INTRODUCTION

Since 1973, Medicare has paid for the medical and related services for over 90 percent of the U.S. population with End Stage Renal Disease (ESRD) (147). The ESRD program has become costly for Medicare. Expenditures have increased from $228 million in 1974 to an estimated $2.7 billion in 1989 (156). After a dialysis patient has met the annual Medicare Part B deductible, either through payment for dialysis or other covered medical services, Medicare pays 80 percent of the cost of medical services, and the patient pays 20 percent. This chapter describes Medicare's payment policies for various products and services provided to ESRD patients, pharmaceuticals provided in different settings, and recombinant erythropoietin itself. This background information provides the basis for the analysis in chapter 1 of payment options for recombinant erythropoietin.

MEDICARE PAYMENT POLICIES FOR ESRD SERVICES

Provisions for Medicare coverage and payment for ESRD services were enacted in the Social Security Amendments of 1972 (Public Law 92-603, Sec. 2991). Congress provided that individuals with ESRD, that is, permanent chronic kidney disease requiring continuous dialysis or a kidney transplant to maintain life, were deemed to be disabled and entitled to Medicare coverage regardless of their age, social status, or ability to pay (42 USC 246(l)(a)).

In 1988, 93 percent of the approximately 105,958 U.S. dialysis patients were approved for Medicare coverage or had Medicare coverage pending (156) (see table 4-l). Medicare coverage for dialysis patients generally begins in the third month after the month in which a regular course of dialysis is initiated (42 CFR 426(l)(a).

ESRD patients are served by 1,915 kidney transplant and dialysis centers, as listed in table 4-2. The majority of these providers are dialysis facilities, of which 63 percent are independent facilities and 37 percent are hospital based (156). The other 214 providers are kidney transplant facilities.

Table 4-l-Coverage for Dialysis-Related Medical Services in the United States, December 31, 1988

Coverage	Number of patients covered	Percent of patients covered
Total Medicare	98,191	92.6
(Medicare approved	91,820	86.6)
(Medicare Pending	6,371	6.0)
Department of Veterans Affairs..	3,722[b]	3.5
Other[c]	4,045	3.9
Total U.S. dialysis population	105,958	100.0

[a]Medicare coverage begins the third month after the month in which the course of maintenance dialysis treatments begin. Medicare coverage may begin in the first month of dialysis if the patient participates in a self-dialysis training program in a Medicare-approved training facility. The Medicare-pending category includes those patients that have applied for and are satisfying the three-month waiting period before dialysis benefits begin (42 CFR 426-lb).

[b]Department of Veterans Affairs (VA) dialysis patients include 3,132 in-unit or home dialysis patients who are affiliated with VA facilities and 590 patients who receive dialysis in Medicare-approved dialysis facilities for which VA makes payment to HCFA (109).

[c]Includes patients covered by Medicaid, private insurance (including those who have employer group health insurance coverage for the first year of ESRD, with Medicare's becoming the primary insurer after the first year), foreign nationals, and individuals who do not have coverage for services. HCFA does not collect separate data on Medicaid coverage of ESRD (123).

SOURCES: Otchin, 1990 (109); US DHHS, HCFA, 1989 (156).

Table 4-2--Dialysis and Kidney Transplant Service Providers in the United States, November 1989[a]

Type of provider	Number of providers
Total providers	1,915
Total kidney transplant providers	214
Total dialysis providers	1,807
Hospital-based dialysis	661
Independent dialysis	1,146
Inpatient dialysis	58

[a]Because some facilities fall into more than one classification, the sum of the individual classifications may exceed the total approved facilities.

SOURCE: US DHHS, HCFA, 1989 (156).

In general, a patient's dialysis facility furnishes a package of services, equipment, and supplies, including laboratory tests and certain drugs, for each dialysis treatment. Items and services in the package include bicarbonate dialysate, catheter changes, shunt declotting, cardiac monitoring, suture removal, surgical dressing changes, oxygen and its administration, and staff time involved in the administration of blood and certain parenteral[1] items (151).

Medicare pays for this package of dialysis services by a composite rate. The composite rate per dialysis treatment, which currently averages $129 for the hospital-based facilities and $125 for independent dialysis facilities, (151) must be accepted as payment in full by the facilities for all covered items and services.[2] The rate is based on a formula that takes into account the mix of patients that receive dialysis at a facility or at home and the relative cost of providing such services in these settings (Public Law 101-239).

Patients that receive dialysis at home may choose one of two payment methods. Under Method I, the dialysis facility is paid and must accept the composite rate as payment in full for providing all services, equipment, and supplies needed for home dialysis. Approximately 64 percent of all home dialysis patients chose Method I in 1988 (124). Under Method II, the patient may deal directly with a supplier to obtain home dialysis equipment and supplies. In 1988, 36 percent of all home dialysis patients chose Method II (124). Under a provision of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239) that took effect Feb. 1, 1990, providers of supplies and equipment to home dialysis patients must also accept the composite rate as payment in full. Previously, reimbursement to suppliers under Method II was calculated on a reasonable charge basis, and suppliers could charge home dialysis patients more than the composite rate. This situation could result in higher cost-sharing for those home dialysis patients who chose Method 11.[3] In addition, all home dialysis patients must now be affiliated with a dialysis facility, whether they receive their home dialysis equipment and supplies from a facility or a supplier (Public Law 101-239). Medicare pays dialysis facilities and suppliers for services not covered under the composite rate according to a fee schedule (126).

Medicare pays for all dialysis-related physician services through a monthly per-patient payment, currently an average $173 (126). The physician, known as the patient's "capitated physician," receives the same amount whether the patient the physician supervises receives dialysis in a facility or at home.

ESRD patients cannot become members of health maintenance organizations (HMOs) or other competitive medical plans (CMPs) that have a risk-sharing contract to serve Medicare beneficiaries.[4] Beneficiaries may retain CMP membership if they develop ESRD subsequent to enrollment. For ESRD patients who are CMP members, Medicare pays a monthly prospective per-capita amount that covers both ESRD and non-ESRD services. Payment is based on the estimated amount (the average adjusted per capita cost)[5] that would be paid for Medicare-covered services if beneficiaries were not enrolled in HMOs and received care from local fee-for-service providers. The rates are adjusted for factors such as age, sex, disability, and, if available and appropriate, welfare and institutional factors (145).

ESRD networks, which function like peer review organizations (PROS) review the quality of care provided to dialysis patients. Under contract to the

1 **Parenteral** refers to some means, other than through the alimentary canal, to introduce a substance into the body. In this case, it refers to intravenous administration of certain drugs.

2 Each facility has its own composite rate, composed of a labor and non-labor portion. To determine a facility's actual payment rate, the labor portion of the appropriate base rate is first adjusted by an area wage index and then added to a **nonlabor** portion (154).

3 **An** exception is that for home patients on Continuous Cycling Peritoneal Dialysis **(CCPD),** Medicare may pay up to 130 percent of the median composite rate for hospital-based facilities (Public **Law** 101-239).

4 In a risk-sharing arrangement, a fiscal intermediary, such as an HMO or other **CMP,** assumes the financial risk of arranging for or providing care to Medicare enrollees (145).

5 See app. D for a definition of average adjusted per capita cost.

Health Care Financing Administration (HCFA), these 17 networks are generally organizations of nephrologists. During each year, the networks select approximately 12 percent of all dialysis patients to review quality-of-care problems. Each network develops its own criteria to assess the quality of care. The networks, which have some limited ability to impose sanctions on providers if problems are detected, do not have the ability to deny payment for claims. In March 1990, some of the networks initiated their own review of various aspects of recombinant erythropoietin use. HCFA has no immediate future plans to require the networks to review whether recombinant erythropoietin is being used appropriately in dialysis patients (99).

Payment for dialysis service claims is made by Medicare contractors. These contractors include intermediaries, which usually process claims for Part A providers, such as hospitals and dialysis facilities; and carriers, which process claims for Part B providers, such as physicians (20). These contractors, typically Blue Cross plans or commercial insurance firms, determine reasonable costs or charges for covered services, make payments, and guard against unnecessary use of Medicare-covered services.

MEDICARE'S PAYMENT POLICIES FOR PHARMACEUTICALS

General Payment Policies

HCFA first decides if a pharmaceutical (a drug or biological) should be covered by the Medicare program and then determines how payment should be made. Coverage and payment rules differ for each Medicare program, depending on whether the pharmaceutical is provided to an inpatient or outpatient.

HCFA's policy is that a pharmaceutical is covered for FDA-approved indications, unless HCFA determines that it is not safe and effective for a particular use or unless it is subject to a specific exclusion, such as self-administered pharmaceuticals, as discussed below. A HCFA contractor may cover and pay for an FDA-approved pharmaceutical for an indication for which there is no FDA approval, if it is documented in the medical literature that the pharmaceutical is commonly used in medical practice to treat that particular condition. These are commonly referred to as off-label uses. HCFA does not pay for the use of investigational pharmaceuticals, except in the case of some cancer agents. When HCFA views a coverage or payment issue to be significant, or contractors' interpretations of FDA actions differ, HCFA may issue specific national guidelines on the coverage status of a particular pharmaceutical (35).

In conjunction with its decision about coverage, HCFA also determines the amount that the program will pay for a particular pharmaceutical. The payment method is based on the setting in which the product is administered.

Under Part A, Medicare pays for the operating expenses associated with inpatient care for a particular diagnosis for the entire length of stay through freed rates set in advance, known as diagnosis-related groups (DRGs). DRGs classify patients according to primary diagnosis, the principal surgical procedure, and the type of discharge. Variations in the DRG rates paid to hospitals are a function of location (urban versus rural), area wage rates, a hospital's teaching affiliation, and the proportion of low-income patients served. Hospitals are paid these rates regardless of the costs that they actually incur (35). The facilities earn a profit when their costs fall below the payment and absorb the loss when the costs are higher than the payment. Payment for pharmaceuticals used during an inpatient stay are included in the predetermined DRG rate.

In accordance with the Social Security Act, Medicare Part B covers pharmaceuticals, if they cannot be self-administered by the patient, such as injectable; are reasonable and necessary for the diagnosis or treatment of an illness by a physician; or are provided incidental to a physician's service (Social Security Act 1861 (s)(2)(A)), or administered to outpatients (even if they are self-administered) for diagnostic purposes (42 CFR 410.28). Therapeutic injectable that are routinely self-administered, such as insulin, are therefore excluded from Medicare

coverage. Whether a drug is self-administrable depends on the usual method of administration of the drug or biologic furnished by the physician. For example, oral dosage forms administered by a physician are not covered (35).

In addition, through legislation, Congress has covered specific pharmaceuticals under Part B, including certain prescription drugs provided incidental to a dialysis treatment, certain immunosuppressive drugs used in transplant therapy for one year following a Medicare-covered organ transplant, pneumococcal vaccine, and hepatitis B vaccine for certain high-risk groups.

Under Part B, pharmaceuticals furnished by physicians, community pharmacies, and independent dialysis facilities are paid on a reasonable charge basis, while those furnished by outpatient hospital facilities are paid on a reasonable cost basis. Medicare pays 80 percent of the reasonable cost of pharmaceuticals provided to patients of an outpatient hospital facility. The reasonable cost of any service is the cost actually incurred by the facility to acquire the product or provide the service, excluding any costs unnecessary for the efficient delivery of needed health services (42 USC 1395v).

Medicare pays 80 percent of the reasonable or approved charge for pharmaceuticals, after a patient has met an annual deductible, currently $75. The patient pays the remaining 20 percent, plus any difference between the actual charge and Medicare's approved charge. HCFA regulations define the reasonable or approved charge as the portion of the charge that is approved for payment by Medicare. The amount is determined by the Medicare contractor according to guidelines developed by HCFA. The approved charge is defined as the lowest of 1) the physician's or supplier's customary charge for that service, 2) the prevailing charge for similar services in that locality, 3) the actual charge made by the physician or the supplier, or 4) the contractor's private business charge for comparable service (35). The method of deriving payment rates for the approved charge is termed the customary, prevailing, and reasonable (CPR) method. For injections, determination of the approved charge is often based on prices in the ***Redbook, Bluebook,*** or ***Medispan,*** which are compendia of pharmaceutical price information (155). The approved charge for injectable, such as recombinant erythropoietin, is based on the cost of the injectable and any supplies used to administer it plus a maximum of $2 for the accompanying staff time (155).

Patients who purchase covered Part B pharmaceuticals from non-Medicare providers, such as community pharmacies, must submit a Medicare claim to the Medicare carrier. Patients are reimbursed at 80 percent of the approved charge for the product (126).

Prescription Drug Coverage Under the ESRD Program

Through the composite rate, Medicare pays for certain routine prescription drugs commonly provided as part of a dialysis treatment. Examples of these drugs include insulin, heparin, protamine, mannitol, saline, xylocaine, antiarrythmic drugs, and antihypertensive medications (151).

Dialysis facilities may bill Medicare separately for other non-routine drugs that may be needed during a dialysis treatment, but are not included in the composite rate. Examples of these drugs include compazine, gentamycin, demerol, morphine, vancomycin, and defer examine. Payment is made for the pharmaceutical and any supplies used for its administration; no additional payment is made for staff time used to administer a pharmaceutical (151).

Hepatitis B Vaccine

The enactment of the Deficit Reduction Act of 1984 (Public Law 98-369) established Medicare coverage for hepatitis B vaccine furnished to a Medicare beneficiary at high or intermediate risk of contracting hepatitis B (150). Hepatitis B is a bloodborne infection that can result in severe morbidity and even death (27). Dialysis patients were included in the high-risk group because they frequently receive blood transfusions. Medicare also pays the facilities for staff time, supplies, and syringes involved in administration of the vaccine (150).

At the time of Medicare coverage of the vaccine, there was only one supplier in the market. In its reimbursement guidelines, HCFA cautioned its con-

tractors that, when they determined the approved charge, lack of competition in the marketplace should not result in overpayments to facilities. The contractor was to consider trade or quantity discounts on purchases of the vaccine that were available to medical providers. In addition, Medicare pays only for the quantity of vaccine that is actually administered to the patient (150). For example, if a facility purchased a vial of hepatitis vaccine for $100 and administered two-thirds of the vial, the reimbursement based on the approved charge method would be approximately $67.

Immunosuppressive Drugs

The enactment of the Omnibus Budget Reconciliation Act of 1986 (Public Law 99-509) established Medicare coverage for certain immunosuppressive drugs for one year after a Medicare beneficiary's discharge from an inpatient hospital stay during which a Medicare-covered organ transplant was performed. The change in the law was precipitated by FDA-approval in 1983 of the immunosuppressive drug cyclosporine, whose annual treatment costs were estimated to be about $5,000 per patient (126). In addition to cyclosporine, the act extended coverage to azathioprine, antithymocyte/globulin, and muromonab-CD3 (153). In December 1987, Medicare coverage was expanded to those drugs that are not used exclusively as immunosuppressive drugs, but that are commonly used as part of immunosuppressive therapy, such as the steroid prednisone.

MEDICARE'S CURRENT COVERAGE AND PAYMENT POLICIES FOR RECOMBINANT erythropoietin

In developing payment rates for recombinant erythropoietin, HCFA had to consider the various facilities in which it would be used, including hospitals, dialysis facilities, physicians' offices, HMOs, and other CMPs.

Payment rates for recombinant erythropoietin were not established for inpatient facilities or CMPs. Medicare pays for recombinant erythropoietin administered to inpatients through the DRG rate. Any additional cost to the facility of using recombinant erythropoietin, however, will not be reflected in a DRG until the rates are recalculated in the future. Similarly, Medicare pays CMPs for use of recombinant erythropoietin through the monthly cavitation payment (126).

Dialysis Facilities

Initial Payment Policy

In July 1989, HCFA issued special coverage and payment instructions to its intermediaries for administration of recombinant erythropoietin to patients in hospital-based and independent dialysis facilities. Coverage was retroactive to June 1, 1989, the day FDA approved recombinant erythropoietin for anemia associated with chronic renal failure. (154).

HCFA determined that it would pay both hospital-based and independent dialysis facilities $40 for any recombinant erythropoietin dose of 10,000 units or fewer, and an additional $30 for any dose over that amount,[6] (154). Payment was to be made in addition to the composite rate and restricted to administration in a dialysis facility. No additional payment would be made for the staff time or supplies involved in administering recombinant erythropoietin. HCFA assumed that the composite rate adequately covered these expenses, and no increase was made in the composite rate. A review of HCFA payment policy for recombinant erythropoietin administered in dialysis facilities commenced in December 1989 (126).

If a dialysis patient received 10,000 units of recombinant erythropoietin or fewer at each of 3 weekly dialysis sessions, for a total of 156 sessions per year, the annual per patient cost would total approximately $6,240. Medicare would pay 80 percent of the costs ($32 per administration), or $4,992, and the patient would pay the remaining 20 percent ($8 per administration), or $1,248 per year in cost-sharing, if one assumes that the patient had previously met the $75 annual Part B deductible.

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6 For doses over 10,000 units, HCFA requires that additional information be reported to the intermediary or carrier, including incidence of iron deficiency, Vitamin B12 or folic acid deficiency, hemolysis, or unrecognized blood loss (1S4).

Self-Administration of Recombinant erythropoietin

Since the Social Security Act prohibits Medicare from paying for self-administration of pharmaceuticals (42 CFR 410.29a), Medicare may not pay for dialysis or other patients to self-administer recombinant erythropoietin. This prohibition affects the approximately 18,000 patients that perform dialysis at home (156). Under current regulations, dialysis patients may self-administer certain drugs in the home setting that are considered dialysis supplies, such as heparin; local anesthetics, such as xylocaine; and antibiotics for peritoneal dialysis patients, when used to treat infections of the catheter site (151).

Method Used To Establish Initial Payment Rates

HCFA established an initial recombinant erythropoietin outpatient payment rate shortly after the agent was approved (see app. E). Approximately 1 year prior to the anticipated approval of recombinant erythropoietin, Amgen and HCFA entered into discussions about payment rates (25). HCFA recognized that recombinant erythropoietin would represent a significant expense for the Medicare ESRD program and for dialysis patients and that HCFA should have an appropriate payment policy ready for its intermediaries. Amgen recognized that the Federal Government, through the Medicare ESRD program, would be the primary payer for recombinant erythropoietin for the foreseeable future and that the payment rate set by HCFA would have a significant impact on the revenues of the company, at least for the near term.

HCFA's initial payment rate of $40 for a dose of recombinant erythropoietin at or under 10,000 units was based, in part, on an analysis of Amgen's cost of producing the amount of recombinant erythropoietin projected to be used by the dialysis population in the first year after FDA approval. HCFA was assisted in analyzing these costs by the Department of Health and Human (DHHS) Services' Office of the Inspector General (OIG) (see app. E). HCFA used this cost analysis along with other factors in setting Medicare's initial payment rate for dialysis facilities.

Several critical decisions had to be made by HCFA and the OIG in analyzing Epogen's costs of production, including estimating the market penetration of Epogen, selecting an appropriate rate of return on Amgen's investment, and identifying the percent of costs from each category that would be allocated to Epogen vs. Amgen's other products.

Based on data supplied by Amgen, HCFA estimated that 20,000-25,000 patients, or about one-fourth of the U.S. dialysis population, would receive recombinant erythropoietin in the first year after FDA approval. After estimating the total costs of production for Epogen, the OIG used this level of initial market penetration to estimate an annual per patient cost of treatment. It then divided this by the number of annual dialysis sessions to estimate a per-administration cost for Epogen.

The OIG used 20 percent as an appropriate return on investment on the grounds that the pharmaceutical industry averaged this profit rate before taxes. In addition, for each cost category, the OIG included only the portion that pertained to Epogen, not to Amgen's other products. For example, in the current research and development and the sales, general, and administrative categories, only that part of costs that the OIG estimated pertained to Epogen was included in the estimate (129).

According to a November 1989-March 1990 survey of dialysis facilities by the OIG, the selling price from wholesalers averaged $41 for the 4,000 unit vial (85). In March 1990, Amgen reported that its list price to wholesalers was $10 for 1,000 units (117). Prices of recombinant erythropoietin in the United States as of December 1989 are compared with prices in other European countries in table **4-3.** As the table indicates, the prices of the product are higher in some countries and lower in others compared with the United States.

Physicians' Offices

In November 1989, HCFA extended coverage to and issued reimbursement instructions for recombinant erythropoietin administration for dialysis patients in physicians' offices. The instructions also

Table 4-3-Prices of a 4,000-Unit Vial to Providers of Recombinant Erythropoietin, by Country, December 1989

Country	Price in country's currency	Purchasing power parities[a]	Price in U.S. dollars
Austria	694.45	16.80	41.34
Belgium	2,022.83	44.50	45.46
Denmark	3%.00	10.20	38.82
Finland	224.39	6.21	36.13
France	330.00	7.43	44.41
Germany	98.00	2.47	39.67
Greece	13,000.00	100.00	130.00
Italy	73,777.00	1,399.00	52.75
Luxembourg	2,023.00	41.00	49.34
Netherlands	114.00	2.40	47.50
Norway	383.00	8.64	44.33
Portugal	9508.00	84.10	113.06
Spain	7,200.00	106.00	67.92
Sweden	360.00	8.69	41.43
Switzerland	88.00	2.43	36.21
United States	41.00[b]	—	41.00
United Kingdom	36.00	0.58	62.00

[a] Represents the purchasing power parities (PPP) for the individual countries, a conversion factor that is based on the purchasing power of foreign currencies relative to U.S. dollars as measured for a given market basket of goods. The measures are 1987 estimates based on extrapolations from 1985 data. The source of the data is the Organization for Economic Cooperation and Development: Health Data File, 1989. Since the purchasing power of U.S. dollars relative to other currencies may have changed over the past 5 years, these measures are subject to some inaccuracy. Purchasing power parities, however, even if dated, are superior to current exchange rates, because the latter are more reflective of the relative demands for the limited goods traded among countries rather than the relative purchasing powers of the respective currencies.

[b] Based on a November 1989-March 1990 survey by the HHS Office of the Inspector General, $41 is the average price of the product to dialysis facility providers, including any markup added by the wholesaler (185).

SOURCES: Schieber and Poullier, 1989 (125); Zahn, 1989 (174).

extended coverage of and payment for recombinant erythropoietin to patients with chronic renal failure who do not yet require dialysis (predialysis patients) (155). Coverage in physicians' offices is possible because Medicare covers pharmaceuticals that are furnished incidental to a physician's professional service (Social Security Act 1861(s)(2)(A)). With the implementation of this coverage, home dialysis patients could receive recombinant erythropoietin from a local physician.

Unlike the case for dialysis facilities, for which the payment rate is $40 for up to 10,000 units of recombinant erythropoietin, Medicare pays the physician an approved charge on a fee-for-service basis; Medicare payment increases with the number of units administered to the patient and the physician's billed charge.

Medicare makes no additional payment for physician's staff time involved in administering injectable to dialysis patients. HCFA assumes that the monthly cavitation rate for physician services adequately covers this time (42 CFR 405.542). Therefore, physicians may not bill Medicare separately for time involved in administering recombinant erythropoietin to dialysis patients in their offices. The capitated physician may bill Medicare for any additional supplies, such as needles and syringes, used to administer the product (155). If a physician other than the capitated one administers recombinant erythropoietin, the administering physician may bill the capitated one for staff time. Medicare pays the administering physician only for the amount of product used and any supplies used for administration. For recombinant erythropoietin administered to non-dialysis patients, physicians may make

an additional charge for staff time and supplies used in administering recombinant erythropoietin.

MEDICAID COVERAGE OF RECOMBINANT erythropoietin

Besides Medicare, other sources of dialysis-related medical service payments are private insurance, Medicaid, and other State programs. Little information is available on the extent to which these sources cover the costs of these services, including recombinant erythropoietin and its administration.

Some information is available, however, on Medicaid coverage. Medicaid is a federally-aided, state-administered program that provides medical assistance to certain low-income people (147). Although over 90 percent of all ESRD patients' medical services is paid for by Medicare, Medicaid covers ESRD services for some individuals ineligible for Medicare, those services not covered by Medicare that a State may choose to provide under Medicaid, and cost-sharing incurred by ESRD patients who are dually eligible for both Medicare and Medicaid. Dually eligible people consist of aged, blind, or disabled Medicare beneficiaries whose income and assets are low enough to meet either Federal or State criteria for Medicaid. Approximately 3.5 million or 12 percent of the aged population fit into this category. Total State Medicaid ESRD expenditures in 1988 were estimated to be $68 million dollars, approximately half of which were paid by the Federal Government. The services covered for ESRD patients vary by State. A recent survey of Medicaid programs indicated that only 6 of 48 States cover prescription drugs as part of ESRD services (75).

As of March 1990, however, 43 State Medicaid programs paid the $8 per dose recombinant erythropoietin Medicare patient cost-sharing for eligible individuals (117). A decision had been made by five States not to pay this cost-sharing, and four States and the District of Columbia had not made a decision. Many of the States had adopted the HCFA payment policy of $40 for any recombinant erythropoietin dose under 10,000 units with an additional $30 add-on for doses over that quantity. That so many of the Medicaid programs adopted HCFA's payment rate for recombinant erythropoietin underscores the importance of HCFA's payment rates.

ESRD patients may also be able to seek financial relief for medical care costs from individual State kidney programs, some of which were operating before Medicare assumed most of the costs of ESRD treatment in 1973. These programs are generally the payer of the last resort, after all forms of public and private insurance have been exhausted. A total of 19 States operate a kidney program to provide financial assistance for ESRD patients who are not eligible for Medicaid (75). As is the case with the State Medicaid programs, the services covered by the kidney programs differ by State. Sixteen of these programs cover prescription drugs, but the extent to which these programs help defray the cost of recombinant erythropoietin is currently unknown.