

Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 27, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

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Health Care Financing Administration

[BPD-812-NC]

RIN 0938-AG83

Medicare Program; Criteria for Medicare Coverage of Lung Transplants

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces a Medicare national coverage decision for lung and heart-lung transplantations. Lung transplantation refers to the transplantation of one or both lungs from a single cadaver donor. Heart-lung transplantation refers to the transplantation of one or both lungs and the heart from a single cadaver donor.

We have determined that, under certain circumstances, lung transplants and heart-lung transplants are a medically reasonable and necessary service when furnished to patients with progressive end-stage pulmonary or cardiopulmonary disease and when furnished by Medicare participating facilities that meet specific criteria, including patient selection criteria.

DATES: This notice is effective February 2, 1995. For information on how this notice effects Medicare payment for lung and heart-lung transplants, see sections E and F of this notice.

ADDRESSES: *Applications.* A facility seeking Medicare coverage and payment for lung transplantation should mail 10 copies of the application 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.

Comments. Comments will be considered if we received them at the appropriate address, as provided below, no later than 5 p.m. on April 3, 1995.

Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-812-NC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3

copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Building, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-812-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 966-5666.

SUPPLEMENTARY INFORMATION:

I. Background

Administration of the Medicare program is governed by the Medicare law, title XVIII of the Social Security Act (the Act). The Medicare law provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility (SNF) care, home health care, and physicians' services. It places general and categorical limitations on the coverage of the services furnished by certain health care practitioners, such as dentist, chiropractors and podiatrists, and it specifically excludes some categories of services from coverage, such as cosmetic surgery, personal comfort items, custodial care, routine physical checkups, and procedures that are not reasonable and necessary for diagnosis or treatment of an illness or injury.

The Act also provides direction as to the manner in which payment is made for Medicare services, the rules governing eligibility for services, and the health, safety, and quality standards to be met in institutions furnishing services to Medicare beneficiaries. The Medicare law does not, however, provide an all-inclusive list of specific items, services, treatments, procedures, or technologies covered by Medicare.

Thus, except for the examples of durable medical equipment in section 1861(n) of the Act, and some of the medical and other health services listed in section 1861(s) and 1862(a) of the Act, the Act does not specify medical devices, surgical procedures, or diagnostic or therapeutic services that should be covered or excluded from coverage.

The intention of the Congress, at the time the Medicare Act was enacted in 1965, was that Medicare would provide health insurance to protect the elderly or disabled from the substantial costs of acute health care services, principally hospital care. The program was designed generally to cover services ordinarily furnished by hospitals, SNFs, and physicians licensed to practice medicine. The Congress understood that questions as to coverage of specific services would invariably arise and would require specific coverage decisions by those administering the program. It vested in the Secretary the authority to make those decisions.

Section 1862(a)(1)(A) of the Act prohibits payment for any expenses incurred for items or services "which are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." We have interpreted this statutory provision to exclude from Medicare coverage those medical and health care services that have not been demonstrated by acceptable clinical evidence to be safe and effective. Effectiveness in this context is defined as the probability of benefit to individuals from a medical item, service, or procedure for a given medical problem under average conditions of use, that is, day-to-day medical practice.

To date, the Medicare program has not issued a national coverage policy on lung or heart-lung transplantation. In the absence of national coverage policy, the contractors that process Medicare claims are authorized to develop Medicare coverage policy for their service area using medical literature, the advice of medical consultants and local medical societies, and their private line business practices.

Several contractors have determined lung transplantation to be a Medicare covered service prior to this notice, and a small number of contractors have covered heart-lung transplant. However, most of these contractors do not have a clearly defined coverage policy that would allow a beneficiary to know in advance if the procedure would be covered. Rather, they review each case individually after it has occurred and determine coverage without published

criteria. Other Medicare contractors do not cover the procedure at all. Thus, there is inconsistency within the nation.

On January 30, 1989, we published a proposed rule in the **Federal Register**, at 54 FR 4302, which describes our process for formulating new national coverage decisions and reevaluating existing decisions. As discussed in that notice, we sometimes rely on the Office of Health Technology Assessment (OHTA) in the Agency for Health Care Policy and Research (AHCPR) of the Public Health Service (PHS) for medical consultation and advice. We also rely on other PHS components, such as the National Institutes of Health.

The AHCPR evaluates the risks, benefits, and clinical effectiveness of new, existing, or unestablished medical technologies. The assessment process includes a comprehensive review of the medical literature and emphasis broad participation from within and outside the Federal government. The OHTA conducted an assessment of lung transplantation in 1991 and concluded that experience has shown that lung transplants can provide adequate pulmonary function for extended periods in some patients with otherwise fatal lung disease. In addition, the National Heart, Lung, and Blood Institute (NHLBI) in the National Institutes of Health, Public Health Service, reported to us in 1993 that lung transplantation in carefully selected patients and by experienced teams yields significant increases in survival with reasonable quality of life.

We believe it is appropriate in the face of these findings to issue a national policy rather than to maintain the current system of inconsistency among the contractors. In addition, we believe it is more beneficial to develop a national policy where facilities and beneficiaries will know in advance the criteria and facilities covered rather than to maintain the system in many areas of making coverage decisions on a case by case basis without clearly defined criteria.

II. Provisions

We have carefully reviewed the reports and recommendations of the Office of Health Technology Assessment and the National Heart, Lung, and Blood Institute. Based on these reports, the opinions of our medical advisors, consultations with PHS, and review of the medical literature, consultation with medical advisors and reconsultation with NHLBI since the OHTA assessment, we are establishing national coverage of lung transplant under the Medicare program, under the authority of section 1862(a)(1)(A) of the Act.

Sections 1869(b)(3)(B) and 1871(a)(2) of the Act specifically exempt national coverage decisions from the notice-and-comment rulemaking process ordinarily required by section 553 of the Administrative Procedure Act. Despite this authority, we have indicated that we would use the prior comment process in discontinuing coverage of procedures. However, we do not believe that the establishment of this policy is a discontinuation of coverage. Rather, we view this policy as establishment of national coverage policy where no such policy previously existed.

Consequently, we are proceeding with a final notice in this regard. Nonetheless, we wish to receive comments on these criteria within 60 days of the publication of this notice.

Medicare will cover lung transplants for beneficiaries with progressive end-stage pulmonary disease and when performed by facilities that (1) make an application to HCFA for approval as a lung transplant facility under the criteria established by this notice; (2) supply documentation showing their satisfaction of compliance with the criteria discussed later in this notice; and (3) are approved by HCFA under these criteria. Medicare will also cover lung transplantation for end-stage cardiopulmonary disease when it is expected that transplant of the lung will result in improved cardiac function.

In addition, Medicare will also cover heart-lung transplants for beneficiaries with progressive end-stage cardiopulmonary disease when they are provided in a facility that has been approved by Medicare for both heart and lung transplantation. The NHLBI's studies of this procedure have persuaded us that, though provided infrequently, this procedure is sometimes the appropriate intervention for specific patients. We believe the procedure may be safely and effectively done in a facility that is Medicare approved for both heart and lung transplantation. We are not establishing specific patient selection criteria for the procedure; however, we expect that facilities that perform heart-lung transplants will develop and use appropriate criteria.

Organs transplanted as a heart-lung procedure should be included in the volume and survival statistics for each organ. Thus, facilities may meet the volume and survival criteria delineated in this notice through both lung and heart-lung transplant procedures.

A. Specific Clinical Conditions Required for Lung Transplantation Coverage

Medicare will cover lung transplants only for those beneficiaries who are

diagnosed as having progressive end-stage pulmonary disease (or, in some instances, end-stage cardiopulmonary disease) and when the procedure is performed in a participating facility that meets specific criteria.

Note: See effective date section for further explanation.

We are requiring that facilities meet specific criteria in areas such as patient selection, patient management, commitment, plans, experience and survival rates, maintenance of data, organ procurement, laboratory services, and billing. Facilities must have patient selection criteria for determining suitable candidates for lung transplants.

B. Facility Requirements

Under current Medicare policies, a procedure can be considered medically reasonable and necessary only if its safety and efficacy have been demonstrated adequately by scientific evidence, such as controlled clinical studies, and it has been generally accepted by the medical community. Normally, surgical procedures and medical regimens, although requiring competent, skilled personnel, are of a nature that they can be performed successfully on most patients who require them in most facilities that meet the Medicare conditions of participation for hospitals in 42 CFR part 482. In the case of lung transplantation, however, we believe many other factors are related to the safety and efficacy of the procedure. Thus, coverage of lung transplants requires detailed criteria to identify the context in which lung transplantations can be considered medically reasonable and necessary.

We are covering only those lung transplantations performed in facilities that demonstrate good patient outcomes (for example, initially a 1-year survival rate of 69 percent for patients receiving a lung transplant) and compliance with the facility criteria. While we believe that survival rates are important measures of successful outcomes, we do not believe that they can serve as the only criteria a center has to meet in order to be approved for Medicare payment for lung transplants. Once a facility applies for approval under these criteria and is approved as a lung transplant facility for Medicare purposes, it is obliged to report immediately to HCFA any events or changes that would affect its approved status. Specifically, a facility is required to report, within a reasonable period of time, any significant decrease in its experience level or survival rates, the departure of key members of the transplant team or any other major

changes that could affect the performance of lung transplants at the facility. Changes from the terms of approval may lead to prospective withdrawal of approval for Medicare coverage of lung transplants performed at the facility.

A discussion of the criteria that we are requiring facilities to meet in order to receive Medicare payment for lung transplantation follows. A very similar approach is being used in determining eligibility of heart and liver transplant facilities and has proved very successful.

1. Patient Selection Criteria

The NHLBI of the National Institutes of Health, Public Health Service, has reported to us that lung transplantation in carefully selected patients and by experienced teams yields significant increases in survival with reasonable quality of life. Therefore, we believe that careful patient selection for lung transplants, as suggested by NHLBI, is essential to achieve optimal results. We require that facilities have written patient selection criteria that they follow in determining suitable candidates for lung transplants, such as the following:

- a. A patient is selected based upon both a critical medical need for transplantation and a strong likelihood of successful clinical outcome.
- b. A patient who is selected for a lung transplant has irreversible, progressively disabling, end-stage pulmonary disease (or, in some instances, end-stage cardiopulmonary disease).
- c. The facility has tried or considered all other medically appropriate medical and surgical therapies that might be expected to yield both short- and long-term survival comparable to that of transplantation.
- d. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the individual patient.

Many factors must be recognized as exerting an adverse influence upon the patient's outcome after transplantation. The following adverse factors are among those that should be considered in selecting patients for transplantation:

- Primary or metastatic malignancies of the lung.
- Current significant acute illness that is likely to contribute to a poor outcome if the patient receives a lung transplant or current use of mechanical ventilation for more than a very brief period.
- Significant or advanced heart, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after lung transplantation.

- Significant extra-pulmonary infection.
- Chronic pulmonary infection in candidates for single lung transplantation.
 - Continued cigarette smoking or failure to have abstained for long enough to indicate low likelihood of recidivism.
 - Systemic hypertension that requires more than two drugs for adequate control.
 - Cachexia, even in the absence of major end-organ failure.
 - Obesity.
 - Previous thoracic or cardiac surgery or other bases for pleural adhesions.
 - Age beyond that at which there has been substantial favorable experience.
 - Chronic corticoid therapy that cannot be tapered to a low dose (10 mg prednisone per day) or discontinued prior to transplantation.
 - A history of behavior pattern or psychiatric illness considered likely to interfere significantly with a disciplined medical regimen.

Except for the matter of primary or metastatic malignancies of the lung, all these factors were explicitly enumerated in the National Heart, Lung, and Blood Institute memorandum upon which we primarily relied in developing this notice. Primary or metastatic malignancies of the lung are implicit in the National Heart, Lung, and Blood Institute's listing of systemic and multi-system diseases as an adverse factor. We are explicitly listing primary or metastatic malignancy of the lung to emphasize it should be an adverse factor in patient selection. We note that we have received a report which surveyed major lung transplant facilities regarding, among other things, appropriate patient selection criteria for lung transplants. The results of the survey indicate Medicare coverage criteria for lung transplantation should include patient selection criteria that exclude malignancies. The American College of Cardiology believes that malignancy (other than basal cell carcinoma) is an absolute contraindication for heart-lung transplant. (See Health Technology Assessment "Institutional and Patient Criteria for Heart/Lung Transplantation," Agency for Health Care Policy and Research). In addition, a New England Journal of Medicine article by Steven E. Weinberger, M.D. (Volume 328, Number 20, May 20, 1993) indicated that lung transplant patients " * * * should not have an underlying cancer or other systemic illness," and that same view was reflected in a survey of lung transplant programs.

These criteria take into consideration advances in the transplantation field and reflect discussions with experts in pulmonary medicine, infectious diseases, transplantation, surgery, biostatistics, and other experts. We realize that the indicators to measure the safety and efficacy of lung transplantations will continue to evolve. Thus, we may need to update the criteria periodically to recognize further developments in lung transplantation technology. We intend to re-evaluate the criteria through survey and data gathering within the next 3 years.

2. Patient Management

A facility must have adequate patient management plans and protocols that include the following:

- Therapeutic and evaluative procedures for the acute and long-term management of a patient, including commonly encountered complications. The facility must state the basis for confidence in these plans.
- Patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.
- Long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for a period of at least 5 years.

3. Commitment

A facility must make a sufficient commitment of resources and planning to the lung transplant program to carry through its application. Indications of this commitment should include a commitment by the facility to the lung transplant program at all levels and which is broadly evident throughout the facility. (A lung transplantation program requires a major commitment of resources, which may intermittently include many other departments as well as the principal sponsoring departments.)

The facility must have expertise in medical, surgical, and other relevant areas, particularly thoracic surgery, vascular surgery, anesthesiology, immunology, infectious diseases, pulmonary diseases, pathology, radiology, nursing, blood banking, and social services. The facility must identify individuals in these areas in order to achieve an identifiable and stable transplant team. Responsible medical/surgical members of the team must be board certified or eligible to take the boards in their respective disciplines or have, in the opinion of the non-Federal experts discussed in section II.D. of this notice, demonstrated

competence irrespective of board status. We believe board eligibility is required to assure high quality care.

The facility's commitment should also be evident by the following:

- The component teams must be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

- The anesthesia service must identify a team for transplantation that must be available at all times.

- The infectious disease service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, many of which are uncommonly encountered.

- The nursing service must identify a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.

- Pathology resources must be available for studying and reporting promptly the pathological responses to transplantation.

- Adequate social service resources must be available.

- Mechanisms must be in place for managing the lung transplant program that assure that patient selection criteria are consistent with those set forth in the facility's written patient selection criteria and that the facility is responsible for the ethical and medical considerations involved in the patient selection process and application of patient selection criteria.

- Adequate plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.

4. Facility Plans

The facility must have overall facility plans, commitments, and resources for a program that will ensure a reasonable concentration of experience; specifically, 10 or more lung transplantation cases per year in patients who have end-stage pulmonary or cardiopulmonary disease. The facility must show that this level of activity is feasible and likely to continue on the basis of plans, commitments, and resources.

5. Experience and Survival Rates

The facility must demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive technique. The facility must have an established lung transplantation program with documented evidence of 10 or more

patients, who have end-stage pulmonary or cardiopulmonary disease, in each of the two preceding 12-month periods.

The facility can use single lung, double lung and heart-lung transplant patients in meeting this criterion. The Medicare cardiac and liver transplant criteria require a minimum volume of 12 transplants annually. However, based on the recommendation of the National Heart, Lung, and Blood Institute, we have established 10 cases per year as the basic standard for a lung transplant program.

We are establishing a minimum volume criterion because we believe a significant number of transplants is generally needed to maintain the entire transplant team commitment and skills to assure that procedures are of appropriate quality and safety. Our own research in heart transplantation has documented improved survival associated with Medicare approved facilities over those that do not meet the Medicare criteria, which includes minimum volume thresholds. In addition, Jeffrey Hosenpud, M.D. et al., reported in the *Journal of the American Medical Association* (volume 271, No. 23, June 15, 1994, page 1844) on the effect of transplant center volume on cardiac transplant outcome. These researchers found increased risk of mortality in centers performing fewer than 9 cardiac transplants per year. Further, research conducted by Erick B. Edward, et al and presented in the Fifteenth world Congress of the Transplantation Society demonstrated that, after correcting for patient mix covariates, patients mortality following liver transplantation in the United States is a function of center transplant volume. Such articles confirm our view that volume generally is a strong factor in predicting survival. Although we are not aware of published studies such as those with heart and liver transplants, empirically demonstrating that volume is associated with successful outcome and team proficiency in lung transplantation, we believe it is reasonable to assume a similar relationship would exist for lung transplants.

We have established the minimum volume of 10 transplants per year for lungs based on the fact that there are fewer lungs than hearts and livers available for transplantation. The NHLBI recommended 10 transplants as an appropriate number.

We have contacted a large sample of active lung transplant programs to gather data regarding the volume of transplants performed over the past three years. In arraying the results of these data, we found that the vast

majority of centers that are designated as lung transplant centers perform a very small number of procedures. In fact, a significant number of these centers performed less than two transplants annually. Over 80 percent of the total transplants in the data were performed in those centers that exceeded the volume threshold recommended by NHLBI. Thus, although a relatively small number of the total facilities designated to perform lung transplants by the organ Procurement and Transplantation Network are expected to qualify initially (approximately 15 of 77), we expect the facilities that are approved initially to perform over 80 percent of the lung transplants. Thus, we do not anticipate adverse impact on beneficiary access as a result of this criterion.

Based on the results of this analysis, we believe that 10 is a reasonable threshold for volume criteria. However, we welcome comments during the comment period as to the appropriateness of the number. Further, as we discuss later, exceptions to the facility criteria, including the number of persons who received transplants, may be warranted if there is justification. However, as a general matter, we believe less than 10 transplants a year is not sufficient to maintain the standard of performance needed for approval.

Survival rates may be influenced by many factors including random chance and patient selection. However, most authorities agree that a patient who is not free of adverse prognostic factors warrants lung transplantation only if he or she has a reasonable prognosis and the donor lung cannot be used in a patient who is a good candidate with at least a moderately urgent need and who is in reasonable geographic proximity. Based on data from the NHLBI report for the 996 patients receiving lung transplants in the United States prior to January 1, 1993, Kaplan-Meier actuarial survivals at 1, 2, and 3 years are 72 percent, 66 percent, and 63 percent, respectively. For patients receiving a single lung transplant (669 patients), and sequential bilateral transplantation of two lungs (161 patients), survival data are similar—73 percent, and 75 percent, respectively, at 1 year, and 67 percent and 71 percent at 2 years. With the two lungs transplanted while joined ("en bloc"), results seem less favorable, with 63 percent and 57 percent 1 and 2-year survivals. When all lung and heart-lung data are aggregated, the U.S. experience for 1,287 patients (1987 through 1992) is 69 percent, 62 percent and 59 percent actuarial survival at 1, 2, and 3 years, respectively.

Since we will be covering single, double and heart-lung transplants and collecting data for all these types of transplants in evaluating volume and survival statistics for applicant hospitals, we believe that we should use the NHLBI reported aggregate survival. That survival is 69 percent at 1 year and 62 percent at 2 years. These numbers reflect the same types of organ transplants (single lung, double lung and heart-lung) as are used by facilities in meeting volume criteria.

At the time of the application, the facility must demonstrate actuarial 1-year survival rates of 69 percent for patients who have end-stage pulmonary or cardiopulmonary disease and who have had lung or heart-lung transplants at that facility using the Kaplan-Meier technique described below and a 2-year survival rate of 62 percent. All patients transplanted after 1989 should be included in the calculation. We have chosen 1990 as the beginning date for the facility's survival rate experience because the procedure was infrequently performed before that date. We specifically invite comment on these percentages.

In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique and must report both 1-year and 2-year survival rates for all transplant cases occurring on or after January 1, 1990. Generally, we would expect applicants to have at least 3 years of lung transplant experience to be used in the data array and survival calculations. The following definitions and rules also must be used:

a. The date of transplantation (or, if more than one transplantation is performed, the date of the first transplantation) must be the starting date for calculation of the survival rate.

b. For those dead, the date of death if used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival.

c. For those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in paragraph (e) below.

Note: The fiducial date cannot be in the future; it must be within 90 days before the date we receive the application.

d. Any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be

considered as "lost to followup" for the purposes of this analysis.

e. Any patient who receives a lung transplant between 61 and 120 days before the fiducial date must be considered as "list to followup" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to followup" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date.

f. A facility must submit its survival analyses using the assumption that each patient in the "lost to followup" category died 1 day after the last date of ascertained survival. However, a facility may submit additional analyses that reflect each patient in the "lost to followup" category as alive at the date of the last ascertained survival.

g. Survival is calculated based on patient survival, not graft survival. Consequently, facilities should not consider retransplantation as termination.

h. In addition to reporting actuarial survival rates, the facility must submit the following actual information on every Medicare and non-Medicare patient who received a lung transplant between January 1, 1990 and the date of the application:

- Patient transplant number.
- Age.
- Sex.
- Clinical indication for transplant (diagnosis).
- Date of transplant.
- Date of most recent ascertained survival.
- Date of death.
- Category of patient (living, dead or "lost to followup").
- Survival after lung transplant in days.
- Type of lung transplant (for example, single, bilateral, double lung or heart-lung).
- Date of retransplant.
- Number of retransplants.

Unique patient identifiers are not needed for data prior to the application. The facility may submit additional information on any of the cases that it would like considered in the review.

Although we are not requiring that these data be submitted in a particular format, our review will be facilitated if the data are submitted as follows:

- Data are tabulated in twelve columns, with data for each patient appearing as one line and listed in the sequence of date of transplant.
- The fiducial date should appear on each page.

- The transplant numbers listed may be existing lung transplant numbers used by the applicant facility. If so, the basis for any missing numbers should be explained.

- The tabulation should include no more than these required data. If more data are provided, they should be provided through additional tables or supplemental explanation.

In addition to the data above on the individual patient, the facility must submit its retransplantation rate per year for the last 2 years for lung transplants.

6. Maintenance of Data

The facility must agree to maintain and, when requested, periodically submit data to HCFA, in standard format, about patients selected (including patient identifiers), protocols used, and short- and long-term outcome on all patients who undergo lung transplantation, not only those for whom payment under Medicare is sought. Such data are necessary to provide a data base for an ongoing assessment of lung transplantation and to ensure that approved facilities maintain appropriate patient selection criteria, adequate experience levels and satisfactory patient outcomes. In addition, facilities must agree to notify HCFA immediately of any change related to the facility's transplant program (including turnover of key staff members) that could affect the health or safety of patients selected for covered Medicare lung transplants or that would otherwise alter specific elements in their application. For example, a facility must report any significant decrease in its experience level or survival rates, the departure of key members of the transplant team, the transplantation of patients who do not meet the facility's patient selection criteria, or any other major changes that could affect the performance of lung transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of lung transplants performed at the facility.

Facilities not approved for Medicare covered lung transplants are not required to maintain data in standard format. However, if and when these facilities apply for Medicare approval, they will be required to submit such data for all patients receiving a lung transplant.

7. Organ Procurement

The facility must be a member of the Organ Procurement and Transplantation Network as a lung transplant center and abide by the Network's approved rules. The Organ Procurement and

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

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

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 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 may 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 transplantation 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.

More importantly, we are concerned that Medicare beneficiaries may be receiving transplants in facilities that do not offer the assurance of high quality services that are commensurate with the criteria contained in this notice. That is, given the reliance on outcome and patient care practices inherent in this coverage policy, we are convinced that facilities meeting the criteria set forth in this notice clearly provide significantly superior services from a quality perspective as demonstrated by the facility's patient care policies and survival data. We are concerned that beneficiaries electing to have lung transplants performed in facilities that do not meet this criteria may not be aware of the increased risk of poor outcome that is associated with this decision.

Further, we are concerned that due to individual contractor local decisions, Medicare program expenditures may be spent in facilities that are not yet proficient in the procedure so as to produce high quality outcomes. Thus, continued coverage of lung transplants in these high risk situations may result in increased expenditures for complications that may arise from the transplant procedure that may have been avoided had the procedure been performed in a facility that meets these criteria.

Thus, it would be impracticable, unnecessary, and contrary to the public interest to delay this extension of coverage until we could publish a proposed notice and solicit comments. That is, since no beneficiaries are disadvantaged by this notice due to the construction of the effective date in a fashion that recognizes the coverage for patients already on the waiting list of facilities so covered, it is impracticable and contrary to public interest to delay implementation of these standards that promote highest quality services to Medicare beneficiaries and the extension of coverage to qualified facilities located in areas where the Medicare contractor local policy excludes or restricts coverage. We, therefore, find good cause to waive prior proposed notice.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on FR documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will

respond to the comments in that document.

V. Paperwork Burden

This notice contains information collection requirements that are subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). When OMB approves these provisions, we will publish a notice to that effect. The information collection concerns the requirement that a facility that wishes to obtain Medicare coverage for lung transplantation submit an application for approval and, once approved, report events or changes that would affect its approved status. We also require that the facility periodically submit data documenting such things as patients selected for transplants, protocols used, short- and long-term outcomes on patients who undergo lung transplantation. Public reporting burden for this collection of information is expected to be 100 hours.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this notice.

VI. Regulatory Impact Analysis

A. Introduction

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all facilities that consider themselves capable of performing lung transplants are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must also 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 which is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

This notice will affect all facilities that are, or are planning on, performing lung transplants and may have an effect on the ability of those facilities to compete. We believe this notice will not have a significant impact on a

substantial number of small rural hospitals since it is unlikely that small rural hospitals will be performing lung transplants. However, if there are any, they will not be affected by this notice differently than any other hospital. We have prepared the following analysis which, in combination with the other sections of this notice, is intended to conform to the objectives of the RFA and section 1102(b) of the Act.

B. Entities Affected

This notice provides for Medicare coverage of lung transplants furnished to patients with certain conditions in facilities approved by HCFA as meeting the minimum criteria specified in the notice. Lung transplantation, as many developing procedures, grew rapidly—from 11 in 1987 to 535 in 1992. However, donor availability is a significant limitation, and the rate of growth is slowing—in 1993 only 654 persons, from a waiting list of 1,300, received lung transplants. Although we do not have complete data, based on informal interviews with staff from a large sample of active lung transplant programs, we believe only a small number of Medicare beneficiaries (approximately 100) presently are lung transplant candidates because of their age and the presence of other complicating conditions. Our billing data indicate that, in 1993, Medicare contractors approved payments associated with 90 transplants.

Typically, a small number of facilities are involved in initially developing procedures such as lung transplantation. As of January 1994, the number of medical institutions in the United States with lung transplant programs had grown to 76 (according to information from the United Network for Organ Sharing). However, data indicate that there still is a concentration of experience among a much smaller number of facilities. We believe that the demand for lung transplants will grow as more physicians and patients recognize lung transplantation as a treatment resulting in increased life expectancy and in improved quality of life, and that the demand will be met by facilities offering the procedure.

The number of lung transplants performed is dependent upon many factors, including the supply of suitable donor organs (only 5 to 10 percent of available donors have lungs considered acceptable for transplantation), the existence of qualified facilities and personnel, and the availability of funding for the procedure.

Payment for lung transplants is available from some third party insurers, some State Medicaid programs,

private funds, and public fund-raising efforts. In the absence of a national Medicare coverage policy, each of the Medicare contractors uses its customary review and approval procedures to determine whether bills or claims associated with lung transplants should be paid.

Payment data indicate that Medicare beneficiaries make up only a small portion of lung transplant recipients. The proportion of transplants covered by Medicare is assumed to grow slightly over time—from 13 percent in 1993 to 20 percent in 1995, and up to 24 percent in 1999—as improved techniques allow transplantation of older and disabled patients.

The United Network for Organ Sharing currently lists 77 facilities as lung transplant centers. Seven of these facilities are children's hospitals and not subject to the criteria in sections II.B.1-9 of this notice. Of the remaining 70 facilities, 40 do not maintain an active ongoing lung transplant program. Although these facilities operate active transplant programs for other organs, they do lung transplantation sporadically, sometimes going an entire year without a single lung transplant. These centers currently have less than 10 people on their waiting list, and based on an informal survey of a sample of these centers, we estimate that it is rare for a Medicare beneficiary to be listed at one of these centers. Consequently, we do not believe that these centers are significantly impacted by this notice.

Based on our experience with application of a similar approval process to liver transplant facilities and review of available data on volume, we estimate that application of the criteria in this notice will result in the approval of 10 to 15 of the remaining 30 facilities within the first year, with the total rising to approximately 20 within the next year. Thus, we expect to approve at least two-thirds of the active lung transplant programs within the first 2 years. Many of the remaining third are expected to qualify by the third year, and we estimate the addition to the list of approved facilities of at least one facility per year for several more years. Ultimately, we expect all 30 of the active programs will be approved for Medicare coverage.

Many facilities that have performed few lung transplants will not meet the levels of experience and success

required under the facility criteria. However, some might be found to have acceptable clinical programs with an adequate prospect for successful outcomes. We would encourage these facilities to apply when they have achieved that success. We recognize that the criteria for experience, survival rates, and facility commitment are demanding. However, our goal in requiring facilities to meet certain criteria is not to restrict competition but to maintain the quality of services required by this complex procedure.

Facilities that apply (or reapply) will continue to be approved as they come to meet the facility criteria. There will be neither a cutoff date for receipt of applications nor a limit on the number of approved facilities. For the purpose of estimating the costs of covering lung transplants, we expect, by fiscal year 1998, that many, if not most, of the hospitals actively performing lung transplants could meet the criteria if they desire Medicare approval. We do not have any advance information on which facilities will apply or meet the criteria.

Medicare approval status could eventually provide those hospitals that meet the criteria for performing lung transplants with what are perceived to be advantages over non-approved facilities. In addition to the guaranteed Medicare payment for approved procedures, these hospitals might expect to see their prestige and standing as health care providers increase as a result of their approval as a Medicare lung transplant center. This, in turn, could enable them to increase their overall market share of lung transplants and other complicated procedures at the expense of hospitals that also perform lung transplants but do not meet our criteria. Therefore, those facilities that do not meet the criteria may view our notice as having a significant adverse effect on competition.

Some facilities may choose to not apply for approval as a transplant facility and to discontinue their transplant programs. So as to not curtail availability of coverage to individuals currently on a waiting list at a facility now recognized by a fiscal intermediary under procedures in effect prior to the date of this notice, we are making a special exception. Lung transplants furnished by a facility to a Medicare patient on its waiting list on the date of this notice, will continue to be paid by

Medicare using the contractor's current coverage criteria, even if the procedure occurs more than 180 days after the publication of the notice and the facility is not approved under the criteria of this notice on the date the transplant occurs. Thus, we do not believe that the criteria would in any way reduce the number or availability of transplants to patients that are currently on a waiting list for a lung transplant.

We expect that Medicare coverage of lung transplantation could prompt additional third party payers, including some State Medicaid plans, to consider covering this procedure and to create incentives for some facilities to establish lung transplant programs. However, third party payers that either already cover or intend to cover lung transplants are not required to adopt our coverage standards.

C. Projected Expenditures Under Medicare

It is difficult to make a precise estimate of future Medicare costs, largely due to the difficulty of predicting the availability of donor organs over the next few years. All dollar estimates depend on assumptions and estimates related to the number of covered transplants. In 1993, Medicare beneficiaries received 122 of the 654 lung transplants performed. In the absence of a national Medicare coverage policy, Medicare contractors approved payments associated with 90 of the 122 transplants.

Our projected estimates are based on some facilities meeting our requirements effective on the date of this notice. In developing these estimates, we made assumptions about the total number of lung transplants performed nationwide and the future rate of increase of the number of transplants performed at approved facilities. We assumed this would go up with the number of facilities, but the rate of increase would level off due to competition for suitable recipients and donor organs. The estimates include not only the cost of transplantation in an approved facility, but associated immunosuppressive drugs, and follow-up care resulting from the extension of this coverage.

Due to the sensitivity of these assumptions and the uncertainty of actual outcomes, we view our projection of expenditure increases as an opinion, rather than an estimate.

Fiscal year	Projected total number of LTs	Number paid by Medicare under current policy	Medicare costs under current policy (millions)	Number of additional LTs as a result of expanded coverage	Additional Medicare costs (millions)
1995	817	162 (20%)	\$18	7	\$1
1996	878	183 (21%)	22	8	2
1997	939	205 (22%)	26	9	3
1998	1003	229 (23%)	31	9	3
1999	1068	254 (24%)	36	10	4

D. Projected Savings Under Medicaid

Medicaid coverage of transplants is a decision of the individual State. As of 1990, lung transplants were covered by 15 States. We cannot predict whether Medicare coverage will increase the number of State Medicaid programs that will cover lung transplants or whether the Medicare coverage criteria will cause more restrictive policies than would otherwise occur. Medicare coverage of lung transplants will reduce States' payments for transplantation in Medicare beneficiaries who also qualify under Medicaid. To the extent that Medicare payment supplants Medicaid funding, the Federal budget receives an offset for the Federal share of Medicaid expenditures. Under current policy, we estimate the annual offset to be \$5 million.

E. Alternatives Considered

We considered allowing all Medicare participating hospitals to establish transplant programs without additional facility criteria. Our major reason for rejecting this alternative was that it would permit uncontrolled proliferation of transplant facilities, raising questions about the quality of services, given the limited availability of donor organs and experienced teams. Further, because the procedure would be spread among a larger number of facilities, it is likely the average experience level would be lower and would probably result in lower success and survival rates among recipients. Our responsibilities for the well-being of Medicare beneficiaries and for the prudent expenditure of Medicare trust funds dictate that we pursue a cautious policy with respect to a procedure as complex as lung transplantation.

F. Conclusion

We believe that the criteria we have developed are the most effective means available to ensure that the lung transplants that are made available to Medicare beneficiaries are provided in a safe and effective manner so that they can be considered to be reasonable and necessary within the meaning of the law. We believe that the conditions set forth in this notice would maintain the

quality of services required by this complex procedure, provide Medicare coverage of the procedure only at facilities and under conditions that have been shown to be safe and effective, and allow entry of new qualified providers. Although the criteria are somewhat restrictive, we believe this approach is justified, particularly in view of the typical relationship between experience and quality of service.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1395y(a)).

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance Program; and No. 13.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 26, 1994.

Bruce C. Vladek,
Administrator, Health Care Financing Administration.

Dated: December 7, 1994.

Donna E. Shalala,

Secretary.

[FR Doc. 95-2559 Filed 2-1-95; 8:45 am]

BILLING CODE 4120-01-M

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications

Name of SEP: Chemistry and Related Sciences

Date: February 9, 1995

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 426A, Telephone Conference

Contact Person: Dr. Martin Padarathsingh, Scientific Review Admin., 5333 Westbard Ave., Room 426A, Bethesda, MD 20892, (301) 594-7192

Name of SEP: Behavioral and Neurosciences

Date: February 22, 1995

Time: 2:00 p.m.

Place: NIH, Westwood Building, Room 305, Telephone Conference

Contact Person: Dr. Peggy McCardle, Scientific Review Administrator, 5333 Westbard Ave., Room 305, Bethesda, MD 20892, (301) 594-7293

Name of SEP: Multidisciplinary Sciences

Date: February 26-28, 1995

Time: 7:00 p.m.

Place: LaGuardia Marriott Airport Hotel, New York City, NY

Contact Person: Dr. Nabeeh Mourad, Scientific Review Administrator, 5333 Westbard Ave., Room 2A04, Bethesda, MD 20892, (301) 594-7213

Name of SEP: Multidisciplinary Sciences

Date: March 2-3, 1995

Time: 8:30 a.m.

Place: Embassy Suites, Washington, DC

Contact Person: Dr. Donald Schneider, Scientific Review Administrator, 5333 Westbard Ave., Room 2A05, Bethesda, MD 20892, (301) 594-7053

Name of SEP: Behavioral and Neurosciences

Date: March 7-8, 1995

Time: 8:30 a.m.

Place: Hyatt Regency, Bethesda, MD

Contact Person: Dr. Peggy McCardle, Scientific Review Administrator, 5333 Westbard Ave., Room 305, Bethesda, MD 20892, (301) 594-7293

Name of SEP: Clinical Sciences

Date: March 8, 1995

Time: 8:30 a.m.

Place: Bethesda Marriott Hotel, Bethesda, MD

Contact Person: Dr. Harold Davidson, Scientific Review Administrator, 5333 Westbard Ave., Room 354A, Bethesda, MD 20892, (301) 594-7313

Name of SEP: Clinical Sciences

Date: March 21, 1995

Time: 3:00 p.m.

Place: NIH, Westwood Building, Room 355B, Telephone Conference

Contact Person: Dr. Jerrold Fried, Scientific Review Administrator, 5333 Westbard Ave., Room 355B, Bethesda, MD 20892, (301) 594-7261

Purpose/Agenda: To review Small Business Innovation Research Program grant applications

Name of SEP: Biological and Physiological Sciences

Date: February 17, 1995

Time: 2:30 p.m.

Place: Crowne Plaza, Rockville, MD

Contact Person: Dr. Abubakar Shaikh, Scientific Review Administrator, 5333 Westbard Ave., Room 218A, Bethesda, MD 20892, (301) 594-7368

Name of SEP: Multidisciplinary Sciences

Date: March 1-3, 1995

Time: 8:00 a.m.