

not comply with those in this notice due to participation in ongoing research work.

Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than 2 years, and applications from consortia will not be approved. We do not believe programs that have been in existence for less than 2 years have data to demonstrate, in a statistically meaningful way, the quality of their program. Further, it is difficult to demonstrate continued commitment to the program without ongoing experience.

We do not believe waivers to allow consortia are appropriate because we have no assurance that the individual facilities that make up the consortia independently meet the conditions of this notice. We believe these conditions must be met individually by a facility in order to demonstrate substantial experience with the procedure. Although we will not approve consortia as lung transplant centers, individual members of a consortium may submit individual applications at any time, and, if they meet the criteria, they will be approved. In these cases, disapprovals would be made by HCFA and do not require prior reviews by the expert consultants. Additionally, exceptions will not be granted on the basis of geographic considerations.

E. Effective Dates

1. Summary of Effective Dates

- A facility that submits a completed application to HCFA by May 3, 1995 and meets all the requirements of this notice will be approved for lung transplants performed beginning February 2, 1995 or the date on which they meet the conditions, whichever is later.
- A facility that submits a completed application to HCFA after May 3, 1995 and meets all the requirements of this notice will be approved for lung transplants performed beginning on the date of the Administrator's approval letter.
- A facility that does not submit application or has not met the requirements of this notice by July 31, 1995 is not eligible for Medicare payment for lung transplants effective July 31, 1995 except as provided below.
- A facility that has received Medicare payment for lung transplants performed based on individual determinations made by the Medicare carrier before July 31, 1995 may continue to receive payment for lung transplants performed for patients who

are on a waiting list with that facility as of February 2, 1995.

2. Discussion of Effective Dates

It is not our intent to disrupt the availability of covered lung transplants for Medicare beneficiaries. Consequently, the 180-day limit on Medicare coverage in facilities not meeting the approved criteria in this notice does not apply to those beneficiaries already on the waiting lists of facilities that are currently being paid under the Medicare contractors' local Medicare coverage policy. The contractor will process the claims for all beneficiaries on the lung or heart-lung transplant waiting list as of February 2, 1995 using its current coverage policy regardless of whether the facility meets the criteria contained in this notice. This policy will continue until all Medicare beneficiaries on the waiting list as of February 2, 1995, have been transplanted.

A beneficiary who is not currently on the lung or heart-lung transplant waiting list will be limited to procedures performed in those facilities that meet the provisions of this notice, unless the beneficiary receives a transplant before July 31, 1995 publication that would have been paid under the Medicare contractors' local Medicare coverage policy that was in effect as of the effective date of this notice. We recognize that those beneficiaries not presently on the waiting lists will not know with assurance which facilities will ultimately be approved for coverage before July 31, 1995. However, we wish to point out that if the facility where a beneficiary is wait-listed is not approved for Medicare coverage as the patient nears the time of transplant, the beneficiary may transfer to an approved center without loss of waiting time. That is, the patient will be transferred to the new center with the date he or she was originally wait-listed at the old facility as the start date.

We recognize that 180 days is more than we generally permit for advance notice of implementation of new policy. However, based on previous experience in the heart and liver transplant center approval process, we anticipate that some facilities that meet the criteria will delay application until the last month of the initial 90 day period. Because it generally takes us approximately 2 months to process a complete application we believe it is a reasonable expectation that facilities will have been notified of the decision on their application by that time. By delaying implementation for 180 days, we will assume that there are not lapses in Medicare coverage due to processing

time. At the end of the 180 day period, Medicare coverage for transplants other than for beneficiaries on the waiting list as of February 2, 1995 will be limited to approved facilities.

For facilities that apply within 90 days of publication of this notice, and are approved based on that application, payment may be made for transplants as early as the date of publication of this notice, or the date on which they met the conditions, whichever is later.

For facilities that apply more than 90 days from the date of this notice, coverage (for beneficiaries other than those on the facility's waiting list as of the date of this notice in those States where the contractors cover lung transplantation) is effective the date of the Administrator's approval letter. Some contractors are currently covering lung transplants in facilities that may not meet the criteria in this notice. Coverage under the contractors' criteria will be maintained until July 31, 1995. After this date, (except for the beneficiaries identified above) only those facilities approved for national coverage may receive Medicare payment for lung transplants.

F. Payment

For facilities that are approved to perform lung transplants, Medicare covers under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. For discharges occurring before October 1, 1994, lung transplants were assigned to DRG 75, Major Chest Procedures. As of that date, we established a new DRG 495, Lung Transplant, for lung transplant cases.

We have assigned a relative weight of 12.8346 to DRG 495. This weight is based on Medicare bill data from the federal fiscal year (FY) 1993 Medicare Provider Analysis and Review (MedPAR) file updated through December 1993. The MedPAR file contains 100 percent of the hospital discharge bills for Medicare beneficiaries received by HCFA.

We used the same methodology to calculate the weight for DRG 495 as we do every year in recalibrating the weights for all DRGs. The final rule implementing the FY 1995 changes to the hospital inpatient prospective payment system, which was published in the **Federal Register** on September 1, 1994 (59 FR 45348), contains a complete description of the methodology used to calculate weights.

The Medicare DRG grouping program used under the prospective payment system already groups heart-lung transplant procedures to DRG 103. The weight for DRG 103 is higher than that