[BERC-362-NR]

Medicare Program; Criteria for Medicare Coverage of Heart Transplants

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

ACTION: Notice of HCFA ruling.

SUMMARY: This notice extends Medicare coverage to heart transplantations when furnished by participating facilities that meet specific criteria, including patient selection criteria. We are extending coverage to heart transplants based on the results of the National Heart Transplant Study and our subsequent determination that heart transplants are a medically reasonable and necessary service when specific criteria are met. Because the HCFA Ruling HCFAR 80–1 excluded heart transplants from coverage under that Medicare program, we are issuing this notice as a new HCFA ruling. It will rescind HCFAR 80–1 and set forth the new coverage policy for heart transplants.

EFFECTIVE DATE: This notice is effective on April 6, 1987, and permits, under certain circumstances, coverage of heart transplants retroactive to October 17, 1986, which was the date of publication of the proposed notice. That notice set forth, for public comment, proposed criteria for coverage of heart transplants. Section VII of this notice contains a discussion of the effective dates in detail.

FOR FURTHER INFORMATION, CONTACT: Barton McCann, M.D., (301) 594–9370.

SUPPLEMENTARY INFORMATION:

I. Background

In November 1979, Medicare began paying for heart transplantation procedures performed for Medicare beneficiaries at Stanford University Medical Center. This was an interim decision, based on preliminary findings by the Public Health Service (PHS) regarding the safety and efficacy of heart transplants performed at that center.

Upon review of Medicare coverage of heart transplants, we determined that the issues were much more complex than originally thought and that adequate data did not exist to resolve many of them. Consequently, the Secretary of HHS announced a decision to exclude heart transplants from Medicare coverage, with the exception of a very few patients previously selected for and awaiting transplantations. That decision was announced June 12, 1980 by the Secretary and published as a notice of HCFA Ruling (HCFAR 80–1) in the Federal Register on August 6, 1980 (45 FR 52296).

Accompanying the decision to exclude heart transplants from Medicare coverage was an announcement that HCFA, in close cooperation with the PHS, would conduct a broad study of heart transplants. On January 22, 1981, we published a notice in the Federal Register (46 FR 7072) that described the study in detail and solicited applications from hospitals and medical centers wishing to participate. We awarded the contract for the National Heart Transplant Study to the Battelle Human Affairs Research Centers of Seattle, Washington.

As part of the January 1981 notice, we stated that when the results of the study were analyzed, we would publish a proposed decision regarding Medicare coverage and would give the public an opportunity to comment on our proposal before developing a final policy. Subsequently, on October 17, 1986, we published a notice in the Federal Register (51 FR 37164) that proposed Medicare coverage of heart transplants when furnished by participating facilities that meet special criteria. The notice also provided a 30-day public comment period.

II. Provisions of the Proposed Notice

In the proposed notice, we stated that after analyzing the findings of the Battelle study and consulting with PHS, we had determined that, for Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria. In accordance with the proposal, facilities that wish to obtain this coverage for their Medicare patients would be required to submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. For each facility for which an application is approved, we would cover under Medicare Part A (Hospital Insurance) and Part B (Supplementary Medical Insurance) medically reasonable and necessary services associated with the actual transplantation and surgery (including organ acquisition), and any covered services needed as followup care. We noted that post-transplant care would not include outpatient, self-administrable immunosuppressive drugs, such as cyclosporine, since Medicare coverage of self-administered drugs is excluded under section 1861(s)(2) of the Social Security Act (the Act).

A. Criteria for Facilities

We stated that we would require facilities to meet criteria relating to the following areas:

- Patient selection.
- Patient management.
- Commitment.
- Facility plans.
- Experience and survival rates.
- Maintenance of data.
- Organ procurement.
- Laboratory services.

We noted that the criteria we proposed may need to be updated periodically to recognize further developments in the technology and procedures for heart transplantations. We stated that after three years of experience with the use of the criteria, we would examine the appropriateness of continuing to use any criteria.

B. Process for Review and Approval of Facilities

Under the proposal, the approval of facilities would be based on a careful review of the materials submitted regarding their experience, survival rates and expertise, as well as their commitment to the heart transplant program. We proposed to conduct the review with the aid and advice of a panel of non-Federal experts in such relevant fields as cardiology, cardiovascular surgery, organ transplantation, immunosuppression and health care resource utilization. The experts would report to us on their findings with respect to individual applications and would provide the basis for decisions as to the approval or disapproval of such applications.

In approving facilities, we would compare the facility's submission against the criteria specified in this notice. The approval granted would be for a three year period. Extensions of approval would require submission of a continuation application and would not be automatic.

Finally, we noted that, in certain limited cases, exceptions to the strict criteria proposed might be warranted. We invited comments on the need for an exceptions policy and the structure this policy might take.

C. Application Procedure

In the proposed notice, we stated that we would accept and begin to review applications from facilities that believe they are qualified based on the proposed criteria. However, we specified that the applications would be approved only on the basis of the criteria to be published in our final notice. We stated that to the extent that the proposed criteria are modified as a

result of public comment, we would give facilities that submitted applications prior to the date of the final notice the opportunity to submit any necessary revisions and additions to their applications.

III. Discussion of Comments

We received 158 timely items of correspondence in response to the proposed notice. Of these, 55 were from transplant centers, 13 were from professional associations, one was from a State governor, seven were from members of Congress, three were from State and local government agencies, 15 were from individual health professionals, 31 were from transplant patients, one was from a Medicare Part A intermediary, three were from heart transplant consortia, one was from an organ procurement agency, and 30 were from private citizens. The comments ranged from general support or opposition to the proposed coverage of heart transplants to very specific questions or comments regarding the proposed criteria. With the exception of comments relating to the impact analysis, a summary of the comments, and our responses to them, follow. The comments relating to the impact are addressed in the Impact Analysis in section VI of this notice.

A. Extension of Comment Period

Comment: Several commenters recommended extending the 30-day comment period to allow more extensive public debate of the complex issues involved in designating approved facilities for Medicare coverage purposes.

Response: We have not accepted this comment because we believe that our need to publish a final notice and institute coverage outweighs the benefits that would be obtained by a longer comment period. Also, our criteria will be under continual review and we will make any changes that become necessary as a result of new information and continued progress in the field of cardiac transplantation.

B. National Heart Transplant Study

Comment: One commenter suggested that basing the guidelines for designation of transplant centers on information derived from the 1984 National Heart Transplant Study is not prudent, since the data are significantly outdated.

Response: When we formulated the criteria, we used the best information available, including information more recent than that presented in the National Heart Transplant Study. The proposed criteria take into consideration advances in the cardiac transplantation field and reflect discussions with experts in cardiology, cardiovascular surgery, cardiac transplantation, biostatistics and experts familiar with the data bank of the International Society for Heart Transplantation. We realize that the indicators to measure the safety and efficacy of heart transplantation will continue to evolve, and we are prepared to update our criteria as further developments in heart transplantation technology occur.

Comment: One commenter was concerned that the six transplant facilities that previously participated in government-sponsored heart transplant studies would receive favored status.

Response: All facilities must meet these final published criteria. No facilities have been pre-selected. We will not know which facilities will qualify until after their applications have been received and reviewed.

C. Opposition to Coverage of Heart Transplants

Comment: Several commenters were opposed to the coverage of heart transplants under Medicare. The reasons for opposition ranged from concerns over the cost of the procedure to a concern that the coverage of heart transplants discriminates against other therapies such as whole body health improvement programs.

Response: We do not find the commenters, arguments against coverage persuasive. Under Medicare, payment must be made for services that are reasonable and necessary and otherwise covered under the program. We have determined that when heart transplants are performed by facilities that meet the criteria we specify, such services are medically reasonable and necessary. The discussion of Medicare coverage of other forms of therapy is beyond the scope of this notice.

D. Other Coverage Issues

Comment: Several commenters requested that the notice be amended to allow coverage of all types of transplants.

Response: We wish to assure these commenters that we are not ignoring the issue of coverage of other types of transplants under Medicare, even though they were not the subject of this notice. As part of our continuing review of Medicare coverage, we are reviewing the medical literature and research available on several other types of transplants. If and when such transplants appear to be at a point where coverage under Medicare would be feasible, we will consider covering them as well. In response to a question on Medicare coverage of combined heart-lung transplants, we note that this procedure is considered experimental and therefore is not covered by Medicare.

Comment: Several commenters asked that special rules be established or that mention be made of the differences between adult and pediatric heart transplants, expressing the concern that adoption of the provisions of the notice by other third parties could adversely affect pediatric heart transplant programs.

Response: We believe that the commenters have raised a valid concern regarding the possible adverse effects of inappropriate adoption of our provisions by other third parties. However, we believe that making such distinctions in this notice is not appropriate. We expect that facilities performing pediatric heart transplants may well have selection criteria that differ from those used for their adult transplant patients. There is nothing in this notice to prevent this, nor will such differentiation between different types of patients adversely affect such a facility's approval to be a heart transplant center.

Very few, if any, pediatric patients are likely to qualify for coverage of a heart transplant under Medicare. However, we add our admonition to that of these commenters that other third parties who may choose to adopt requirements similar to those of this notice for their own programs recognize that it applies primarily to adults, and should be modified or otherwise adapted for programs that may involve children.

Comment: Several commenters asked that artificial hearts be covered when used as a "bridge" for a person awaiting a donor heart.

Response: We have not accepted this suggestion. Several months ago we published an instruction indicating that artificial hearts and ventricular assist devices were not covered under Medicare, either when used as a replacement for the individual's natural heart, or when used as a "bridge to transplant." We have not seen anything since that time that would convince us to change that policy. These devices continue to be considered investigational by the Food and Drug Administration. We will, of course, continue to monitor the research in this area with a view toward determining whether that policy should be amended.

E. Immunosuppressive Drugs

Comment: Numerous commenters objected to the lack of coverage of immunosuppressive drugs, despite the explanation in the proposed notice that

the Medicare statute did not permit coverage of outpatient prescription drugs that can be self-administered. One commenter, aware of the recent legislation described below, asked that such coverage be extended to permanently cover such drugs.

Response: On October 21, 1986, four days after the date of publication of the proposed notice, legislation was enacted to provide for the coverage of immunosuppressive drugs under Medicare, beginning January 1, 1987, for up to one year following the date of a covered Medicare transplant. Coverage for immunosuppressive drugs was contained in section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), and amended section 1861(s)(2) of the Act.

We have implemented these new coverage provisions through the issuance of instructions to hospitals, carriers, and fiscal intermediaries. We also are preparing a Notice of Proposed Rulemaking to address specifically the coverage of immunosuppressive drugs for all Medicare covered transplants. We note that we cannot change the statutory provision to provide coverage of immunosuppressive drugs for more than a year. That would require a further amendment to the law, and would have to be made by Congress.

F. Eligibility

Comment: Several commenters objected to the waiting period of 29 months between the onset of a disability and the beginning of Medicare coverage for a disabled individual as being too long.

Response: This requirement is based on sections 223(c)(2) and 226(b)(2)(A) of the Act, and is not a requirement adopted specifically for heart transplant recipients. Under section 226(b)(2)(A) of the Act, a Social Security disability beneficiary must receive disability insurance benefits under Social Security for 24 months before becoming entitled to Medicare benefits. In addition, section 223(c)(2) of the Act provides that the beneficiary must serve a five-month waiting period from the date of onset of the disability before cash benefits begin. While it is true that this statutory waiting period for Medicare coverage of the disabled represents a disadvantage to an individual who requires a transplant before completion of the waiting period, we would remind commenters that the coverage of heart transplants is an administrative decision, and no statutory provisions regarding either coverage or eligibility have changed.

Comment: One commenter suggested that successfully transplanted recipients who return to work should continue to receive transplant related services under Medicare.

Response: Under provisions of the Social Security Act, a beneficiary who is no longer disabled and therefore no longer receiving disability benefits is no longer entitled to receive benefits under Medicare. Any changes in these provisions would have to be legislated by Congress, and are outside the scope of our authority.

G. Facility Criteria

Comment: Several commenters objected to the use of any facility criteria, claiming that limiting coverage only to selected centers was anti-competitive and would restrain the development of such centers, to the detriment of those who require heart transplants.

Response: In the case of heart transplants, we have determined that in carefully selected patients, managed according to specific protocols by experienced medical teams at institutions with a substantial dedication to and experience with the procedure, cardiac transplantation has resulted in major increments in life expectancy and in improvements in the quality of life. We recognize that the proposed criteria for experience, survival rates, and facility commitment are somewhat restrictive. 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, provide coverage of the benefit at facilities and under conditions that have been shown to be safe and effective, and allow entry of new, qualified providers. We believe this approach is justified, particularly in view of the typical relationship between experience and quality of services. Facilities will continue to be approved as they come to meet the facility criteria. There will be neither a cut off date for receipt of applications nor a limit on the number of approved facilities, and hospitals that may be considering initiating a heart transplant program may do so with the clear understanding of what criteria they will have to meet.

Comment: Several commenters were opposed to any facility criteria, arguing that all hospitals that choose to do heart transplants should be allowed to do so and be paid by Medicare.

Response: We have not accepted this approach. As has been mentioned above, there are good reasons for the use of specialized criteria to select facilities in which heart transplants may be performed safely and efficaciously. Again, the approval process will remain open, and many Medicare-approved hospitals that do not now meet the criteria may someday do so. Also, we are committed to conducting a full scale reevaluation of the need for any criteria after a three-year period.

Comment: Several commenters stated that the proposed notice established a regrettable precedent in identifying only certain institutions as being eligible for reimbursement for specific procedures. A concern was expressed that the rationale would be applied inappropriately to other services such as cataract surgery, major joint replacements or routine open heart surgery.

Response: We do not have any plans at present to apply criteria as outlined for heart transplants to other types of surgery. If such plans were put into effect, we would do so for reasons of assuring quality of care and only after we provided the public with an opportunity to comment.

Comment: One commenter, opposed to limiting coverage of heart transplants to facilities that meet certain criteria, suggested that it would be appropriate for us to develop guidelines for fiscal intermediaries, carriers, and Peer Review Organizations to utilize in their individual coverage determinations.

Response: We have not accepted this suggestion. We believe that the most appropriate means of assuring that Medicare beneficiaries receive heart transplants under conditions that are safe and effective is to provide for coverage only at those facilities with demonstrated experience and success.

Comment: Several commenters objected to the use of any criteria and expressed the opinion that the limitations contained in the proposed notice go well beyond our authority under the Social Security Act.

Response: We disagree. Under section 1862(a)(1) of the Act, payment may not be made under the Medicare program for services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury." This provision prohibits payment for services that are not recognized as effective and proven treatment for a given medical [illegible]on and that are experimental or investigational in nature. In the case of heart transplants, we have determined that in carefully selected patients, managed according to specific protocols by experienced medical teams at institutions with a substantial dedication to and experience with the procedure, cardiac transplantation has resulted in major increments in life expectancy and in improvements in the quality of life. Such practice has become

widely accepted by the medical profession. Thus, cardiac transplantation under such circumstances, and only under such circumstances, is safe, effective and widely accepted; that is, reasonable and necessary.

Comment: One commenter recommended that we make the principles of the proposed notice a part of the hospital conditions of participation rather than a coverage notice so that our staff and the expert panel would not be bogged down in a burdensome review process.

Response: We have not accepted this recommendation because to do so would be inconsistent with our determination that heart transplants can be considered reasonable and necessary only when performed in qualified facilities that meet certain criteria. Further, we believe that the conditions of participation procedures are too cumbersome for such a narrow purpose coverage decision.

Comment: Several commenters suggested that we expand our facility guidelines to include additional criteria. For example, it was recommended that we require the availability of a neurologist for establishing criteria for brain death and that the facility be a full service tertiary care center.

Response: We do not agree with these suggestions. We believe our guidelines are sufficient to initiate the heart transplant program. Any revisions that may be necessary in the future will be made at that time.

Comment: One commenter stated that, with the exception of experience and survival rates, the criteria are unduly broad and general, and lack objectivity. A concern was expressed that this lack of specificity and objectivity would result in an unjustified denial of approval.

Response: We disagree that our lack of specificity will result in unjustified denials. We expect applicant facilities to submit all relevant information about their program that they believe demonstrates their capabilities to provide safe and effective heart transplants. Details of criteria, such as patient protocols, are not provided because we recognize that there are acceptable variations in practice in different regions of the country.

Comment: One commenter suggested that the criteria for transplant facilities be reviewed annually and asked if there were any "hidden" criteria that already exist or that will be designated later.

Response: We will review continually the transplant facility criteria and publish any revisions or changes that we find necessary. There are no "hidden" criteria. At this time we cannot predict what changes may be made in the criteria, but the public should understand that whenever necessary changes are identified, they will be published in the **Federal Register** and an opportunity will be given for public comment.

Comment: One commenter suggested that a graduate medical education (GME) program be in place or that a university affiliation be maintained before a facility could become an approved transplant center.

Response: We disagree with this suggestion. Although most centers that qualify probably will have a GME program, we do not believe it is essential to a center that meets all the facility criteria. Further, we do not wish to restrict the technology of heart transplantation to academic institutions.

H. Exceptions to Facility Criteria

Comment: In the proposed notice, we indicated that in certain limited cases, exceptions to the strict criteria might be warranted. We invited comments on the need for an exceptions policy and the structure such a policy might take. The majority of the comments recommended exceptions for centers which did not meet the experience criteria but which were geographically distant from other centers, were members of a consortium, had significant experience in other organ transplants, or had higher survival rates over a period of time less than two years. Many of the commenters recommended provisional approval with close monitoring of those centers that lacked the required experience but met the other criteria. Several commenters recommended incorporating greater flexibility into the criteria, thereby removing the need for an exceptions process. One commenter expressed opposition to the incorporation of formal comprehensive guidelines into an exceptions process and recommended the granting of exceptions based on merit. Several others recommended that the exceptions process rely on critical assessments by the expert review panel to identify institutions that can demonstrate their ability to provide satisfactory care to heart transplant patients. It was pointed out that it would be difficult to anticipate or articulate in the final notice all of the alternatives that might provide reasonable assurance that a facility may offer safe and effective heart transplants. It was proposed that we rely on the panel of experts to recommend exceptions to the specific criteria rather than attempt to describe all of the acceptable variations. One commenter recommended that no exceptions should be made until the criteria had been in place for 18 months. Finally, one commenter recommended that exceptions be granted for patients in life or death situations who are transplanted in non-approved facilities.

Response: On the basis of the comments received, we believe that there will be a need to make some limited exceptions to the facility criteria if there is justification. Further, we believe that, in each case in which an exception to one or more criteria is justified, we must ensure that our objectives of ensuring safety and efficacy are met. We agree with the commenters who recommended that we rely on the professional expertise and judgment of the expert panel in determining whether heart transplants may be performed safely and effectively in a given facility. However, as we have explained in response to the comments regarding the functions of the panel (see section III.U. of this notice), we intend to solicit individual expert consultants. Since we have decided to use the advice of consultants in making exceptions, we have not developed specific alternative criteria for facilities that do not meet all the criteria. The exceptions will be limited to specific cases which, taking into consideration the consultants' professional judgments, would not compromise the use of facility criteria as a measure of the facility's commitment and quality of care. All decisions regarding approval or disapproval will be made by the Administrator of HCFA after considering the findings and recommendations of the consultants.

Further, we have identified those circumstances for which exceptions may not be made. Specifically, facilities whose transplant programs have been in existence for less than two years will not be approved. Geographic considerations will not be taken into account. Applications from consortia will not be approved. The basis of our decision to restrict exceptions for these three circumstances is described in our analysis of the comments we received on each of those subjects.

We have rejected the recommendations we received to grant conditional approvals to facilities that do not meet the required experience criteria. Such approvals are not consistent with the intent of the criteria, which is to ensure that Medicare beneficiaries in need of heart transplants receive them only in facilities with substantial dedication to and experience with the procedure. While we agree that significant experience in other organ transplants is of value and should be taken into account in the review of a facility's

application, we do not believe that other organ transplants are sufficiently analogous to heart transplants to permit an exception to the criteria based on the substitution of that experience for the required experience in heart tranplants. Finally, no exceptions will be granted for patients in "life or death" situations who are transplanted in non-approved centers. In view of the fact that any patient in need of a heart transplant could be considered to be in a "life or death" situation, the granting of exceptions on this basis would undermine our determination that heart transplants can be considered reasonable and necessary only when provided in certain qualified facilities. Our determination took into account the fact that, in spite of the very poor prognosis and often grave clinical condition of potential heart transplant recipients, the onset and progression of the underlying heart disease is rarely, if ever, so rapid that there is insufficient time for a referral to and, if needed, a transplant by an approved facility with extensive experience and demonstrated successful outcomes.

Comment: Two commenters suggested that Medicare risk contractors be excepted from a requirement that the heart transplants provided for their enrollees be performed in Medicare approved transplant facilities.

Response: Under the provisions of section 1876 of the Act, an organization with a risk contract (for example, a health maintenance organization or competitive medical plan) must provide all covered Medicare services to its enrollees. This will include a heart transplant for any enrollee in need of this complex procedure. Although there is no general prohibition against risk organizations providing noncovered services to Medicare beneficiaries, we believe that the circumstances present here would ordinarily preclude a risk organization from furnishing a heart transplant to an enrollee in other than a Medicare approved facility. Section 1876(i)(6) of the Act provides that any risk organization that fails substantially to provide medically necessary services covered by Medicare is subject to a civil money penalty if that failure has adversely affected or has a substantial likelihood of adversely affecting the beneficiary. In our view, a risk organization that substituted a noncovered heart transplant for a heart transplant in a Medicare approved facility could be found to violate this provision in light of the greater assurance of favorable outcome available in the Medicare approved facility. This conclusion is not necessarily affected by the patient's consent to the substitution of noncovered services, since it is unlikely that the beneficiary would fully understand the implications of the substitution. When the risk organization uses a facility approved by Medicare, it may agree with the facility as to the amount of the charges, or it may ask Medicare to pay the facility the DRG payment plus pass throughs under section 1876(g)(4) of the Act, for which the organization would then be liable to Medicare.

Comment: One commenter, while agreeing with the proposed experience and survival rates outlined in the proposed notice, raised the issue of whether some different rates should be applied to facilities engaged in clinical research on patients who fall outside the patient selection guidelines (for example, those over age 60). The commenter pointed out that such research is necessary to extend the coverage of heart transplants to those who are not currently acceptable candidates for such surgery. One commenter recommended that facilities be allowed some limited flexibility in applying their patient selection criteria. One other commenter questioned whether the patient selection criteria applied to all patients and pointed out that this issue has significant implications for the ability of transplant centers to engage in innovation and experimentation.

Response: These comments raise an important issue that requires some elaboration and explanation. It is not our intent to limit the ability of transplant facilities to engage in innovation and experimentation. All patients undergoing heart transplantation at the facility must enter into the statistics reported, but if the applicant facility judges that research has adversely affected the survival experience, it should so explain in sufficient detail that the expert consultants can take it into account. We recognize that some transplant facilities are actively engaged in clinical research; for example, the evaluation of the transplantation of lungs in combination with the transplantation of a heart. This procedure is considered investigational and is not covered by Medicare. The clinical indications for this procedure should be governed by the facility's research protocol and are likely to differ from the facility's heart transplant patient selection criteria. Under these circumstances, the patient selection criteria called for by our notice would not apply to all patients of the facility and should not be viewed as a restriction on a facility's ability to engage in clinical research. However, for circumstances other than clinical research we expect that the patient selection criteria will be applied uniformly across all Medicare and non-Medicare patients.

The suggestion to allow facilities some flexibility in the application of their own patient selection criteria relates to the proposed facility criterion at II.A.3(c)(8)(B), which states that the facility is responsible for the ethical and medical considerations involved in the patient selection process and the application of patient selection criteria. We believe that it would be inappropriate to transplant any patient who does not meet the facility's selection criteria without review by the facility's institutional review board or a comparable body responsible for considering in a comprehensive, deliberate, and documented manner the unique circumstances of a given case. With the approval, of such a body, minor departures from the established criteria might be allowed. In the absence of this approval, failure to adhere to the facility's patient selection criteria will result in the transplant not being covered.

This notice delineates those conditions under which heart transplants may be covered by the Medicare program. Generally, heart transplants that are performed in settings or under circumstances not in conformance with standard Medicare rules of coverage and payment or with the provisions of this notice will not be covered. This would include not only heart transplants performed in facilities that were not approved as Medicare heart transplant centers, but also might include heart transplants performed on patients who did not meet an approved facility's patient selection criteria or who were transplanted under a research protocol.

I. Patient Selection Criteria

Comment: We received numerous comments on the proposed guidelines for patient selection criteria. Two commenters felt that the guidelines were unnecessary. One recommended that we include a positive definition of those patients for whom heart transplants are indicated so that unnecessary transplants at an early stage of disease would be avoided. One commenter stated that the criteria were slanted so that only extremely low risk patients would qualify. Several commenters felt that some of the listed adverse factors were not in keeping with current standards. For example, many felt that

the age guideline was restrictive and should be raised. One commenter recommended that we clarify our policy to indicate that an individual may be a candidate for a heart transplant even though he or she fails to meet all of the elements in the patient selection criteria.

Response: We have not amended this section, since these are only guidelines for facilities to indicate the type of factors or areas we would like to see addressed in their patient selection criteria. As we stated in the proposal, the patient selection criteria are the responsibility of the heart transplant facility. We expect that different facilities will have differing patient selection criteria. We will be relying on the expert consultants to identify, during the review of a given facility, any criteria that, in their judgments, are not consistent with current medical practice.

Because it is not our intent to dictate the practice of medicine, we purposely avoided a list of absolute indications and contraindications for heart transplantation. However, we believe that the guidelines are reasonable and expect to disapprove any facility whose patient selection criteria depart so significantly from the guidelines that the performance of heart transplants in accordance with those criteria could not be considered medically reasonable and necessary on the basis of currently available knowledge. For example, we believe that an individual who fails to meet all the criteria would not be a suitable transplant candidate. Our rationale for rejecting a facility that proposes to accept patients who are far outside our guidelines is twofold. First, the use of significantly less restrictive criteria could place Medicare beneficiaries unnecessarily at risk. Second, the use of criteria that would permit the transplantation of patients with only a small likelihood of survival could lead to circumstances in which a scarce resource would be wasted. While we have not identified the specific indications for a transplant, we believe that unnecessary transplants will be avoided since our guidelines indicate that patients must have a very poor prognosis and all other therapies must have been tried or considered.

Comment: One commenter suggested that we develop a standardized, quantifiable method for determining physiologic age.

Response: We do not intend to develop any methods for determining physiologic age. The patient's physician is responsible for making this determination and for determining whether the patient is a candidate for transplantation based on a particular facility's patient selection criteria, which will follow the guidelines outlined in section V, of this notice.

Comment: One commenter proposed that obtaining a transplant patient's informed consent be added as one of the patient selection criteria.

Response: We believe that this would be unnecessary. Obtaining a patient's informed consent is an accepted standard of practice before performing any type of surgery. We expect this to be a standard procedure at any approved facility.

J. Patient Management

Comment: One commenter recommended that the first three months of postoperative care should be provided only in a designated center.

Response: We do not agree with this suggestion. We are not placing a specific time limit on how long a transplant recipient must remain in the designated facility. Under the final facility criteria (at V.A.2.c.), we require that the transplant facility maintain liaison with the patient's attending physician when the patient returns home or is transferred to another facility after discharge from the designated transplant facility.

K. Transplant Team Expertise

Comment: Several commenters suggested that the experience of the transplant team, rather than the experience of the facility, be used to determine a hospital's fitness as a heart transplant center.

Response: While we understand and appreciate the concern that is evidenced by these questions and comments, we have not been persuaded to change our position that the facility, not the team, is the proper repository for experience and survival rates. The suggestion to base experience on the team rather than the facility also relates to the issue of approval of the type of consortium that is designed to share a single transplant team that rotates among the member hospitals.

Our position is based upon several considerations. First, we believe we must deal with hospitals individually, and that it is inappropriate to apply the experience of one hospital's team to another hospital that lacks experience but acquires the services of that team. Neither can we average or group the experience of several hospitals when reviewing their applications. Second, while important, more than just a successful heart transplant team seems to contribute to the development of good experience and survival rates. The facility criteria measure a number of factors beyond the qualifications of the transplant team in determining the overall commitment of the facility to a successful transplant program. Finally, the use of criteria, including the relatively long-term survival rate, are predicated on the need to measure a facility's long range commitment to a heart transplant program. To allow the experience of an individual or group of individuals to substitute for that institutional commitment would call into question the entire rationale for the facility criteria we have proposed. Although the loss of key members of the transplant team will require a review by HCFA to assure that the facility continues to meet the criteria, their acquisition by another facility should not, in our view, entitle that other facility to obtain the first facility's hard-won experience and success.

Comment: One commenter claimed that our proposed facility criteria failed to recognize the role of the organized medical staff.

Response: We disagree with this comment. The term facility includes the medical staff. In addition to the responsibilities of the medical staff outlined in the proposed notice at II.A.3.b., we fully expect the medical staff to be primarily responsible for the development of the patient selection criteria and the patient management protocols and to be intimately involved in all other aspects of the heart transplant program.

Comment: One commenter stated there are no specific criteria that the transplant surgeon must meet. Another recommended that experienced personnel whose transplantation competence is well established should be considered qualified.

Response: The proposed criteria at II.A.3.b., concerning a facility's commitment of resources and planning, requires board certification or eligibility in the physician s respective medical or surgical field. We have, however, modified the criteria to allow the substitution of relevant experience for board certification or eligibility.

L. Expertise and Commitment to Cardiovascular Medical and Surgical Program

Comment: Several commenters suggested changing the number of cardiac catheterizations and coronary arteriograms (500) or the number of open heart surgical procedures (250) performed annually, which were included in the proposal under criteria II.A.3.b.(2), which addresses the facility's expertise and commitment to an active cardiovascular medical and surgical program.

Response: We believe this criterion is important, but the number of procedures are only general indicators of experience, not absolute standards that must be met for Medicare approval. The expert consultants will carefully weigh all factors and apply reasonable standards when reviewing a facility's application. Therefore, we have made no change to the criteria.

M. Experience

Comment: The greatest number of comments received dealt with the criterion requiring a facility to have had more than two years experience performing heart transplants. Specifically, these commenters requested either the elimination of the requirement that facilities had performed at least 12 transplants in the period preceding the last two years or the adoption of transitional provisions for facilities with two years or less experience, which would rely more upon survival rates than numbers of transplants performed.

Response: While we have not fully accepted these comments, we believe that it is important to explain the basis for this requirement and why we have chosen to retain it. Among the criteria for approval, we give considerable weight to the criteria related to survival rates. We are convinced that full one-year and full two-year survival statistics are necessary to provide an adequately reliable measure of the success of an applicant facility. We sustain the judgement that there must be at least 24 patients with whom one full-year of survival experience has taken place and at least 12 patients with whom two full-years of survival experience have taken place. It is for these reasons that the proposed experience levels remain unchanged. We note that in order to meet the experience criteria, a facility must have performed at least 36 transplants; that is, twelve or more patients in each of the two preceeding 12 month periods and twelve patients prior to that. However, it is not required that the facility have at least 36 months of experience since beyond the second 12 months period, a facility could perform the required twelve transplants over a period of less than 12 months. Conversely, these 12 transplants could have been performed over a period of more than 12 months, but no earlier than January 1, 1982.

We are clarifying that experience and survival rates must be presented on all patients receiving cardiac transplants since January 1, 1982, and that it is on this basis that experience and survival are assessed. The applicant facilities will be required to report experience and survial rates as of a given point in time. That point in time must be within 90 days of the date we receive the application and will be referred to as the fiducial date. The fiducial date for experience and survival results must be the same and it must be stated.

It is emphasized that the ruling does not specify the date by which this experience must be achieved. Some facilities that do not currently meet the requirements of experience will undoubtedly meet them in the future, and can apply at that time.

Consistent with the previous notice, a facility that applies within 90 days of this notice and is accepted may receive retroactive approval to as early as October 17, 1986, or the date upon which it first met the criteria, whichever occurred later. A facility that seeks retroactive approval must show that it met the experience and survival criteria on the date to which it seeks retroactive approval, as well as show its experience and survival to the stated fiducial date.

Comment: A commenter noted that the criteria only recognize a facility's current ability to provide heart transplants and ignore future capabilities to provide this service.

Response: This observation is correct. The criteria used to select a transplant facility are based on demonstrated experience and success and do not take into account future capabilities.

Comment: One commenter suggested allowing hospitals with a minimum of two years' experience with over 250 open heart surgical procedures per year to submit experience data for those procedures in lieu of heart transplant data.

Response: We have rejected this comment. Open heart surgical procedures are not directly analogous to heart transplant procedures, and open heart procedures do not demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive techniques.

N. Survival Rates

Comment: Numerous comments were received regarding our proposed criteria of one- and two-year actuarial survival rates of 73 and 65 percent respectively. Many of the commenters recommended increasing the standards in view of better results obtained at certain transplant centers. Many others expressed concern that the proposed standards do not provide allowances for facilities that are: (1) Involved in clinical research; (2) treating high risk patients; or (3) utilizing artificial hearts or ventricular assist devices as bridges to transplants. They contended that adherence to the criteria would inhibit clinical progress and could make it more difficult for a high risk patient to receive a needed transplant. One commenter suggested the use of actual rather than actuarial survival rates since actuarial rates may be based upon a number of assumptions or statistical analysis methods that differ among the reporting facilities. To reflect accurately the true survival rates associated with the procedure it was suggested that we specify that determination of survival rates begin with the date of the transplant.

Response: Our standards of 73 percent one-year and 65 percent two-year actuarial survival rates are based upon an analysis of available survival data and judgments about what can reasonably be expected. We recognize that several facilities have reported considerably higher survival rates recently, but it is premature to fix such higher rates as standards until it is clear that such rates can be reasonably widely expected. Others argue that the proposed survival rates are too high if high risk patients are to be treated. It is our judgment that patients meeting the criteria in section V.D. should have at least the specified survival rates. Thus, we note both proponents of higher and lower survival standards, and at this time, we reiterate the proposed standards. If further experience suggests that these survival rate standards need to be changed, particularly moved to higher levels, the standards will be changed accordingly. We will depend heavily upon the advice of the expert consultants.

The expert consultants may also take into account, to the extent they deem necessary, the consequences of clinical research upon the survival data. The utilization of artificial hearts or ventricular assist devices as bridges-to-transplant certainly fits the category of clinical research, and its potential impact upon survival would be handled in this manner.

The comment that actual rather than actuarial survival rates be specified has not been accepted because the actual survival rate for a period takes into account only those who were operated upon before that period. Thus, the experience with more recent patients, whether it is good or bad, does not enter into that calculation. We regard the survival rate criteria as important. Because of this, we also believe that it is important that there be uniformity in the method used by hospitals to support their survival rates. Therefore, in addition to requiring that all facilities provide actual data on survival, we also are requiring that they perform actuarial

statistical analyses using the Kaplan-Meier technique, and we have established uniform definitions that are necessary for comparability of statistical analyses of survival. In deciding upon what approach should be followed, we were guided by accepted statistical conventions. The Kaplan-Meier actuarial procedure is a well established and sound procedure for reporting medical phenomena.

In using the Kaplan-Meier technique, facilities will be required to provide survival analyses on all patients transplanted since January 1, 1982. The following definitions and rules must be used:

(a) The date of transplantation must be the starting date for calculation of the survival rate.

(b) For those dead, the date of death is used if known. If the date of death is unknown, it must be assumed as one 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, survival is considered to be the date of last ascertained survival, except for patients described in paragraph (e) below.

(d) Any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days of the fiducial date, must be considered as "lost to followup" for the purposes of this analysis.

(e) Any patient transplanted between 61 and 120 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 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 specified in paragraphs (d) and (e) died one day after the last date of ascertained survival. However, a facility may submit an additional analyses that reflects each patient in the "lost to followup" category as alive at the date of the last ascertained survival.

Because of the importance of survival data and to provide maximum information to the reviewers, a limited amount of actual information on every heart transplant performed at the facility since January 1, 1982, is required. No patient may be omitted, but any unique circumstances that the facility believes should be considered may be described. Unique patient identifiers are not needed. The minimum data are:

1. Transplant number
2. Age
3. Sex
4. Date of transplant
5. Date of most recent ascertained survival
6. Date of death
7. Category of each patient (that is: living, dead, or "lost to followup" according to criteria (d) or (e) above).

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 seven 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 heart transplant numbers used by the applicant facility. If so, the basis for any missing numbers should be explained.
- The tabulation should include no more that these required data. If more data are provided, they should be through additional tables or supplemental explanation.

O. Data Maintenance

Comment: We received several comments on the proposed criteria that facilities must agree to maintain and, when requested. Periodically submit to HCFA summary data, in standard format. All of the commenters supported routine collection and analysis of data. Two recommended that the data be made available to the public. One commenter recommended against the release of any data in raw form and one other offered assistance in the acquisition, analysis and presentation of data.

Response: We agree with the recommendation to require the routine submission of data by facilities. We will require facilities to maintain summary data in standard format and to submit that data on an ongoing basis. Facilities not approved for Medicare covered heart transplants are not required to maintain summary data in standard format. However, these facilities should be aware that, if and when they apply for Medicare approval, they will be required to submit such data for all patients receiving a heart transplant beginning 30 days after being notified of our data requirements. We plan to provide such notification to all hospitals regarding the data requirements in the near future.

We have not yet finalized the standard format to be used by the facilities. In view of our need to publish a final notice so that the approval of qualified centers may begin, we have decided against delaying this notice while the standard format is finalized. We appreciate the concerns of the commenters on the release of raw data, and we will provide the affected institutions the opportunity for review and comment on the data prior to its release. We note that the raw data would not include patient specific information.

P. Organ Procurement Agency

Comment: One commenter believed our definition of an organ procurement agency (OPA) in the proposed criteria at II.A.7.b. was misleading in that it did not recognize that some facilities harvest and preserve donor hearts without the use of an OPA.

Response: We recognize that some transplant facilities rely on organ procurement agencies only for locating donors and coordinating activities and assume responsibility for harvesting and preserving donor hearts. Such facilities may continue to harvest and preserve organs, although we expect that more will elect to affiliate with an organ procurement agency. We define an organ procurement agency in the final criteria (V.A.7.b.) as an organization that meets the criteria of section 371(b) of the Public Health Service Act.

Q. Oral Applications

Comment: One commenter suggested that facilities be given the opportunity to present oral, as well as written, applications to HCFA.

Response: We have not accepted this recommendation because we believe this procedure would be very time-consuming and costly. Written applications should provide sufficient information for a determination to be made. All applicants will be asked to furnish the name and telephone number of a contact person so that additional information, if any is required, may be obtained quickly.

R. Review by Other Agencies or Networks

Comment: One commenter recommended that we require facilities to submit a copy of their applications to the appropriate state health planning agency and that we provide these agencies with the opportunity to review and comment on the applications.

Response: We have not accepted this recommendation. Facilities will be reviewed and approved or disapproved based on whether or not they meet the required criteria. While we appreciate

the interest of health planners in our process. We do not believe that their participation is neessary in assuring that Medicare beneficiaries receive heart transplants only at qualified facilities

Comment: One commenter recommended that we delegate the responsibility for the approval of heart transplant centers to an organization such as the National Organ Procurement and Transplant Network.

Response: We have not accepted this recommendation because decisions as to whether a facility meets HCFA's criteria or standards must be made by HCFA or its fiscal agents.

S. Geographic Access

Comment: Numerous commenters requested that some type of regional access or allocation be allowed in order to assure that there would be approved heart transplant centers in all regions of the country and that certain populations would not be denied access. Some commenters recommended waiving or easing the facility criteria to assure that such areas and populations would have approved centers as soon as possible. Many of these commenters pointed out that, in various areas of the country, travel distances present problems of time and expense, not only for the patient and family members, but for the organs being transplanted.

Response: We have not accepted these comments because we do not believe that geographical distribution can be equitably determined within the framework of an ongoing approval process. We recognize the hardship that this may place on some transplant recipients and their families, but we do not believe it adversely affects the clinical outcomes of the procedures. We also note that the issue of geographic access will diminish over time as more centers gain the necessary experience to meet the criteria. We do not propose to assure an even geographic distribution, nor do we propose to limit the number of facilities that may qualify in a given area. The determinant of whether a facility will be approved will depend overwhelmingly upon whether the facility meets the coverage criteria set forth in this notice

Comment: One commenter stated that proximity to other approved heart transplant centers should not be a consideration of approval

Response: We agree with this comment. In the proposed notice, we did not include proximity to other centers as a criterion for approval, nor will we include it in this final notice. If more than one facility in a given area meet the criteria, then all that qualify will be approved.

T. Consortia

Comment: Several commenters requested that various types of "consortia" be approved as heart transplant centers. In arguing for the approval of consortia by the Medicare program, some commenters cited State or local government requirements that hospitals join consortia in order to be licensed to perform heart transplants. However, there was no consensus on what the term "consortia" should mean in this context. The term consortia as used by the various commenters described a variety of distinctly different programs including cooperative arrangements:

Among hospitals in a given city, state, or region; between university and Veterans Administration hospitals; and between adult and pediatric hospitals of a university system. Additionally, one commenter opposed the approval of consortia and expressed concern that facilities might apply as a consortium in order to bolster, numerically, their experience and results as a group. It was pointed out that, in actuality, the procedures would be done individually at various institutions making up the consortium and thus, could have highly variable experiences. A fear was expressed that small programs without true commitment and dedication to cardiac transplantation might band together causing, ultimately, a significant decrement in survival rates.

Response: At this time, we have not accepted the comment to grant approval to consortia as Medicare heart transplant centers in spite of the problems that some hospitals face. These criteria are based on analyses of patient outcomes for transplants provided in single-facility, single staff programs. We have no experience with other institutional arrangements (such as consortia) and are uncertain what criteria to apply to these alternative institutional arrangements to be assured of their qualifications and accountability to provide medically reasonable and necessary heart transplants to Medicare beneficiaries. Substantial analytical work would be needed to develop appropriate criteria that would take account of the many arrangements that currently exist. Of greater concern, however, is the fact that the criteria for facility approval are based on the performance of individual heart transplant facilities. They are designed to assure that Medicare beneficiaries receive only reasonable and necessary heart transplants that we believe can be provided only at facilities with substantial dedication to and experience with the procedure. Failure to apply these criteria to all the individual members of a consortia could result in the loss of that assurance.

Although we will not approve consortia as heart transplant centers, we note that individual members of a consortium may submit individual applications at any time and, if they meet the criteria, they will be approved. As stated elsewhere, these criteria will be reviewed after three years. We will continue to examine possible modifications to the criteria and their potential application to alternative institutional arrangements.

U. Expert Consultants

Comment: Several commenters requested clarification of the bylaws of the panel and recommended that its role and latitude be defined. One commenter stated that the panel should have the authority to approve, disapprove or rescind approvals. One commenter requested access to the deliberations of the panel. One commenter recommended that we utilize the expert panel in the identification of the appropriate data to be maintained by the facilities.

Response: In considering the role of the panel, we realized that we do not expect that there will be a need for the consultants to meet as a group on a routine basis to discuss matters relating specifically to all facility applications. Thus, it is inappropriate to refer to the consultants as a panel and we have changed the criteria to refer to them as "expert consultants". 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. In this fashion, we expect to maximize the benefit to be gained by employing such diverse and well-qualified consultants. The consultants will serve in purely advisory roles. All decisions regarding approval, disapproval or withdrawal of approval will be made by the Administrator of HCFA after considering the findings and recommendations of the consultants. Each individual consultant will review every application, except those from heart transplant programs that have been in existence less than two years and from consortia, and will identify its strengths or weaknesses. A short summary of the findings and a recommendation regarding approval or disapproval will be forwarded to the Administrator. The findings of the

consultants will be considered pre-decisional and not subject to public disclosure. However, every facility will be notified of its approval or disapproval and the basis for that decision. In addition to reviewing applications, the consultants may propose specific changes to the coverage criteria or offer advice and suggestions regarding the process of review, approval, and monitoring of cardiac transplant facilities.

Comment: We received several comments regarding the composition of the panel. Most commenters recommended including individuals with expertise in hospital administration. We received recommendations to include experts in health planning, ethics and law and to consider demographic representation as well. We also were advised to include representatives of private community hospitals in addition to academic teaching centers. One commenter recommended that we solicit nominations from the industry while two others submitted nominations as part of their comments.

Response: After the publication of the proposed notice, we solicited nominations from various professional organizations and consumer representative groups. In response to our request, we received the names of over 50 individuals to serve as consultants to us in reviewing applications from hospitals wishing to be approved heart transplant centers for Medicare coverage purposes.

After consideration of these nominations as well as the nominations and comments received from the proposed notice, we selected nine individual consultants. Our selection was based on three primary considerations: Professional qualifications related particularly to heart transplantation; the need for a balance among the related specialties as well as perspectives towards heart transplantations; and interest and availability of the individuals to participate in this activity. We agreed with the recommendation to include among those experts individuals with expertise in hospital administration and solicited nominations from this field as well as from the fields of cardiology, cardiovascular surgery, organ transplantation, immunosuppression and health care resource utilization. We did not believe that it was appropriate to consider experts in health planning, ethics or law, although the individuals we selected have some familiarity with these areas. Although the principal basis for selecting the individuals was clinical or administrative expertise, we considered, to the extent possible, demography and representation of community hospitals in making our selections. All of the consultants chosen are eminent and widely recognized experts and practitioners in their fields. We believe we achieved the desired balance among the specialties by our selection of representatives from the major relevant disciplines.

Comment: One commenter stated that the criteria are flawed because the experts in the field of cardiac transplantation who assisted in the development of the criteria may have a conflict of interest in the approval of facilities.

Response: We disagree with this statement. We believe that the criteria represent a general consensus of the experts in the field of heart transplantation who provided their technical expertise and advice without consideration for personal or institutional gain.

Comment: One commenter suggested that they expect the panel to be limited to 90 days in which to make a decision on an application.

Response: We do not feel a specific time limit should be placed on reviewing an application to become a transplant facility. We would expect that these decisions would be made timely and generally within 90 days.

Comment: One commenter suggested that the language in the proposed criterion II.B. be modified to add the word "predominantly" in the second sentence before the word "non-Federal."

Response: We disagree with this modification. The individual consultants will be non-Federal people.

Comment: One commenter suggested that the review process for applications be two-fold: Those meeting the numercial standards need only a staff review, while those not meeting the numerical standards be reviewed by the panel.

Response: We disagree with this suggestion. For purposes of fairness and consistency, applications will be reviewed by the expert consultants. However, we have identified two situations in which applications will not be reviewed by the expert consultants. These are cases in which disapprovals will be made by HCFA based on the fact that: (1) A facility's heart transplant program has not been in existence for at least two years; or (2) a consortium has submitted an application.

V. w. Appeals

Comment: Two commenters objected that there was no provision allowing a hospital to appeal HCFA's decision to disapprove their application to become a heart transplant facility under Medicare.

Response: Although the proposed notice did not contain a provision allowing a facility to appeal a disapproval of its application, we wish to make it clear that we are prepared to reconsider any application if requested to do so. The basis of any decision to disapprove a facility will be made known to that facility, and if the facility believes that we have made some factual error, then it will be given the opportunity to rebut our findings and submit additional or corrected information regarding its application for approval to provide Medicare covered heart transplants. We do not believe that the appeal provisions in 42 CFR Part 405, Subpart O are appropriate for heart transplant facility appeals since the decision involves the coverage of the underlying procedure itself. By contrast, in the instances specified in Subpart O, basic coverage of services is not in question, only whether it was performed by entities or facilities meeting specific requirements. In the case of heart transplants, however, the procedure remains generally experimental and not covered, except when done in approved facilities. In addition, it requires a high degree of specialized expertise to judge whether a heart transplant facility meets the criteria, and it would be inappropriate to have an administrative law judge make this decision in the context of an administrative hearing.

W. x. Payment

Comment: One commenter asked that flexibility be built into the payment level within DRG 103.

Response: There is no need to incorporate any flexibility into DRG 103. As with all other DRG cases for hospitals under the prospective payment system, additional payments are available for cost and day outliers. Further, this DRG, as is the case with all others, will be recalibrated annually.

Comment: One commenter suggested that we take a conservative approach to adjusting the DRG weight and recommended that we not recalibrate the DRG weight until the second or third year. By doing this, the commenter suggested that we would have a better statistical sample of Medicare transplants on which to base the recalibration.

Response: Section 9302 of OBRA requires the Secretary to adjust DRG classifications and weighting factors for FY 1988 and at least annually thereafter. At the time of the first review under this provision, we will examine the issue of whether to use only Medicare data in

setting the weight of heart transplants. In the interim, we will use the weight of 14.9944 for heart transplant payment.

Comment: One commenter questioned whether DRG 103, "Heart Transplants," encompasses the preoperative evaluation necessary to determine whether the patient is an appropriate candidate for heart transplantation.

Response: DRG 103 provides payment for all services furnished during the hospitalization in which the transplant is performed. Payment for preoperative evaluation to determine if the patient is an appropriate candidate is included in DRG 103 if it was performed during the same admission as the transplant. Payment for medically necessary inpatient preoperative evaluations prior to the hospital stay during which the transplant is performed also will be made under the prospective payment system. The amount of payment will vary depending on the DRG to which the patient is assigned.

Comment: One commenter suggested that the acquisition cost of hearts be included in the DRG 103 payment, rather than paid as a cost pass-through.

Response: We have not accepted this comment at this time. For the future, we are considering paying for heart acquisitions on a prospective basis, possibly including them in the DRG payment. However, it is necessary to pay for heart acquisitions in FY 1987 on a cost basis since the DRG weight for heart transplants does not include the costs associated with heart acquisitions. Revising the DRG weight for heart transplants to include acquisition costs is not possible at this time since accurate data on heart acquisition costs are not readily available.

Comment: One commenter suggested that no reimbursement limit be placed on teaching hospitals since heart transplants are on the cutting edge of medical technology.

Response: We have not accepted this suggestion. As with all other Medicare admissions under the prospective payment system, payments for heart transplantation will be limited by the DRG weight and any day or cost outlier payments. We note that teaching hospitals receive direct and indirect medical education payments in addition to DRG and outlier payments.

Comment: One commenter thought that some consideration should be given to increasing payment for services furnished by anesthesiologists during heart transplantation operations.

Response: We do not believe that this issue is germane. Payments to anesthesiologists will not change as a result of this notice.

Comment: One commenter wanted to know if the military insurance program, CHAMPUS, would expand their coverage to include heart transplantation.

Response: On December 11, 1986, the Department of Defense announced in the **Federal Register** (51 FR 44601) that the CHAMPUS program will provide coverage of heart transplants under certain conditions.

Comment: One commenter stated that Part A intermediaries will be required to establish a cardiac acquisition payment rate for all independent organ procurement agencies that procure hearts.

Response: Due to the anticipated difference in the Medicare utilization between kidney procurement and heart procurement, we do not anticipate a cost reimbursement system for heart acquisition identical to that used for kidneys. Instructions will be issued in the near future dealing with the payment of heart acquisition costs.

Comment: One commenter submitted the results of an analysis of operating cost information related to heart transplants and recommended that it be used to establish a more appropriate weight for DRG 103. The results were based on data gathered from eleven transplant facilities between January, 1985 and June, 1986, and included 36 Medicare-eligible patients and 202 non-Medicare-eligible patients. When Medicare-eligible and non-Medicare eligible patients were separated, the average cost per case was $85,412 and $59,279, respectively. It was concluded that if the weight for DRG 103 remained at 14.9944 as proposed, then hospitals that provided heart transplants to Medicare beneficiaries would be reimbursed for 77 percent of their operating costs. Several other commenters expressed concern that the proposed weight was too low, and one commenter recommended that we analyze more current cost and charge data.

Response: In studying the appropriateness of the proposed relative weight, we reviewed the best data available to us at the time which included Medicare and non-Medicare charge data accumulated under the National Heart Transplant Study (NHTS). Because the six hospitals included the NHTS met comparable standards of experience, expertise, resources, and commitment to their transplant programs, the NHTS provided the most reliable and comprehensive compilation of cost data.

The relative weight for DRG 103 will be recalculated when the classifications and weighting factors for all 473 DRGs are recalibrated for FY 1988. In the interim, we will use the relative weight of 14.9944 that was proposed in the October 17, 1986 notice.

Comment: One commenter stated it is unclear whether follow-up care is available under Part A.

Response: Follow-up care is available under Part A for any medically necessary admission.

X. Effective date

Comment: One commenter pointed out that the proposed effective date (October 17, 1986) for Medicare coverage of heart transplants does not give State Medicaid programs time to comply with the requirements and time frames of the Administrative Procedures Act, to which they are bound.

Response: State Medicaid programs are not bound by Medicare's effective date of coverage and may choose any effective date they wish.

Y. Specific Testimonials

Comment: About one-fourth of the comments were testimonials in favor of a transplant facility with which the commenter was familiar.

Response: While we appreciate the interest which prompted such comments, testimonials, by themselves, are not considered when reviewing applications of facilities that wish to become heart transplant centers under Medicare.

IV. Summary of Changes

On the basis of comments received, as well as certain provisions of the Omnibus Budget Reconciliation Act of 1986 (OBRA), which was signed by the President four days after the publication of the proposed notice, we have made several changes to our proposed policies. These changes are summarized below:

A. Coverage of Immunosuppressive Drugs

Section 9335(c) of OBRA modified section 1861(s)(2) of the Act to provide coverage of immunosuppressive drugs furnished, to an individual who receives an organ transplant for which payment is made, within one year after the date of the transplant procedure. This coverage applies to immunosuppressive drugs furnished on or after January 1, 1987. We have issued instructions to participating hospitals and Medicare contractors to implement this new provision. Medicare beneficiaries who receive heart transplants at non-approved facilities will not be eligible for coverage of their immunosuppressive

drugs since no payment will have been made for the transplant at the facility.

B. Qualifications of Transplant Team

We have modified our requirement that responsible medical/surgical members of the transplant team must be board certified or eligible in their respective disciplines to allow the substitution of relevant experience.

C. Experience and Survival Criteria

We are requiring that all facilities report their actuarial statistical analyses using the Kaplan-Meier technique, and we have established uniform definitions that are necessary for comparability of statistical analyses of survival. We have added a requirement that facilities must submit a minimal amount of data on every patient transplanted at the facility between January 1982 and the date of the application. Facilities may submit additional patient information that they believe should be taken into account during our review of their applications.

D. Maintenance and Submission of Data

We have modified our requirements that the facility must agree to maintain and, when requested, periodically submit summary data to indicate that the facility must maintain and routinely submit the data on an ongoing basis. Facilities not approved for Medicare covered heart transplants are not required to maintain summary data in standard format. However, these facilities should be aware that, if and when they apply for Medicare approval, they will be required to submit such data for all patients receiving a heart transplant beginning 30 days after being notified of our data requirements. We plan to issue instructions to all hospitals regarding the required summary data in the near future.

E. Organ Procurement

We have clarified the language concerning the organ procurement program recognize that some facilities may operate their own programs. Thus, the proposed language stating that a facility must "participate" in an organ procurement program has been changed to state that a facility must "operate or participate" in an organ procurement program.

Additionally, we have revised the definition of an organ procurement agency to reflect that it must meet the criteria of section 371(b) of the Public Health Service Act.

F. Expert Consultants

We have changed the references to the "panel of experts" to indicate that we will be relying on the advice of "individual expert consultants". In considering the role of the panel, we realized that we do not expect that there will be a need for the consultants to meet as a group on a routine basis to discuss all of the facility applications. A consensus of the consultants is not required. We also have specified that the consultants will review applications at the request of HCFA, make recommendations to HCFA on a timely basis, and support each recommendation with written documentation.

G. Exceptions

We have privided for some limited exceptions to the facility criteria if there is justification. We intend to rely on the professional expertise and judgment of expert consultants in determining whether heart transplants may be performed safely and effectively in a given facility. Consequently, we have not developed specific alternative criteria for facilities that do not meet all the criteria. However, we have identified three circumstances for which exceptions may not be made. First, facilities whose transplant programs have been in existence less than two years will not be approved. Second, applications from consortia will not be approved. Third, geographic considerations will not be taken into account. Disapprovals of facilities whose transplant programs have been in existence less than two years and of consortia will be made by HCFA and will not require prior reviews by the individual expert consultants.

H. Forthcoming Changes

Section 9318 of OBRA 1986 included other provisions related to organ transplantation and procurement that are summarized here for informational purposes:

- To participate in Medicare and Medicaid, all hospitals will be required to establish protocols to encourage organ and tissue donation.
- Any hospital performing transplants will be required to be a member of and abide by the rules of the Organ Procurement and Transplantation Network.
- To receive payment under title XVIII or XIX for the cost of organ procurements, organ procurement agencies (OPAs) will be required to be a qualified OPA operating under a grant under section 371(a) of the Public Health Service Act, or have been certified or recertified by the Secretary within the previous two years as meeting the standards to be a qualified OPA as described by section 371(b) of the PHS Act.
- OPAs will be required to meet performance-related standards to be designated as an OPA so that payments may be treated as organ procurement costs for the purposes of reimbursement. The Secretary may designate only one OPA per service area.

The instructions and any necessary regulations to implement these provisions will be published in the future. The statute provided an effective date of October 1, 1987 for these provisions.

V. Provisions of this Notice and Ruling

We have determined that, for Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria. Because the HCFA Ruling HCFAR 80-1 excluded heart transplants from coverage under the Medicare program, we are issuing this notice as a new HCFA ruling. It will rescind HCFAR 80-1 and set forth the new coverage policy for heart transplants. We plan to compile and publish all HCFA Rulings in the "Health Care Financing Administration Rulings" booklet which will be indexed for citation purposes. When this Ruling is republished in the booklet, it will be known as HCFAR 87-1. The text of the HCFA ruling is as follows:

Criteria for Medicare Coverage of Heart Transplants—HCFAR 87-1

Purposes

This Ruling rescinds the HCFA ruling, HCFAR 80-1 that excludes coverage of heart transplants under the Medicare program. It also provides public notice of HCFA's new coverage policy for heart transplants.

Citiations

Sections 1102, 1862(a)(1) and 1871 of the Social Security Act [42 U.S.C. 1302, 1395y(a)(1) and 1395hh].

Ruling

HCFAR 80-1 that excludes heart transplants from coverage under the Medicare program is rescinded. Facilities that wish to obtain coverage of heart transplants for their Medicare patients must submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. For facilities which are approved, Medicare will cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. Payment for these services generally will be made under the Diagnosis Related Group (DRG) classification code #103, "Heart transplants". Organ acquisition costs will be paid separately on a cost-reimbursement basis. Physician services, related to the transplant, as well as non-hospital services related to pre- and post-transplant care, will be covered under Part B (Supplementary

Medical Insurance) and reimbursed on the basis of reasonable charges. In accordance with the provisions of section 9335(c) of OBRA, post-transplant care for covered transplants includes outpatient, self-administrable immunosuppressant drugs, such as cyclosporine, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed. If a Medicare beneficiary receives a covered heart transplant from an approved facility, reasonable and necessary services for followup care and for complications are covered, even if such services are furnished by a hospital that is eligible for Medicare reimbursement but is not specifically approved by Medicare for heart transplantation.

Medicare will not cover transplants or re-transplants in facilities which have not been approved as Medicare transplant facilities. If a Medicare beneficiary receives a heart transplant from a facility that is not approved by Medicare for heart transplantation, we will not cover any inpatient services associated with the transplantation procedure. Neither will we cover physician services associated with the transplantation procedure. Thus, payment will not be made for the performance of the transplant or for any other services which are incorporated into a global fee.

However, after a beneficiary has been discharged from a hospital (which has not been approved by Medicare as a heart transplant center) in which he or she receives the heart transplant; medical and hospital services required as a result of the prior non-covered transplant may be covered in a facility otherwise eligible for Medicare reimbursement when they are reasonable and necessary in all other respects. Thus, coverage will be provided for subsequent inpatient stays or outpatient treatment (exclusive of self-administrable immunosuppressive drugs) ordinarily covered by Medicare even if the need for treatment arose because of a previous non-covered heart transplant procedure. These services also will be covered for Medicare beneficiaries who were not beneficiaries at the time they received a heart transplant regardless of whether or not the transplant was performed at an approved facility.

Once a facility applies for approval and is approved as a heart transplant facility for Medicare purposes, it is obliged to report immediately to HCFA any events or changes which would affect its approved status. Specifically, a facility must report any significant decrease in its experience level or survival rates, the transplantation of patients who do not meet its patient selection criteria, the loss of key members of the transplant team, or any other major changes that could affect the performance of heart transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of heart transplants performed at the facility.

A facility that we approve as meeting the criteria set forth in this notice may seek Medicare payment from its Medicare intermediary for heart transplants performed on Medicare patients. For facilities receiving Medicare payment under the Medicare prospective payment system, we will use the DRG classification #103, "Heart transplants". We have established a relative weight of 14.9944 for DRG 103 and a 51 day outlier threshold.

Heart acquisition costs will be reimbursed as a cost pass through.

The criteria that we will require facilities to meet in order to receive Medicare payment for heart transplantations follow.

A. Criteria for Facilities

1. *Patient selection.* A facility must have adequate written patient selection criteria and an implementation plan for their application. (Guidelines for patient selection criteria appear in section V. D. of this ruling.)

2. *Patient management.* A facility must have adequate patient management plans and protocols that include the following:

a. Detailed plans for therapeutic and evaluative procedures for the acute and long-term management of a patient, including commonly encountered complications. The basis for confidence in these plans must be stated.

b. The logistics of the plans for patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.

c. The logistics of the plans for 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 five years.

3. *Commitment.* A facility must make a sufficient commitment of resources and planning to the heart transplant program to carry through its application. Indications of this commitment could include the following:

a. Commitment of the facility to the heart transplant program is at all levels and broadly evident throughout the facility. (A cardiac transplantation program requires a major commitment of resources. These may intermittently include many other departments as well as the principal sponsoring departments.)

b. The facility has both the expertise and the commitment for participation in medical, surgical, and other relevant areas, particularly cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, pulmonary diseases, pathology, radiology, nursing, 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 in their respective disciplines or have demonstrated transplantation competence irrespective of board status.

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

(2) The facility must have an active cardiovascular medical and surgical program. (General indicators of this type of program would be a minimum of 500 cardiac catheterizations and coronary arteriograms annually, with the ability and willingness to do these procedures on an emergency basis, and a surgical group that has demonstrated low mortality rates in an active open heart surgical program involving at least 250 procedures a year.) The surgical team responsible for transplantation must be an identified, stable group.

(3) The anesthesia service must identify a team for transplantation that must also be available at all times.

(4) The infectious diseases service must have both the profesional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range or organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.

(5) 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.

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

(7) Adequate social service resources must be available.

(8) Mechanisms must be in place for managing the heart transplant program which assure that—

(A) Patient selection criteria are consistent with those set forth in the facility's written patient selection criteria;

(B) The facility is responsible for the ethical, and medical considerations involved in the patient selection process and application of patient selection criteria.

(9) 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 assure a reasonable concentration of experience; specifically, 12 or more cardiac transplantation cases per year. This level of activity must be shown feasible and likely 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 evaluation of a facility's experience and survival rates will be made on patients transplanted since January 1, 1982.

The facility must have an established cardiac transplantation program with documented evidence of 12 or more patients in each of the two preceding 12-month periods and twelve patients prior to that but since January 1, 1982. Such programs are deemed to have the potential for acceptable data bases for estimating survival.

The applicant facilities will be required to report experience and survival rates as of a given point in time. That point in time must be within 90 days of the date we receive the application and will be referred to as the fiducial date. The fiducial date for experience and survival results must be the same and it must be stated.

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 cardiac transplantation only if he or she has a reasonable prognosis and the donor heart 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. Initially, the facility must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years for patients who have had heart transplants since January 1, 1982 at that facility. In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique. The following definitions and rules also must be used:

a. The date of transplantation must be the starting date for calculation of the survival rate.

b. For those dead, the date of death is used if known. If the date of death is unknown, it must be assumed as one 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, survival is considered to be the date of last ascertained survival, except for patients described in paragraph (e) below.

d. Any patient who is not known to be dead by 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 transplanted between 61 and 120 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 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 (according to the criteria A.5.d. or e. above), died one day after the last date of ascertained survival. However, a facility may submit an additional analyses that reflects each patient in the "lost to followup" category as alive at the of the last ascertained survival.

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 heart transplant between January 1, 1982 and the date of the application:

- Transplant number.
- Age.
- Sex.
- Date of transplant.
- Date of most recent ascertained survival.
- Date of death.
- The category of each patient (that is: Living, dead, or "lost to followup" according to the criteria A.5.d. or e. above).

Unique patient identifiers are not needed. The facility may submit additional information on any of the cases that it would like the expert consultants to consider in their reviews.

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 seven 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 heart 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 through additional tables or supplemental explanation.

6. *Maintenance and submission of data.* The facility must agree to maintain and routinely submit to HCFA in a standard format prescribed by HCFA, summary data about patients selected, protocols used and short- and long-term outcome on all patients undergoing cardiac 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 cardiac transplantation and to assure 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 that could affect the health or safety of patients selected for covered Medicare heart transplants or which 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 loss of key members of the transplant team, or the transplantation of patients who do not meet the facility's patient selection criteria.

Facilities not approved for Medicare covered heart transplants are not required to maintain summary 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 heart transplant beginning 30 days after being notified of our data requirements. We plan to issue instructions to all hospitals regarding the required summary data in the near future.

7. *Organ procurement.* The facility must operate or participate in an organ procurement program to obtain donor organs.

a. If a cardiac transplantation center utilizes the services of an outside organ procurement agency to obtain donor organs, it must have a written arrangement covering these services. The cardiac transplantation center must notify the Secretary in writing within 30 days of terminating such arrangements.

b "Organ procurement agency" is defined as an organization that meets the criteria of section 371(b) of the Public Health Service Act.

8. *Laboratory services.* The facility must make available, directly or under arrangements, laboratory services to meet the needs of patients. Laboratory services are performed in a laboratory facility approved for participation in the Medicare program.

B. Process for Review and Approval of Facilities

The approval of facilities will be based on a careful review of the materials submitted regarding their experience, survival rates, and expertise, as well as their commitment to the heart transplant program. We will conduct the review with the aid and advice of individual 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 will report to us on their findings with respect to individual applications and will provide the basis for decisions as to the approval or disapproval of such applications.

In approving facilities, we will compare the facility's submission against the criteria specified in this notice. The approval granted will be for a three year period and extensions of approval will require submission of a continuation application and will not be automatic.

In addition to reviewing applications, the individual expert consultants may propose specific changes to the coverage criteria. Finally, in certain limited cases, exceptions to the strict criteria proposed may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved. In these two cases, disapprovals will be made by HCFA and will not require prior reviews by the expert consultants. Additionally, exceptions on the basis of geographic considerations will not be granted.

C. Application Procedure

In order to facilitate the approval of qualified facilities, we announced in the proposed notice that we would begin accepting and reviewing applications from facilities that believed they were qualified based on the proposed criteria. Because the applications will be approved only on the basis of the criteria published in this final notice, facilities which have submitted applications prior to the publication date of this final ruling April 6, 1987, have the opportunity to submit any necessary revision and additions to their applications.

A facility that seeks retroactive approval must show that it met the experience and survival criteria on the date to which it seeks retroactive approval, as well as show its experience and survival to the stated fiducial date.

The applications procedure is as follows: 1. An original and two copies of the application must be submitted 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, and the name and telephone number of an individual we could contact should we have questions regarding the application.

2. Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this notice. Each page must be numbered.

3. To the extent possible, the application should be organized into eight sections corresponding to each of the eight major criteria and addressing, in order, each of the sub-criteria identified.

4. The application should be mailed to the address below in a manner which provides the facility with documentation that it was received by us.

Administrator, Health Care Financing Administration, c/o Office of Executive Operations, Room 777 East High Rise, 6325 Security Blvd., Baltimore, Maryland 21207.

D. Guidelines for Patient Selection Criteria

Included in section V.A., Criteria for Facilities, is the requirement that a facility must have adequate written patient selection criteria and an implementation plan for their application. Such criteria should include or be comparable to, but need not be limited to, the guidelines below that indicate the type of factors or areas we would like to see addressed. We expect to disapprove any facility that departs so significantly from the guidelines that Medicare beneficiaries would be placed at risk.

1. Patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.

2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status, but must otherwise have a good prognosis.

3. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.

4. Many factors must be recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies. A patient who meets patient selection criteria under section D. 2., 3., and 5., and is free of the adverse factors under this section 4a. and b., is considered a good candidate for cardiac transplantation. Some experts would not require freedom from all adverse factors under this section 4b. We recognize that some who may not be considered "good candidates" may also benefit, but the likelihood or extent of benefit is significantly less.

a. Strongly adverse factors include: (1) Advancing age; for example, a patient beyond 53 to 57 years of age (the mid 50's). Until not long ago, limited experience with patients over age 50 showed that these patients had both impaired capacity to withstand post-operative and immunosuppressive complications and lessened survival. More recently, carefully selected patients through age 55 have had good survival experience; but experience with patients beyond age 55 is limited. The selection of any patient for transplantation beyond age 50 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.

(2) Severe pulmonary hypertension (because of the limited work capacity of the typical donor right ventricle which is an important consideration in orthotopic cardiac transplantation). Generally, pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg is a serious adverse factor. However, these patients may be acceptable if a pulmonary vasodilator drug reduces both pulmonary vascular resistance below 3 Wood units and pulmonary artery systolic pressure below 50 mm Hg.

(3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine). For patients who are to receive azathioprine and high-dose corticosteroid rather than cyclosporine, a slightly higher level of hepatic or renal dysfunction is acceptable, but substantial dysfunction is still a contraindication (because of the likelihood of early exacerbation postoperatively and because of interference with immunosuppressive regimens).

(4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).

(5) Symptomatic peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

(6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).

(7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).

(8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or of abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).

(9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control (for example, multidrugs to bring diastolic pressure below 105 mm Hg) for patients who would be on cyclosporine protocols (because of the substantial exacerbation of hypertension with cyclosporine and the difficulty of its management).

(10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

(11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).

(12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow (because this represents the coexistence of significant disease, and because multi-organ transplantation must still be considered experimental).

(13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

(14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or pre-existing disease.

b. Other factors given less adverse weight by some experts but considered importantly adverse by others include:

(1) Insulin-requiring diabetes mellitus, in the judgment of most experts (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy; even current cyclosporine immunosuppression regimens require chronic long-term corticosteroid, though at a lower dose, and high dose corticosteroid is used in the treatment of acute rejection).

(2) Asymptomatic severe peripheral or cerebrovascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).

(3) Documented peptic ulcer disease (because of the likelihood of early postoperative exacerbation).

(4) Current or recent history of diverticulitis (which must be considered a source of active infection that may be exacerbated with the initiation of immunosuppressant).

5. Plans for long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

VI. Regulatory Impact Analysis

A. Introduction

Executive Order 12291 requires us to prepare and publish a final regulatory impact analysis for any document such as this that meets one of the executive order criteria of a "major rule"; that is, it is likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we prepare and publish a final regulatory flexibility analysis, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through, 612), for documents such as this, unless the Secretary certifies that implementation will not have a

significant economic impact on a substantial number of small entities.

Implementation of this proposal is not likely to have an annual economic effect exceeding $100 million, or result in a major increase in costs or prices. However, it will affect all facilities that consider themselves capable of performing heart transplants. These facilities are considered small entities under the Regulatory Flexibility Act.

B. Affected Entities

In the initial impact analysis, we stated that in calendar year 1985 there were 72 facilities that characterized themselves as heart transplant facilities and that had performed at least one heart transplant. As a result of applying our selection criteria, we expected that approximately ten facilities would initially be approved for Medicare coverage with a total of about 20 facilities receiving Medicare approvals a year later.

Comment: One commenter asked whether our estimate of ten hospitals receiving immediate approval reflected our judgement on the number of facilities meeting the selection criteria or if this reflected the minimum number of facilities we believe were required in order to meet the demand for Medicare heart transplants.

Response: The estimate of ten hospitals receiving initial approval for Medicare heart transplant coverage was our best guess of the number of hospitals that will immediately meet the determination criteria. It should be noted, however, that this estimate was developed primarily for the purpose of estimating the costs of covering heart transplants and was not intended to be a judgement on the number of hospitals capable of meeting the coverage criteria. That is, we do not have any advance information on which facilities will apply or meet the criteria.

Comment: A number of commenters expressed concern that as a result of establishing qualifying criteria for selecting heart transplant centers, we will be giving the facilities that qualify a significant advantage. Qualifying facilities, the commenters point out, will gain significant amounts of Medicare revenues at the expense of non-qualifying facilities. Also, one commenter argued that the prestige of being selected as a Medicare heart transplant center will help those hospitals to increase their share of related cardiovascular markets. Moreover, commenters were concerned that other third party payers may adopt Medicare's selection criteria, thus virtually shutting those facilities that do not meet the Medicare criteria out of the heart transplant market.

Response: These commenters have a legitimate concern, but we do not believe the effects of these criteria will be as drastic as they suggest. As we stated in the initial impact analysis, hospitals meeting the selection criteria for Medicare coverage of heart transplant may well increase their share of the transplant market and the added prestige of being an approved Medicare heart transplant center also could result in other benefits accruing to those facilities. We stated that noncertified facilities would view our coverage policy as having a potentially negative effect on them.

We do not, however, agree that the economic consequences for failing to be approved for Medicare are as serious as the commenters believe. We are not convinced that other third party payers will automatically fall into line with our coverage criteria. While some State Medicaid programs that either already cover or will cover heart transplants may adopt our coverage standards, they are not required to do so. The Blue Cross Association is an example of one major third party payer that has adopted hospital selection criteria for its member plans that are somewhat less restrictive than ours. Consequently, their policy may permit a number of hospitals that fail to meet our standards to be covered by Blue Cross payment plans.

In view of the small number of Medicare patients we anticipate will receive heart transplants, compared to the number of non-Medicare heart transplant cases, hospitals failing to meet the Medicare coverage requirements but which are able to meet standards established by other payers may not experience any adverse impact. To illustrate the relative sizes of the Medicare and non-Medicare markets, we estimate, that there will be, at most, 98 Medicare heart transplant cases for FY 1988, the first full year of coverage. By contrast, the number of non-Medicare cases for the same period is expected to be about 1900 cases. Thus, Medicare's share of the total heart transplant market is expected to be only about five percent. Clearly, hospitals that fail to meet the Medicare coverage criteria but meet the criteria of other insurers may enjoy significant benefits and may not be affected at all by failure to meet our criteria, depending on the distribution of Medicare and non-Medicare cases.

Nevertheless, should most or all third party payers eventually adopt our policy, it may, indeed, adversely affect those facilities that fail to meet the criteria. Yet, we must point out that we have no authority to regulate private insurers, nor to limit any decision they may make to adopt policies similar to our own. If such conformance were to occur, we believe it would merely reflect a general medical consensus that might have formed even if we had not addressed the issue.

C. Impact on Beneficiaries

In the initial impact analysis, we pointed out that because of Medicare eligibility requirements we did not expect that many Medicare beneficiaries to become suitable candidates for heart transplants. Either the age requirements or the long waiting period for persons with disabilities would tend to reduce the number of potential heart transplant recipients eligible for Medicare

Comment: Several commenters expressed concern that the restrictive nature of our facility selection criteria will result in beneficiaries having to travel long distances from their homes and having, as a result, to incur higher travel and accommodation expenses in order to receive a heart transplant. These commenters argue that if our criteria were more lenient, more hospitals in more areas of the country could be certified to perform heart transplants. Beneficiaries would then not have to travel as far to receive service and would not, therefore, have to incur the higher personal expenses.

Response: We acknowledged in our initial impact analysis that our policy was fairly restrictive. We believe, however, that our approach is justified on the basis of our concern for patient safety and the success rates currently achievable with this type of procedure. Furthermore, we believe the benefit of affording beneficiaries the opportunity of undergoing this type of procedure with a very reasonable assurance of a successful outcome must be weighed against the possibility of somewhat higher personal expenses.

D. Alternatives Considered

In the initial analysis, we considered the alternatives of either:

- Continuing not to cover heart transplants; or
- Allowing all Medicare participating hospitals to establish transplant programs without additional facility criteria, although requiring the use of patient selection criteria.

We continue to reject the first alternative because we have now determined that heart transplants, when performed in accordance with the proposed criteria, are medically

reasonable and necessary and meet the requirements for Medicare coverage.

Our major reason for continuing to reject the second alternative is that it would permit uncontrolled proliferation of transplant facilities, thus raising all the concomitant questions about quality of services, given the limited availability of donor organs and experienced transplant teams. Although adoption of this policy alternative would help in the faster proliferation of this treatment modality among the approximately 200 hospitals that could be interested in qualifying over the next five years, the diffusion of this procedure over such a broad base is likely to lower the experience level and would probably lead to lower success and survival rates among Medicare heart transplant patients. 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 heart transplantation.

E. Summary and Final Expenditure Estimate

In the initial impact analysis, we discussed in some detail the difficulties of estimating the costs of covering heart transplants. The major problem was in accurately estimating the number of suitable Medicare eligible candidates for the procedure. As a result of this uncertainty in our projections, we presented a high and a low cost estimate for each of the five successive fiscal years. The differences between the two projections reflected different assumptions about the growth rate of Medicare heart transplant candidates. We also assumed that once Medicare began covering heart transplants, all State Medicaid programs that currently do not cover this procedure would do so within the next five years.

We did not receive any comments on our cost estimates. Thus, the only change we are making in our final cost projections is to reflect the enactment of section 9335(c) of Pub. L. 99-509 that amended section 1861(s)(2) of the Act. This provision allows for the payment for immunosuppressive drugs that are required in connection with a covered organ transplant for a one year period following the transplantation. In the initial cost estimates, we assumed the cost of immunosuppressive drugs would be covered over the life of the patient. As a result of the enactment of Pub. L. 99-509, we are lowering the high cost estimate for FY 1991 from $25 million to $20 million. The following table presents our minimum and maximum estimates in the growth of Medicare expenditures and the Federal share of Medicaid expenditures for the coverage of heart transplants through FY 1991.

PROJECTED INCREASES IN HEART TRANSPLANT EXPENDITURES

	Fiscal year				
	1987	1988	1989	1990	1991
Federal Expenditures (rounded to nearest $5 million)					
Medicare Low	(1)	(1)	(1)	(1)	(1)
Medicare High	5	10	15	20	20
Medicaid	(1)	(1)	5	5	5

[1] Less than $2.5 million.

In conclusion, we have examined two alternative approaches to the coverage of heart transplants and the concerns raised by commenters. We acknowledged in our responses to comments that non-qualifying hospitals might be disadvantaged financially as a result of hospital selection criteria. However, we pointed out that patient safety and the need for the judicious expending of Medicare trust funds dictates the careful selection of facilities. Thus, we are maintaining the policy we proposed in our October 17 notice. Nevertheless, as we state elsewhere in this notice, the expert consultants may, under certain circumstances, recommend exceptions to the criteria. Also, we will be reviewing the selection criteria over the next three years and revising them based on new data and changes in the technology and methods of performing this procedure.

VII. Waiver of 30-Day Delay in Effective Date

In the Notice of Proposed Rulemaking published on October 17, 1986, we proposed to make the effective date of coverage of heart transplants the date of publication of the proposed notice (that is, October 17, 1986). Coverage as of October 17, 1986 would be effective only for those facilities which would have qualified as heart transplant facilities when the transplant was performed and whose applications are received by HCFA within 90 days of the **Federal Register** publication of this final notice announcing our policy (that is, July 6, 1987). The effective date of coverage for heart transplants performed at facilities applying after July 6, 1987, will be the date the facility receives approval from HCFA as a heart transplant facility.

VIII. Paperwork Burden

This final notice contains information collection requirements that are subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980. Specifically, facilities that wish to obtain approval for Medicare coverage of heart transplantation services must submit an application and documentation pertinent to the transplantation services We submitted a copy of this proposed notice to the Executive Office of Management and Budget (EOMB) for its review of these information collection requirements. EOMB has approved the information collection requirements contained in this proposed notice under OMB Control No. 0938-0490.

(Secs. 1102, 1862(a)(1) and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y(a)(1) and 1395hh))

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare-Hospital Insurance Program)

Dated: March 20, 1987.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: March 30, 1987.

Otis R. Bowen,

Secretary.

[FR Doc. 87-7490 Filed 4-3-87; 8:45 am]

BILLING CODE 4120-01-M

Office of Human Development Services

Administration for Children, Youth, and Families; Head Start Name and Logo Trademark Registration

AGENCY: Administration for Children, Youth and Families (ACYF), Office of Human Development Services (OHDS), Department of Health and Human Services (DHHS).

ACTION: Notice of Trademark Registration for Head Start Name and Logo.

SUMMARY: This Administration for Children, Youth and Families' Notice provides information and instructions to all Head Start grantees and delegate agencies and the general public on the use of the Head Start name and logo.

EFFECTIVE DATE: April 6, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Foster, Director, Program Operations Division, ACYF/Head Start Bureau, P.O. Box 1182, Administration for Children, Youth and Families, Washington, DC 20013, (202) 755-8208.