

Transplantation Network is currently administered under an HHS contract by the United Network for Organ Sharing. The facility must participate in an organ procurement program to obtain donor organs.

If a lung transplantation center is not a Medicare approved organ procurement organization, it must have a written arrangement with such an approved organization to share organs. The authority for this requirement is section 1138(a)(1) of the Act. The lung transplantation center must notify HCFA in writing within 30 days of terminating such arrangements.

An "organ procurement organization" is defined as an organization that meets the criteria in section 371(b) of the Public Health Service Act, 42 U.S.C. 273(b), and has been designated by HCFA as an organ procurement organization under section 1138(b) of the Act. Such an agency performs or coordinates all of the following services:

- Retrieval of donated lungs.
- Preservation of donated lungs.
- Transportation of donated lungs.
- Maintenance of a system to locate prospective recipients for retrieved organs.

8. Laboratory Services

The facility must make available, directly or under arrangements, laboratory services (including blood banking) to meet the needs of patients. Laboratory services are performed in a laboratory facility certified for those services under the Clinician Laboratories Improvement Amendments of 1988.

9. Billing

The facility must agree to submit claims to Medicare only for lung transplants performed on individuals who have been diagnosed as having end-stage pulmonary or cardiopulmonary disease.

10. Pediatric Hospitals

The Congress addressed the issue of Medicare coverage of pediatric heart transplants. It enacted section 4009(b) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203) which essentially deemed pediatric facilities to be certified as heart transplant facilities if they met certain specified conditions. We have adopted these same conditions that were specified for pediatric heart centers for use in pediatric liver transplantation, and we believe it is appropriate to do so likewise for pediatric lung transplantation.

There fore, lung transplantation will be covered for Medicare beneficiaries when performed in a pediatric hospital

that performs pediatric lung transplants if the hospital submits an application that HCFA approves as documenting the following:

The hospital's pediatric lung transplant program is operated jointly by the hospital and another facility that has been found by HCFA to meet the institutional coverage criteria in this notice; the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and the hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric lung transplant patients.

C. Application Procedure

We will accept and begin to review applications after the publication date of this notice. The application procedure is as follows.

An original and 10 copies of the application must be submitted to HCFA on 8½ by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicare and must specify its provider number, the name and title of its chief executive officer, and the name and telephone number of an individual we could contact should we have questions regarding the application.

Information and data must be clearly stated, well organized, and appropriately indexed to aid in review against the criteria specified in this notice. Each page must be numbered. To the extent possible, the application should be organized into nine sections corresponding to each of the nine major criteria and addressing, in order, each of the sub-criteria identified.

The application should be mailed to the address below in a manner which provides the facility with documentation that it was received by us: Director, Office of Hospital Policy, Room 189 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207.

D. Process for Review and Approval of Facilities

We are requiring that facilities that wish to obtain lung transplantation coverage for their Medicare patients under this notice submit an application and supply documentation showing their compliance with the criteria at the time of application, and, in some instances, their ongoing compliance with the criteria. We will approve facilities based on a review of the materials submitted regarding their experience and expertise, as well as their commitment to the lung transplant program. We intend to conduct the review using the aid and advice of non-

Federal expert consultants in relevant fields. Generally, the consultants will have the responsibility of reviewing applications at the request of HCFA, making recommendations to HCFA on a timely basis concerning qualified facilities, and supporting each recommendation with written documentation. Consensus of the consultants is not required. The individual consultants report to us on their findings with respect to individual applications. Based on these findings and our evaluations and review, HCFA makes decisions as to the approval or disapproval of such applications.

Based on our experience in using a similar approach to review applications from hospitals seeking approval as Medicare heart or liver transplant programs, we believe this method is the most effective way to determine promptly and efficiently whether applicants meet the lung transplant facility criteria. It permits relatively rapid implementation of the criteria and should help assure applicants that their qualifications have been thoroughly and objectively reviewed by experts in the field of lung transplantation. While the amount of time needed to process applications will vary depending on the quality of the application and the volume of applications on hand, we believe those applications that fully address and demonstrate meeting all of the criteria may be completed within 60-90 days.

In approving facilities, we compare the facility's submission against the criteria specified in this notice. In addition to reviewing applications, the individual expert consultants may propose specific changes to the coverage criteria. Changes in coverage criteria will not be implemented, however, without appropriate notice and opportunity for public comment.

Finally, in certain limited cases, exceptions to the strict criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. We would consider an exception or waiver of a particular criterion if all other criteria are met and the facility is able to provide reasonable justification for not meeting the criterion. For example, we have granted exceptions under the heart transplant program to facilities that fail to meet the volume or survival criteria in one year by a small number due to extraordinary circumstances. We would also consider exceptions for a facility that has only minimally missed the volume criteria but has displayed exemplary survival performance. Another example of a potential exception situation may involve patient selection criteria that do