



Human Resources Division

B-257891

August 1, 1994

The Honorable Jimmy Hayes  
House of Representatives

Dear Mr. Hayes:

Most patients who receive organ transplants take immunosuppressant drugs to lower the chance that their bodies will reject the transplanted organs. These drugs are quite expensive--costing from \$4,000 to \$6,000 per patient per year--and most patients must continue to take them throughout their lives. You expressed concern about patients' ability to afford these drugs. You asked us to obtain information on the number of organ transplants, survival rates for patients who receive them, the cost of extending Medicare coverage of immunosuppressant drugs, and whether such drugs would be covered under the various health reform proposals.

Over 16,000 organ transplants were performed in 1991, the latest year for which published data are available, and the number of transplants is increasing steadily. The length of time that patients survive after a transplant has also been increasing. These two factors indicate that the number of patients needing immunosuppressant drug therapy is increasing and will probably continue to do so over time.

Under the administration plan, the W. Thomas/Chafee proposal, and the McDermott/Wellstone single-payer option, prescription drugs would be included in the benefit package. The Cooper/Breaux plan does not explicitly define the benefits to be provided.<sup>1</sup> Medicare currently covers immunosuppressant drugs for 1 year after transplantation, but this is being increased incrementally to 3 years by 1998. Extending coverage to 6 years would essentially double the costs to Medicare, adding annual costs of approximately \$115 million to the program (see pp. 5 and 6). The administration plan would add coverage of

<sup>1</sup>The administration plan is H.R. 3600/S. 1757, the W. Thomas/Chafee plan is H.R. 3704/S. 1770, the McDermott/Wellstone plan is H.R. 1200/S. 491, and the Cooper/Breaux plan is H.R. 3222/S. 1579.

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outpatient prescription drugs, including immunosuppressants, for Medicare beneficiaries, without time limits.

#### OVERALL TRANSPLANT STATISTICS

The number of organ transplants done and the length of time patients live after transplantation have increased. For example, between 1980 and 1990, the number of kidney transplants more than doubled. For some diseases, a transplant is a life-saving measure. For others, such as kidney failure, a transplant may be the optimal and most cost-effective form of treatment. Table 1 presents national information on the number, cost, and survival rates for selected transplants.<sup>2</sup>

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<sup>2</sup>The National Organ Transplant Act (P.L. 98-507) required collection of information about transplant recipients. This information is used to establish the Scientific Registry for Organ Transplantation. The contract for the registry was awarded to the United Network for Organ Sharing (UNOS) and is administered by the Health Resources and Services Administration. Currently, information on long-term survival rates are not available on a national basis but rather only through individual transplant centers or through published research on particular groups of patients. Eventually, nationwide long-term survival rates will be available through the registry.

Table 1: Number, Average Cost and 1- and 2-Year Patient Survival Rates, by Type of Transplant

Type	Organ transplants 1991	Average cost <sup>a</sup>	Percent of patients surviving <sup>b</sup>	
			1 year	2 year
Kidney <sup>c</sup>	9,989	\$ 51,000	--	--
Kidney: Cadaver donor	--	--	93.0	90.0
Kidney: Living related donor	--	--	97.1	95.6
Liver	2,951	235,000	73.9	69.4
Pancreas	533	70,000	89.2	84.1
Heart	2,127	148,000	81.6	77.0
Heart and lung	51	210,000	55.4	48.8
Lung	402	--	67.2	57.7
Total	16,053			

<sup>a</sup>Source: Questions and Answers about Organ Transplantation, U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration. Data are from 1988.

<sup>b</sup>For transplants between October 1, 1987, and December 31, 1991, the latest available data. Source for number of transplants and percent surviving: 1993 Annual Report of the U.S. Scientific Registry for Transplant Recipients and the Organ Procurement and Transplantation Network - Transplant Data: 1988-1991 U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration.

<sup>c</sup>In the case of kidney transplants, if the transplant fails, patients can turn to dialysis, which substitutes for kidney function. Thus, kidney transplant failure does not mean that the patient dies.

Many transplant patients survive at least 5 years post-transplant. For example, over 75 percent of end-stage renal disease (ESRD) kidney transplant patients are alive 5 years after transplantation, with over 90 percent of patients under age 25 surviving five years. A study at the University of Minnesota found that for patients who had a functioning kidney graft at 1 year post-transplant, the 10-

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year graft survival rate was approximately 80 percent. Also, 44 percent of lung transplant patients (including heart-lung transplants) from one transplant center were alive 5 years post-transplant.

#### NATIONAL DATA ON USE AND COSTS OF IMMUNOSUPPRESSANTS

Immunosuppressive drug therapy is an integral component of organ transplants. These drugs are used to prevent rejection of the transplanted organ and almost all transplant recipients must receive some form of immunosuppressive drug therapy. Immunosuppressants act by preventing the production of antibodies to the transplanted organ. They are used both immediately after transplant and as maintenance treatment, which is usually on an outpatient basis. In most cases, immunosuppressive therapy must be continued throughout the patient's life.

The cost of immunosuppressive therapy varies with the patient's condition. The cost of cyclosporine-based treatment (which the vast majority of transplant patients receive) can range from \$4,000 to \$6,000 per person per year. The Office of Technology Assessment (OTA) estimates that in 1988 expenditures for outpatient immunosuppressants totalled between \$185 and \$280 million.<sup>3</sup> The Health Care Financing Administration (HCFA) estimates that in 1991 total U.S. spending on immunosuppressive drugs was approximately \$230 million. Moreover, because the number of transplants and patient survival rates are increasing, more patients will be receiving immunosuppressants on an outpatient basis in the future, and total costs are liable to be higher.

#### MEDICARE COVERAGE AND COSTS OF TRANSPLANTS

Medicare is a health insurance program that covers almost all Americans age 65 or older, persons who have received Social Security disability benefits for at least 24 months, and most people with ESRD. Medicare is administered by the HCFA and covers a wide range of health services from inpatient hospital and physician services to laboratory tests and medical equipment for use in the home. With a few exceptions, Medicare does not cover prescription drugs that can be administered by patients themselves.

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<sup>3</sup>U.S. Congress, Office of Technology Assessment, Outpatient Immunosuppressive Drugs Under Medicare, OTA-H-452 (Washington, DC: U.S. Government Printing Office, Sept. 1991).

In the area of organ transplantation, Medicare will pay for kidney, heart, liver, and bone marrow transplants. Because of the ESRD program, Medicare pays for the vast majority of kidney transplants. However, Medicare pays for few other transplants.<sup>4</sup> Most beneficiaries are poor candidates for transplants because their chance of survival is relatively low due to their age and multiple health problems.

For those beneficiaries who have a covered transplant, Medicare currently pays for the necessary immunosuppressant drugs for the first year after the operation. In 1991 Medicare spent approximately \$25 million on outpatient immunosuppressive drugs. However, the Omnibus Budget Reconciliation Act of 1993 included a provision (see sec. 13565) under which the coverage period is being extended by 6 months each year from 1995 through 1998, when coverage will be for 3 years. Because Medicare eligibility for ESRD beneficiaries ends 3 years after a transplant, the effect of the 1993 law is to extend immunosuppressant drug coverage to the entire period of Medicare eligibility for most people who have Medicare-covered transplants.

The Congressional Budget Office (CBO) estimated that the additional 2 years of coverage would increase annual costs by \$77 million. HCFA's estimate was \$115 million. CBO calculated its estimate by multiplying the number of kidney transplant patients (adjusted by survival rates) by annual drug costs estimated at \$5,000. CBO's cost estimate also reflects adjustments to account for beneficiary copayments, Medicare's role as a secondary payer,<sup>5</sup> and Medicaid. HCFA calculated its estimate by following a group of transplant patients through each of the years they would be covered. It estimated drug costs at \$6,000 per patient per year. As with CBO, the number of transplants and survival rates were based on data on kidney transplant patients.

A rough estimate of the costs involved in extending coverage an additional 3 years (that is, to 6 years) is that the number of people covered would essentially double,

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<sup>4</sup>In 1992 Medicare paid for about 350 heart and 300 liver transplants, compared with almost 9,500 kidney transplants.

<sup>5</sup>Section 1862(b) of the Social Security Act requires that Medicare act as a secondary payer for the first 18 months of eligibility for ESRD beneficiaries covered by employer-sponsored group health plans. The health plan pays up to its normal limits and Medicare pays any remaining costs up to its limits.

thus, costs would double.<sup>6</sup> If coverage was extended to the beneficiary's lifetime, the number of people covered and the costs would increase each year until a steady state is reached (that is, the number of new transplants would equal the number of transplant recipients dying).

INSURANCE COVERAGE OF IMMUNOSUPPRESSANTS  
UNDER CURRENT LAW AND  
UNDER SEVERAL REFORM PROPOSALS

The majority of private insurance companies offer policies that pay for drug therapy and almost all states offer Medicaid coverage for outpatient immunosuppressive drugs. As discussed above, Medicare coverage of immunosuppressants is being extended from 1 to 3 years post-transplant.

The administration's plan includes outpatient prescription drugs as part of its required minimum benefits package. This coverage would be a new benefit for Medicare beneficiaries and is identical to the administration's proposed outpatient prescription drug coverage for non-Medicare beneficiaries. While Medicare and non-Medicare beneficiaries would have an identical drug coverage benefit, beneficiary financial responsibility would be different. Medicare beneficiaries would be responsible for a \$250 deductible, 20 percent coinsurance, and an out-of-pocket cap of \$1,000. Coverage for non-Medicare beneficiaries would be subject to three different levels of cost sharing, with different copayments and deductibles.

The McDermott/Wellstone plan replaces both public and private coverage with a national insurance program with standard benefits. Thus, Medicare and Medicaid would be eliminated and current Medicare and Medicaid beneficiaries would receive the same benefits package as all other beneficiaries. Prescription drugs are listed in the McDermott/Wellstone proposal as part of the benefits package. No deductibles or coinsurance would apply.

Under the W. Thomas/Chafee proposal, all persons would be required to purchase coverage through a qualified health plan. While employers would not be required to pay any portion of the costs for an employee, employers would be required to offer their employees enrollment in a qualified health plan. Specific benefits to be included in the

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<sup>6</sup>Because of the gradual increase in the number of transplants and survival rates and the potential for new developments in the transplant field this estimate could be low.

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packages would be established by a commission and approved by the Congress. Prescription drugs are listed as one of the items to be included in the standard benefits package.

The Cooper/Breaux proposal is intended to improve the availability and affordability of health insurance using the managed competition approach.<sup>7</sup> The specific benefits that would be included in the minimum benefits package are not stated in the bill. Under the Cooper/Breaux proposal, a Health Care Standards Commission (House version) or National Health Board (Senate version) would develop a benefits package and submit it for congressional consideration, and make recommendations on cost sharing. Medicare would be retained, while Medicaid would be eliminated. There is no mention of changes in Medicare's benefits for immunosuppressants. Coverage for immunosuppressants for former Medicaid beneficiaries who enroll in health plans would be the same as other health plan enrollees and, thus, would depend on which benefits are included in the minimum benefit package.

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I trust that this letter answers your questions. If you or your staff have any questions about this information, please call me on (202) 512-7119 or Thomas Dowdal, Assistant Director, on (410) 965-8021. Anita Roth was the Evaluator-in-Charge for this assignment.

Sincerely yours,



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<sup>7</sup>The plan does not require people to obtain health insurance.

