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 followup 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.