additional percentum...thereafter as the Secretary, in consultation with the medical review board, shall determine.

What was not being done by physicians and patients, what could not be done by administrative action, was to be accomplished by legislative fiat.

At a one-day hearing, April 25, most witnesses supported the general effort to eliminate financial disincentives to home dialysis.[47] But no one supported the establishment of quotas. HEW, the Renal Physicians Association, the National Kidney Foundation, the National Association of Patients on Hemodialysis and Transplantation, National Medical Care, Inc., and others all opposed the proposed quotas for home dialysis.

A clean bill, H.R. 8423, reported by the subcommittee to the full committee, introduced some important modifications. Facilities could now be reimbursed for providing home-dialysis supplies to home patients. Reimbursement for 100% of equipment costs was also authorized for home patients where equipment was purchased by facilities responsible for patient management. Reimbursement for home dialysis was to be based on a target rate, not to exceed 70% of the national average rate, adjusted for regional variations. Quotas were deleted, but the substitute language stated: "The national objective with respect to the appropriate proportion of patients in self-dialysis settings and preparing for or undertaking transplantation is that a majority of new patients being accepted for end-stage renal disease treatment should be in self-dialysis settings or be transplanted." The House of Representatives, adopting the measure under a

"suspension of the rules" on September 12, 1977, appeared determined to wrest economies from the ESRD program.

Events took a different turn in the Senate. There, H.R. 8423 was introduced by Senator Long and was the subject of a hearing on October 21, 1977.[48] The health subcommittee of the Senate Finance Committee, chaired by Senator Herman Talmadge, with Senator Robert Dole as ranking minority member, was disposed to enact the House bill with relatively few changes, as was the committee staff. Witnesses for the Renal Physicians Association and the National Kidney Foundation adopted a posture of basic support for the bill. Dr. Arvin Weinstein, president of the Foundation, for instance, testified that "We are much more comfortable with the articulation of national goals rather than what was in an earlier version of a bill; that is, fixed quotas for self-dialysis," and concluded by saying, "We endorse virtually all of the important provisions of the bill."

But the hearing itself might be termed National Medical Care's revenge. National Medicare Care, Inc., a Boston-based corporation founded in 1968 and publicly owned since 1970, provides maintenance dialysis in nonhospital limited care centers throughout the United States. It has prospered under the ESRD program, in part because the facility reimbursement screen forced outpatient maintenance dialysis from hospital-based facilities into less expensive settings and partly because of disincentives to home dialysis. Its president, Dr. Eugene Schupak, testified before the Ways and Means Committee in April. Preceding him, however, was Dr. Belding H. Scribner, from Seattle, who charged: "What started out in 1960 as a noble experiment gradually has degenerated into a highly controversial billion-dollar program riddled with cost overruns and enormous profiteering." Noting the decline in the proportion of home patients, Scribner attributed it to disincentives in the regulations and to the fact that "the present regulations have encouraged the rapid expansion of a very profitable business, selling in-center dialysis to the Government." He was to repeat the profiteering charge later that fall on the nationally telecast program, "60 Minutes."[49]

There exists a long-standing Boston-Seattle rivalry, if not enmity, on issues of end-stage renal disease. National Medical Care, by the time of the Senate hearing in October, had prepared its response. Dr. Edmund Lowrie of Peter Bent Bringham Hospital attacked the Seattle experience directly on two points: "Our analysis indicates that the cost of self-care

dialysis is not significantly less than limited care dialysis, and that the indiscriminate use of home dialysis may lead to unacceptable patient mortality.'' Though he buttressed his cost argument with a comparison of Boston and Seattle costs, seeking to show that the latter could not really do home dialysis as cheaply as they claimed, and that the cost differential between home and limited care dialysis was very slight, no one took the point very seriously: the bill, after all, would limit home dialysis reimbursement to no more than 70% of facility maintenance dialysis. The mortality argument was more telling. Lowrie cited material submitted by Blagg, director of the Northwest Kidney Center, to Vanik's subcommittee in 1975, indicating three-year patient survival to be 58% in a program having trained 80% of its patients for home dialysis. That, he noted, was less than the national average and well below most major centers. ''After careful analysis,'' Lowrie claimed, ''the only obvious reason for this inferior patient survival that we can think of is the indiscriminate use of home dialysis therapy.'' Lowrie's testimony created the impression that three-year survival of home patients in Seattle was unacceptably low. But, as Blagg later pointed out, the 58% applied to all Seattle patients, center and home, and included elderly and diabetics in significant numbers.[50] ''When we look at patient survival on home dialysis,'' Blagg wrote, ''and exclude the center dialysis patients, the 3-year survival in our program is 74 percent including diabetics; if we exclude diabetics, the 3-year survival rate in patients aged 55 or less is 81 percent on home dialysis, and for patients over the age of 55 is 55 percent. These results are comparable to other programs.''

But the political damage had been done. Senator Dole asked the General Accounting Office to update its 1975 report relative to mortality and costs of home versus center dialysis. That office reported that National Dialysis Registry data for 1972 to 1974 showed mortality slightly lower for home patients than center patients. Dole issued a press release expressing his concern for not wanting to encourage a ''form of treatment that might prove to be a risk to patients,'' noting cryptically that the GAO report addressed many of his concerns.[51]

The legislative process was arrested. No further action occurred until early February 1978, when the Senate committee mark-up of H. R. 8423 occurred and a bill was reported to the Senate on March 22, 1978. Eliminated was any reference to national goals for home dialysis and transplantation. The Senate adopted the revised bill on April 10.

There followed lengthy negotiations between staff of the two committees and several complicated congressional maneuvers; finally, agreement on a bill was reached. Public Law 95-292, signed on June 13, 1978, retained the early entitlement for self-dialysis training, provided that facilities could be reimbursed for furnishing home patients with equipment and supplies, provided 100% reimbursement for home-dialysis equipment if managed by a facility, and limited home dialysis reimbursement to 70% of facility reimbursement. The intent of congress, restated in a muted form, was that "the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated." A far cry from where the House began.

An effort to address the home-dialysis issue by amending legislation had taken three full years. Some disincentives to home treatment had been eliminated. Efforts to create positive incentives, however, had run into intense political opposition and had effectively been thwarted. The net effect on the proportion of home patients in the total dialysis patient population will be seen only in the years ahead.

Summary and Conclusions

What can we learn from the ESRD program about the politics of health cost containment?

First, the costs of the ESRD program have been widely perceived as "out of control." This perception is based upon the very high costs of treatment by dialysis or transplantation and by the high total program costs for a relatively few beneficiaries. Growth in total program costs, however, appears to be a function of patient population growth and inflation. Costs per patient year, in constant dollars, have remained stable over five years. The lesson? In politics, as in life, appearances are sometimes deceiving.

Second, the renal share of total Medicare expenditures is significant, being 1.3% of Part A, 10 percent of Part B, and 3% of the total Medicare expenditures. ESRD costs, moreover, basically constitute one half of one percent of total national health expenditures. The share of scarce medical resources being devoted to sustain the lives of 50,000 individuals is sizable.

Third, transplantation has failed as a cost control treatment strategy. Though one can save costs by transplanting patients rather than dialyzing them, there is an offsetting increase in patient mortality. But expectations

about the effects of transplantation were based upon steadily improving clinical practice. And while patient survival for cadaver kidney transplant recipients has improved, the survival rate of the transplanted kidney has declined. Cadaver transplantation increasingly must be seen as an expensive surgical procedure sandwiched between dialysis treatment rather than an inexpensive alternative to dialysis. There are, moreover, no policy instruments available to the federal government to change these painful clinical realities.

Fourth, for institutional dialysis the screen on outpatient treatment was critical to cost containment, representing an imaginative response to the government's responsibility in a situation where the non-Medicare market had been eliminated. The screen, in my judgment, is the primary reason for steady per-patient costs. The dynamic effect of the screen has been to shift the outpatient treatment of patients from hospital-based to nonhospital limited care treatment facilities. Among the latter institutions, proprietary dialysis centers have flourished; the costs of proprietary efficiency in quality of delivered care have not been assessed.

Fifth, there is reason to believe that the screen has influenced the rate and direction of technical change in dialysis. The screen constitutes a second-order signal to manufacturers and suppliers to compete for market share through cost-reducing technical change. The broader implications of this lesson for government reimbursement of medical services deserve thorough analysis for their application elsewhere.

Sixth, the problems of data collection to reduce costs are substantial, and include legal challenges to the government's authority to secure such data. Indeed, a closely related lesson is that litigation has to be expected as a concomitant of cost containment.

Seventh, home dialysis, the least costly mode of dialysis treatment, was inadvertently placed at a disadvantage by the ESRD Program. A legislative remedy for the situation was long and uncertain and, of course, highly political. The removal of all financial disincentives to home dialysis, morever, was partially checked by the desire to avoid setting precedents for other Medicare programs.

Finally, we observe in general, as in renal, that cost containment derives from a basic policy decision to provide treatment. The advocates of treatment, initially at least, wear the white hats, and the cost control proponents have a certain stingy cast to their appearance. More pertinently, while the benefits of treatment are narrowly focused on a few

identified beneficiaries, the benefits of cost containment are diffused widely as an imperceptible "saving" to a large number of taxpayers. The constituency for cost containment simply does not exist, even in kidney disease, with its high costs for few beneficiaries.

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16. Medicare reimburses 80% of the allowable charge.
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19. Schupak was the sole proprietor of the Queens Artificial Kidney Center, and leased the facility and equipment from National Medical Care, an arrangement which differed from most NMC facilities which were wholly owned by the Boston corporation.
20. Schupak v. Matthews, No. 75-1109 (D.D.C., filed July 11, 1975).
21. A summary judgment is warranted when the material facts are not in dispute, a trial is therefore unnecessary, and the judge need only rule on the law relative to the facts.
22. If Schupak had prevailed, BHI calculated that it might be liable for as much as $2 -3 million in retroactive reimburse-

ments due to Queens for the three years beginning July 1, 1973. Thomas Tierney, director of BHI, decided the government should respond to the litigation because of the cost implications. "If I am going to have to pay out $3 million, I want to be told to do so by the Court."
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