Calendar No. 656

95TH CONGRESS
2d Session

SENATE

REPORT
No. 95-714

END STAGE RENAL DISEASE PROGRAM

MARCH 22 (legislative day, FEBRUARY 6), 1978.—Ordered to be printed

Mr. LONG, from the Committee on Finance, submitted the following

REPORT

[To accompany H.R. 8423]

The Committee on Finance, to which was referred the bill (H.R. 8423) to amend titles II and XVIII of the Social Security Act to make improvements in the end stage renal disease program presently authorized under section 226 of that act, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

I. PURPOSE AND BACKGROUND OF THE BILL

During the past several years a number of studies and public hearings have been conducted in order to assess the operation and effectiveness of the medicare end stage renal disease program. The results of these efforts indicate that the program has been generally successful in meeting the needs of renal disease patients for protection against the catastrophic costs of dialysis and transportation. However, at the same time, it has become clear that the program is plagued by a number of serious problems which threaten to undermine its continuing stability and effectiveness.

The committee is concerned about the high and steadily rising cost of the program and the burden it can place on the medicare trust funds unless steps are taken to put it on a more cost-effective basis. The committee believes that there are several areas of potential cost savings, including the increased use of self-dialysis settings and tranplantation, where medically appropriate, and the use of incentive reimbursement methods to encourage economies in the delivery of services.

The introduction of appropriate incentives to encourage the medically appropriate use of lower cost treatment modalities is compatible with the best interests of renal disease patients. The patient who successfully undergoes transplantation can return to a relatively

normal and stable life. The patient who can successfully manage self-dialysis either in his own home or in a self-care dialysis unit of a facility regains a significant measure of control over his own care and escapes from what might otherwise be a permanently dependent relationship. And in both types of cases, program savings over the long run can be substantial.

The committee wishes to stress its intent that patients who are medically, psychologically, and socially inappropriate for home dialysis are not to be forced, through administrative procedure, into home dialysis. Objective professional judgment, along with the needs and wishes of the patient, should be the principal determinants of the locus of treatment.

II. SUMMARY OF THE BILL

The medicare renal disease program amendments are designed to accomplish four objectives: Provide incentives for the use of lower cost, medically appropriate self-dialysis (particularly home dialysis), as an alternative to high-cost institutional dialysis; eliminate current program disincentives to the use of transplantation; provide for the implementation of incentive reimbursement methods to assure more cost-effective delivery of services to patients dialyzing in institutions and at home; and provide for studies of alternative ways to improve the program and for regular reporting to the Congress on the renal disease program. The summary presented below briefly outlines these principal features of the bill and, in addition, an unrelated medicare amendment which deals with payment for physicians' services in teaching hospitals.

INCENTIVES FOR USE OF SELF-DIALYSIS

Several provisions are designed to provide incentives for more extensive use of lower cost, medically appropriate self-care dialysis settings. Although the cost of treatment in self-dialysis settings is usually considerable less for the program than facility dialysis, there has been a steady decline in the percentage of patients on home dialysis. Experience indicates that one of the reasons for this decline is the existence of financial disincentives, resulting from the benefit structure of the medicare program, for patients to undertake self-dialysis. The bill modifies present law to eliminate these disincentives by:

1. Waiving the present 3-month waiting period for a beneficiary who enters a self-care training program prior to the end of the third month after the month his regular course of dialysis begins;
2. Providing coverage for disposable supplies (such as syringes, needles, and sterile drapes) required for home dialysis;
3. Providing coverage for periodic supportive services, including emergency visits and servicing of dialysis equipment, furnished by facilities to individuals dialyzing at home; and
4. Authorizing full reimbursement to facilities for dialysis equipment purchased by facilities for the exclusive use of patients dialyzing at home.

The bill also provides coverage for services of a self-care dialysis unit maintained by a renal dialysis facility.

ELIMINATE DISINCENTIVES TO TRANSPLANTATION

Several provisions are designed to eliminate disincentives to transplantation which expose transplant candidates to significant financial risk. Thus, the bill provides for:

1. Coverage for a transplant patient beginning with the month he is hospitalized, without regard to the waiting period of present law, if transplant surgery takes place within that month or the following 2 months;
2. Extension of the period of post-transplantation medicare coverage from 12 months to 36 months;
3. Immediate resumption of coverage, without a waiting period, whenever a transplant fails; and
4. Coverage for expenses incurred by live kidney donors, including the period of the donor's recovery.

REIMBURSEMENT METHODS

To assure more cost-effective reimbursement for dialysis services the bill provides for use of incentive reimbursement methods for services furnished by renal dialysis facilities to patients dialyzing in the facility or at home. Such methods may include prospectively set rates, a system for classifying comparable facilities, the use of target rates (adjusted for regional differences) with provision for sharing savings attributable to efficient and effective delivery of services, and other incentives to efficient performance. (The Secretary may use competitive-bid procedures, prenegotiated rate procedures or such other procedures as he finds feasible and appropriate in establishing the home dialysis target rates.)

The bill also clarifies present law concerning the alternative reimbursement methods available to physicians with respect to services provided in connection with routine maintenance dialysis episodes.

STUDIES, REPORTS, AND ADMINISTRATION

The bill requires the Secretary to conduct experiments and studies on ways to reduce program costs, without impairing quality of care, including studies relating to reuse of dialysis filters and the use of dietary controls, to increase public participation in organ donation programs and to assess alternative ways of financing renal disease services. The bill also requires the Secretary to submit an annual report to the Congress on the cost and operation of the program, and on developments in basic and applied research in the field of renal disease. The Secretary is authorized to develop appropriate administrative structures and arrangements to carry out his responsibilities.

TEACHING PHYSICIANS

In a provision whose applicability is not limited to the ESRD portion of medicare, the bill defers the effective date of a previously enacted provision (sec. 227 of P.L. 92–603) which deals with reimbursement under medicare for the services of physicians in teaching hospitals.

MINOR AND TECHNICAL AMENDMENTS

The bill amends the entitlement provisions of present law to clarify the intent that individuals with end stage renal disease are deemed to satisfy the requirements relating to disability beneficiaries. The bill also provides that the Administrator of the Health Care Financing Administration shall serve, in lieu of the Commissioner of Social Security, as the Secretary of the Board of Trustees of the Hospital Insurance and Supplementary Medical Insurance Trust Funds and shall be responsible for making reimbursement to HMO's under the medicare program.

III. GENERAL STATEMENT

A. Incentives for Use of Self-Dialysis

Several provisions are included to provide incentives for more extensive use of lower cost, medically appropriate self-care dialysis settings. Although dialysis can be performed in either the home or in an institutional setting, the choice of dialysis location has significant cost implications. The cost of home dialysis is considerably less than institutional dialysis. Studies indicate that the current annual cost of home dialysis (after the initial year) is about $8,000 while the annual cost of institutional dialysis is around double that figure.

However, since 1972, the year in which the medicare renal disease program was enacted, there has been a steady decline in the percentage of patients on home dialysis. According to the National Dialysis Register, over 40 percent of the total patients on dialysis were dialyzing at home in 1972. By the beginning of 1975, the percentage on home dialysis had declined to 25 percent; and, according to data just released by the Department the decline has continued—as of calendar year 1976, according to this data, less than 10 percent of dialysis patients are on home dialysis. While various reasons for this decline have been offered (including changes in the patient population under treatment, professional disinterest in encouraging home dialysis, and increased access to institutional facilities), evidence suggests that one of the major reasons is the existence of financial disincentives for patients to undertake self-care dialysis.

At the same time that the use of home dialysis has been declining, renal disease program costs have been rising at a significantly higher rate than forecast. Current estimates furnished by the Department indicate that renal disease program costs for fiscal year 1978 will be $0.9 billion and will increase substantially in subsequent years. The following table furnished by the Department illustrates the anticipated increases:

Estimate of annual benefits paid

Fiscal year:	*Benefits in billions*
1980	$1.3
1982	1.9
1987	3.6
1992	6.3

Moreover, the patient population for which these costs would be incurred is a relatively small one. As of March 1977, about 36,000 renal disease patients were covered by the program. The rate of increase in

enrolled beneficiaries is about 4 percent per year and is expected to decline to about one-half of 1 percent by 1985. Thus, it is estimated that the program will have an enrolled renal population of approximately 60,000 by 1986 and a stable population of about 75,000 by the year 2000.

While it is true that the high cost of the program is, in part, a reflection of the costly technology required for treatment, and the need in most cases for lifetime care, it is generally agreed that rising program costs are also a reflection of disincentives in the program to the use of lower cost self-dialysis procedures and settings. Appropriate incentives for more cost-effective use of self-care dialysis settings can help significantly to contain rising program costs without impairing the quality or availability of needed services.

WAIVER OF 3-MONTH WAITING PERIOD FOR SELF-CARE TRAINING

The bill would provide for waiver of the waiting period where an individual begins a self-care training program prior to the end of the third month after the month he initiates a regular course of dialysis.

Under present law, a renal disease patient under age 65 becomes entitled to medicare benefits beginning with the first day of the third month after the month a course of dialysis is initiated. This 3-month waiting period discourages prompt entry into a self-care training program since the beneficiary would also have to bear the additional cost of this training out-of-pocket. Moreover, once adjusted to facility dialysis, patients are often reluctant to make the change to self-care dialysis.

This provision may help to overcome the reluctance on the part of many beneficiaries to undertake self-dialysis training. However, it is expected that the Secretary will take appropriate steps to assure that it is understood the waiver is intended for those individuals who can be reasonably expected to complete the training program and, on completion, to enter into a self-dialysis setting.

COVERAGE OF SUPPLIES NECESSARY TO PERFORM HOME DIALYSIS

The bill provides coverage for all supplies, including disposable supplies, required for the effective performance of home dialysis.

Under present law, home dialysis results in a substantially larger out-of-pocket expense to the patient than facility dialysis. This is so because under the existing medicare benefit structure certain expenses that are covered in an institutional setting are not covered at the patient's home. Where dialysis is done in a facility, for example, disposable items and supplies which are necessary for the performance of dialysis (such as syringes, alcohol wipes, sterile drapes, needles, topical anesthesias, and rubber gloves) and various types of supportive equipment are covered. When dialysis is performed at home, these items—which represent as much as 15 percent of costs incurred by beneficiaries who self-dialyze at home—are not covered and the patient must pay for them out of his personal funds.

Although it has been argued that coverage of disposable items and supplies for renal patients would represent a departure from tradi-

tional medicare coverage provisions, there is a precedent for such coverage in the current provision of medicare law under which all colostomy supplies, including disposables, are covered. The reason for extending coverage in both of these cases is the unique nature of the medical procedures involved and the indispensable and continuing need for the supplies in the effective management of the patient's care. Moreover, the committee believes that coverage of renal supplies would eliminate a significant disincentive to home dialysis.

COVERAGE OF HOME DIALYSIS SUPPORT SERVICES

The bill provides coverage for periodic support services, to the extent permitted in regulations, furnished by a renal dialysis facility or hospital to an individual dialyzing at home. Support services could include periodic monitoring of the patient's adaptation to self-dialysis, emergency visits where necessary, help in the installation and maintenance of dialysis equipment and any additional supportive services the Secretary determines will be useful in helping patients to remain on home dialysis.

Under present law, mechanisms do not exist to either monitor actual home dialysis performance or provide backup professional and maintenance assistance in the home. If trained technical personnel (functioning under physician supervision) were permitted to periodically observe the patient's management of his dialysis, assist with difficult access situations, or occasionally function as a dialysis assistant, incentives to continued use of home dialysis would result by precluding the need for unnecessary inpatient treatment or backup institutional dialysis. Moreover, help in maintaining equipment is generally regarded as a vital element in the overall effort to assist those beneficiaries who might otherwise become discouraged by the problems and expense involved in servicing their own equipment to remain on home dialysis.

COVERAGE FOR SERVICES OF A SELF-CARE DIALYSIS UNIT

The bill provides for reimbursement of facilities for the maintenance of a self-dialysis unit in which a patient can manage his own treatment with a lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis. Under the bill, a self-dialysis unit must, at a minimum, furnish the services, equipment, and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for such appropriate lesser degree of ongoing medical supervision and assistance) and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

The committee recognizes that many patients who are otherwise motivated to undertake self-dialysis are unable to do so because of physical or social circumstances in the home environment. For such patients the only alternative usually available to them at present is full care maintenance dialysis in an institutional setting.

The committee has, therefore, included in the bill a provision which encourages the use of self-care stations in renal dialysis facilities. Under the bill, the Secretary would be authorized to define what constitutes self-care dialysis outside the home and to identify

the institutional settings in which it can be appropriately performed. In defining appropriate self-care dialysis settings, the Secretary is expected to identify those factors which differentiate full-care dialysis from self-care dialysis—for example, staff-to-patient ratios. In addition, the definition of self-care dialysis should specify the types of support services the facility is required to provide as an integral part of self-care, as well as those services which are not required but which would be considered an acceptable part of self-care for reimbursement purposes.

The committee does not intend that there be a proliferation of underutilized self-care units. Thus, it is expected that the Secretary will apply minimum utilization requirements and will take appropriate steps to assure himself that a need exists for the unit before authorizing its reimbursement.

REIMBURSEMENT TO FACILITIES FOR REASONABLE COST OF DIALYSIS EQUIPMENT FOR HOME DIALYSIS PATIENTS

The bill authorizes the Secretary, pursuant to agreements with approved renal dialysis facilities, to reimburse such facilities for the full reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent reuse of artificial kidney and automated dialysis peritoneal machines (including supporting equipment) which are reserved for the exclusive use of medicare patients dialyzing at home. In order to waive the coinsurance amount the Secretary would be required to assure by formal agreement that the provider or facility will: (a) Use the equipment only for medicare patients who dialyze at home; (b) recondition the equipment, as needed, for reuse by other medicare patients; (c) provide full access for the Secretary to all records and information relating to the purchase, maintenance and use of the equipment; and (d) submit such reports as the Secretary may require with respect to the management and use of the equipment. Supporting equipment would include blood pumps, heparin pumps, bubble detectors, other alarm systems and such other items as the Secretary may determine are medically necessary.

As a result of the recent enactment of P.L. 95–142, medicare can make lump-sum payments that cover 80 percent of the reasonable purchase price of durable medical equipment in cases where purchase is more economical than rental. The patient is, of course, expected to pay the remaining 20 percent.

In the case of a $5,000 dialysis machine, patient purchase is difficult or impossible even though purchase would in the long run be most economical for both the medicare program and the patient. In this example, the patient would be faced with financing a coinsurance payment of $1,000. The result is that few home dialysis patients purchase their own equipment. Instead, patients rent equipment. Some rental charges are now running more than $300 per month. In addition, maintenance charges by equipment companies appear to be significantly higher than the cost to facilities to repair their own equipment. Examples provided to the committee show that in many cases, within 1½ to 2 years, the patient and medicare will often pay in rent an amount equal to the total purchase price of the equipment. While many rental contracts provide for the servicing of the equipment and a lowering

of the rent and/or an option to buy after several years, the fact remains that rental payments are generally many times the purchase price of the equipment.

While it is difficult to estimate precisely the program saving that might be expected to result from direct purchase, data submitted to the committee indicate that annual savings, even assuming the present proportion of patients on home dialysis, could be as high as $3 million. The committee wishes to emphasize, however, that such savings are attainable on the assumption that the equipment approved for purchase is neither extravagant nor excessive. It is expected, therefore, that the Secretary will develop appropriate criteria and procedures to assure that such equipment as is approved for purchase will be limited to equipment that is sufficient for the medical purposes required and that facilities exercise prudence and sound business practices in the purchase of such equipment.

But perhaps even more important than the direct dollar savings projected on these purchases would be the removal of this significant financial disincentive to home dialysis that is posed by the 20-percent cost sharing applicable to the large purchase and rental charges. The committee believes that the larger savings that would accrue to the program from increased use of home dialysis warrant the use of an arrangement under which approved facilities purchase and maintain dialysis equipment exclusively for the use of patients dialyzing at home. Moreover, utilizing such arrangements with approved facilities will assure the most effective, continued use of this expensive equipment throughout its useful life and a greater degree of professional supervision over the medical management of the patient's home care.

B. Incentives for Renal Transplantation

The cost of a kidney transplant now runs between $20,000 and $25,000. A successful patient would then incur costs of about $3,000 in the first year following transplantation for drugs and physician services, and between $1,000 and $2,000 a year thereafter. Slightly over 3,000 patients (about 10 percent of the renal patient population) attempted transplantation in 1976, and many nephrologists believe that with appropriate encouragement that figure could be significantly increased. The committee believes that the elimination of disincentives to transplantation is essential to assure that patients and their physician have the opportunity to make the important medical choice between dialysis and transplantation unencumbered by financial considerations imposed by the coverage provisions of medicare.

COVERAGE BEGINNING WITH MONTH OF HOSPITALIZATION

The bill modifies present law by beginning coverage for a transplant patient with the month of hospitalization if the surgery takes place within the following 2 months, rather than the following 1 month as under present law. Transplantation is a two-step process: First, the removal of the diseased kidney; second, the implantation of a new kidney which, in some cases, may not take place for as long as 6 to 8 weeks after the first step. A 2-month provision would assure equitable coverage of all transplant patients.

POST-TRANSPLANT COVERAGE EXTENDED TO 36 MONTHS

The bill would extend the period of medicare coverage for patients who undergo transplantation from 12 to 36 months.

Under present law, medicare entitlement for a transplant patient terminates at the end of the 12th month following transplantation. However, a great many transplants have not stabilized or cannot be deemed successful after 12 months. As a result, many patients are either hospitalized or undergoing intensive out-patient treatment for rejection episodes during or shortly after the twelfth month, at the very time their medicare benefits are being terminated. Moreover, even successful transplant patients incur substantial medical costs directly related to the transplant for several years following the surgery, although the heaviest costs are incurred in the first 3 years. The bill would alleviate this problem by affording an adequate period of post-transplant medicare protection.

IMMEDIATE RESUMPTION OF COVERAGE WITHOUT A WAITING PERIOD IF TRANSPLANT FAILS

Under present law, a patient whose transplant fails after his entitlement ends is liable for the substantial costs associated both with the failure of the transplant and any dialysis required during the waiting period before medicare coverage resumes. The bill eliminates this disincentive by providing for the immediate resumption of medicare coverage whenever a transplant is rejected.

CLARIFY PRESENT LAW RELATING TO EXPENSES INCURRED BY KIDNEY DONORS

The bill clarifies the Secretary's authority under present law to provide reimbursement for the costs incurred in connection with kidney donations. The committee believes that such a policy is essential both to assure a continued supply of live donor organs and to take into account, in the medicare reimbursement system, appropriate medical costs related to organ procurement (which cannot always be assigned to a particular beneficiary), including a donor's postoperative recovery costs.

C. Reimbursement Methods

When the Congress enacted the renal disease program in 1972, it did so in full recognition of the fact that substantial difficulties would be encountered in the development of equitable reimbursement policies. Little data was then available either on treatment costs or on prevailing charges. Moreover, there was a great variety of arrangements through which services in the relatively new field of renal dialysis were rendered. As a result, the Congress authorized the Secretary to develop and apply reimbursement policies and procedures on the basis of evolving experience. Based on this extensive program experience the committee believes that several changes that would result in more cost-effective reimbursement can be made both in the method for paying facilities for dialysis services rendered to patients dialyzing in the facility, and in the method by which payment is made for expenses incurred by patients dialyzing at home under the supervision of ap-

proved facilities. In addition, it is now appropriate to clarify present law relating to the alternative reimbursement methods available to renal physicians.

ALTERNATIVE REIMBURSEMENT METHODS FOR PHYSICIANS' SERVICES

The bill clarifies the Secretary's authority under present law to provide reimbursement for physicians' services in connection with routine maintenance dialysis in accordance with alternative reimbursement methods.

Under present program policies, physicians have a choice between two methods for receiving reimbursement for routine maintenance dialysis services. Under one method, the physician can bill the medicare program reasonable charges for all emergency services he furnishes during a maintenance dialysis episode; the physician looks to the facility for payment for his routine dialysis services and the facility is reimbursed for these payments by the program.

The second method, called "comprehensive reimbursement," provides for payment of a reasonable charge for all medical services furnished to a maintenance dialysis patient during a month, other than inpatient hospital services and services not related to the patient's renal problem that require extra visits. (Reasonable charges for these latter services may be billed separately.) About one-fourth of all nephrologists have elected this method of reimbursement.

Use of these optional reimbursement methods is consistent with the congressional intent to develop reimbursement methods and procedures designed to address the unique circumstances involved in the provision of maintenance dialysis services.

REIMBURSEMENT FOR RENAL DIALYSIS PROVIDED IN A DIALYSIS FACILITY

The bill modifies present law by directing the Secretary of HEW to promulgate regulations establishing an incentive reimbursement system with respect to dialysis services furnished by facilities to patients dialyzing in the facility. The new reimbursement system would provide appropriate incentives for encouraging more efficient and effective delivery of dialysis services, including (to the extent and in such combination as he determines feasible), the use of prospectively set rates, a system for classifying comparable facilities (taking into consideration in various facilities of the relative complexity, or lack of complexity generally characteristic of their patients' renal treatment needs), target rates with arrangements for sharing such reductions in cost as may be attributable to more efficient and effective delivery of services, and such other incentives as he finds will encourage more cost-effective delivery consistent with proper care. The incentive reimbursement system, which may be established on a cost-related or other equitable and economically efficient basis, would become effective with respect to a facility's first accounting period after the 12th month following the month of enactment.

The Secretary should also establish appropriate limits on reimbursement options which may be elected by facilities so as to preclude shifting back-and-forth from one method to another by facilities so as to

maximize reimbursement. The bill authorizes the Secretary to prescribe in regulations such methods and procedures as are necessary to determine costs incurred in furnishing renal dialysis services and to determine amounts payable in accordance with the incentive reimbursement system. Moreover, such regulations, in the case of services furnished by proprietary facilities may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on net equity capital, providing such rate of return does not exceed the rate currently provided for in the Social Security Act for other proprietary institutions participating in the medicare program.

The bill addresses these problems directly by providing for the implementation of an incentive reimbursement method designed to encourage facilities to deliver services on a cost-effective basis. To an increasing degree, congressional attention has been focused on the need to develop prospective reimbursement methods and target rates to encourage more efficient management of health facilities and to stimulate better planning in the delivery of services. The method included in the bill reflects this general philosophy; it provides for the use of prospectively set rates and for the use of arrangements under which efficiently managed facilities may share in the savings they produce.

Although the bill authorizes the use of various types of incentives for more efficient delivery of services, it is recognized that some testing and phasing-in of these incentives may be necessary. Thus, the bill authorizes the implementation of incentives in such combination and in accordance with such timing as the Secretary finds administratively feasible, consistent with the intent to establish at least an initial incentive reimbursement system no later than a year after enactment.

In addition, the bill clarifies the Secretary's authority under present law to (a) require facilities reimbursed on a cost-related basis to agree not to charge beneficiaries more for covered services they provide than the applicable deductible and coinsurance amounts, and (b) to provide for reimbursement to hospitals for their costs attributable to payments made to an organ procurement agency or histocompatibility laboratory in amounts that may not exceed costs incurred by that agency or laboratory. The bill further provides that renal dialysis facilities reimbursed on a cost-related basis will have the same appeal rights as hospitals and other providers of services now have under medicare when a disagreement results with respect to program reimbursement.

The two criticisms most often made of the present "reasonable charges" method for reimbursing renal dialysis facilities is that (1) it does not permit the program to effectively adjust payment limits as prices and circumstances vary or as new facilities come into operation; and (2) it allows facilities to receive reimbursement based on their own charges regardless of the relationship to cost. The congressional intent was to provide for the development of a "charges related to reasonable cost" method of reimbursement for dialysis facilities based on appropriate cost data collected from the facilities by the Secretary. However, efforts to obtain this cost data in accordance with congressional intent have been challenged by some facilities. Accordingly the committee believes that reiteration of the Secretary's authority to collect such cost information is necessary.

Consistent with the provision for cost-related reimbursement, the bill reaffirms the Secretary's authority to reimburse a facility for furnishing covered services under the program only if the facility accepts such payment as payment in full, except for applicable deductible and coinsurance amounts. The facility could, of course, charge the beneficiary or other party for noncovered services.

The committee expects that the Secretary will continue to require renal dialysis facilities to furnish such reports and information concerning the costs of their operations as a condition of reimbursement. The Secretary is also authorized to condition participation upon their compliance with such other requirements relating to program participation as are specified in the Social Security Act and regulations promulgated in accordance with it, including notification to the Secretary if a facility can no longer meet the conditions for participation as an approved supplier or if it contemplates the expansion or addition of services. These requirements will help assure the orderly expansion of facility treatment resources and prevent wasteful duplication of services by precluding expansion without the express approval of the Secretary. The committee believes these requirements should help to restrain the cost escalation of the program by assuring maximum utilization of existing facilities, personnel, and equipment.

The committee realizes that disputes may arise with respect to determinations of the costs incurred by renal dialysis facilities and the amounts payable under the program. The medicare intermediary appeals process should suffice to resolve disputes involving small amounts. Where the amounts in controversy are substantial—$10,000 or more for an individual facility, or $50,000 or more in the aggregate for a group of facilities—the committee has provided that renal dialysis facilities may appeal to the Provider Reimbursement Review Board.

Under present law, pretransplant services furnished by organ procurement agencies and histocompatibility laboratories are reimbursed as inpatient hospital services at the time of transplantation. This policy has been effective in providing coverage of pretransplant services; however, it has not provided the program with adequate fiscal controls. For example, when an organ procurement agency provides a kidney to a transplant hospital, it is billed to the hospital directly and the components of the charge are not subject to the review of the medicare intermediary as are other services provided directly by the hospital. In addition, a kidney may be handled by several agencies before it is delivered to the transplant hospital and each agency will add an amount to the charge which is not necessarily related to the cost of processing the kidney. The bill, therefore, provides for reimbursement of organ procurement agency and histocompatibility laboratory services on a reasonable cost basis.

In implementing this provision, it is expected that the Secretary will apply recognized principles of cost reimbursement, obtain periodic cost reports, and provide for an intermediary hearing for an agency or laboratory which disagrees with a cost determination. The committee also expects that the services of these agencies will continue to be reimbursed through the hospital; however, in view of the evolving relationships in this particular field, the Secretary may institute, if he finds it

appropriate, a system whereby such agencies are reimbursed directly for their services.

The bill authorizes the Secretary to develop and apply appropriate requirements with respect to providers of services and renal dialysis facilities furnishing dialysis and transplant services. The committee expects that the Secretary will develop, in addition to such requirements as are currently applicable with respect to such providers and facilities, appropriate requirements relating to the provision of self-dialysis services in a self-care dialysis unit and home dialysis support services furnished by a provider or facility.

REIMBURSEMENT TO RENAL DIALYSIS FACILITIES FOR PATIENTS DIALYZING AT HOME

The bill would provide for the implementation of an incentive reimbursement system with respect to payment for the dialysis of patients dialyzing at home under the supervision of a facility. Under the bill, the Secretary would be authorized to provide for payment on the basis of a target reimbursement rate for home dialysis for all necessary home dialysis medical supplies, equipment, and supportive services (including the services of qualified home dialysis aides), as are medically necessary to enable patients to continue dialyzing in the home setting. Payment would be made to the facility which is supervising the patient's home care and is willing to assume responsibility for obtaining the necessary equipment, arranging for its maintenance, purchasing medical supplies, and arranging for the provision of needed supportive services.

In establishing the home dialysis target rate (which would be adjusted for regional differences), the Secretary would include his estimate of the cost of providing medically necessary home dialysis supplies and equipment (including such medically necessary routine laboratory services as are required); an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and an allowance, in an amount determined by the Secretary, to cover the facility's administrative costs and to provide an incentive for the efficient delivery of home dialysis; but in no event may the target rate exceed 70 percent of the national average reimbursement rate (i.e., the average amount approved by medicare before application of the coinsurance requirement), adjusted for regional variations, for institutional maintenance dialysis in the preceding fiscal year. Any target rate so established for a calendar year would not be subject to renegotiation during that year. Moreover, in establishing such a rate, the Secretary would be authorized to utilize a competitive-bid procedure, a prenegotiated rate procedure, or any other procedure he determines is appropriate and feasible.

The implementation of a home dialysis target rate addresses the critical problem of encouraging more efficient delivery (and more effective supervision) of home dialysis services. Because of their responsibilities for overseeing home patients and their desire to budget moneys as adequately as possible to provide all the services they deem necessary for their patient population, the committee believes that facilities would have an incentive under this method to exercise additional restraints on home dialysis costs by implementing more effec-

tive purchasing procedures for supplies and equipment and by more rigorously assessing the actual need for particular services. Moreover, all necessary services, supplies, and equipment to perform home dialysis would be controlled under one account maintained by the facility, thereby improving the program's ability to accurately identify home dialysis costs, evaluate the effectiveness of facility management of home care, and provide realistic incentives for cost-effective delivery of services.

Such a reimbursement method offers other significant advantages. In order to qualify for reimbursement under this method, a facility would have to assume full responsibility for the supervision of patients dialyzing at home. This should facilitate improved supervision of the care rendered to home patients. Moreover, since the supervising physician at the facility would have the flexibility to use the reimbursement for home dialysis patients in the manner he determines would be most appropriate medically for each particular patient, more effective management of patient care is possible.

While recognizing that this method represents a new and innovative approach to the management and reimbursement of home dialysis services, the committee believes it offers an opportunity both for facilities and patients to effect economies, while at the same time maintaining a high level of quality care. The concept of an incentive target rate encompasses both of these ideas. The committee expects, therefore, that the Secretary will implement this reimbursement system prudently with due regard for the need to carefully assess its effects and to assure that services rendered meet the tests of medical necessity and reasonableness.

On the other hand, it is not the committee's intent that the target rates be automatically reduced in cases where facilities have demonstrated effective performance, but rather that such rates be designed so as to assure efficient facilities of an incentive to continue to deliver services on an efficient basis. Thus, in developing the target rates, it is expected that the Secretary will take into account the differential in the costs involved in the use of peritoneal dialysis, as well as regional variations in the provision of home dialysis services generally, with a view to achieving the purpose of increased and more effective utilization of the home dialysis setting.

D. Peer Review

The bill assigns to the network peer review organization (a coordinating council, it's executive committee and a medical review board) the responsibility for encouraging the use of those treatment settings most compatible with the successful rehabilitation of the patient, and placement of suitable candidates in self-care settings and transplantation. Under the bill, each renal disease network and its medical review board would be responsible for—

(*a*) Developing criteria and standards relating to the quality and appropriateness of patient care, and

(*b*) Evaluating the procedures by which facilities in the network assess the appropriateness of patients for proposed treatment modalities.

Recognizing the active and continuing role that renal patients play in their own treatment, the committee has added to the House bill a provision that at least one patient representative be included on each network coordinating council and on the council's executive committee.

Present law is silent about the eligibility of individuals who have a financial interest in a renal dialysis facility to serve on renal network coordinating councils, their executive committees and medical review boards. To avoid conflicts of interest, the committee has added to the House bill a provision that would bar from serving on one of these network organizations any individual, or a member of his family who has a significant ownership or control interest in a dialysis institution or who has been paid compensation by such an institution in excess of what could be considered to be reasonable when compared to any services or goods he may have supplied to the facility.

E. Studies, Reports and Administration

EXPERIMENTS AND STUDIES

The bill requires the Secretary to conduct the following studies and experiments: (a) pilot projects relating to the use of durable medical equipment by renal disease patients; (b) experiments and studies to evaluate methods for reducing the costs of the renal disease program, including experimentation with reimbursement for home dialysis aides and evaluations of the cost-saving potential of the reuse of dialysis filters, and the use of methods of dietary control; (c) studies of methods to increase public participation in kidney and other organ donation programs; (d) a study of reimbursement for physician services furnished to renal patients; and (e) a study of possible ways to assist renal patients not eligible for medicare to meet their medical care costs. The Secretary would be required to submit the results of these studies and experiments, along with any recommendations for legislative changes, to the Congress by October 1, 1979.

There is widespread agreement on the need for further study and experimentation with a variety of issues relating to more cost-effective measures for providing renal disease treatment. Many of these issues, such as the reuse of dialysis filters and the utilization of dietary controls, are matters involving differing professional judgments, and it is expected that the Secretary will employ the services of the appropriate professional disciplines in conducting these experiments. In particular, the committee expects that the experiments relating to dietary control will use the expertise of registered dietitians and of board-certified nephrologists who devote a substantial part of their professional practice to problems of patients with end stage renal disease. Moreover, the committee has added to the House bill a provision that would assure that experiments in the reuse of dialysis filters would be conducted only after the Secretary of HEW has determined, following review by appropriate authorities such as the FDA, the Center for Disease Control or the National Institutes of Health, that the study will be carried out under circumstances that will assure that the filter reuse will be safe and medically appropriate.

The committee recognizes that major obstacles to the increased use of transplantation is the problem of an adequate supply of suitable

organs. Due to lack of public understanding of the need for organ donation, each year thousands of cadaver organs that are suitable for transplantation are not used. The committee believes, therefore, that there is a need to find ways to increase public participation in organ donation programs.

ANNUAL REPORT ON RENAL DISEASE PROGRAM

The bill requires the Secretary to submit a report on the renal disease program to the Congress on October 1, 1978, and on October 1 of each year thereafter. This report is to include data and information on program experience, operations and cost, as well as information on the results of cost-saving experiments and research into the causes, prevention, and treatment of renal disease.

ADMINISTRATION

The bill clarifies present law by explicitly authorizing the Secretary to establish appropriate organizational and informational structures to effectively administer the program, including renal disease network areas, network organizations to assure professional participation, and a renal disease medical information system. The bill also provides authority for the Secretary to develop mechanisms, consistent with the responsibilities assigned to network organizations and their medical review boards, for the coordination of network planning and quality assurance activities with other health planning and peer review activities authorized under the National Health Planning and Resources Development Act (Public Law 93-641) and the Professional Standards Review Organization provisions of the Social Security Act and for the exchange of aggregate data and information among these organizations.

Some concern has been expressed about the extent of the Secretary's authority under present law to establish the necessary administrative structures in the renal disease networks to assure professional participation in the planning and review of network performance. The intent of the bill is to eliminate this uncertainty. It is also the committee's intent that medical data derived from this program be governed by the same policies with respect to the confidentiality of individual medical records as are applicable under present law.

F. Reimbursement for Services of Physicians Provided in Teaching Hospitals

When medicare was enacted, the general expectation reflected in the law was that the patient care services of physicians would be reimbursed under part B (supplementary medical insurance) on the basis of reasonable charges. Hospital costs, including salaries of interns and residents, as well as supervising physicians participating in educational program in the hospital, were to be reimbursed under part A of medicare (hospital insurance) on a reasonable cost basis.

These distinctions, however, are not easily made with respect to services in a teaching hospital, where teaching and patient care are often inseparable. The original medicare law did not address the specific issue of how medicare should determine reimbursement for the

services of a physician when he supervises interns and residents in the care of patients.

This ambiguity led in practice to a variety of arrangements for reimbursing the services of physicians in teaching hospitals. Out of concern about the lack of uniformity in these arrangements and reimbursement improprieties the Congress included a provision (section 227) in the 1972 social security amendments (Public Law 92–603) that was intended to remedy these problems.

Adoption of this provision, however, brought forth expressions of serious concern from the medical education community about whether the legislation in fact established a workable and equitable reimbursement policy for the teaching hospital setting and the effective date of the provision has been deferred to provide time for study. The committee has added to the House bill an amendment that would further defer the effective date until October 1, 1978. This delay was requested by the administration to afford it additional time to publish the necessary implementing regulations and to propose possible legislative changes.

G. Minor and Technical Amendments

The bill includes two minor changes in the rules concerning entitlement to end stage renal disease.

First, the bill deletes the requirement in present law that an individual be under 65 years of age to qualify as a renal disease beneficiary. This provision has caused hardship in cases where the onset of renal disease was after 65 and entitlement could only be based on the work of another related individual. The committee's proposed change, of course, would not affect the entitlement of individuals to medicare based on their own work, nor would it impose a 3-month waiting period for entitlement to renal disease benefits on such individuals.

Second, the committee has clarified the intent of present law that individuals with end stage renal disease be deemed to satisfy the entitlement requirements applicable to medicare disability beneficiaries.

The committee recognizes that renal disease is a progressive disease; and that in many cases, it may be difficult to decide whether or when maintenance dialysis treatments should be initiated, and the exact point at which a person with a severe kidney disorder can be determined to have end stage renal disease and thus be entitled to medicare protection. In the medical community, decisions as to appropriate treatment, including the point at which maintenance dialysis is initiated, may be subject to change over time in the light of improved understanding of the disease. The bill therefore recognizes that there is a need for some flexibility in policies concerning entitlement, termination, and/or reentitlement to medicare. The committee expects the Secretary to be guided in establishing the necessary rules not only by the need for flexibility, but by the basic purpose of the ESRD program, which is to relieve individuals of the catastrophic costs associated with the treatment of this disease.

The bill also makes a change in the structure of the Hospital and the Supplementary Medical Insurance Trust Funds' Boards of Trustees and, under a committee amendment, in the name of the agency responsible for making medicare payments to HMO's, by replacing the Com-

missioner of Social Security with the Administrator of the Health Care Financing Administration. Such a change was made necessary by the reorganization of the Department of Health, Education, and Welfare as a result of which responsibility for the administration of medicare program was transferred from the Social Security Administration to the Health Care Financing Administration.

The committee added to the House bill technical amendments that are necessary to carry out the intent of the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Public Law 95–142). One of the changes would extend to patients of intermediate care facilities the protection afforded the personal funds of patients in extended care facilities.

IV. REGULATORY IMPACT OF THE BILL

In compliance with paragraph 5 of rule XXIX of the Standing Rules of the Senate, the following statements are made concerning the regulatory impact of the bill.

The provisions of the bill should not act to bring about major and continuing regulatory activity following issuance of the initial regulation modifying present law. Virtually no additional paperwork requirements are anticipated with respect to patients and providers. No change in the personal privacy aspects of the program under present law are expected as a consequence of this legislation.

V. VOTE OF THE COMMITTEE IN REPORTING THE BILL

In compliance with section 133 of the Legislative Reorganization Act of 1946, the following statement is made relative to the vote by the committee to report the bill.

The bill was ordered reported by a voice vote.

VI. BUDGETARY IMPACT OF THE BILL

In compliance with section 252(a) of the Legislative Reorganization Act of 1970 and sections 308 and 403 of the Congressional Budget Act, the following statements are made relative to the costs and budgetary impact of the bill.

The provisions of the bill do not provide new budget authority or tax expenditures. The committee accepts the estimates of the Congressional Budget Office on the impact of the bill. The report received by the committee from the Congressional Budget Office is included in this report.

CONGRESSIONAL BUDGET OFFICE,
U.S. CONGRESS,
Washington, D.C., March 6, 1978.

Hon. RUSSELL LONG,
Chairman, Committee on Finance,
Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the CBO has reviewed H.R. 8423 as ordered reported by your committee. This bill amends Titles II and XVIII of the Social Security Act to make improvements in the end stage renal

disease program (E.S.R.D.) in order to encourage and facilitate the use of home dialysis. Also, H.R. 8423 provides for improved coverage for eligible patients receiving kidney transplants.

Provisions of this bill are intended to increase both the support services and equipment available to home dialysis patients in order to expand the number of individuals who would take advantage of the lower cost method of treatment rather than more expensive institutional dialysis services. Thus, while increasing medicare costs through provision of services and equipment, these expenses would be somewhat offset by the reduced number of institutionally treated E.S.R.D. patients.

It is difficult to estimate both the specific costs attributable to the individual section of H.R. 8423 and the savings due to the higher participation rate of home dialysis beneficiaries. CBO has reviewed the estimates prepared by the H.E.W. Office of the Actuary and believes that they are reasonable. However, they assume full year effects of the bill in fiscal years 1979 and 1980 and, given the lag in bringing participation rates up to the projected 10 percent level, estimates for both costs and savings might be too high. Using the actuaries' estimates as a base, however, CBO would project that costs and savings would essentially offset each other in fiscal year 1979 and, thus, no net increases or decreases over current law would occur. Savings in the second year of about $10 million would accrue, and in subsequent years, given both a reduction in start-up costs and increases in participation, larger savings in the range of $30–40 million would occur.

If we can be of further assistance in this matter, please do not hesitate to contact us.

Sincerely,

ALICE M. RIVLIN, *Director.*

VII. CHANGES IN EXISTING LAW

In compliance with paragraph 4 of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman) :

SOCIAL SECURITY ACT, AS AMENDED

* * * * * * *

TITLE II—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE BENEFITS

* * * * * * *

Entitlement to Hospital Insurance Benefits

SEC. 226.

(a) Every individual who—

(1) has attained age 65, and

(2) is entitled to monthly insurance benefits under section 202 or is a qualified railroad retirement beneficiary,

shall be entitled to hospital insurance benefits under part A of title XVIII for each month for which he meets the condition specified in [subparagraph (B)] *paragraph (1)*, beginning with the first month after June 1966 for which he meets the conditions specified in [subparagraphs (A) and (B)] *paragraphs (1) and (2)*.

(b) Every individual who—

(1) has not attained age 65, and

(2) (A) is entitled to, and has for 24 consecutive calendar months been entitled to, (i) disability insurance benefits under section 223 or (ii) child's insurance benefits under section 202(d) by reason of a disability (as defined in section 223(d)) or (iii) widow's insurance benefits under section 202(e) or widower's insurance benefits under section 202(f) by reason of a disability (as defined in section 223(d)), or (B) is, and has been for not less than 24 consecutive months a disabled qualified railroad retirement beneficiary, within the meaning of section 7(d) of the Railroad Retirement Act of 1974,

shall be entitled to hospital insurance benefits under part A of title XVIII for each month beginning with the latter of (I) July 1973 or (II) the twenty-fifth consecutive month of his entitlement or status as a qualified railroad retirement beneficiary described in paragraph (2), and ending with the month following the month in which notice of termination of such entitlement to benefits or status as a qualified railroad retirement beneficiary described in paragraph (2) is mailed to him, or if earlier, with the month before the month in which he attains age 65.

(c) For purposes of subsection (a)—

(1) entitlement of an individual to hospital insurance benefits for a month shall consist of entitlement to have payment made under, and subject to the limitations in, part A of title XVIII on his behalf for inpatient hospital services, post-hospital extended care services, and post-hospital home health services (as such terms are defined in part C of title XVIII) furnished him in the United States (or outside the United States in the case of inpatient hospital services furnished under the conditions described in section 1814(f)) during such month; except that (A) no such payment may be made for post-hospital extended care services furnished before January 1967, and (B) no such payment may be made for post-hospital extended care services or post-hospital home health services unless the discharge from the hospital required to qualify such services for payment under part A of title XVIII occurred (i) after June 30, 1966, or on or after the first day of the month in which he attains age 65, whichever is later, or (ii) if he was entitled to hospital insurance benefits pursuant to subsection (b), at a time when he was so entitled; and

(2) an individual shall be deemed entitled to monthly insurance benefits under section 202 or section 223, or to be a qualified railroad retirement beneficiary, for the month in which he died if he would have been entitled to such benefits, or would have been a qualified railroad retirement beneficiary, for such month had he died in the next month.

(d) For purposes of this section, the term "qualified railroad retirement beneficiary" means an individual whose name has been certified

to the Secretary by the Railroad Retirement Board under section 7(d) of the Railroad Retirement Act of 1974. An individual shall cease to be a qualified railroad retirement beneficiary at the close of the month preceding the month which is certified by the Railroad Retirement Board as the month in which he ceased to meet the requirements of section 7(d) of the Railroad Retirement Act of 1974.

[(e) Notwithstanding the foregoing provisions of this section, every individual who—

[(1) has not attained the age of 65;

[(2) (A) is fully or currently insured (as such terms are defined in section 214 of this Act) or would be fully or currently insured if his service as an employee (as defined in the Railroad Retirement Act of 1974) after December 31, 1936, were included in the term "employment" as defined in this Act, or (B) is entitled to monthly insurance benefits under title II of this Act or an annuity under the Railroad Retirement Act of 1974, or (C) is the spouse or dependent child (as defined in regulations) of an individual who is fully or currently insured or would be fully or currently insured if his service as an employee (as defined in the Railroad Retirement Act of 1974) after December 31, 1936, were included in the term "employment" as defined in this Act, or (D) is the spouse or dependent child (as defined in regulations) of an individual entitled to monthly insurance benefits under title II of this Act or an annuity under the Railroad Retirement Act of 1974; and

[(3) is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease;

[shall be deemed to be disabled for purposes of coverage under parts A and B of Medicare subject to the deductible, premium, and copayment provisions of title XVIII.

[(f) Medicare eligibility on the basis of chronic kidney failure shall begin with the third month after the month in which a course of renal dialysis is initiated and would end with the twelfth month after the month in which the person has a renal transplant or such course of dialysis is terminated.

[(g) The Secretary is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe: *Provided*, That such requirements must include at least requirements for a minimal utilization rate for covered procedures and for a medical review board to screen the appropriateness of patients for the proposed treatment procedures.]

[(h)](*e*)(1) For purposes of determining entitlement to hospital insurance benefits under subsection (b) in the case of widows and widowers described in paragraph (2)(A)(iii) thereof—

(A) the term "age 60" in sections 202(e)(1)(B)(ii), 202(e)(5), 202(f)(1)(B)(ii), and 202(f)(6) shall be deemed to read "age 65"; and

(B) the phrase "before she attained age 60" in the matter following subparagraph (F) of section 202(e)(1) and the phrase "before he attained age 60" in the matter following subparagraph (F) of section 202(f)(1) shall each be deemed to read "based on a disability".

(2) For purposes of determining entitlement to hospital insurance benefits under subsection [b] (*b*) in the case of an individual under age 65 who is entitled to benefits under section 202, and who was entitled to widow's insurance benefits or widower's insurance benefits based on disability for the month before the first month in which such individual was so entitled to old-age insurance benefits (but ceased to be entitled to such widow's or widower's insurance benefits upon becoming entitled to such old-age insurance benefits), such individual shall be deemed to have continued to be entitled to such widow's insurance benefits or widower's insurance benefits for and after such first month.

(3) For purposes of determining entitlement to hospital insurance benefits under section [b] (*b*) any disabled widow age 50 or older who is entitled to mother's insurance benefits (and who would have been entitled to widow's insurance benefits by reason of disability if she had filed for such widow's benefits) shall, upon application, for such hospital insurance benefits be deemed to have filed for such widow's benefits and shall, upon furnishing proof of such disability prior to July 1, 1974, under such procedures as the Secretary may prescribe, be deemed to have been entitled to such widow's benefits as of the time she would have been entitled to such widow's benefits if she had filed a timely application therefor.

(4) For purposes of determining entitlement to hospital insurance benefits under subsection (b) in the case of an individual described in clause (iii) of subsection (b)(2)(A), the entitlement of such individual to widow's or widower's insurance benefits under section 202 (e) or (f) by reason of a disability shall be deemed to be the entitlement to such benefits that would result if such entitlement were determined without regard to the provisions of section 202(j)(4).

[(i)](*f*) For entitlement to hospital insurance benefits in the case of certain uninsured individuals, see section 103 of the Social Security Amendments of 1965.

Special Provisions Relating to Coverage Under Medicare Program for End Stage Renal Disease

Sec. 226A. (a) Notwithstanding any provision to the contrary in section 226 or title XVIII, every individual who—

(1)(A) is fully or currently insured (as such terms are defined in section 214 of this Act) or would be fully or currently insured if his service as an employee (as defined in the Railroad Retirement Act of 1974) after December 31, 1936, were included in the term "employment" as defined in this Act, or (B) is entitled to monthly insurance benefits under title II of this Act or an annuity under the Railroad Retirement Act of 1974, or (C) is the spouse or dependent child (as defined in regulations) of an individual who is fully or currently insured or would be fully or currently insured if his service as an employee (as defined in the Railroad Retirement Act of 1974) after December 31, 1936, were included in the term "employment" as defined in this Act, or (D) is the spouse or dependent child (as defined in regulations) of an individual entitled to monthly insurance benefits under title II of this Act or an annuity under the Railroad Retirement Act of 1974;

(2) is medically determined to have end stage renal disease; and

(3) has filed an application for benefits under this section,

shall, in accordance with the succeeding provisions of this section, be entitled to benefits under part A and eligible to enroll under part B of title XVIII, subject to the deductible, premium, and coinsurance provisions of that title.

(b) Subject to subsection (c), entitlement of an individual to benefits under part A and eligibility to enroll under part B of title XVIII by reasons of this section on the basis of end stage renal disease—

(1) shall begin with—

(A) the third month after the month in which a regular course of renal dialysis is initiated, or

(B) the month in which such individual receives a kidney transplant, or (if earlier) the first month in which such individual is admitted as an inpatient to an institution which is a hospital meeting the requirements of section 1861(e) (and such additional requirements as the Secretary may prescribe under section 1881(b) for such institutions) in preparation for or anticipation of kidney transplantation, but only if such transplantation occurs in that month or in either of the next two months,

whichever first occurs (but no earlier than one year preceding the month of the filing of an application for benefits under this section); and

(2) shall end, in the case of an individual who receives a kidney transplant, with the thirty-sixth month after the month in which such individual receives such transplant or, in the case of an individual who has not received a kidney transplant, and no longer requires a regular course of dialysis, with the twelfth month after the month in which such course of dialysis is terminated.

(c) Notwithstanding the provisions of subsection (b)—

(1) in the case of any individual who participates in a self-dialysis training program prior to the third month after the month in which such individual initiates a regular course of renal dialysis in a renal dialysis facility or provider of services meeting the requirements of section 1881(b), entitlement to benefits under part A and eligibility to enroll under part B of title XVIII shall begin with the month in which such regular course of renal dialysis is initiated;

(2) in any case in which a kidney transplant fails (whether during or after the thirty-six-month period specified in subsection (b)(2)) and as a result the individual who received such transplant initiates or resumes a regular course of renal dialysis, entitlement to benefits under part A and eligibility to enroll under part B of title XVIII shall begin with the month in which such course is initiated or resumed; and

(3) in any case in which a regular course of renal dialysis is resumed subsequent to the termination of an earlier course, entitlement to benefits under part A and eligibility to enroll under

part B of title XVIII shall begin with the month in which such regular course of renal dialysis is resumed.

* * * * * * *

Part A—Hospital Insurance Benefits for the Aged and Disabled

Description of Program

SEC. 1811. The insurance program for which entitlement is established by [section 226] *sections 226 and 226A* provides basic protection against the costs of hospital and related post-hospital services in accordance with this part for (1) individuals who are age 65 or over and are entitled to retirement benefits under title II of this Act or under the railroad retirement system [and], (2) individuals under age 65 who have been entitled for not less than 24 consecutive months to benefits under title II of this Act or under the railroad retirement system on the basis of a disability, *and (3) certain individuals who do not meet the conditions specified in either clause (1) or (2) but who are medically determined to have end stage renal disease.*

* * * * * * *

Conditions of and Limitations on Payment for Services

Amount Paid to Providers

(b)(1) The amount paid to any provider of services with respect to services for which payment may be made under this part shall, subject to the provisions of section 1813, be—

(1) the lesser of (A) the reasonable cost of such services, as determined under section 1861(v) *and as further limited by section 1881(b)(2)(B)*, or (B) the customary charges with respect to such services; or

(2) if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such reasonable cost which the Secretary finds will provide fair compensation to such provider for such services.

Federal Hospital Insurance Trust Fund

* * * * * *

(b) With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees") composed of the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health, Education, and Welfare, all ex officio. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees (hereinafter in this section referred to as the "Managing Trustee"). The [Commissioner of Social Security] *Administrator of the Health Care Financing Administration* shall serve as the Secretary of the Board of Trustees. The Board of Trustees shall meet not less fre-

quently than once each calendar year. It shall be the duty of the Board of Trustees to—

(1) Hold the Trust Fund;

(2) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years;

(3) Report immediately to the Congress whenever the Board is of the opinion that the amount of the Trust Fund is unduly small; and

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The report provided for in paragraph (2) shall include a statement of the assets of, and the disbursements made from, the Trust Fund during the preceding fiscal year, an estimate of the expected income to, and disbursements to be made from, the Trust Fund during the current fiscal year and each of the next 2 fiscal years, and a statement of the actuarial status of the Trust Fund. Such report shall be printed as a House document of the session of the Congress to which the report is made.

* * * * * * *

Part B—Supplementary Medical Insurance Benefits for the Aged and Disabled

Payment of Benefits

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to expenses incurred for radiological or pathological services for which payment may be made under this part, furnished to an inpatient of a hospital by a physician in the field of radiology or pathology, the amounts paid shall be equal to 100 percent of the reasonable charges for such services, (C) with respect to expenses incurred for those physicians' services for which payment may be made un-

der this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, [and] (D) with respect to diagnostic tests performed in a laboratory for which payment is made under this part to the laboratory, the amounts paid shall be equal to 100 percent of the negotiated rate for such tests (as determined pursuant to subsection (g) of this section), (*E*) *with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881, and*

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraph (D) of section 1832(a)(2)—with respect to home health services, 100 percent and with respect to other services (*unless otherwise specified in section 1881*) 80 percent of—

(A) the lesser of (i) the reasonable cost of such services, as determined under section 1861(v), or (ii) the customary charges with respect to such services; or

(B) if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2); or

(C) if such services are services to which the next to last sentence of section 1861(p) applies, the reasonable charges for such services, and

(3) in the case of services described in section 1832(a)(2)(D), 80 percent of costs which are reasonable and related to the cost of furnishing such services or on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A).

* * * * * * *

Part C—Miscellaneous Provisions

Definition of Services, Institutions, etc.

SEC. 1861. For purposes of this title—

* * * * * * *

Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services; [and]

(E) rural health clinic services; *and*

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for a reduction of fractures and dislocations;

(6) durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) or (j)(1) of this section), whether furnished on a rental basis or purchased;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) including replacement of such devices; and

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

No diagnostic tests performed in any laboratory which is independent of a physician's office, a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

(10) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(11) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which—

(12) would not be included under subsection (b) if it were furnished to an inpatient of a hospital; or

(13) is furnished under arrangements referred to in such paragraph (2)(C) unless furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

* * * * * * *

Agreements With Providers of Services

SEC. 1866. (a)(1) * * *

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1) or (a)(3), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B. In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 per centum the proportion which is appropriate under such section (*but in the case of items and services furnished to individuals with end stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary*).

* * * * * * *

Payments to Health Maintenance Organizations

SEC. 1876. (a)(1) * * *

(b)(1) The term "health maintenance organization" means a legal entity which provides health services on a prepayment basis to individuals enrolled with such organizations and which—

(A) provides to its enrollees who are insured for benefits under parts A and B of this title or for benefits under part B alone, through institutions, entities, and persons meeting the applicable requirements of section 1861, all of the services and benefits covered under such parts (to the extent applicable under subpara-

graph (A) or (B) of subsection (a)(1)) which are available to individuals residing in the geographic area served by the organization;

(B) provides such services in the manner prescribed by section 1301(b) of the Public Health Service Act, except that solely for the purposes of this section—

(i) the term "basic health services" and references thereto shall be deemed to refer to the services and benefits included under parts A and B of this title;

(ii) the organization shall not be required to fix the basic health services payment under a community rating system;

(iii) the additional nominal payments authorized by section 1301(b)(1)(D) of such Act shall not exceed the limits applicable under subsection (g) of this section; and

(iv) payment for basic health services provided by the organization to its enrollees under this section or for services such enrollees receive other than through the organization shall be made as provided for by this title;

(C) is organized and operated in the manner prescribed by section 1301(c) of the Public Health Service Act, except that solely for the purposes of this section—

(i) the term "basic health services" and references thereto shall be deemed to refer to the services and benefits included under parts A and B of this title;

(ii) the organization shall not be reimbursed for the cost of reinsurance except as permitted by subsection (i) of this section; and

(iii) the organization shall have an open enrollment period as provided for in subsection (k) of this section.

(2)(A) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a "health maintenance organization" within the meaning of paragraph (1), shall be administered through the Assistant Secretary for Health and in the Office of the Assistant Secretary for Health, and the administration of such duties and functions shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(B) Except as provided in subparagraph (A), the Secretary shall administer the provisions of this section through the [Commissioner of Social Security] *Administrator of the Health Care Financing Administration.*

* * * * * * *

Medicare Coverage for End Stage Renal Disease Patients

Sec. 1881. (a) The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end-stage renal disease as provided in section 226A, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this title, the type, duration, and scope of the benefit provided by parts A and B with respect to individuals who have been determined to have end-stage renal disease and who are entitled to such benefits without regard to section 226A shall

in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b) (1) Payments under this title with respect to services, in addition to services for which payment would otherwise be made under this title, furnished to individuals who have been determined to have end-stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end-stage renal disease are made on the basis specified in paragraph (3) (A) of this subsection, and (B) payments to or on behalf of such individuals for home dialysis supplies and equipment. The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for covered procedures and for self-dialysis training programs.

(2) (A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end-stage renal disease for which payments may be made under part B of this title, such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this title, the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in accordance with section 1861(v). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagaph (B) and the deductible amount imposed by section 1833(b).

(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing cover services to individuals determined to have end-stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1861(v)), the amounts of payments to be made for part B services furnished by such providers and facilities to such individuals. Such regulations shall provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services (consistent with quality care), and shall include, to the extent determined feasible by the Secretary, a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing

such reductions in costs as may be attributable to more efficient and effective delivery of services.

(C) Such regulations, in the case of services furnished by proprietary providers and facilities may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1861(v)(1)(B).

(D) For purposes of section 1878, a renal dialysis facility shall be treated as a provider of services.

(3) With respect to payments for physicians' services furnished to individuals determined to have end-stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services—

(A) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services) except that payment may not be made under this subparagraph for routine services furnished during a maintenance dialysis episode, or

(B) on a comprehensive monthly fee or other basis for an aggregate of services provided over a period of time (as defined in regulations).

(4) Pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payment to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility, on the basis of a target reimbursement rate (as defined in paragraph (6)).

(5) An agreement under paragraph (4) shall require that the provider or facility will—

(A) assume full responsibility for directly obtaining or arranging for the provision of—

(i) such medically necessary dialysis equipment as is prescribed by the attending physican;

(ii) dialysis equipment maintenance and repair services;

(iii) the purchase and delivery of all necessary medical supplies; and

(iv) where necessary (as determined by the Secretary under regulations), the services of trained home dialysis aides;

(B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A);

(C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment, supplies, and services furnished to the facility's home dialysis patient population; and

(D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section.

(6) The Secretary shall establish, for each calendar year, commencing with January 1, 1978, a target reimbursement rate for home dialysis which shall be adjusted for regional variations in the cost of providing

home dialysis. In establishing such a rate, the Secretary shall include—

(A) the Secretary's estimate of the cost of providing medically necessary home dialysis supplies and equipment;

(B) an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and

(C) an allowance, in an amount determined by the Secretary, to cover administrative costs and to provide an incentive for the efficient delivery of home dialysis;

but in no event shall such target rate exceed 70 percent of the national average payment, adjusted for regional variations, for maintenance dialysis services furnished in approved providers and facilities during the preceding fiscal year. Any such target rate so established shall be utilized, without renegotiation of the rate, throughout the calendar year for which it is established. During the last quarter of each calendar year, the Secretary shall establish a home dialysis target reimbursement rate for the next calendar year based on the most recent data available to the Secretary at the time. In establishing any rate under this paragraph, the Secretary may utilize a competitive bid procedure, a prenegotiated rate procedure, or any other procedure which the Secretary determines is appropriate and feasible in order to carry out this paragraph in an effective and efficient manner.

(7) For purposes of this title, the term 'home dialysis supplies and equipment' means medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end-stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.

(8) For purposes of this title, the term 'self-care home dialysis support services', to the extent permitted in regulation, means—

(A) periodic monitoring of the patient's home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan prepared and periodically reviewed by a professional team (as defined in regulations) including the individual's physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

(9) For purposes of this title, the term 'self-care dialysis unit' means a renal dialysis facility or a distinct part of such facility or of a provider of services, which has been approved by the Secretary to make self-dialysis services, as defined by the Secretary in regulations, available to individuals who have been trained for self-dialysis. A self-care dialysis unit must, at a minimum, furnish the services, equipment and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for such appropriate lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis), and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

(c)(1)(A) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secre-

tary shall establish, in accordance with such criteria as he finds appropriate, renal disease network areas, such network organizations (including a coordinating council, an executive committee of such council, and a medical review board for each network area) as he finds necessary to accomplish such purpose, and a national end stage renal disease medical information system. The Secretary may by regulations provide for such coordination of network planning and quality assurance activities and such exchange of data and information among agencies with responsibilities for health planning and quality assurance activities under Federal law as is consistent with the economical and efficient administration of this section and with the responsibilities established for network organizations under this section.

(B) At least one patient representative shall serve as a member of each coordinating council and executive committee.

(C) No person—

(i) with an ownership or control interest (as defined in section 1124(a)(3)) in a facility or provider which provides services referred to in section 1861(s)(2)(F) or provides kidney transplants, or

(ii) who has received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services or goods supplied to such facility or provider, or

(iii) who is the spouse, parent, son, daughter, brother or sister of a person described in clause (i) or (ii) (or who bears such relationship to the spouse of such a person),

shall serve as a member of any network organization.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for—

(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient;

(B) developing criteria and standards relating to the quality and appropriateness of patient care; and

(C) evaluating the procedures by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities.

(d) Notwithstanding any provision to the contrary in section 226, any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of this title with respect to such donation. Reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions of this title), in such manner as may be prescribed by the Secretary in regulations, for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation, including but not limited to the expenses for which payment could be made if he were an eligible individual for purposes of parts A and B of this title without regard to this subsection. Payments for postoperation recovery expenses shall be limited to the actual period of recovery.

(e)(1) Notwithstanding any other provision of this title, the Secretary may, pursuant to agreements with approved providers of services

and renal dialysis facilities, reimburse such providers and facilities (without regard to the deductible and coinsurance provisions of this title) for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines (including supportive equipment) which are to be used exclusively by entitled individuals dialyzing at home.

(2) An agreement under this subsection shall require that the provider or facility will—

(A) make the equipment available for use only by entitled individuals dialyzing at home;

(B) recondition the equipment, as needed, for reuse by such individuals throughout the useful life of the equipment, including modification of the equipment consistent with advances in research and technology;

(C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and

(D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment.

(3) For purposes of this section, the term 'supportive equipment' includes blood pumps, heparin pumps, bubble detectors, other alarm systems, and such other items as the Secretary may determine are medically necessary.

(f) (1) The Secretary shall initiate and carry out, at selected locations in the United States, pilot projects under which financial assistance in the purchase of new or used durable medical equipment for renal dialysis is provided to individuals suffering from end stage renal disease at the time home dialysis is begun, with provision for a trial period to assure successful adaptation to home dialysis before the actual purchase of such equipment.

(2) The Secretary shall conduct experiments to evaluate methods for reducing the costs of the end stage renal disease program. Such experiments shall include (without being limited to) reimbursement for nurses and dialysis technicians to assist with home dialysis, and reimbursement to family members assisting with home dialysis.

(3) The Secretary shall conduct experiments to evaluate methods of dietary control for reducing the costs of the end stage renal disease program, including (without being limited to) the use of protein-controlled products to delay the necessity for, or reduce the frequency of, dialysis in the treatment of end stage renal disease.

(4) The Secretary shall conduct a comprehensive study of methods for increasing public participation in kidney donation and other organ donation programs.

(5) The Secretary shall conduct a full and complete study of the reimbursement of physicians for services furnished to patients with end stage renal disease under this title, giving particular attention to the range of payments to physicians for such services, the average amounts of such payments, and the number of hours devoted to furnishing such services to patients at home, in renal disease facilities, in hospitals, and elsewhere.

(6) The Secretary shall conduct a study of the number of patients with end stage renal disease who are not eligible for benefits with respect to such disease under this title (by reason of this section or otherwise), and of the economic impact of such noneligibility of such individuals. Such study shall include consideration of mechanisms whereby governmental and other health plans might be instituted or modified to permit the purchase of actuarially sound coverage for the costs of end stage renal disease.

(7) The Secretary shall conduct a study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients. In such cases in which the Secretary determines that such home cleaning and reuse of filters is a medically sound procedure, the Secretary shall conduct experiments to evaluate such home cleaning and reuse as a method of reducing the costs of the end stage renal disease program.

(8) The Secretary shall submit to the Congress no later than October 1, 1979, a full report on the experiments conducted under paragraphs (1) (2), (3), and (7) and the studies under paragraphs (4), (5), (6), and (7). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of such experiments and studies.

(g) The Secretary shall submit to the Congress on October 1, 1978, and on October 1 of each year thereafter, a report on the end stage renal disease program, including but not limited to—

(1) the number of patients, nationally and by renal disease network, on dialysis (self-dialysis or otherwise) at home and in facilities;

(2) the number of new patients entering dialysis at home and in facilities during the year;

(3) the number of facilities providing dialysis and the utlization rates of those facilities;

(4) the number of kidney transplants, by source of donor organ;

(5) the number of patients awaiting organs for transplant;

(6) the number of transplant failures;

(7) the range of costs of kidney acquisitions, by type of facility and by region;

(8) the number of facilities providing transplants and the number of transplants performed per facility;

(9) patient mortality and morbidity rates;

(10) the average annual cost of hospitalization for ancillary problems in dialysis and transplant patients, and drug costs for transplant patients;

(11) medicare payment rates for dialysis, transplant procedures, and physician services, along with any changes in such rates during the year and the reasons for those changes;

(12) the results of cost-saving experiments;

(13) the results of basic kidney disease research conducted by the Federal Government, private institutions, and foreign governments;

(14) information on the activities of medical review boards and other network organizations; and

(15) estimated program costs over the next five years.

* * * * * * *

Definitions

SEC. 1905. For purposes of this title—

* * * * * * *

(c) For purposes of this title the term "intermediate care facility" means an institution which (1) is licensed under State law to provide, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, (2) meets such standards prescribed by the Secretary as he finds appropriate for the proper provision of such care, [and] (3) meets such standards of safety and sanitation as are established under regulation of the Secretary in addition to those applicable to nursing homes under State law, *and (4) meets the requirements of section 1861(j)(14) with respect to protection of patients' personal funds.* The term "intermediate care facility" also includes any skilled nursing facility or hospital which meets the requirements of the preceding sentence. The term "intermediate care facility" also includes a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts, but only with respect to institutional services deemed appropriate by the State. The term "intermediate care facility" also includes any institution which is located in a State on an Indian reservation and is certified by the Secretary as meeting the requirements of clauses [(2) and (3)] *clauses (2), (3) and (4)* of this subsection and providing the care and services required under clause (1). With respect to services furnished to individuals under age 65, the term "intermediate care facility" shall not include, except as provided in subsection (d), any public institution or distinct part thereof for mental diseases or mental defects.

* * * * * * *

Excerpts From Public Law 93-233, As Amended

* * * * * * *

Payment for Services of Physicians Rendered in a Teaching Hospital

SEC. 15. (a)(1) Notwithstanding any other provision of law, the provisions of section 1861(b) of the Social Security Act, shall, subject to subsection (b) of this section, for the period with respect to which this paragraph is applicable, be administered as if paragraph (7) of such section read as follows:

> "(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this title.".

(2) Notwithstanding any other provision of law, the provisions of section 1832(a)(2)(B)(i) of the Social Security Act, shall, subject to subsection (b) of this section, for the period with respect to which this paragraph is applicable, be administered as if subclause II of such section read as follows:

"(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1861(b) (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital), where the conditions specified in paragraph (7) of such section are met, and".

* * * * * * *

(d) The provisions of subsection (a) shall apply with respect to cost accounting periods beginning after June 30, 1973, and prior to October 1, [1977] *1978*.

Excerpts From Public Law 95-142

* * * * * * *

Delay In, and Waiver of, Imposition of Reduction of Federal Medical Assistance Percentage Due to a State's Failure to Have an Effective Medicaid Utilization Control Program

SEC. 20. (a) * * *

* * * * * * *

(c)(1) Except as provided in paragraph (2), the amendments made by this section shall be effective on October 1, 1977, and the Secretary of Health, Education, and Welfare shall promptly adjust payments made to States under section 1903 of the Social Security Act to reflect the changes made by such amendments.

(2) The amount of any reduction in the Federal medical assistance percentage of a State, otherwise required to be imposed under section 1903(g)(1) of the Social Security Act because of an unsatisfactory or invalid showing made by the State with respect to a calendar quarter beginning on or after January 1, 1977, shall be determined under such section as amended by this section. Subparagraph (B) of paragraph (4) of section [1905(g)] *1903(g)* of such Act, as added by this section, shall apply to any showing made by a State under such section with respect to a calendar quarter beginning on or after January 1 1977.

* * * * * * *

○