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-state 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