

1996, 1997, and 1998. We estimate that the annual drug cost following transplantation for a full time user of immunosuppressive drugs will be as follows:

ESTIMATED ANNUAL COST OF IMMUNOSUPPRESSIVE DRUGS FOR EACH TRANSPLANT PATIENT

CY 1995	CY 1996	CY 1997
\$5580	\$5910	\$6275

This final rule also differs from the proposed rule in that the term "immunosuppressive drugs" has been changed to "prescription drugs used in immunosuppressive therapy" to conform with section 4075 of OBRA '87. This expanded coverage will allow payment for other necessary drugs used in conjunction with immunosuppressive drugs.

**B. Regulatory Flexibility Act**

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmacists, physicians who perform transplantation services, and manufacturers of covered pharmaceuticals are considered to be small entities. Although pharmaceutical manufacturers are frequently not considered to be small entities, the possibility exists that certain manufacturers affected by this final rule may meet the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Because of the high cost of a majority of the drugs used for immunosuppressive therapy and the extended time that beneficiaries are required to take the drugs to ensure that the transplanted organ is not rejected, all Medicare transplant patients and many small entities will benefit by this regulation. In many cases, 1 year of immunosuppressive therapy is not sufficient. Also, it is possible that we may avoid the additional cost of a

second transplant if a patient is kept on immunosuppressive drug therapy beyond the original 12 month coverage period.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 410**

Medical and other health services, Medicare.

For the reasons set forth in the preamble, 42 CFR chapter IV, part 410 is amended as set forth below:

**PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

1. The authority citation continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 410.10, the introductory text is republished and a new paragraph (u) is added to read as follows:

**§ 410.10 Medical and other health services: Included services.**

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

\* \* \* \* \*

(u) Prescription drugs used in immunosuppressive therapy.

3. A new § 410.31 is added to read as follows:

**§ 410.31 Prescription drugs used in immunosuppressive therapy.**

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C

of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Period of eligibility.* Coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who receives an organ or tissue transplant for which Medicare payment is made, for the following periods:

(1) For drugs furnished before 1995, for a period of up to 1 year beginning with the date of discharge from the hospital during which the covered transplant was performed.

(2) For drugs furnished during 1995, within 18 months after the date of discharge from the hospital during which the covered transplant was performed.

(3) For drugs furnished during 1996, within 24 months after the date of discharge from the hospital during which the covered transplant was performed.

(4) For drugs furnished during 1997, within 30 months after the date of discharge from the hospital during which the covered transplant was performed.

(5) For drugs furnished after 1997, within 36 months after the date of discharge from the hospital during which the covered transplant was performed.

(c) *Coverage.* Drugs are covered under this provision irrespective of whether they can be self-administered.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: January 9, 1995.

**Bruce C. Vladeck,**  
Administrator, Health Care Financing Administration.

Approved: February 9, 1995.

**Donna E. Shalala,**  
Secretary.

[FR Doc. 95-3835 Filed 2-15-95; 8:45 am]

BILLING CODE 4120-01-P