IMPLEMENTATION OF THE END-STAGE RENAL DISEASE PROGRAM:
A MIXED PATTERN OF SUBSIDIZING AND REGULATING THE DELIVERY
OF MEDICAL SERVICES

Richard A. Rettig
and
Thomas C. Webster

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The Rand Corporation
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IMPLEMENTATION OF THE END-STAGE RENAL DISEASE PROGRAM:
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OF MEDICAL SERVICES*

Richard A. Rettig
The Rand Corporation, Washington, D.C.

Thomas C. Webster
Pennsylvania State University, State College Pennsylvania

I. Introduction

End-stage renal** disease is that clinical condition reached when an individual has experienced such a degree of irreversible deterioration of kidney function that—without treatment—death will soon follow. The two principal means of treating end-stage renal disease are hemodialysis, or cleansing the metabolic waste products in the blood by use of the artificial kidney machine, and renal transplantation.

The costs of dialysis have always been high. Based upon 1972 data for 10 home dialysis programs in 6 states and 96 center dialysis programs (81 hospital and 15 non-hospital) in 11 states and 2 counties, a recent General Accounting Office (GAO)\(^1\) study indicated the following:

<table>
<thead>
<tr>
<th></th>
<th>Center Dialysis</th>
<th>Home Dialysis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Total (96)</td>
<td>Hospital (81)</td>
</tr>
<tr>
<td>Average Charge</td>
<td>$30,100</td>
<td>$30,500</td>
</tr>
<tr>
<td>Range</td>
<td>11,500-49,100</td>
<td>12,800-46,800</td>
</tr>
</tbody>
</table>

NOTE: Data are for 1972.

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** Renal means pertaining to the kidneys, from *ren*, the Latin word for kidney.
The costs of transplantation are also significant. Charges during 1973 in 24 facilities analyzed by the GAO ranged from $5,500 to $20,500 and averaged about $12,800. The Department of Health, Education, and Welfare (DHEW) cited costs to the GAO of $14,000 for a living related donor transplant. Included in the costs were hospital room, board, ancillary charges, and professional fees.\textsuperscript{2}

The costs of therapy to a given individual can vary substantially according to the therapy or combination of therapies received and a number of other contingencies. The general point, however, is that neither type of therapy is inexpensive, though for the individual patient a successful transplant is by far the least costly.

In order to provide the life-saving, or life-prolonging, therapies of dialysis and transplantation to those who could benefit from them but could not pay for them, Congress included Sec. 2991 in the Social Security amendments of 1972. This provision extended Medicare coverage to the individual under 65 who is "medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease."\textsuperscript{3} The only requirement is that the recipient be fully or currently insured or entitled to monthly benefits under the provisions of the Social Security Act or be the spouse or dependent child of such an individual.

The End-Stage Renal Disease Program (ESRD) as established by Public Law 92-603 was primarily intended to subsidize the costs of providing therapy. The provision of a subsidy, however, was accompanied by regulatory constraints. The language of the statute required that the Secretary of Health, Education, and Welfare establish minimum utilization rates and medical review boards. Both of these requirements were intended to regulate the quality of care. Although it was not mentioned in the statute, cost control was also a regulatory objective.

The emergence of cost control as an objective of regulation is attributable to several factors. The entire 1972 legislation was permeated with a desire to control the costs of Medicare which had continuously escalated since its enactment in 1965. Since the ESRD Program established

\textsuperscript{*} Chronic and end-stage are used interchangeably.
nearly universal coverage for kidney failure, the private market was essentially eliminated as a basis for determining the "reasonable cost" and "reasonable charge" of treatment. An alternative to standard Medicare procedures had to be developed for reimbursement purposes. Consequently, as DHEW officials articulated the ESRD Program's goals, they included cost control as a major objective.

Cost control remains a continuing concern of policy makers for the ESRD Program. The program which went into effect on July 1, 1973, had total first year costs of approximately $250 million for approximately 20,000 beneficiaries. Second year costs are estimated to be $350 million, and it is expected that total costs will exceed $1 billion by 1984. The magnitude of the resource requirements for the small number of beneficiaries, then, is a constant stimulus to cost control.

It is important to emphasize that cost control within the ESRD Program is a secondary objective. The ESRD Program's primary purpose is to subsidize the provision of medical services. We have, therefore, another instance of the mixed pattern of subsidy and regulation as the means for achieving public policy objectives.

Within this context of subsidy and regulation, the ESRD Program stands out as a potential prototype of either a catastrophic health insurance program or a more comprehensive national health insurance program. End-stage renal disease was not thought to be a typical disease, but the ESRD Program was and is thought to constitute a small-scale "experiment" to test the administrative capability of the federal government to handle national health insurance.

The purpose of this paper is to analyze the cost control strategy of the Social Security Administration and the Department of Health, Education, and Welfare in the design and execution of the ESRD Interim Program. From this analysis we attempt to draw some lessons for any future program of national health insurance.

II. The ESRD Interim Program

A. Origins

Public Law 92-603 stipulated that the end-stage renal disease pro-
vision was to become effective on July 1, 1973. It was not until June 29, however, just three days before this date, that Interim Regulations were published in the Federal Register. These implementing regulations deal primarily with reimbursement issues and not at all with the two quality-of-care requirements of the law—minimum utilization rates and medical review boards. At this writing, the ESRD Program is still being administered under these Interim Regulations.

The decision to separate reimbursement from quality-of-care issues and to deal with the former in an Interim Program arose from two sources. First, renal disease was a new and practically unknown phenomenon for the Social Security Administration's (SSA) Bureau of Health Insurance (BHI). While Medicare had provided end-stage renal disease benefits for those over 65 prior to July 1, 1973, the beneficiaries were few and the administrative experience was not especially informative for administering the new program. Moreover, Sec. 299I was an unanticipated part of the 1972 legislation. In the prolonged legislative history of H.R. 1, which became P.L. 92-603, no hearings were held in either the House or the Senate on end-stage renal disease, and Sec. 299I was incorporated into the bill on the Senate floor just one month before the act was signed into law. In response to this new provision, BHI established a task force on chronic kidney disease immediately upon enactment of the law in order to educate itself on the requirements for implementing the ESRD Program. The task force and higher level BHI officials soon discovered that the treatment of end-stage renal disease was highly complex.

BHI further discovered in the degree of administrative complexity within DHPEW the second source of the Interim Program. Administrative complexity arose mainly from ambiguity about how the HEW Secretary's authority would be exercised in the ESRD Program. Since the ESRD Program was part of Medicare, it might be expected that responsibility for its implementation would be delegated to the Commissioner of Social Security and by him to the BHI. Since the Commissioner reports directly to the Secretary, it might further be expected that BHI would have substantial autonomy in the administration of the ESRD Program.

The Assistant Secretary for Health of HEW, though lacking line authority over the Social Security Commissioner, had recently been given the
responsibility for coordinating Medicare issues with the other health concerns of DHHS. The manner in which this coordination was to occur, however, was not an established administrative procedure. The role of "H", as the Health activity of DHHS is bureaucratically known, was carved out by the forceful insertion of Dr. Ronald Klar, on behalf of the Assistant Secretary, into the regulation writing process. Klar's efforts brought about a sharing of responsibility between SSA and "H", though the resulting conflict threatened serious delay in issuing the implementing regulations. The technical complexity of treating end-stage renal disease, the administrative complexity of relations between SSA and "H", and the necessity of issuing implementing regulations resulted in the decision to issue Interim Regulations which covered the essential reimbursement issues and to leave the more complicated organizational questions to be resolved later. These Interim Regulations were published in the late spring of 1973.

B. The Implementation Issue Structure

The implementation of public policy can be understood as a process of transforming public policy objectives into policy outputs which approximate the initial policy intentions. In fact, there are numerous multidimensional transformations which occur as policy is implemented.

One important transformation is the conversion of policy objectives from ends-oriented statements to means-oriented statements. We refer to this as the transformation of the goal structure into the implementation issue structure. The implementation issue structure represents a factoring of the goal structure into administrative processes and subprocesses, and constitutes a map to sources of potential conflict. This instrumental factoring of goals into administrative processes is especially important because it establishes the frame of reference within which both the design and execution of program implementation occurs.

The administrative processes into which the policy goals and objectives are factored will depend, of course, on the bureaucratic situation existing at the outset of the implementation process. If an established organization will administer the policy, the implementation issue structure will be determined mainly by pre-existing standard operating proce-
dures. If a new organization is to administer the policy, the implementation issue structure will become a template used to design new procedures.

The goal structure of the ESRD Program included the following:

- The guarantee of access to ESRD medical services by all those eligible for such care,
- The provision of high quality care,
- The assurance of efficient and economical allocation and use of medical resources, and
- The containment of costs.

Since the Interim Program for end-stage renal disease addressed itself mainly to the urgent issues of reimbursement, the primary administrative responsibility for implementation fell to the BHI. Not surprisingly, therefore, the implementation issue structure was derived from standard Medicare categories. Included were the following six issues:

- Patient eligibility,
- Patient entitlement,
- Facility certification,
- Covered services,
- Facility reimbursement, and
- Physician reimbursement.

The first two of these issues—patient eligibility and entitlement—were spelled out in all essential details in the law, with some further elaboration in the Interim Regulations. These issues, while critical to program implementation, do not bear directly on the cost control efforts of the ESRD Program. The latter four issues, however, constitute the heart of the cost control strategy for this program, and it is to them that we now turn our attention.

C. The Cost Control Strategy

1. Facility certification. The program planners desired to
initiate the ESRD Program in a way which restricted sudden growth in the number of provider facilities on the eve of the establishment of a guaranteed patient market. A "freeze" was placed on new facilities in an effort to maintain or increase the utilization rates for the covered procedures until the minimum utilization rates could be developed for the long-range program, or until procedures for permitting treatment capacity to grow in relation to increased patient demand could be developed.\textsuperscript{16} The Interim Regulations, therefore, limited certification in general to facilities which were providing end-stage renal disease treatment prior to June 1, 1973, and which had not substantially increased their services at the time of the regulations. Transplant hospitals which had been participating in the Medicare program would continue to be reimbursed in the interim period for renal transplantation until further conditions of participation were promulgated and applied.

Dialysis facilities which met the above general conditions would be certified if they met the following "minimal conditions":

(1) If hospital operated, the hospital is participating in the Medicare program; (2) if free-standing, the facility (a) meets State or local licensure requirements, if any, (b) is a facility in which treatment is under the general supervision of a physician (who need not be a full-time supervisor), (c) has an affiliation, e.g., has arrangements for back-up care, etc., with a participating hospital, and (d) agrees that no charge will be made for a covered dialysis service provided by the facility that is in excess of the charge determined to be the reasonable charge of that facility.\textsuperscript{17}

Based upon information about transplantation and dialysis facilities which was provided by the Comprehensive Health Planning (CHP) Program and the Regional Medical Programs Service of DHEW at the request of the BHI, a list of certified facilities was compiled by the SSA in early 1973. The initial design decision about facility certification, therefore, was to "grandfather" in all those facilities providing services on the eve of the program's becoming operational and to impose a freeze
on expansion of their services and creation of new facilities.

At the same time that the freeze on new facilities and the expansion of existing ones was being imposed, policymakers recognized that additional treatment capacity would be needed to handle increased patient demand. So, in August 1973, the task of developing "exception criteria and procedures" for the certification of new facilities and the disposition of requests by existing facilities to expand was given to the newly created End-Stage Renal Disease Program in the Bureau of Quality Assurance (BQA/ESRD) of DH&HEW. This task was deemed to be "medical" and not "financial" and therefore was allocated to the "H" side of DH&HEW. The process of drafting the criteria and procedures statement, informally clearing the statement with the field, and securing higher-level bureaucratic clearance took four months, but approval came for the statement's release in early December.18

There then began the adjudication process by which applications for permission to build new facilities or expand existing ones were submitted to the government and processed. A quite lengthy chain of review, beginning with the initial submission of an application to a local CHP "B" agency, eventually would lead to a five-member adjudication group in DH&HEW. This group, composed of two individuals from the BHI, two from the BQA/ESRD unit, and one from the CHP Program, reviews applications and recommends that they be approved, deferred pending submission of more information, or disapproved. These recommendations are then transmitted to the SSA for final disposition.

In general, the adjudication group has been very reluctant to approve any additional transplantation capacity on the grounds that sufficient capacity currently exists. Criteria for approving new dialysis facilities have included (1) an assessment of need based upon the number of patients requiring care and the capacity of other dialysis facilities in a given geographic area and (2) consideration of the estimated maximum time a patient would have to travel in order to reach a dialysis facility.

Close observers of the adjudication process have indicated that SSA has been reluctant to disapprove an application, even when disapproval has been recommended by the adjudication work group. In this certification process, substantial rights are given to facilities providing
treatment, and a disapproved application can easily become a litigated court case. Since it is the SSA which must represent the U.S. Government in court if a disapproved application is litigated, the legal advice it is given strongly recommends accepting for litigation only those cases which the government is likely to win. In the close case, therefore, the benefit of the doubt is given to the applying facility.

The certification of facilities is seen by DHEW as a way to avoid undue buildup of capacity and to insure adequate use of existing facilities. In essence, the certification process is a cost control process. Generally, this process has been employed to permit capacity to increase in accordance with increasing patient demand. But one cannot overlook the ESRD's hesitency to disapprove facility certification applications. The establishment of bureaucratic mechanisms for implementing cost control incentives in the ESRD Program is significantly affected by the threat of litigation. Prospectively, any national health insurance program will also confront this same problem.

2. Covered services. A major problem in third party financing of health services, as Berk19 has noted, is that the nature of the health product is seldom specified. Without such specification there is no enforceable limit on the quantity or quality of health services provided. While the requirement that there be a local medical review board held out the promise of a process by which medically unnecessary services would be limited, that requirement remains to be implemented. In the absence of the review board, the Interim Program sought to eliminate unnecessary services in two major areas with great potential for abuse--the extent of use of laboratory procedures and the provision of physician services for stabilized patients.

The implementing instrument in each case, however, was not the published Interim Regulations but the initial Intermediary Letter issued by the SSA.20 The Intermediary Letter listed those laboratory procedures which could be employed and the frequency with which they could be employed without additional medical justification. Additional tests beyond those on the list, or tests at a greater frequency than indicated, had to be accompanied by a statement of medical necessity if the provider was to be reimbursed.
In a similar manner, office visits for stabilized patients were limited to one per month and extensive examinations to two per year. This restriction, however, quickly became one of the most controversial in the actual implementation of the new program, though not as controversial as the issue of physician reimbursement. It was thought to reflect the clinical views of the Seattle dialyzers and clearly did not reflect consensus among clinicians regarding standard medical practice. Though these restrictions on physician services came under sharp attack, they were not modified. But the difficulty in proscribing such services was spelled out in December 1973 in a memorandum to the Assistant Secretary for Health from the Director of the Office of Health Financing Policy Development:

While it is ... appropriate to reimburse for these [routine physician] services, it would seem reasonable to expect that some standards of "acceptable" medical practice could be established for these services. Development of criteria has been most difficult for the category of routine physician services during maintenance dialysis. The kinds and amount of "supervision" have varied considerably by physician and area as well as by patient, ranging from "on-call" availability to performing routine physical examinations. Consultations with numerous professionals have failed to yield a consensus on professional standards—we cannot specify or quantify any one set of services constituting acceptable medical practice.21

The regulation of covered services, the ESRD Program's experience would suggest, depends upon there being an ascertainable and respected point of view within the physician community regarding standard medical practice. That point of view need not reflect widespread consensus within the physician community. On the other hand, given the discrepancies which exist in the provision of ESRD Program's services, it may not be possible to establish widespread consensus. The absence of widespread consensus, however, suggests that there are substantial difficulties in imposing the "best" medical practice as the norm for all physicians.

3. Facility reimbursement. In a departure from prior Medicare practice, the Interim Regulations indicated that "customary and prevailing charges" could not be used as a basis for reimbursing facilities providing
end-stage renal disease services. The reason for this was quite simple. The nearly universal coverage established for ESRD by Sec. 299I effectively eliminated the normal medical market as a basis for establishing reimbursement rates. Instead, the regulations called for reasonable charges for services defined in relation to "charges or costs prior to July 1, 1973, [to] the costs and profits that are reasonable when the treatments are provided in an effective and economical manner, and/or [to the] charges made for other services, taking into account comparable physicians' time and skill requirements."23

The implementing Intermediary Letter indicated that screens of $150 per dialysis for maintenance dialysis and $190 for self-dialysis training would constitute the basis for reasonable charges. Though the BHI emphasized that a screen was not a ceiling, all charges above these levels had to be justified before they would be reimbursed. The screens, therefore, effectively functioned as ceilings on reimbursable charges for participating facilities.

From a cost control standpoint, the screen for maintenance dialysis was designed to provide an incentive toward efficiency for those facilities whose costs were higher than $150 per dialysis. However, no incentives toward efficiency were provided to facilities able to deliver dialysis at less than the $150 level. Some physicians reacted to this latter fact by suggesting that the government permit facilities billing below the screens to capture a portion of the savings for their own purposes. No action was taken on this suggestion, however, and charges by the more efficient providers have moved upward toward the screen.

It was the widely shared intention among policy makers in Congress, the Office of the HEW Secretary, and BHI to create cost containment incentives in the implementation of the ESRD Program. It is also important to note that there were strong voices within the nephrology community urging the government to take effective action in limiting total program costs through the establishment of incentives for cost control. Government policy on limiting facility reimbursement, in short, had substantial support among a significant portion of the specialist medical community.

Two factors have been at work to modify the initial screens. First, there has been a steady differentiation of dialysis treatments and a corol-
lary differentiation of appropriate screens. In July 1974, for example, the $150/$190 screens were removed on inpatient dialysis services and reimbursement was to be based instead upon "a reasonable cost basis in the same manner as any other inpatient services when the inpatient stay is determined to be reasonable and medically necessary." The second factor affecting the screens has been the form of physician reimbursement to which we turn next.

The costs of providing ESRD services, of course, are vulnerable to the effects of inflation. While no adjustment has yet been made for inflation, one will probably occur in the near future in accordance with standard Medicare procedures. In any event, the most effective means of cost containment which has been employed in the implementation of the ESRD Program has been the use of the screens on facility reimbursement for dialysis services.

4. Physician reimbursement. One of the most startling features of the Intermediary Letter which followed the Interim Regulations was the requirement that physicians be paid out of the reimbursement to the facility. Not surprisingly, this departure from fee-for-service billing procedures aroused a storm of protest from the medical community.

This protest was by no means a unanimous expression of opinion among nephrologists engaged in the clinical practice of dialysis. Many such individuals had been among the pioneers in providing dialysis services to patients prior to the 1972 legislation under circumstances where bootstrap economy was the prevailing practice. These economizing pioneers frequently had an academic affiliation or were institutionally-based without a private practice and thus constituted a salaried physician group. It was this group which, in many ways, was extremely influential at the outset of the ESRD Program in urging cost containment incentives upon the government.

But this group hardly spoke for all nephrologists. There had also developed a substantial number of nephrologists in private practice, usually in situations where third party financing had been established, who had discovered that quite a good living could be made by dialyzing patients. In fact, there developed several proprietary dialysis-providing
enterprises, at least one of which was nation-wide in scope. To be made salaried employees of the facilities in which they dialyzed patients was outrageous to many of these nephrologists.

This is not the place to record in full the protest over physician reimbursement, but a brief overview is appropriate. Perhaps auspiciously, the protest began on Friday, July 13, 1973, at a hotel near Chicago's O'Hare Airport where sixty or more nephrologists from across the country met to express their strong concern about the elimination of fee-for-service reimbursement. One result of that meeting was the establishment of the Physicians for Renal Replacement Therapy, later superceded by the Renal Physicians Association. This latter group, which came to have a leadership much broader than the original composition of the Friday the 13th group, did incorporate as a private, not-for-profit organization. It did not seek Sec. 501(c)(3) tax exempt status, however, in order to be free to represent its members' interests regarding the implementation of the ESRD Program to both the Congress and the Executive branch.

A more direct protest against the Interim Regulations was the legal action initiated by nephrologists in New Jersey and California against the Secretary of HEW. A group of physicians in each of these states communicated extensively with various officials of DHEW by means of personal visits, correspondence, and telephone calls, all extending over the period from July 1973 through February 1974. Members of the bureaucracy responded by internally debating the idea of a "retainer" or a capitation fee basis for reimbursement. The two physician groups were assured in late November by the BHI that an Intermediary Letter establishing the option of a retainer concept was ready to be issued. In January, however, DHEW first indicated that it had rejected the retainer concept and then indicated that it had made no decisions and was still considering various options. Exasperated after eight months of unsatisfactory petitioning of the government, the New Jersey group filed suit against the HEW Secretary in U.S. District Court in Newark on March 4, 1974.

Action inside DHEW moved ahead, stimulated by the impending legal action. By early April, the decision had been made to permit physician reimbursement either through the provider facility, as initially specified, or directly to the physician on a retainer concept basis. Physicians
were required to be uniform in their preferences within a facility; that is, all physicians associated with a given provider facility could be reimbursed in one way only, though they had the choice of determining which way that was to be. Secretary of HEW Casper Weinberger announced this modification in the physician reimbursement procedure in New York City, April 17, 1974, in a Final Policies statement. 30

The amount of the capitation or retainer fee allowed by the Intermediary Letter of June 1974 that implemented the Secretary's announced decision was a minimum of $160 and a maximum of $240 per patient per month. 31 Facility reimbursement screens were adjusted accordingly in those instances where physicians indicated a desire to be billed on the retainer basis.

Under the Interim Regulations, where payment of physician services was made by the provider facility, the effect was to establish a system of mandatory assignment of patient insurance benefits to the physician through the facility. That is, the facility, as a condition of participation, agreed to accept the established reimbursement rate for the dialysis procedure and to bill the program rather than the patient for services provided. The physician had no option but to acquiesce in the arrangement. When the alternative form of physician reimbursement was established by the Final Policies, this technically gave the physician the option of accepting or rejecting on a voluntary basis the assignment of patient benefits to him. Acceptance of voluntary assignment by the physician meant that he agreed to the established reimbursement rate and would bill the program rather than the patient. Rejection of assignment meant that the physician could bill the patient directly for services at any rate he desired. But the Final Policies clearly and forcefully indicated to the physician community that failure to accept voluntary assignment of patient benefits could well result in the establishment of a mandatory assignment requirement. 32

We do not have data which would indicate the impact of the alternative physician reimbursement method on the total costs of the program or on incentives to contain costs. But we may make several observations about the problems of regulating the costs of medical services through controls on physician reimbursement. First, a sweeping revision of fee-for-service reimbursement of physicians is probably impossible under even the most
favorable of situations. Second, modifications of fee-for-service payment in the direction of retainer or capitation fees might lead to a split between the American Medical Association and medical specialty groups, depending on the particular medical specialty. Third, the presence of a substantial number of salaried physicians among the total physician population might ease the modification of physician reimbursement procedures in the direction of a cost-reducing arrangement. Finally, the design of incentives for economy and efficiency in the delivery of medical services, as a matter of simple prudence, must allow for the significant effect that both the contingency and the threat of litigation have on policy.

D. Unaddressed Cost Control Issues.

There are at least two issues of a clinical nature which strongly affect the ESRD Program's costs but which have not been addressed in the Interim Program. The first is patient selection criteria, and the second is the modality of treatment for the dialysis patient.

1. Patient selection criteria. Hemodialysis was established as a therapy through a process of selecting the most medically suitable patients for treatment. Gradually, as experience developed in treating ESRD patients, first age criteria were relaxed and then criteria pertaining to other complicating medical problems were also relaxed. In the current context, in which financial barriers to treatment have been removed, we are witnessing what one physician calls "diminished contraindications for therapy." In other words, there are fewer and fewer clinical reasons to deny therapy to an individual able to benefit from it in even a small way. The consequence is that many centers are seeing the marginal patient become an increasing proportion of their total patient population. Overall estimates of the ESRD beneficiaries, therefore, tend to be biased downward because this dynamic is either overlooked or its implications are difficult to estimate. Total program costs, quite obviously, are pushed upward by this phenomenon. Moreover, the recent General Accounting Office report reflects the pressures generated by the public for establishing uniformity of patient selection criteria by liberalizing these criteria.
2. Modality of treatment. The most recent and best available data on dialysis costs indicates that cost is primarily sensitive to the location of treatment. In-center (or hospital) dialysis is more expensive than limited care dialysis which, in turn, is more expensive than home dialysis. The critical variable, of course, is the medical and health professional's time. One of the more interesting aspects of the ESRD experience is that Medicare coverage of home dialysis, which is administered under Part B, does not cover all the expenses which are covered if an individual is dialyzed within an institution. The SSA has recognized this somewhat ironic situation, but has pointed out that changes in the law will be required before it can be responsive to the problem. Those changes have been proposed in legislation (S. 1492) introduced this past April by Senator Russel B. Long (D-La.). Similar legislation is also being considered by the House Ways and Means Committee. In the meantime, though, the ESRD Program has been implemented in a way that provides no financial incentives for choosing home dialysis instead of institutional dialysis and actually provides disincentives to home dialysis. Such are the problems of incorporating a new program into the standard operating procedures of an established program.

IV. Tentative Lessons from the ESRD Program Experience

It is far too early to draw definitive conclusions from the experience of the ESRD Program. More extensive quantitative analysis of the actual experience of the program is obviously required. But there are a few tentative lessons which may be extracted:

1. Cost control is an instrumental objective of program implementation which is secondary to the basic purpose of providing ESRD services.

2. The design phase of implementation is crucial for cost control since the subsequent problems of implementation emphasize routine processing of a highly administrative nature. Cost control is not the dominant administrative concern of implementation.

3. Bureaucratic competition and conflict between the SSA's BHI and the Office of the Assistant Secretary for Health of HEW will
strongly affect cost control design. BHI is likely to favor cost control mechanisms which incorporate administrative simplicity and maximum consistency with existing Medicare procedures. The Office of the Assistant Secretary is more likely to be concerned with an overall cost control strategy, though it is also susceptible to the representation of other interests.

4. The design and execution of cost control strategies for national health insurance programs requires some rationalization of the relations between the "insurance company" resources of BHI and the medical resources of the "Health" side of DHHS.

5. Cost control and general program design efforts involved in the financing of medical services will take place in a context in which the threat of litigation is ever-present. That threat, moreover, will tend to induce conservative interpretations of close cases by administrators confronting the possibility of going to court over their decision. These contingencies cannot be avoided. They constitute an important aspect in the distribution of rights.

6. Regulation of medical services cannot move too far from the prevailing medical consensus in imposing cost control constraints. It is not always easy to determine what the clinical consensus is, especially in something as complex as end-stage renal disease. The "best" clinical practice can be imposed as the norm only if a substantial minority supports that definition of "best."

7. The existence of a salaried physician population as a significant proportion of the total physician population can be regarded by the government as advantageous to cost control. Such physicians have no financial stake in defending fee-for-service; they may also be more sensitive to institutional needs for efficiency in the allocation of scarce resources.

8. Screens or ceilings on reimbursable expenses constitute a reasonably effective means for controlling costs. Such screens will be most effective where the medical procedures to which they are applied are relatively homogeneous in nature. Screens, as administered under ESRD Medicare, offer no incentive to a provider to charge at lesser rates.
9. There are likely to be a number of key variables affecting cost which are medical or clinical in nature, such as patient selection criteria or modality of treatment. If these variables are defined primarily as clinical, public officials are likely to regard them as beyond the boundaries of legitimate government action. Physicians are highly likely to regard government regulation of such variables as government interference in the practice of medicine. The policy toward such variables may have substantial cost implications.

10. The design of incentives to simultaneously promote the delivery of medical services and control the costs of those services remains a highly complex task.
NOTES


2. Ibid., pp. 43-44.


5. See Allen V. Kneese and Charles L. Schultze, *Pollution, Prices, and Public Policy*, Washington, D.C., Brookings, 1975, for a critical discussion on the use of subsidy and regulation to achieve water quality and an argument for the substitution of an incentive system including effluent charges. Providing ESRD medical services and controlling water quality are asymmetric, of course; one is directed to encouraging the private sector to produce an economic good and the other is intended to dissuade the private sector from producing an economic "bad."

6. In B. D. Cohen, "Treatment Program Cost Questioned," *Washington Post*, June 17, 1975, Senator Russel B. Long, chairman of the Senate Finance Committee, was quoted as saying: "It's a forerunner [for catastrophic health insurance] and will definitely give us a lot of help in deciding how it can be administered."


8. On July 1, 1975, fully two years later, proposed Final Regulations were published; see "Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services," *Federal Register*, Vol. 40, No. 127, July 1, 1975, pp. 27782-27793. A sixty-day period was provided for public comments. Consideration of these comments will occur before final adoption of the proposed regulations. The publication, therefore, of "final" Final Regulations might be expected in late 1975 or early 1976. On most of the major issues in the proposed Final Regulations, however, implementation has already been initiated.
9. It is true that the Gottschalk Committee Report, in 1967, had recommended patient care financing for ESRD through Title XVIII of the Social Security Act. That recommendation was then incorporated into a number of legislative proposals, but nothing came of this approach until 1972. See Report of the Committee on Chronic Kidney Disease, Washington, D.C., September 1967, p. 14.

10. The House Ways and Means Committee did receive testimony by dialysis patients on November 4, 1971, and from William J. Flanigan, M.D., on November 11, but this was in connection with national health insurance, not with H.R. 1 to which the ESRD provision would later be attached. See U.S. House of Representatives, Committee on Ways and Means, National Health Insurance Proposals, Hearings, Pt. 7, pp. 1524-1546, and Pt. 10, pp. 2226-2228, 92nd Congress, 1st Session, 1971. Subsequent to these hearings, Rep. Wilbur Mills introduced a bill to provide financing for patients with end-stage renal disease, but this also was never the subject of hearings.


12. The administrative complexity was even greater than indicated in the text, though this paper is not the vehicle for fully explicating this dimension. The Kidney Disease Control Program (KDCP), which had existed since 1965, was the principal source of bureaucratic competence within the federal government at the time of passage of P.L. 92-603. The BHI task force began asking the KDCP for assistance in November 1972, which the latter cooperatively provided. The fate of the KDCP was sealed in early 1973, however, when the Nixon Administration's budget request to the Congress for fiscal 1974 contained no funds for the Regional Medical Programs Service, of which the KDCP was a part. In its waning months, the KDCP not only provided assistance and information to BHI, but also provided staff support for Klar as he involved himself in the regulation writing process. Furthermore, though KDCP expired by the end of the fiscal year, "H" constituted an end-stage renal disease unit, this time within the Bureau of Quality Assurance (BQA), by August 1973. The End-Stage Renal Disease Division of BQA has had relatively little to do with the design of the Interim Program and only somewhat more to do with its execution; it has been primarily engaged in design of the long-range program. Parenthetically, this episode highlights the prospective problem of effectively utilizing existing sources of competence in "Health" when national health insurance becomes a reality.

13. We again note parenthetically a general problem which prospectively confronts the nation in any national health insurance program, namely, the resolution of respective authorities and responsibilities of the Office of the Secretary of Health, Education, and Welfare and those of the Commissioner of the Social Security Administration.


18. This statement was later published as "Facilities Providing Treatment for End-Stage Renal Disease; Interim Period Qualification and Exception Criteria," Federal Register, Vol. 39, No. 194, October 4, 1974, pp. 35811-35819.


23. Ibid.


26. Op.cit., Part A I.L. No. 73-25, Part B I.L. 73-22, pp. 16-17: "Furthermore, with respect to physicians' services, for each routine dialysis performed there will be recognized only a facility component of service; consequently, the cost of the administrative and supervisory role of the physician in the facility would be recognized only as part of the facility overhead, and included in the renal dialysis cost center."

27. While little data is publicly available on the proprietary chains, a series of articles in the Boston Globe in 1971 discussed the development of the Babcock Artificial Kidney Center, the initial center of the National Medical Care/Biomedical Applications, Inc. chain,

28. There are strong indications of fairly intense internal DHHEW discussion of the issues and their implications. The memorandum cited in fn. 22 above stated: "While it is clear that the AMA has been opposed to any mechanism other than unit 'fee-for-service,' nephrologists have expressed both interest and support." A memorandum of March 8, 1974, added that "the AMA recently has limited their objection to any mechanism that established rigid fees": see Memorandum, From Director, Office of Health Financing Policy Development, To Assistant Secretary for Health, "Kidney Disease Treatment Program of Medicare--Reimbursement Policy Issues--INFORMATION," December 19, 1973, revised January 4, 1974, revised February 12, 1974, revised March 8, 1974, p. 13.


33. Op.cit., Comptroller General of the United States, p. 54, recommended that the Secretary should encourage "liberalized treatment criteria at facilities not accepting patients because of age, suitability for home dialysis, and diabetes and other diseases by establishing guidelines for treatment under Medicare."

34. Ibid., pp. 39-50.

35. See S. 1492, Introduced in the Senate of the United States, April 21, 1975, by Senator Russell B. Long. See also U.S. House of Representatives, Committee on Ways and Means, Background Information on Kidney Disease Benefits Under Medicare, Committee Print, 94th Congress, 1st Session, June 24, 1975, Medicare's Kidney Disease Benefits Program, Hearings, 94th Congress, 1st Session, June 24,

36. It is precisely this position which was adopted recently by the Republican members of the Subcommittee on Oversight of the House Ways and Means Committee. "The Social Security Administration," they wrote, "should not set a 'norm', or even a goal for what is basically and most clearly a medical determination. Even though home dialysis is less costly than treatment in an institution, it should be left entirely up to the physicians and the patient to determine the best treatment alternative." See p. 18 of the Report on Administration by the Social Security Administration of the End-Stage Renal Disease Program Established by Public Law 92-603 and On Social Security Medicare Research Studies, cited in fn. 35.
RETAIL AND WEBSTER

IMPLEMENTATION OF THE END-STAGE RENAL DISEASE PROGRAM:

A MIXED PATTERN OF SUBSIDIZING AND REGULATING THE DELIVERY OF MEDICAL SERVICES