assigned to DRG 495, the new lung transplantation DRG. We intend to continue to pay for heart-lung transplants under DRG 103. The mechanisms by which DRG weights are updated allows us to continue to examine the costs associated with heart and heart-lung transplants to assure that payments reflect service intensity.

Organ acquisition costs will be paid separately on a cost basis, in the same manner as kidney acquisition costs are handled in the End-Stage Renal Disease program under Medicare. Physician services, as well as other non-hospital services related to the transplant, and pre- and post-transplant care, may be covered under Medicare Part B and paid under the physician fee schedule or on a reasonable cost basis or other bases.

In accordance with section 1861(s) of the Act, outpatient drugs used in immunosuppressive therapy, including drugs that a patient can self-administer, such as cyclosporine, are covered under Medicare for a period of up to 1 year beginning with the beneficiary's date of discharge from the inpatient hospital stay during which a covered organ transplant was performed. Beginning in 1995, Medicare coverage will be extended to 18 months after the date of discharge for the covered transplant procedure. During 1996, Medicare coverage will be extended to 24 months, and during 1997 to 30 months. For all years thereafter, Medicare coverage will be extended to 36 months after the date of discharge for the covered transplant procedure.

If a Medicare beneficiary receives a covered lung transplant from an approved facility, reasonable and necessary services for follow up care and for complications are covered, as determined by our contractors. In fact, as discussed below, such follow-up or remedial services may be covered even if they are furnished by a hospital that is eligible for Medicare payment but was not specifically approved by Medicare for lung transplantation at the time the lung transplant was performed.

With the exception of those individuals on the waiting list of a facility currently approved for coverage by the fiscal intermediary on the date of this notice, noted earlier, Medicare will not cover lung transplants or retransplants in facilities that have not been approved as Medicare lung transplant facilities under the criteria of this notice as of July 31, 1995. If a Medicare beneficiary received a lung transplant from a facility that is not approved by Medicare for lung transplantation at the time the lung transplant was performed, we will not cover any hospital inpatient services associated with the transplantation procedure. Nor will we cover physician services associated with the transplantation procedure in such cases. Thus, payment will not be made for the performance of the transplant or for any other services associated with the transplantation procedure if performed in a nonapproved facility.

However, after a beneficiary has been discharged from a hospital (whether or not it has been approved by Medicare as a lung transplant center) in which he or she received the noncovered lung transplant, subsequent medical and hospital services required as a result of the transplant are covered in a facility otherwise eligible for in a facility otherwise eligible for Medicare payment if they are reasonable and necessary in all other respects. Thus, coverage is provided for subsequent inpatient stays or outpatient treatment ordinarily covered by Medicare even if the need for treatment arose because of a previous noncovered lung transplant procedure. These services also are covered for Medicare beneficiaries who were not beneficiaries at the time they received a lung transplant, regardless of whether or not the transplant was performed at an approved facility.

We will pay those hospitals currently receiving coverage by local contractors for transplants furnished on or before July 31, 1995. For transplants furnished after that date, except for those beneficiaries on their waiting list on the date of this notice, we will pay only approved facilities. For facilities approved for coverage, we will pay for any covered transplants furnished on or after the date of publication of this notice (if the facility applied during the initial 90 day period) or the date the facility is approved, whichever is later.

III. Waiver of Proposed Notice

We ordinarily publish a proposed notice in the **Federal Register** and invite prior public comment before issuing a final notice. However, the Medicare law, at sections 1871(a)(2) and 1869(b)(3)(B), provide for exception of prior public notice in the establishment of national coverage policy. Specifically, section 1871(a)(2) of the Act states that ''No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes * * * shall take effect unless it is promulgated by the Secretary under regulation * * *'' Section 1869(b)(3)(B) of the Act further specifies that a national coverage determination under section 1862(a)(1) shall not be set aside on the grounds that publication in the **Federal Register** or an opportunity for public comment was not satisfied.

Despite this clear statutory authority to issue national coverage policy without prior public comment, we have historically offered an opportunity for prior public comment in establishing our national coverage policy for heart and liver transplantation. However, in the case of these organ transplants, we had previously established a uniform non-coverage policy. In the case of lung transplants, there is not pre-existing national coverage policy and differing policies have been established by our local intermediaries. Consequently, we believe it is impracticable, unnecessary and contrary to public interest to delay the implementation of this policy while awaiting public comment.

In this final notice with comment period, we are extending Medicare coverage to lung transplantation in facilities that meet specified criteria. Patients currently on the waiting list in facilities that are being paid under the Medicare contractor's local policy will continue to retain coverage regardless of whether the facility is approved under the criteria contained in this notice.

Patients not currently on a waiting list for a lung transplant may be listed at the facility of their choice pending approval of the facility by the Administrator. If the facility is not approved when the patient is getting close to the top of the list, the patient my be transferred to an approved center without loss of waiting time. That is, it is the policy of the United Network for Organ Sharing (UNOS) to manually adjust the waiting time for patients who transfer facilities so that patients are credited wait time from when they were first listed. UNOS has adopted this policy to encourage patients to be transplanted at centers that are most proficient in transplantation. Consequently, no Medicare beneficiaries would be adversely impacted by this rule.

On the other hand, delay of this final notice until we could publish a proposed notice would result in the unavailability of coverage of lung transplantion to some facilities that would meet the quality standards, due to the fact that the contractor in their area has not determined the procedure to be covered under Medicare. In an informal survey of the Medicare contractors, we believe at least 16 contractors are not currently covering lung transplantation and even do not cover heart-lung transplantation. Further, immunosuppressive drug therapy is covered only if the transplant is covered. Thus, beneficiaries currently being denied coverage under local contractor policies are excluded from coverage of needed drug therapy.