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 polices 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 rapidlyfrom 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,