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 multisystem 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 postdischarge, 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