DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPD-648-FN]

RIN 0938-AE96

Medicare Program; Criteria for Medicare Coverage of Adult Liver Transplants

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

ACTION: Final notice.

SUMMARY: This notice provides for Medicare coverage of liver transplantations in adults under certain circumstances. We are providing coverage for adult liver transplants based on our determination that liver transplants are medically reasonable and necessary services if furnished to adult patients with certain conditions and if furnished by particpating facilities that meet specific criteria, including patient selection criteria.

FOR FURTHER INFORMATION CONTACT: Vilis Kilpe, M.D., (301) 966-9365.

EFFECTIVE DATE: This notice is effective on April 12, 1991, and permits, under certain circumstances, coverage of adult liver transplants as early as March 8, 1990, which was the date of publication of the proposed notice. Section VII of this notice contains a detailed discussion of the effective dates of coverage.

SUPPLEMENTARY INFORMATION:

I. Background

Administration of the Medicare program is governed by the Medicare law, title XVIII of the Social Security Act (the Act). The Medicare law provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility (SNF) care, home health care, and physicians' services. It places general and categorical limitations on the coverage of the services furnished by certain health care practitioners, such as dentists, chiropractors, and podiatrists, and it specifically excludes some categories of services from coverage, such as cosmetic surgery, personal comfort items, custodial care, routine physical checkups, and procedures that are not reasonable and necessary for diagnosis or treatment of an illness or injury. The statute also provides direction as to the manner in which payment is made for Medicare services, the rules governing eligibility for services, and the health, safety and quality standards to be met in institutions furnishing services to Medicare beneficiaries.

The Medicare law does not, however, provide an all-inclusive list of specific items, services, treatments, procedures, or technologies covered by Medicare. Thus, except for the examples of durable medical equipment in section 1861(m) of the Act, and some of the medical and other health services listed in sections 1861(s) and 1862(a) of the Act, the statute does not specify medical devices, surgical procedures, or diagnostic or therapeutic services that should be covered or excluded from coverage.

The intention of Congress, at the time the Medicare Act was enacted in 1965, was that Medicare would provide health insurance to protect the elderly or disabled from the substantial costs of acute health care services, principally hospital care. The program was designed generally to cover services ordinarily furnished by hospitals, SNFs, and physicians licensed to practice medicine. Congress understood that questions as to coverage of specific services would invariably arise and would require specific coverage decisions by those administering the program. It vested in the Secretary the authority to make those decisions.

Section 1862(a)(1)(A) of the Act prohibits payment for any expenses incurred for items or services "which are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." We have interpreted this statutory provision to exclude from Medicare coverage those medical and health care services that have not been demonstrated by acceptable clinical evidence to be safe and effective. Effectiveness in this context is defined as the probability of benefit to individuals from a medical item, service, or procedure for a given medical problem under average conditions of use, that is, day-to-day medical practice. On January 30, 1989, we published a notice of proposed rulemaking in the **Federal Register** (54 FR 4302) which describes the process we use in reaching new coverage decisions and reevaluating coverage decisions already made. That notice includes a discussion of our reliance on the Office of Health Technology Assessment (OHTA) of the Public Health Service (PHS) for medical and scientific advice. These functions continue to be performed by the OHTA, which is now within the PHS' Agency for Health Care Policy and Research.

OHTA conducted an assessment of liver transplantation in 1983. At that time, the procedure was determined to be experimental in adults because its safety and efficacy had not been demonstrated. However, liver transplantation to treat children with extrahepatic biliary atresia and other end-stage liver disease was considered safe and effective. Therefore, based on its "reasonable and necessary" criteria, the Department concluded that liver transplantation in children should be covered by Medicare and that liver transplantation in adults (age 18 and above) should not be covered. Although few children requiring this procedure have been eligible for Medicare benefits, the Medicare decision probably served to encourage Medicaid and private insurers to provide coverage for some children requiring liver transplantation.

In 1986, the Department of Health and Human Services' Task Force on Organ Transplantation issued a report recommending that Medicare provide coverage for liver transplantation in adults. Subsequently, HCFA asked the PHS, through OHTA, to review the scientific evidence for the safety and effectiveness of this procedure.

OHTA reported that since the 1983 assessment, there has been a substantial increase in the clinical experience with liver transplantation in the United States as well as Europe. More than 3,500 transplants have been carried out in the United States. OHTA derived the evidence for the safety and effectiveness of this procedure from clinical case reports and from outcomes data published in scientific journals. In the OHTA assessment, the amount of experience with transplantation for a given condition and the 5-year survival rate were important considerations. In a few instances, the 5-year survival rate is so high that coverage has been recommended by the PHS despite limited experience.

Based on their review of data, the PHS experts have recommended that orthotopic adult liver transplantation is safe and effective in the treatment of end-stage liver disease when performed in facilities that meet certain criteria and for patients with one of the following specific conditions:

Primary biliary cirrhosis;
Primary sclerosing cholangitis;
Postnecrotic cirrhosis, hepatitis B surface antigen negative;
Alcoholic cirrhosis;
Alpha-1 antitrypsin deficiency disease;
Wilson's disease; or
Primary hemochromatosis.

Available evidence does not indicate at this time that liver transplantation is effective in treating adult patients with primary or metastatic malignancies of

the liver. Consequently, the PHS does not recommend Medicare coverage, at this time, for liver transplantation performed on patients with these conditions. Also, coverage of liver transplantation was not recommended for patients with other conditions because there is insufficient information to reach conclusions about effectiveness.

The PHS also has concluded that survival rates are associated with the condition of the patient at the time of surgery and the characteristics of the treatment facility. Therefore, the recommendations include specific criteria for selecting patients who might be candidates for surgery and identifying facilities where the procedure can be performed safely and effectively.

On March 8, 1990, we published notice of our intent to provide coverage of liver transplantations in adults under certain circumstances (55 FR 8545).

II. Summary of Provisions of Proposed Notice

In the proposed notice, we announced our intent to issue a national coverage decision, under section 1862(a)(1)(A) of the Act, that, for Medicare coverage purposes, liver transplants in adults with certain specified conditions are medically reasonable and necessary if performed in facilities that meet certain criteria and that are approved by the Secretary for liver transplants. We proposed that, for facilities that are approved, Medicare would cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. For facilities receiving Medicare payment under the Medicare prospective payment system, we proposed to use the diagnosis related group (DRG) classification 478 with a relative weight of 21.000 and a 64-day outlier threshold.

We also proposed the following:

- The application procedure.
- The process for review and approval of facilities.
- Guidelines for patient selection criteria.

III. Discussion of Comments

We received 66 timely items of correspondence in response to the proposed notice. Of these, 29 were from hospitals and transplant centers, 16 were from professional associations, 12 were from Health Maintenance Organizations (HMOs) and other risk contractors, 4 were from government entities, and 5 were from private citizens. The comments ranged from general support or opposition to the proposed coverage of liver transplants to very specific questions or comments related to the list of indications for which liver transplants will be covered. A summary of the comments, and our responses to them, follow.

A. Coverage Issues

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. They thought a waiting period of 29 months is 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 liver 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 5-month waiting period from the date of onset of disability before cash benefits begin. It is true that this statutory waiting period for Medicare coverage on account of disability would disadvantage an individual who requires a transplant before completion of the waiting period. However, this result flows directly from the general provisions relating to Medicare eligibility and is not particular to transplant recipients. Our decision to extend coverage to liver transplants does not change any statutory provisions regarding either coverage or eligibility.

Comment: Several commenters thought that Medicare should provide coverage and payment for immunosuppressive therapy for as long as a patient remains a Medicare beneficiary.

Response: Section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) amended section 1861(s) of the Act to provide for the coverage of immunosuppressive drugs under Medicare, beginning January 1, 1987, for up to 1 year following the date of a Medicare-covered transplant. (We have implemented these new coverage provisions to permit coverage of immunosuppressive drugs for up to 1 year following the date of discharge from an inpatient hospital stay during which a covered transplant was performed.) Congress would have to change the law to provide coverage of immunosuppressive drugs for more than 1 year.

B. Clinical Conditions

Comment: Of the 66 commenters responding to the notice, 7 objected to including alcoholic cirrhosis as a covered indication. One other commenter thought it should be a low priority indication. The various reasons for the objections included: There is no guarantee that abstinence would be maintained or that the transplant candidate would comply with the immunosuppressive therapy; the condition is clearly a self-inflicted complication resulting from a chosen lifestyle; coverage would undermine efforts at treatment and rehabilitation of alcoholics; and coverage would be a misallocation of government funds.

Response: We do not agree that coverage of transplants for individuals with alcoholic cirrhosis should be excluded. As mentioned in the proposed notice, available data suggest that the procedure is safe and effective for these patients under specified conditions. In these cases, we would require that the patient meet the hospital's requirement for abstinence and have documented evidence of the social support essential to assure both recovery from alcoholism and compliance with immunosuppressive therapy.

Comment: In the proposed notice we indicated that Medicare provides for coverage of liver transplantation for children under age 18 with extrahepatic biliary atresia. Several commenters thought that Medicare should provide for coverage of liver transplantation for children for other indications.

Response: The statement regarding coverage of liver transplantation for children with extrahepatic biliary atresia does not reflect the entire Medicare coverage policy as stated in our manual instruction to our contractors. The statement should have said that coverage is provided for children with extrahepatic biliary atresia or any other form of end-stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Comment: We had proposed portal vein thrombosis as a contraindication to liver transplantation. Several commenters felt that portal vein thrombosis should not be included as a contraindication.

Response: We agree with these commenters. We now have information from transplant surgeons that indicates that unless the entire abdominal venous system is thrombosed, successful transplantation can be carried out in the presence of portal vein thrombosis. Furthermore, OHTA had reported in its assessment report that portal vein thrombosis was only a relative contraindication in candidates for liver transplantation. We have, therefore,

deleted portal vein thrombosis from our guidelines for patient selection (section II.E. in the proposed notice, section V.E. in this final notice).

Comment: Nearly half of the commenters indicated that the list of covered conditions for liver transplantation is too restrictive and that it does not include conditions such as fulminant hepatic failure, Budd-Chiari syndrome, etc. Many of these commenters believed that liver transplants should be covered for all end-stage liver diseases, except for patients with primary or metastatic malignancies of the liver.

Response: As explained in the notice, the data available to us suggest that the coverage of liver transplantation for the listed indications is safe and effective. In order to determine what other clinical conditions should be covered by Medicare, we will continue to collect data and clinical information on these and other conditions and in the future will request that the PHS's Agency for Health Care Policy and Research review the data to determine if any revision to the current list of covered conditions is necessary.

Comment: One commenter pointed out that hepatitis B, antigen negative is not a disease and that what was probably meant was "hepatitis B, antigen negative postnecrotic cirrhosis" which the commenter called "an awkward phrase for cryptogenic cirrhosis." The commenter stated that these terms refer to end-stage cirrhosis in which a specific etiologic diagnosis has not been made. Furthermore, the commenter indicated that most cases of cryptogenic cirrhosis represent the end stage of autoimmune hepatitis or chronic non-A, non-B (type C) hepatitis.

Response: Review of the original medical journal article (Iwatsuki, S. et al., "Experience in 1000 Liver Transplants Under Cyclosporine-Steroid Therapy: A Survival Report." Transplantation Proceedings 1988, Vol XX, Supplement 1 (February), pp 498–504) referenced in the OHTA Assessment of Liver Transplantation indicates that the category of postnecrotic cirrhosis included chronic active hepatitis and cryptogenic cirrhosis. Furthermore, the hepatitis B antigen referenced in the article was hepatitis B surface antigen (HBsAg). We have therefore revised the clinical indication, "hepatitis B, antigen negative (postnecrotic cirrhosis)" to read "postnecrotic cirrhosis, hepatitis B surface antigen negative."

We recognize that there are various classifications of liver disease and that a variety of terms are used to describe cirrhosis. The term "postnecrotic cirrhosis" may not be entirely satisfactory; however, it is used in the medical literature and refers to cirrhosis of varied etiology and characterized pathologically by a shrunken liver containing large areas of collapse, broad scars, and regenerating nodules up to several centimeters in diameter. The postnecrotic cirrhosis may be due to viruses, drugs, toxins and/or other diseases. Anyone who has been found to be hepatitis B surface antigen negative and has been diagnosed on pathological examination to be cirrhotic, notwithstanding the cause of the postnecrotic cirrhosis, would fall within this classification.

Comment: Several commenters thought that the need for or prior transplantation of a second organ, in particular, a kidney, should not be a contraindication to a liver transplant. They argued that combined kidney/liver transplants have been performed successfully.

Response: We disagree with this comment. There is not enough data available on multi-organ transplantations to fully evaluate their success, and we, therefore, did not consider these types of transplants in conjunction with the publication of this notice. We will continue to follow the issue of multi-organ transplantation.

C. Patient Selection Criteria

Comment: Several commenters suggested that we specify that there be no required period of abstinence for those transplant candidates diagnosed as having alcoholic cirrhosis.

Response: We disagree with this suggestion. We believe the transplant surgeon and the rest of the team are best qualified to determine the suitability of a patient to receive a transplant, and this includes making a decision regarding the need for a period of abstinence.

D. Facility Requirement

Comment: Several commenters requested that we require hospitals to include a physician who is an expert in alcoholism and/or a psychiatrist on the transplant team.

Response: We disagree that this should be a requirement for hospitals. We have no objection to a hospital including a physician who is an expert in alcoholism or including a psychiatrist, but we do not believe it should be required to do so.

Comment: One commenter who agreed with including alcoholic cirrhosis as a covered indication for transplantation suggested, however, that HCFA limit funding for these types of transplantation to those facilities that have experience in attempting to transplant these patients and that the facilities be required to maintain a registry in order to permit the expeditious assessment of efficacy rates.

Response: We disagree with this approach. The reason alcoholic cirrhosis and all the other listed indications are covered is because the information and data collected on these indications have shown that a reasonable success rate has been demonstrated. We have established that transplantations for these indications are reasonable and necessary based on these results; we have found no basis for coverage distinctions among these indications. A liver registry is maintained under contract with the United Network for Organ Sharing, Inc.

Comment: We invited comment on the feasibility of specific facility criteria for coverage of liver transplantation in children. Several commenters responded to this request and asked that we develop special criteria for pediatric hospitals because they were concerned that adoption of the provisions of this notice by other third party payers could adversely affect pediatric liver transplant programs.

Response: As stated above, we specifically invited comment on the feasibility of pediatric facility criteria. Issues have arisen in the past with respect to coverage of pediatric transplants. When we formulated our policies with regard to Medicare coverage of heart transplants, there was concern that children would be disadvantaged by policies that were established for coverage of heart transplants in adults. These issues have arisen again as we finalize our policy with respect to adult liver transplants.

Congress itself addressed the concerns regarding pediatric heart transplants. It enacted section 4009(b) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) which essentially deemed pediatric facilities to be certified as heart transplant facilities if they met certain specified conditions. After careful consideration of the comments received on this notice and our experience with the criteria for pediatric heart transplant facilities, we are adopting the same criteria and are applying them to pediatric liver transplant facilities. The criteria, which represent Congress' view of the appropriate contours for coverage for certain pediatric transplants, have worked successfully in the heart transplant program, and we believe that they answer the concerns of those who

commented on pediatric liver transplants.

Therefore, liver transplantation will be covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application that HCFA approves as documenting the following:

> The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by HCFA to meet the institutional coverage criteria in this notice; the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and the hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

We are not changing the current covered clinical conditions for which a pediatric liver transplant can be performed. Liver transplantation for children under age 18 is covered for those children with extrahepatic biliary atresia or any other form of end-stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Comment: We had proposed that we would cover only those liver transplantations performed in facilities that demonstrate good patient outcomes, for example, initially a 1-year survival rate of 77 percent for patients receiving a liver transplant. Several commenters suggested that 77 percent was too high and that since even some of the larger transplant centers are not experiencing such a high rate of success as this, it would be even more difficult for the smaller centers to achieve this rate of success.

Response: We will retain the 77 percent 1-year and 60 percent 2-year survival requirements for patients receiving liver transplants because data indicate that such outcomes have been achieved and are realistic for the listed covered indications.

Comment: Several commenters disagreed with the requirement of performing 12 transplants per year. Some suggested the transplant rate should be 20–25 per year, others suggested it should be lower than 12 per year.

Response: We disagree with these commenters. To require more than 12 transplants per year would disadvantage some smaller transplant centers, and to require fewer than 12 would mean that it would be difficult for a facility to gain the experience and demonstrate the commitment necessary to safely and effectively perform liver transplants. A more detailed explanation of this requirement can be found in the OHTA assessment of liver transplantation mentioned in section I (Background) of this final notice.

Comment: One commenter said that there is no mention of cost containment relating to individual facilities. The commenter said that limitations should be spelled out and centers with high costs should be excluded from participation.

Response: Under the prospective payment system (PPS), the payment to hospitals providing liver transplantations to Medicare beneficiaries will be at an established rate. The proposed notice indicated that liver transplants would be classified under DRG 478 with a relative weight of 21.0000. This relative weight was based on FY 1984 Medicare bill data and 1983 and 1984 sample claims from three hospitals. Since this relative weight was calculated, we have reclassified liver transplants as DRG 480 and have recomputed the relative weight on the basis of the most recent data. The FY 1991 DRG 480 weight is 15.2645. This weight is based on 29 liver transplant cases in the FY 1989 Medicare Provider Analysis and Review (MEDPAR) file. The MEDPAR data include detailed information on approximately 10 million Medicare discharges and were used to calculate the liver transplant DRG weight and all other DRG weights. We have also carefully reviewed the final FY 1989 MEDPAR data for liver transplant cases to ensure that they met the proposed coverage criteria and were performed by hospitals that have the potential to become Medicare-approved transplant centers.

The methodology as described in our final rule on PPS and fiscal 1991 rates published in the **Federal Register** on September 4, 1990 (55 FR 35990) used to recalibrate the DRG weights requires a minimum of 10 cases to compute a reasonable DRG weight. Since the FY 1989 MEDPAR data included more than 10 (that is, 29) liver transplant cases that meet the proposed Medicare criteria for coverage, these cases were used to determine the liver transplant DRG weight in a manner consistent with the other DRG weights. The 29 liver transplant cases used to determine the DRG weight of 15.2645 include patients ranging in age from 23 to 69 years of age with only 4 patients over the age of 65.

A more detailed explanation of the methodology used in recomputing the relative weight of DRG 480 can be found in our final rule regarding changes to the inpatient hospital prospective payment system and fiscal year 1991 rates published in the **Federal Register** on September 4, 1990.

Comment: Several commenters suggested that HCFA consider adopting the United Network for Organ Sharing (UNOS) standards to approve liver transplant facilities under Medicare.

Response: We have not accepted this approach. Under section 1862 of the Act, we must determine what services are reasonable and necessary, and we are adopting criteria consistent with those that have been successfully applied for coverage of heart transplants. The criteria that we are establishing to select facilities in which liver transplants may be performed under Medicare ensure that these procedures will be performed safely and efficaciously. Although the criteria for experience, survival rates, and facility commitment are somewhat demanding, our goal is to maintain the quality of services required by this complex procedure. The approval process will remain open, and those facilities that do not now meet the criteria may someday do so. The reader should note that, under section 1138(a)(1) of the Act, a hospital in which organ transplants are performed must be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). UNOS is under contract to the Department to administer the OPTN. The policies developed by UNOS are currently being reviewed to determine which of them are appropriate to implement as OPTN rules and requirements.

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 liver transplant center.

Response: While we understand and appreciate the concern that is evidenced by these 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.

We believe we must evaluate 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 aggregate the experience of several hospitals in reviewing applications. Each transplant facility must be willing and able to provide the many resources

that are required to assure a successful transplant program.

While a successful liver transplant team is important, other factors seem to contribute to the development of good experience and survival rates. Thus, a facility must provide not only the transplant team itself, but must provide administrative and operational resources that direct and support the team. Our facility criteria measure a number of factors beyond the qualifications of the transplant team to determine the facility's overall commitment to a successful transplant program.

In addition, the criteria, including the long-term survival rate, are intended to measure a facility's long-range commitment to a liver transplant program. We do not believe that the experience of an individual or group of individuals is a satisfactory substitute for that institutional commitment. Although the loss of key members of the transplant team will require a review by HCFA to ensure that the facility continues to meet the criteria, their acquisition by another facility should not, in our view, permit that other facility to claim the first facility's hard-won experience and success.

Comment: Several commenters objected to our prohibition of applications from consortia and believed that this type of application should be treated the same as individual applications.

Response: We disagree with this comment. The criteria for facility approval are based on the performance of individual liver transplant facilities. They are designed to ensure that Medicare beneficiaries receive only reasonable and necessary liver transplants, which 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 consortium would result in the loss of that assurance. Although we will not approve consortia as liver transplant centers, individual members of a consortium may submit individual applications at any time and, if they meet the criteria, they will be approved.

Comment: Several commenters requested that some type of regional access or allocation be allowed in order to ensure that there would be approved liver 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 ensure 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. We do not propose to ensure an even geographic distribution, nor do we propose to limit the number of facilities that may qualify in a given area. Whether a facility will be approved will depend upon whether the facility meets the coverage criteria set forth in this notice. We recognize the hardship that this may place on some transplant recipients and their families, but we do not believe our position adversely affects the clinical outcomes of the procedures. We also note that the issue of geographic access will probably diminish over time as more centers gain the necessary experience to meet the criteria.

Comment: One commenter believed that our criteria are too restrictive and limit the number of eligible providers.

Response: In the case of liver 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, liver transplantation has resulted in increased life expectancy and in improved quality of life. We recognize that the proposed criteria for experience, survival rates, and facility commitment are somewhat demanding. However, our goal in requiring facilities to meet certain criteria is not to restrict competition but to maintain the quality of services required by this complex procedure, 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 cutoff date for receipt of applications nor a limit on the number of approved facilities, and hospitals that may initiate a liver transplant program may do so with the clear understanding of what criteria they will have to meet.

E. HMOs, CMPs, and HCPPs

Comment: Several health maintenance organizations (HMOs), competitive medical plans (CMPs), and Health Care Prepayment Plans (HCPPs) contracting with HCFA for the care of Medicare beneficiaries and one entity representing such organizations stated that it is unfair to require these organizations to cover liver transplants for their Medicare enrollees. Instead, HCFA should administer this benefit separately for enrollees of such organizations and all costs, including coinsurance and deductible costs, should be borne by HCFA, either as a separate payment or in a manner similar to the way Medicare hospice benefits are provided to the Medicare enrollees of HMOs and CMPs. The commenters suggested that if HCFA cannot pay separately for liver transplants and associated costs, it should delay the effective date of coverage for liver transplants until the 1991 contract year, so that organizations can adjust their premium and benefit levels and HCFA can adjust its payments to organizations to account for the new service.

Response: HMOs, CMPs and HCPPs contract with Medicare on an annual basis for care of Medicare beneficiaries who enroll with their organizations. HMOs and CMPs are required to furnish the full range of covered services under Parts A and B to Medicare enrollees, except for hospice benefits under section 1812(a)(4) of the Act. HCPPs furnish no part A services and may choose to cover less than the full range of Part B covered services, within certain limitations. Beneficiaries enrolled in risk contracting organizations are required to receive all services covered under the plan from or through the organization; if this restriction, commonly called the lock-in restriction, is violated, neither the organization nor Medicare is required to pay for the service. There are no lock-in restrictions for enrollees of cost-contracting organizations.

Medicare pays HMOs and CMPs contracting on a risk basis amounts that are fixed in advance at the beginning of each calendar year and are based on average costs for similarly situated Medicare beneficiaries who reside in the counties from which the organization draws its enrollees, but who are not enrolled in the organization. Medicare pays an HMO, CMP, or HCPP contracting on a cost basis the reasonable costs incurred by the organization in furnishing covered Medicare services to its enrollees. In addition, organizations collect directly from beneficiaries, often by fixed monthly premium payments and/or copayments at the time of service. Insofar as these premium and copayment amounts are for Medicare covered services, they may not exceed the actuarial value, in the aggregate, of Medicare deductibles and coinsurance attributable to Medicare covered

services. Additional amounts may be charged for supplemental services an organization chooses to include in its benefit plan. HMOs and CMPs are not permitted to increase their charges to Medicare enrollees or to decrease the scope of services offered during the term of the contract. HCPPs must agree not to charge Medicare enrollee amounts in excess of the applicable Medicare deductibles and coinsurance for covered services.

Medicare's payments to organizations contracting on a risk basis cannot be adjusted at the conclusion of the contract term to account for actual use of Medicare covered services by enrollees. Medicare's payments to cost-contracting HMOs, CMPs, and HCPPs are adjusted at the end of the contract term to account for actual use of services, but Medicare deducts the normal parts A and B deductible and coinsurance amounts from the adjustment. All HCPPs and some HMOs and CMPs contract on a cost basis.

We cannot agree to these commenters' requests that HCFA exclude liver transplants and associated services from the scope of services that must be furnished by HMOs and CMPs. Section 1876(c)(2) of the Act provides that HMOs and CMPs must provide all services covered under Parts A and B, for persons entitled to Parts A and B respectively, that are available to beneficiaries residing in the geographic area served by the organization. A statutory change contained in section 4204(c) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) provides that HMOs/CMPs contracting on a risk basis are not responsible for paying for new or expanded services required by a national coverage determination until the costs for those services are included in the Adjusted Average Per Capita Cost (AAPCC) calculation. This statutory change is effective January 1, 1991. However, this change does not apply to liver transplants because the costs of adult liver transplants are included in the AAPCC calculations for 1991. Thus, no payment beyond the regular capitation amounts will be paid to risk HMOs and CMPs for covered adult liver transplants furnished to enrollees in 1990 or in any year following. However, the 1990 AAPCC rate did include allowance for benefits including long term hospitalization under the Medicare Catastrophic Coverage Act (Pub. L. 101-234), which was subsequently repealed.

Coverage of liver transplants is not comparable to hospice benefits, and it is not equitable or desirable to treat them similarly for the purposes of HMOs and CMPs. Hospice benefits are unique in that they represent an alternative form of treatment from regular Medicare program benefits, and accordingly the law provides that a beneficiary who elects hospice benefits does so in place of coverage of all other benefits related to the terminal condition. The beneficiary formally waives coverage of all Part A and B services related to his or her terminal condition. Regulations at 42 CFR 417.414(a)(3) exclude hospice services under Medicare from the usual Part A and B scope of services that must be provided by HMOs and CMPs. Medicare enrollees of HMOs and CMPs who elect hospice benefits under Medicare are, in effect, suspended from their enrollment in the organization for most Medicare services related to the terminal condition and instead receive palliative treatment only from the hospice. HCFA also adjusts the payment to the organization by subtracting the cost for providing Parts A and B services to the enrollee (called the organization's adjusted community rate) from the monthly payment due the organization. If any Part A or Part B covered services are provided by an HMO or CMP to a hospice patient, such as those not related to the terminal condition or attending physician services, the HMO or CMP bills Medicare for them on a fee-for-service basis. The hospice is paid separately for the services it provides under rules at 42 CFR part 418.

HCPPs contracting with Medicare under section 1833(a)(1)(A) of the Act do not provide benefits under Part A, so they are not required to pay for the majority of services that are covered if a beneficiary receives a covered liver transplant. HCPPs will be paid 80 percent of their reasonable costs of covering liver transplant-related Part B services, less applicable deductible amounts. HMOs/CMPs contracting with Medicare on a reasonable cost basis will similarly be paid the reasonable costs they actually incur in connection with covered liver transplants less applicable coinsurance and deductibles. The applicable coinsurance and deductibles are recouped through premium and other charges to beneficiaries. We cannot adjust risk-basis HMO/CMP payment amounts to include costs of liver transplants until January 1991, however, because section 1876(a)(1)(A) of the Act requires the Secretary to determine payment rates annually in advance for each calendar year and does not permit retroactive adjustment of payment rates.

HCFA does not believe it is appropriate to change the effective date for liver transplant coverage. Section 1862(a)(1)(A) of the Act requires the Medicare program to pay for items and services that are reasonable and necessary for diagnosis and treatment of an illness or an injury. We determined on March 8, 1990 that liver transplants are reasonable and necessary treatment under the conditions delineated in this notice that ensure that such services are safe and effective. We believe we are legally precluded from delaying coverage of these services and, thus, denying Medicare beneficiaries the benefit of this treatment for an interim period after we have already determined that such transplants are reasonable and necessary if performed under certain conditions.

Comment: An HMO suggested that patients requiring liver transplants should be barred from enrolling in an HMO or CMP that contracts on a risk basis with Medicare.

Response: Section 1876(d) of the Act provides that every individual enrolled in Parts A and B of Medicare, or Part B only, may enroll with any HMO or CMP contracting with Medicare that serves the geographic area in which the beneficiary resides, except for persons medically determined to have end stage renal disease (ESRD). Section 1876(b)(3)(A)(i) of the Act requires that during any open enrollment period, HMOs and CMPs must accept all eligible individuals, up to the limits of their capacity and without restrictions, except as may be authorized in regulations. Regulations at 42 CFR 417.422 define the criteria for eligibility to enroll in an HMO or CMP and exclude from eligibility persons who have been determined to have ESRD or who have elected hospice benefits under Medicare. Beneficiaries who have elected hospice benefits under Medicare, by definition, are expected to live 6 months or less. This fact, coupled with the requirement that beneficiaries elect the hospice benefit in place of Parts A and B services that are related to the terminal condition (as discussed above), formed the basis for our decision to permit HMOs and CMPs to deny enrollment to beneficiaries who have elected hospice benefits. Another factor is that hospice care is an election that may be revoked by the beneficiary at any time and that, if revoked, the beneficiary is then eligible to enroll in an HMO or CMP. These two instances are the only exceptions to the rule that HMOs and CMPs may not screen enrollees based on their health status. In fact, if a current enrollee of an HMO or CMP develops ESRD or elects the hospice benefit, the organization may not disenroll that person. The law does

not permit health screening in part because our payments to HMOs and CMPs are based on average costs of all beneficiaries in the county of residence in the rating group (rating groups are based on age, sex, disability, institutionalization, and welfare status). To permit HMOs and CMPs to disenroll or deny enrollment to sicker beneficiaries would skew payments and be unfair to beneficiaries.

Comment: An organization representing HMOs, CMPs, and HCPPs requested that the ruling clarify that enrollees of organizations contracting on a risk basis may not refer themselves for liver transplants out-of-plan and that lock-in restrictions apply to this benefit. This organization and several HMOs also requested that HCFA make an exception to the requirement that liver transplants be performed at centers which have been approved for that service, if an emergency prevents the procedure from being performed at a liver transplant center approved by HCFA.

Response: The requirement at 42 CFR 417.448 that the services must be furnished by the organization or through arrangements made by the organization applies to liver transplants.

Under 42 CFR 417.416, HMOs and CMPs must supply or arrange for Medicare-covered services to be provided by providers and suppliers that meet the Medicare conditions of participation and coverage. If, even on an emergency basis, a liver transplant occurs at a hospital that has not been approved as a Medicare liver transplant facility, it would not be a covered service. Neither Medicare nor the HMO or CMP would be required to pay for this service.

Comment: A HMO wanted to know if HMOs and CMPs would be held liable for denying liver transplants to persons during the period of March 8, 1990 and the date of this final notice.

Response: No HMO or CMP will be subject to sanctions for failure to arrange for or authorize liver transplants to otherwise eligible enrollees for the period between March 8, 1990 and the date of this notice. Risk HMOs and CMPs must, however, cover liver transplants actually received by enrollees if the liver transplants were performed after March 8, 1990 at a transplant center which is approve by HCFA based on the conditions in this notice to perform that service, just as the Medicare program will cover such transplants for beneficiaries who are not enrolled in an HMO or CMP. In such cases, the transplant would be deemed to be authorized by the HMO/CMP, since it could not actually have been authorized as a covered service prior to this notice. After the date of this notice, a Medicare-covered transplant will only be covered by a risk HMO or CMP if it is authorized by the HMO or CMP or if it is determined on reconsideration that coverage was improperly denied.

Comment: An HMO requested that HCFA develop a specific rating group for enrolled beneficiaries who have undergone a liver transplant, similar to the special rating category in effect for enrollees who have ESRD.

Response: We cannot agree with this commenter's request to develop a specific rating group for beneficiaries who have undergone a liver transplant. The expansion of Medicare coverage to include liver transplants is not comparable to the situation involving ESRD beneficiaries. ESRD, rather than being a Medicare covered service, is a basis for Medicare entitlement. Specific rates developed for ESRD, as for the aged and disabled, reflect the distinct category of beneficiary.

As with previous coverage expansions, payment for liver transplants will be incorporated into the existing per capita rating groups. However, if a diagnosis-related cost adjustment to the payment rates is later adopted, perhaps liver transplant enrollees will fall into a higher payment group.

F. Miscellaneous

Comment: One commenter suggested that since live liver donation is a viable option for transplantation, HCFA should consider providing criteria for those centers that wish to provide this type of transplantation.

Response: We have not accepted this comment. Live liver donation in use for transplantation is still considered an investigational procedure, and the recipients are predominately children. We, therefore, do not feel it necessary to provide any criteria for this type of liver transplantation. In addition, the OHTA assessment report was based on the use of orthotopic adult liver transplantations.

Comment: One commenter suggested we create a conditional designation status for facilities that have not done the required number of liver transplants but have experience with other types of organ transplants.

Response: We have rejected this suggestion 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 liver 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 liver transplants to permit an exception to the criteria based on the substitution of the experience for the required experience in liver transplants.

Comment: One commenter noted that we have stated that facility-specific heart transplant coverage has been a great success but we have not offered any data to support that contention.

Response: As of this writing, 46 facilities have been approved by Medicare to perform heart transplants. Of these 46, only 13 have been performing Medicare-covered transplants for 4 years. The other 33 have been performing them for 3 years or less. Therefore, we are just now beginning to experience the numbers of transplants necessary to gather meaningful data. The data gathering process has begun, and we will offer those data to the public at a future date.

Comment: Several commenters indicated that a facility retransplantation rate should be considered a critical requirement for approval as a liver transplant facility.

Response: We disagree with the notion of considering the retransplantation rate as a critical requirement because we do not have enough data to employ it as a qualifying criterion. We are, however, requiring reporting of the retransplantation rate per year for the last 2 years as part of the data collection requirements contained in section V.A. 5. We have included this requirement to obtain a better overall picture of the facility's experience with liver transplants.

IV. Summary of Changes

We have listed below the changes made from our proposal. Changes 2, 3, and 4 are discussed in section III of this notice.

1. We are using the DRG classification 480, "Liver transplants" (rather than 478, "Liver transplants") and have established a relative weight of 15.2645 (rather than 21.000). This relative weight was determined using the methodology established by our September 4, 1990 final rule on FY 1991 prospective payment rates for hospitals (55 FR 35990).

2. We are deleting portal vein thrombosis, as a contraindication to transplant, from the guidelines for patient selection criteria for liver transplants.

3. Our proposed notice listed "hepatitis B, antigen negative (postnecrotic cirrhosis)" as a qualifying clinical condition. This has been corrected to "postnecrotic cirrhosis, hepatitis B surface antigen negative".

4. In section V.B.5 of this notice (which concerns experience and survival rates), we are including the requirement that hospitals submit data on their retransplantation rates.

V. Provisions of This Notice

We are providing a national coverage decision, under section 1862(a)(1)(A) of the Act, that, for Medicare coverage purposes, liver transplants in adults with certain specified conditions are medically reasonable and necessary if performed in facilities that meet certain criteria and are approved by HCFA for liver transplants. A facility that wishes to obtain coverage of liver transplants for its Medicare patients must submit an application and supply documentation showing its initial and ongoing compliance with each of the criteria.

For facilities that are approved, Medicare will cover under Part A (Hospital Insurance) all medically reasonable and necessary inpatient services. For facilities receiving Medicare payment under the Medicare prospective payment system, we will use DRG classification 480, "Liver transplants." We have established a relative weight of 15.2645 for DRG 480 and a 52-day outlier threshold. (DRG 480 has the highest relative weight among the 490 DRGs.) Organ acquisition costs will be paid separately on a cost 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 paid based on the generally applicable rules for Part B. Outpatient, self-administrable drugs used in immunosuppressive therapy, such as cyclosporine, are covered under Medicare for a period of up to 1 year beginning with the beneficiary's date of discharge from the inpatient hospital stay during which a covered organ transplant was performed. Medicare will cover retransplants in approved facilities only if the initial transplant was performed for a covered condition, regardless of whether it was a Medicare-covered transplant.

If a Medicare beneficiary receives a covered liver transplant from an approved facility, reasonable and necessary services for followup care and for complications are covered, as determined by our contractors, even if such services are furnished by a facility that, although eligible for Medicare payment, is not specifically approved as a Medicare liver transplant facility.

Medicare will not cover liver transplants or retransplants in facilities that have not been approved as Medicare liver transplant facilities. If a Medicare beneficiary received a liver transplant from a facility that is not approved as a Medicare liver transplant facility or received a liver transplant for a condition for which a transplant is not covered under Medicare, we will not cover any inpatient services associated with the transplantation procedure. In such cases, physician services associated with the transplantation procedure are not covered. Thus, payment will not be made for the performance of the transplant or for any other services associated with the transplantation procedure if performed in a non-approved facility.

However, after a beneficiary has been discharged from a hospital (which was not approved as a Medicare liver transplant facility) in which he or she received a liver transplant, medical and hospital services required as a result of the non-covered transplant will be covered in a facility otherwise eligible for Medicare payment if the services are reasonable and necessary in all other respects. Thus, coverage will be provided for subsequent inpatient stays or outpatient treatment ordinarily covered by Medicare even if the need for treatment arose because of a previous non-covered liver transplant procedure. These services also will be covered for Medicare beneficiaries who were not beneficiaries at the time they received a liver 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 liver transplant facility for Medicare purposes, it is obliged to report immediately to HCFA any events or changes that would affect its approved status. Specifically, a facility must report any significant decrease in the number of liver transplants performed 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 changes that could affect the performance of liver transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of liver transplants performed at the facility.

A. Requirements for Coverage

1. *Specific clinical conditions required for liver transplantation coverage.* Medicare coverage of liver transplants in adults will only be made for those beneficiaries who meet the applicable criteria and who are diagnosed as having one of the following clinical conditions:

a. Primary biliary cirrhosis;

b. Primary sclerosing cholangitis;

c. Postnecrotic cirrhosis, hepatitis B surface antigen negative;

d. Alcoholic cirrhosis;

e. Alpha-1 antitrypsin deficiency disease;

f. Wilson's disease; or

g. Primary hemochromatosis.

2. *Other coverage criteria.* Facilities must have written patient selection criteria for determining suitable candidates for liver transplants. When specific criteria are considered in connection with the assessment of an individual patient's suitability for a liver transplant, we believe that liver transplants are medically reasonable and necessary. Therefore, we have developed patient selection guidelines (contained in section V.E. of this notice) that are a subset of the criteria that facilities are required to meet so that we may be assured of their qualifications to provide medically reasonable and necessary liver transplants to Medicare patients.

B. Facility Requirements

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

1. *Patient selection.* A facility must have adequate written patient selection criteria and an implementation plan for their application.

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

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

b. Patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.

c. Long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for a period of at least 5 years.

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

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

b. The facility has expertise in the following areas: Medical, surgical, and other relevant areas, particularly hepatology, vascular surgery, anesthesiology, immunology, infectious diseases, pulmonary diseases, pathology, radiology, nursing, blood banking, and social services. The facility must identify individuals in these areas in order to achieve an identifiable and stable transplant team. Responsible medical/surgical members of the team must be board certified or eligible to take the boards in their respective disciplines or have, in the opinion of the non-Federal experts (discussed in V.C. of this notice) demonstrated 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 anesthesia service must identify a team for transplantation that must be available at all times.

(3) The infectious disease service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, many of which are not commonly encountered.

(4) 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.

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

(6) Adequate social service resources must be available.

(7) Mechanisms must be in place for managing the liver transplant program that 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.

(8) 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 ensure a reasonable concentration of experience; specifically, 12 or more liver transplantation cases per year in adults who have one or more of the covered conditions. 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 clinical organ transplantation.

The facility must have an established liver transplantation program with documented evidence of 12 or more adult patients, who have one or more of the covered conditions, in each of the two preceding 12-month periods.

Initially, the facility must demonstrate an actuarial 1-year survival rate of 77 percent and an actuarial 2-year survival rate of 60 percent for adult patients who have one of the seven covered conditions and who have had liver transplants at that facility during the time the facility is calculating its experience and survival rates. In reporting their actuarial survival rates, facilities must use the Kaplan-Meier technique and must report both 1-year and 2-year survival rates. The following definitions and rules also must be used:

a. The date of transplantation (or, if more than one transplantation is performed, the date of the first 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 1 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 (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in paragraph (e) below.

Note: The fiducial date cannot be in the future; it must be within 90 days before the date we receive the application.

d. Any patient who is not known to be dead but 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 died 1 day after the last date of ascertained survival. However, a facility may submit additional analyses that reflect each patient in the "lost to followup" category as alive at the date 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 liver transplant for one of the seven covered indications between January 1, 1982 and the date of the application:

- Transplant number.
- Age.
- Sex.
- Date of transplant.
- Clinical indication for 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 B.5.d or e above.

Unique patient identifiers are not needed for data prior to the application. The facility may submit additional information on any of the cases that it would like considered in the review.

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 liver 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 provided through additional tables or supplemental explanation.

g. In addition to the data above on the individual patient, the facility must submit its retransplantation rate per year for the last 2 years for all transplants.

6. *Maintenance of data.* The facility must agree to maintain and, when

requested, periodically submit data to HCFA, in standard format, about patients selected (including patient identifiers), protocols used, and short- and long-term outcome on all patients who undergo liver 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 liver transplantation and to ensure 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 (including turnover of key staff members) that could affect the health or safety of patients selected for covered Medicare liver transplants or that 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, the transplantation of patients who do not meet the facility's patient selection criteria, or any other changes that could affect the performance of liver transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicare coverage of liver transplants performed at the facility.

Facilities not approved for Medicare covered liver transplants are not required to maintain data in standard format. However, if these facilities apply for Medicare approval, they will be required to submit such data for all patients receiving a liver transplant. The facility must submit these data beginning 30 days after notification of the data requirements. We plan to issue instructions in the near future to all hospitals regarding the required data.

7. *Organ procurement.* The facility must be a member of the Organ Procurement and Transplantation Network (OPTN) as a liver transplant center and abide by its approved rules. The OPTN is currently administered under a HHS contract by the United Network for Organ Sharing. However, to date, the Secretary has approved no rules binding upon Medicare and Medicaid participants. The facility must have an agreement with a designated organ procurement organization to obtain donor organs.

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

b. "Organ procurement organization" is defined as an organization that has been designated by HCFA as an organ procurement organization and that meets the criteria in section 371(b) of the Public Health Service Act, 42 U.S.C. 273(b). Such an agency performs or coordinates all of the following services:

(1) Retrieval of donated livers;

(2) Preservation of donated livers;

(3) Transportation of donated livers; and

(4) Maintenance of a system to locate prospective recipients for retrieved organs.

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

9. *Billing.* The facility must agree to submit claims to Medicare only for adult liver transplants performed on individuals who have been diagnosed as having one of the following conditions:

a. Primary biliary cirrhosis;

b. Primary sclerosing cholangitis;

c. Postnecrotic cirrhosis, hepatitis B surface antigen negative;

d. Alcoholic cirrhosis;

e. Alpha-1 antitrypsin deficiency disease;

f. Wilson's disease; or

g. Primary hemochromatosis.

C. Process for Review and Approval of Facilities

Facilities that wish to obtain liver transplantation coverage for their Medicare patients are required to submit an application and supply documentation showing their initial and ongoing compliance with each of the criteria. We will reexamine the use of the criteria in 3 years to verify its continuing appropriateness.

The approval of facilities will be based on a review of the materials submitted regarding their experience and expertise, as well as their commitment to the liver transplant program. We will conduct the reveiw with the aid and advice of non-Federal experts 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 will not be 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 3-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 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 2 years. This means that the 2-year period begins on the first day a facility actually performs an adult human orthotopic liver transplant. Also, 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 will not be granted on the basis of geographic considerations.

D. Application Procedure

The application procedure is as follows:

1. An original and 10 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, the name and title of its chief executive officer, 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 review against the criteria specified in this notice. Each page must be numbered.

3. To the extent possible, the application should be organized into nine sections corresponding to each of the nine 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 Boulevard, Baltimore, Maryland 21207.

E. Guidelines for Patient Selection Criteria

Included in section V.B., Facility Requirements, is the requirement that facilities must have adequate patient selection criteria and an implementation plan for their application. Section V.A., Requirements for Coverage, also requires that facilities have patient selection criteria that they will follow in determining suitable candidates for liver transplants. Such criteria should include or be comparable to, but need not be limited to, the following:

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 end-stage liver disease with a life expectancy of less than 12 months and no medical or surgical alternatives to transplantation.

3. In the case of alcoholic cirrhosis, selection of a patient who needs a liver transplant should include evidence of sufficient social support to assure assistance in alcohol rehabilitation and in immunosuppressive therapy following the operation. Although the center should require abstinence at the time of the operation, we do not specify how long the patient should be abstinent prior to the operation. We believe the hospital and the transplant team should establish such guidelines. Facilities will be required to submit, as part of their application, the period of time they require for abstinence in patients with end-stage liver disease due to alcoholic cirrhosis.

4. The patient must not have the following:

a. Significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease.

b. Systemic infection.

c. Presence of malignancies either hepatic, extrahepatic, or metastatic.

d. Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs.

e. Active alcohol or drug abuse.

f. The need for prior transplantation of a second organ, such as lung, heart, or kidney, or marrow, if this represents the coexistence of significant disease.

g. 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).

5. Many other factors must be recognized with regard to an adverse outcome after liver transplantation. The manner and extent to which adverse risk is translated into contraindication varies. For example, presence of insulin-dependent diabetes mellitus may have to be considered in relation to transplantation because of possible adverse effects on outcome as well as complications related to chronic immunosuppressive therapy.

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

These criteria take into consideration advances in the transplantation field and reflect discussions with experts in hepatology, infectious diseases, transplantation, surgery, and biostatistics, and other experts. We realize that the indicators to measure the safety and efficacy of liver transplantations will continue to evolve. Thus, the criteria may need to be updated periodically to recognize further developments in liver transplantation technology.

VI. Regulatory Impact Analysis

A. Introduction

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any final notice that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be 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.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all facilities that consider themselves capable of performing liver transplants are treated as small entities. In this impact analysis, any reference to liver transplant/transplantation will mean liver transplantation in adults (age 18 or older). Liver transplantation to treat children (individuals under the age of 18) with extrahepatic biliary atresia was previously approved for Medicare coverage.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final notice that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis also must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

As stated in the initial impact analysis, this final notice is considered a major rule under E.O. 12291 criteria based on our cost projections for the next five fiscal years (FYs). Additionally, this final notice will affect all facilities that consider themselves capable of performing liver transplants and may have an effect on the ability of those facilities to compete. We believe this final notice will not have a significant economic impact on a substantial number of small rural hospitals since it is unlikely that they will be performing liver transplants. However if there are any small rural hospitals performing liver transplants, they will be affected by this final notice in the same way as any other hospital. We have revised and amended certain provisions of the proposed notice in this final notice based on response to public comment. However, these revisions will not have a significant economic impact on beneficiaries or hospitals. All comments, even those concerning this regulatory impact analysis, have been addressed in the preamble. The following analysis, which, in combination with the other sections of this final notice, is intended to conform to the objectives of E.O. 12291, the RFA, and section 1102(b) of the Act.

B. Entities Affected

In the initial impact analysis, we stated that the criteria that we have developed are essential to the maintenance of high standards of quality and the most successful outcomes. There are currently 73 liver transplant facilities in the United States according to information from the United Network for Organ Sharing. We estimate that the application of these criteria will result in the approval initially of about 10 of these facilities with a total of approximately 20 a year later. These estimates are being used primarily for the purpose of estimating the costs of covering liver transplants. We do not have any advance

information on which facilities will apply or meet the criteria.

In the initial impact analysis, we estimated that there would be, at most, 74 covered Medicare liver transplant cases for FY 1990. Based upon the later effective date of March 8, 1990, we now estimate 37 covered Medicare liver transplant cases for FY 1990. By contrast, the number of non-Medicare cases for the same period is expected to be over 1500 cases. Thus, Medicare's share of the total liver transplant market for FY 1990 is expected to be only about 2.5 percent, rather than the 4.7 percent originally projected. However, by FY 1994, we expect that 19 percent of all liver transplants will be Medicare covered. Initially, we estimate that 10 hospitals out of the 73 hospitals currently performing liver transplants will meet the Medicare coverage criteria. However, by FY 1994, we expect that many, if not most, of the hospitals performing liver transplants will meet the criteria. A hospital that performs liver transplants but does not meet our Medicare coverage criteria could eventually be disadvantaged to the extent that the hospital performs liver transplants for Medicare beneficiaries and to the extent that the hospital must compete with nearby hospitals that meet Medicare coverage criteria for liver transplants.

Consequently, this final notice could eventually provide those hospitals that meet the criteria for performing liver transplants with a significant amount of additional Medicare revenue. Also, these hospitals could use their status as Medicare liver transplant centers to enhance their prestige and standing as health care providers. This, in turn, could enable them to increase their overall market share of liver transplants at the expense of hospitals that also perform liver transplants but do not meet our criteria. Those facilities that do not meet the criteria may view this final notice as having a significant adverse effect on competition. It is important to emphasize, however, that since the market for liver transplants is constrained by the number of livers available for transplant, we do not believe that the criteria will in any way reduce the number of transplants.

Many facilities that have performed at least one liver transplant will not meet the levels of experience and success required under the facility criteria that we are proposing. However, some might be found to have acceptable clinical programs with an adequate prospect for successful outcomes. We encourage these facilities to apply when they have achieved that success. We expect that Medicare coverage of liver transplantation could prompt additional third party payers, including State Medicaid plans, to cover this procedure and create incentives for some facilities to establish liver transplant programs. However, third party payers that either already cover or will cover liver transplants are not required to adopt our coverage standards.

Nonetheless, 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 coverage of liver transplants by private insurers or to limit any decision they may make to adopt policies similar to our own. If such a result were to occur, we believe it will merely reflect a general consensus that might have formed even if we had not addressed this issue.

Due to the sensitivity of these estimates and the uncertainty of actual outcomes, we view our estimates of the number of liver transplant cases and the number of hospitals that will meet Medicare coverage criteria as opinions, rather than estimates.

C. Impact on Beneficiaries

In the initial impact analysis, we pointed out that it is likely that few beneficiaries entitled to Medicare on the basis of age will be suitable liver transplant recipients because the advanced age of these beneficiaries will generally make them poor medical candidates for this procedure. Beneficiaries entitled to Medicare on the basis of disability are required by law to serve a 24-month waiting period in addition to the 5 months they must have been disabled prior to entitlement to disability cash benefits. We recognize that the need for liver transplantation among some of those disabled by liver disease may arise earlier than the twenty-nine months that they must wait until they are entitled to Medicare.

We believe that the criteria we are implementing are the most effective means available to ensure that the liver transplants that are made available to Medicare beneficiaries are provided in a safe and effective manner so that they can be considered to be reasonable and necessary within the meaning of the law. Although we have made some changes to the criteria in response to public comments, we recognize that the criteria are still fairly restrictive. Beneficiaries may have to travel long distances from their homes and have to incur travel expenses in order to receive a liver transplant at a Medicare approved facility. However, we believe this approach is justified, considering both our concerns for patient safety and the success rates that are currently achievable with this modality. 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. In any event, we do not believe that the criteria will have an effect on the number of liver transplants performed.

D. Projected Expenditures Under Medicare

In the initial impact analysis, we discussed in some detail the difficulties of estimating the cost of covering liver transplants. The major problem was in estimating the availability of donor organs over the next few years. Our projected estimates were based on coverage becoming effective February 1, 1990. We made assumptions about the total number of liver transplants performed nationwide and the future rate of increase of the number of transplants performed at approved facilities. We assumed that the number of transplants would go up with the number of facilities, but the rate of increase would level off due to competition for suitable recipients and donor organs.

The only change we are making in our final cost projection is to reflect the March 8, 1990 effective date for liver transplant coverage. As a result, we are lowering the Medicare cost estimate for FY 1990 to $5 million. The following table presents estimates in the growth of Medicare expenditures for coverage of liver transplants through FY 1994.

Again, due to the sensitivity of these assumptions and the uncertainty of actual outcomes, we view our projection of expenditure increases as an opinion, rather than an estimate.

PROJECTED EXPENDITURES FOR MEDICARE COVERAGE OF LIVER TRANSPLANTS

[In Millions] *

Fiscal year				
1990	1991	1992	1993	1994
$5	$25	$55	$85	$120

* Rounded to nearest $5 million.

E. Projected Savings Under Medicaid

In the initial impact analysis, we recognized that changes in Medicare coverage of liver transplants would affect Medicaid. Presently 35 States and

the District of Columbia cover liver transplants. Medicare coverage of liver transplants will mean that if the transplant qualifies for Medicare coverage, these States will only be required to pay the coinsurance and deductible for the transplant. There are no changes in the Medicaid savings projected for this final notice. In FY 1990 and 1991, we estimate the total Medicaid savings to be considerably less than $5 million. However, by FY 1992, we expect to see a noticeable increase in Medicaid savings because the number of approved Medicare liver transplant facilities and transplant operations is expected to increase substantially.

PROJECTED SAVINGS IN MEDICAID LIVER TRANSPLANT EXPENDITURES

[In Millions] *

Fiscal year				
1990	1991	1992	1993	1994
0	0	$5	$5	$5

* Rounded to nearest $5 million

F. Alternatives Considered

In the initial impact analysis, we considered the alternative of allowing all Medicare participating hospitals to establish transplant programs without additional facility criteria, although the patient selection criteria would have to be used. We continue to reject this alternative because it would permit uncontrolled proliferation of transplant facilities, raising all the concomitant questions about the quality of services, given the limited availability of donor organs and experienced teams. Further, because the procedure would have been spread among a larger number of facilities, it would be likely that the average experience level would be lower and would probably result in lower success and survival rates among recipients. 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 liver transplantation.

G. Conclusion

We believe that the conditions set forth in this final notice will maintain the quality of the services required by this complex procedure, permit transplantation only at facilities and under conditions which have been shown to be safe and effective, and allow entry of new qualified providers. Although the criteria for experience, survival rates and facility commitment are somewhat demanding, we believe this approach is justified, particularly in view of the typical relationship between experience and quality of service.

VII. Waiver of 30-Day Delay in Effective Date

In the proposed notice published on March 8, 1990, we proposed to permit coverage of adult liver transplants as early as the date of publication of the proposed notice (that is, March 8, 1990). If a facility applies within 90 days of the date of publication of this notice and is accepted on the basis of that application, coverage may be effective as early as March 8, 1990 (the date of the proposed notice) or the date upon which the facility is found to have met the conditions, whichever occurred later. Coverage for liver transplants performed at a facility applying after the 90-day timeframe will begin on the date we approve its application.

VIII. Paperwork Burden

This notice contains information collection requirements that are subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Specifically, facilities that wish to obtain approval for Medicare coverage of liver transplantation are required to submit an application and documentation pertinent to liver transplantations. Public reporting burden for this collection of information is expected to be 100 hours.

A notice will be published in the **Federal Register** after approval is obtained. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron, HCFA Desk Officer.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance Program)

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

Dated: January 14, 1991.

Gail Wilensky,

Administrator, Health Care Financing Administration.

Approved: March 26, 1991.

Louis W. Sullivan,

Secretary.

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