

Comment: One commenter recommended that all payments, including those to hospital outpatient departments, should be made under Part B on a reasonable charge basis. The commenter maintained that payments based on costs do not allow the hospital to be paid a reasonable rate for pharmaceutical services and overhead and that many hospitals maintain separate inventory and purchasing practices for drugs used in the outpatient setting.

Response: The statute mandates that the outpatient department of a hospital be paid based on the lower of reasonable cost or customary charges as established in the following sections of the Act:

- Sections 1832(a)(2)(B) and 1861(s)(2)(J), which establish that drugs used in immunosuppressive therapy furnished in a provider are a covered medical service.

- Section 1833(a)(2)(B), which states that payment is based on the lesser of the reasonable cost of hospital outpatient department services as determined under section 1861(v), or the customary charges with respect to these services.

- Section 1861(u), which defines a provider of services to include a hospital.

- Section 1862(a)(14), which states, in part, that no payment may be made under Part A or Part B for any expenses incurred for items or services, other than for statutorily specified exceptions, that are furnished to an individual who is a patient of a hospital by an entity other than the hospital or under arrangements with the hospital. ("Patient" means inpatients and outpatients of a hospital.)

Therefore, if a patient is an outpatient of a hospital and receives prescription drugs from the hospital pharmacy, payment would have to be made to the hospital pharmacy according to the mandate of section 1833(a)(2)(B) of the Act. That section establishes that payment to any provider of services (in this case, the outpatient pharmacy department of a hospital) must be the lesser of the reasonable cost of these services, as determined under section

1861(v) (which includes recognition of both direct and indirect costs), or the customary charges with respect to these services.

Comment: One commenter suggested that we improve our communication with fiscal intermediaries, because some intermediaries are unaware that they should be paying for prescription drugs used in immunosuppressive therapy.

Response: We have taken steps to ensure that all contractors processing claims for prescription drugs used in immunosuppressive therapy are aware of current Medicare coverage and payment policies. We have not been informed of any specific problems in this area of program administration.

IV. Provisions of This Final Rule

The provisions of this final rule restate the provisions of the January 1988 proposed rule. The final rule differs from the proposed rule in that we have changed the term "immunosuppressive drugs," wherever it appears, to "prescription drugs used in immunosuppressive therapy" to conform with section 4075 of OBRA '87. Also, we have redesignated the proposed § 410.65 as § 410.31. The final rule also differs from the proposed rule in that we have specified that drugs also will be covered if they have been determined, by a Part B carrier in processing a Medicare claim, to be reasonable and necessary (that is, safe and effective) for the purpose of treating or preventing the rejection of a patient's transplanted organ or tissue, or for use in conjunction with these immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. The carriers make these determinations by considering factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications. This change makes the policy governing drugs used in immunosuppressive therapy consistent with Medicare's general drug coverage policy.

An additional point of clarification is that the coverage of prescription drugs

for transplants under this rule includes prescription drugs used in immunosuppressive therapy furnished to an individual who receives a bone marrow tissue transplant for which Medicare payment is made. For purposes of this rule, we consider bone marrow tissue transplants to be subsumed within the term "organ transplant" under section 1861(s)(2)(J) of the Act. Medicare currently covers heart, kidney, bone marrow, and certain liver transplants.

The final rule also differs from the proposed rule in that OBRA '93 requires phased-in extensions (up to 3 years) to the coverage period for prescription drugs used in immunosuppressive therapy.

V. Collection of Information Requirements

This notice does not impose information collection or recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C 3501 *et seq.*).

VI. Regulatory Impact Statement

A. Introduction

This final rule amends the regulations to provide Medicare coverage for prescription drugs used in immunosuppressive therapy following an inpatient hospital stay during which a Medicare-covered organ transplant was performed. OBRA '86 amended section 1861(s)(2) of the Act to provide Part B coverage for a period not to exceed 1 year beginning July 1, 1987. As a result of OBRA '93, the period of coverage of prescription drugs used in immunosuppressive therapy after the discharge from a hospital has been increased to 18 months for drugs furnished in 1995, 24 months for drugs furnished in 1996, 30 months for drugs furnished in 1997, and 36 months for drugs furnished after 1997. The following table shows the estimated additional expenditures as a result of the extended coverage.

ESTIMATED ADDITIONAL COST BECAUSE OF EXTENDED COVERAGE OF DRUGS FOR IMMUNOSUPPRESSIVE THERAPY—
ROUNDED TO THE NEAREST \$5 MILLION

FY 1995	FY 1996	FY 1997	FY 1998	FY 1999
\$20	\$60	\$90	\$110	\$120

The use of immunosuppressive drug therapy is indicated for the prevention of organ rejection when an organ or tissue transplant is performed. The

estimated number of transplants that will be performed in CY 1994 is 10,125, some of which will have an effect on immunosuppressive drug therapy

expenditures in CYs 1995 and 1996. The estimated 10,850 transplants that will be performed in CY 1995 will have an effect on drug therapy costs in CYs