Office by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings shall be open to the public and, if possible, notices of the meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each public meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernment relations, Surface mining, Underground mining.

Dated: March 10, 1995.

Richard J. Seibel,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 95–6591 Filed 3–16–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA28

[DOD 6010.8–R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Transplants

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This rule proposes to establish coverage for heart-lung, single or double lung, and combined liver-kidney transplantation for those patients who meet specific patient selection criteria; establish preauthorization requirements for heart, liver, heart-lung, single or double lung, combined liver-kidney transplantation, high dose chemotherapy and stem cell transplantation, and air ambulance (in conjunction with lung or heart-lung transplantation preauthorizations); extend coverage of cardiac rehabilitation to those patients who have had heart valve surgery, heart or heart-lung transplantation, authorize an exception to the ambulance benefit to allow organ transplantation candidates to be transported to a certified CHAMPUS organ transplant center instead of the closest appropriate facility, and authorize pulmonary rehabilitation for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Director, OCHAMPUS, or a designee, recognize certain transplant centers that meet specific criteria as an authorized CHAMPUS institutional provider, and clarify the CHAMPUS position on consortium programs for organ transplantation to allow individual hospitals which are members of a consortium to use the combined (pooled) experience and survival data of the consortium team to meet CHAMPUS requirements for authorization as a certified CHAMPUS organ transplant center.

DATES: Comments must be received on or before May 16, 1995.

ADDRESSES: All comments concerning this proposed rule should be addressed to the Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Program Development Branch, Aurora, CO 80045–6900.

FOR FURTHER INFORMATION CONTACT: Marty Maxey, OCHAMPUS, Program Development Branch, telephone (303) 361–1227.

SUPPLEMENTARY INFORMATION: OCHAMPUS has been actively following the development of organ transplantation for the past 10 years to define an established method of treatment for patients who have exhausted more conservative medical and surgical treatments. Following is an overview of the events which have led to the decision to allow CHAMPUS coverage for heart-lung, single or double lung, and combined liver-kidney transplantation:

- In November 1990, OCHAMPUS requested the Agency for Health Care Policy and Research (AHCPR) to conduct a technology assessment on the safety and efficacy of heart-lung and single or double lung transplantation. In response to our request, AHCPR informed OCHAMPUS that an assessment was already in progress as a result of a request by the Health Care Financing Administration (HCFA).

Because of an increase in demand for heart-lung and single or double lung transplantation by the CHAMPUS beneficiary population, OCHAMPUS urged AHCPR to provide preliminary interim guidelines for heart-lung and single or double lung transplantation which could be used until finalization of their formal technology assessment. In response to this request, AHCPR asked the National Heart Lung and Blood Institute (NHLBI) to assist in the development of interim guidelines. On February 28, 1991, NHLBI completed the AHCPR request for preliminary

interim guidelines on heart-lung and single or double lung transplantation.

• In September 1992, CHAMPUS requested the AHCPR to conduct a technology assessment regarding the safety and efficacy of combined liver-kidney transplantation. The AHCPR technology assessment was completed on November 12, 1992. The findings of the AHCPR assessment indicated that combined liver-kidney transplantation is an effective intervention in improving survival in patients with end-stage renal and hepatic disease.

• By August 1993, AHCPR finalized the formal technology assessment on both heart-lung and single or double lung transplantation for HCFA and forwarded a copy to OCHAMPUS. The AHCPR assessments indicated that heart-lung and single or double lung transplantations were safe and effective treatment for patients meeting specific clinical criteria when performed by institutions having demonstrated certain levels of experience and success. The patient selection and institutional criteria recommended by the AHCPR technology assessments were very similar to the interim guidelines developed by NHLBI in February 1991.

Due to the Presidential moratorium on publication of regulations, OCHAMPUS decided to proceed without rulemaking and to implement the recommendations of the interim guidelines for heart-lung and single or double lung transplantations from NHLBI and the final recommendations from AHCPR for combined liver-kidney transplantation to meet the increasing needs of the CAMPUS beneficiary population for coverage of these procedures. OCHAMPUS established effective dates of coverage based on NHLBI and AHCPR reports. OCHAMPUS adopted the following beginning dates of coverage for:

• Combined liver-kidney transplantation on November 12, 1992.

• Heart-lung and single or double lung transplantations on February 28, 1991. However, CHAMPUS would consider retroactive coverage for any heart-lung; single or double lung transplantation performed at a facility which met the interim criteria established by NHLBI for both patient selection and facility certification criteria.

OCHAMPUS is publishing this proposed rule to formally notify the public of the specific CHAMPUS requirements for coverage of benefits for heart-long, single or double lung and combined liver-kidney transplantations to include related services and supplies such as air ambulance in certain circumstances when determined to be medically necessary.

This proposed rule also authorizes cardiac rehabilitation following heart valve surgery, heart and heart-lung transplantation, and pulmonary rehabilitation for beneficiaries who conditions are considered appropriate according to guidelines that will be implemented by the Director, OCHAMPUS, or a designee.

In addition, this proposed rule outlines the specific requirements for providers who wish to be certified as a CHAMPUS approved organ transplant center including requirements for consortia programs. CHAMPUS recognizes that many facilities performing organ transplantations (particularly pediatric hospitals) are not able to meet CHAMPUS standards for certification as an authorized transplant center. However, CHAMPUS will allow facilities not able to meet the standards to qualify as a CHAMPUS authorized transplant center when they belong to a consortium program whose combined experience and survival data meet the CHAMPUS criteria for qualifying as a certified CHAMPUS organ transplant center.

The specified definitions and procedures outlined in the rule for facilities to use in calculating survival rates for transplantation use a simpler format but are indential to those published by HCFA (52 FR 10947, April 6, 1987).

At this time, OCHAMPUS, wishing to protect beneficiaries from incurring out-of-pocket expenses as a result of noncovered care related to organ transplantation and to ensure the prudent expenditure of public funds, is proposing to require transplantation preauthorization for high dose chemotherapy and stem cell transplantation, all initial and retransplanted organs, except kidney and cornea, and preauthorization for air ambulance for heart-lung and single or double lung transplantation. The preauthorization requirement will protect both the beneficiary and the provider.

Regulatory Procedures

OMB has determined that this is not a significant rule as defined by Executive Order 12866.

The Regulatory Flexibility Act (RFA) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues regulations which would have a significant impact on a substantial number of small entities.

This proposed rule will not involve any significant burden on OCHAMPUS beneficiaries or providers. Based on national statistics for heart-lung, single or double lung and combined liver-kidney transplantation, it is estimated that .005% or less of the 6 million CHAMPUS user population, will require a heart-lung, single or double lung, or a combined liver-kidney transplantation. The proposed rule will broaden the scope of CHAMPUS benefits while protecting the beneficiaries and providers from incurring additional costs.

This rule represents an expansion of benefits under the CHAMPUS program, resulting in facility certification of transplant centers and narrative summaries for evaluation and assessment for preauthorization of transplantations. These transplant centers are accustomed to the proposed reporting requirements and would not review this as an administrative intrusion. Based on the above rationale, it is felt that proposed reporting requirements would not need to be reviewed by the Executive Office of Management and Budget under authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance, Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 is proposed to be revised to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.4 is proposed to be amended by revising paragraphs (d)(3)(v)(B), (d)(3)(v)(D), and (e)(5) and by adding paragraphs (d)(3)(v)(E), (e)(18)(i)(F), (e)(18)(i)(G), and (e)(20) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(v) * * *

(B) Ambulance service cannot be used instead of taxi service and is not payable when the patient's condition would have permitted use of regular private transportation; nor is it payable when transport or transfer of a patient is primarily for the purpose of having the patient nearer to home, family, friends, or personal physician. Except as described in paragraph (d)(3)(v)(A) and (d)(3)(v)(E) of this section transport

must be to the closest appropriate facility by the least costly means.

* * * * *

(D) Except as described in paragraph (d)(3)(v)(E) of this section ambulance service by other than land vehicles (such as a boat or airplane) may be considered only when the pickup point is inaccessible by a land vehicle, or when great distance or other obstacles are involved in transporting the patient to the nearest hospital with appropriate facilities and the patient's medical condition warrants speedy admission or is such that transfer by other means is contraindicated.

(E) (*i*) Advanced life support air ambulance and certified advanced life support attendant are covered services for heart-lung; single or double lung transplantation candidates and may be preauthorized in conjunction with the preauthorization for the transplantation. Air ambulance transport for organ transplantation candidates other than heart-lung; single or double lung transplantation may be covered if determined to be medically necessary.

(*ii*) Advanced life support air ambulance and certified advanced life support attendant shall be reimbursed subject to standard reimbursement methodologies.

* * * * *

(e) * * *

(5) *Organ transplanation*—(i) *General.* (A) CHAMPUS may cost-share medically necessary services and supplies related to organ transplants for:

(*1*) Evaluation of a potential candidate's suitability for organ transplant, whether or not the patient is ultimately accepted as a candidate for transplant.

(*2*) Pre- and post-transplant inpatient hospital and outpatient services.

(*3*) Pre- and post-operative services of the transplant team.

(*4*) Blood and blood products.

(*5*) FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the general medical community, (i.e., non-investigational).

(*6*) Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

(*7*) Periodic evaluation and assessment of the successfully transplanted patient.

(*8*) The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplant center.

(*9*) The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

(B) CHAMPUS benefits are payable for recipient costs when the recipient of the transplant is a beneficiary, whether or not the donor is a beneficiary.

(C) Donor costs are payable when:

(*1*) Both the donor and recipient are CHAMPUS beneficiaries.

(*2*) The donor is a CHAMPUS beneficiary but the recipient is not.

(*3*) The donor is the sponsor and the recipient is a beneficiary. (In such an event, donor costs are paid as a part of the beneficiary and recipient costs.)

(*4*) The donor is neither a CHAMPUS beneficiary nor a sponsor, if the recipient is a CHAMPUS beneficiary. (Again, in such an event, donor costs are paid as a part of the beneficiary and recipient costs.)

(D) If the donor is not a beneficiary, CHAMPUS benefits for donor costs are limited to those directly related to the transplant procedure itself and do not include any medical care costs related to other treatment of the donor, including complications.

(E) CHAMPUS benefits will not be allowed for:

(*1*) Expenses waived by the transplant center.

(*2*) Services and supplies not provided in accordance with applicable program criteria.

(*3*) Administration of an experimental or investigational immunosuppressant drug that is not FDA approved.

(*4*) Pre- or post-transplant nonmedical expenses.

(*5*) Transportation of an organ donor.

(ii) *Preauthorization requirements.* The Director, OCHAMPUS, or a designee, is the preauthorizing authority for stem cell transplantation and all initial and retransplanted solid organs, except kidney and corneal. Preauthorization approval for stem cell, solid organ transplantations, and transportation by air ambulance (for lung or heart-lung transplantation patients) shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth herein, or until the approved transplant occurs.

(iii) *Kidney transplantation.* (A) With specific reference to acquisition costs for kidneys, each hospital that performs kidney transplantations is required for Medicare purposes to develop for each year separate standard acquisition costs for kidneys obtained from live donors and kidneys obtained from cadavers. The standard acquisition costs for cadaver kidneys is compiled by dividing the total cost of cadaver kidneys acquired by the number of transplantations using cadaver kidneys. The standard acquisition cost for kidneys from live donors is compiled similarly using the total acquisition cost of kidneys from live donors and the number of transplantations using kidneys from live donors. All recipients of cadaver kidneys are charged the same standard cadaver kidney acquisition cost and all recipients of kidneys from live donors are charged the same standard live donor acquisition cost. The appropriate hospital standard kidney acquisition costs (live donor or cadaver) required for Medicare in every instance must be used as the acquisition cost for purposes of providing CHAMPUS benefits.

(B) In most instances for costs related to kidney transplantation, Medicare (not CHAMPUS) benefits will be applicable. If a CHAMPUS beneficiary participates as a kidney donor for a Medicare beneficiary, Medicare will pay for expenses in connection with the kidney transplantation to include all reasonable preparatory, operation and postoperation recovery expenses associated with the donation (postoperative recovery expenses are limited to the actual period of recovery). (Refer to § 199.3(e)(3)(vi), ''Eligibility.'')

(iv) *Liver transplantation.*—(A) *Patient selection criteria.* On July 1, 1983, CHAMPUS benefits are payable for liver transplantation for beneficiaries who:

(*1*) Are suffering from an irreversible liver process; and,

(*2*) Have exhausted more conservative medical and surgical treatments; and,

(*3*) Are approaching the terminal phase of their illness (e.g., death is imminent, irreversible damage to the central nervous system is inevitable, or the quality of life has deteriorated to unacceptable levels), and

(*4*) Are considered appropriate for liver transplantation according to guidelines adopted by the Director, OCHAMPUS.

(B) *Contraindications.* CHAMPUS shall not provide coverage for liver transplantation when any of the following contraindications exist;

(*1*) Significant systemic or multisystemic disease (other than hepatic failure) which limits the possibility of full recovery and may compromise the function of the newly transplanted organ.

(*2*) Active alcohol or other substance abuse.

(*3*) Malignancies metastasized to or extending beyond the margins of the liver; or

(*4*) Life threatening or uncontrollable abdominal or systemic sepsis.

(v) *Combined liver-kidney transplantation*—(A) *Patient selection criteria.* On November 12, 1992, CHAMPUS benefits are payable for combined liver-kidney transplantation for beneficiaries who:

(*1*) Are suffering from concomitant, irreversible hepatic and renal failure; and

(*2*) Have exhausted more conservative medical and surgical treatments for hepatic and renal failure; and

(*3*) Have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic; and

(*4*) Are considered appropriate for combined liver-kidney transplantation according to guidelines adopted by the Director, OCHAMPUS.

(B) *Contraindications.* CHAMPUS shall not provide coverage for combined liver-kidney transplantation when any of the following contraindications exist:

(*1*) Significant systemic or multisystemic disease (other than hepatorenal failure) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

(*2*) Active alcohol or other substance abuse.

(*3*) Malignancies metastasized to or extending beyond the margins of the liver and/or kidney.

(*4*) Life threatening or uncontrollable abdominal or systemic sepsis.

(vi) *Heart transplantation: Patient selection criteria.* On November 7, 1986, CHAMPUS benefits are payable for heart transplantation for beneficiaries who:

(A) Have an end-stage cardiac disease which has not responded to or no longer responds to other appropriate medical and surgical therapies which might be expected to yield both short- and long-term (3 to 5 year) survival comparable to that of heart transplantation; and

(B) Have a very poor prognosis as a result of poor cardiac functional status (e.g., less than a 25 percent likelihood of survival for six months); and

(C) Have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

(D) Are considered appropriate for heart transplantation according to guidelines adopted by the director, OCHAMPUS.

(vii) *Heart-lung and lung transplantation: Patient selection criteria.* On February 28, 1991, CHAMPUS benefits are payable for heart-lung and lung transplantation for beneficiaries who:

(A) Have irreversible, progressively disabling, end-stage pulmonary or cardiopulmonary disease (for example, less than a 50 percent likelihood of survival for 8 months). Prognosis otherwise must be good for both survival and rehabilitation.

(B) Have tried or considered all other medical and surgical therapies that might have been expected to yield both short- and long-term survival comparable to that of transplantation.

(C) Have a realistic understanding of the range of clinical outcomes that may be encountered.

(D) Have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

(E) Are considered appropriate for heart-lung or lung transplantation according to guidelines adopted by the Director, OCHAMPUS.

(viii) *High dose chemotherapy and stem cell transplantation.* CHAMPUS benefits are payable for beneficiaries whose conditions are considered appropriate for high dose chemotherapy and stem cell transplantation according to guidelines adopted by the Director, OCHAMPUS, or a designee.

* * * * *

(18) * * *

(i) * * *

(F) Heart valve surgery.

(G) Heart or Heart-lung Transplantation.

* * * * *

(20) *Pulmonary rehabilitation.* CHAMPUS benefits are payable for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Director, OCHAMPUS, or a designee.

* * * * *

3. Section 199.6 is proposed to be amended by revising paragraph (b)(4)(ii), by removing paragraph (b)(4)(iii); and redesignating paragraphs (b)(4)(iv) through (b)(4)(xiv) as (b)(4)(iii) through (b)(4)(xiii) to read as follows:

§ 199.6 Authorized providers.

* * * * *

(b) * * *

(4) * * *

(ii) *Organ transplant centers*—(A) *Certification requirements.* To obtain CHAMPUS approval as an organ transplant center, the center must have:

(*1*) An active solid organ transplant program.

(*2*) Participation in a donor organ procurement program and network.

(*3*) An interdisciplinary team to determine the suitability of candidates for transplantation on an equitable basis.

(*4*) An anesthesia team that is available at all times.

(*5*) A nursing service team trained in the hemodynamic support of the patient and in managing immunosuppressed patients.

(*6*) Pathology and immunology resources that are available for studying and reporting the pathological responses to transplantation.

(*7*) Evidence that the center safeguards the rights and privacy of patients.

(*8*) Continual compliance with State transplantation laws and regulations, if any.

(*9*) Legal counsel familiar with transplantation laws and regulations.

(B) *Administrative requirement.* A CHAMPUS authorized organ transplant center must provide a written statement to the certifying authority agreeing to the following administrative requirements:

(*1*) Bill for all services and supplies related to the organ transplantation performed by its staff and bill for services rendered by the donor hospital after all existing legal requirements for excision of the donor organ are met.

(*2*) Bill all donor services in the name of the CHAMPUS patient.

(C) *Reporting requirements.* The transplant center must report to the certifying authority any decrease in actuarial survival rates below the actuarial survival rate established by CHAMPUS for initial facility certification.

(D) *Liver transplant centers.* CHAMPUS shall provide coverage for liver transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions in paragraph (b)(4)(ii)(A) of this section. The transplant center must:

(*1*) Have board eligible or board certified physicians and other experts in the fields of hepatology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, and anesthesiology to complement a qualified transplant team.

(*2*) Have a transplant surgeon that is specifically trained for liver grafting who can assemble and train a team to function successfully whenever a donor liver is available.

(*3*) Have at least a 70 percent one year actuarial survival rate for 10 cases as calculated using the Kaplan-Meier product limit method. At least a 70 percent one year actuarial survival rate for all subsequent liver transplants must be maintained for continued CHAMPUS approval.

(E) *Heart transplant centers.* CHAMPUS shall provide coverage for heart transplantation procedures performed only by experienced

transplant procedures performed only by experienced transplant surgeons at centers complying with provisions in paragraph (b)(4)(ii)(A) of this section. The transplant center must:

(*1*) Have experts in the fields of cardiology, cardiovascular surgery, anesthesiology, immunology, infectious disease, nursing, social services, and organ procurement to complement the transplant team.

(*2*) Have an active cardiovascular medical and surgical program as evidenced by a minimum of 500 cardiac catheterization and coronary arteriograms and 250 open heart procedures per year.

(*3*) Have an established heart transplant program with documented evidence of 12 or more heart transplants in each of the three consecutive preceding 12-month periods prior to the date of application (a total of 36 or more heart transplant procedures).

(*4*) 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. The Kaplan-Meier product limit method shall be used to calculate actuarial survival.

(*5*) CHAMPUS approval will lapse if either the number of heart transplants falls below 8 in 12 months or if the one-year actuarial survival rate falls below 60 percent for a consecutive 24-month period.

(F) *Lung transplant.* This policy applies only to those centers seeking CHAMPUS certification for lung transplantation only. Centers seeking CHAMPUS certification as heart-lung transplant centers must meet additional requirements outlined in paragraph (b)(4)(ii)(H) of this section.

(*1*) CHAMPUS shall provide coverage for lung transplant procedures performed only be experienced transplant surgeons at centers complying with the provisions outlined in paragraph (b)(4)(ii)(A) of this section, and meeting the following criteria:

(*2*) The center must have:

(*i*) Experts in the fields of cardiology, cardiovascular surgery, pulmonary disease, anesthesiology, immunology, infectious disease, nursing, social services, and organ procurement to complement the transplant team.

(*ii*) Performed lung (single and/or double) transplantation in at least 10 patients within the 12 months prior to application and in at least an additional 10 patients prior thereto.

(*iii*) Demonstrated Kaplan-Meier actuarial survival rates of no less than 65 percent at one-year post-transplant for patients who have undergone a lung transplantation at the center since January 1, 1987.

(G) *Heart-Lung and lung transplant.* CHAMPUS shall provide coverage for heart-lung transplantation procedures performed only by experienced transplant surgeons at centers complying with the provisions outlined in paragraph (b)(4)(ii)(A) of this section, and meeting the following criteria:

(*1*) The institutional and team experience shall be based upon all lung and heart-lung transplantations performed since January 1, 1987, both for transplant experience and actuarial survival rates.

(*2*) To be accepted for lung transplantation (single and/or double), an institution and team must have:

(*i*) Performed lung and/or heart-lung transplantation in at least 10 patients within the 12 months prior to application and in at least an additional 10 patients prior thereto, and

(*ii*) Achieved a documented Kaplan-Meier actuarial survival rate of no less than 65 percent at one-year.

(*iii*) Fulfilled existing facility certification criteria for heart transplantation (either Medicare or CHAMPUS); or fulfilled the CHAMPUS facility certification criteria for facilities applying only for lung transplantation as outlined in paragraph (b)(4)(ii)(G) of this section.

(*3*) To be accepted for heart-lung transplantation, an institution and team must fulfill the CHAMPUS facility certification criteria for lung transplantation and the existing facility certification criteria (either Medicare of CHAMPUS) for heart transplantation.

(*H*) *Calculation of survival rates for transplantation.* Each facility seeking CHAMPUS certification as a transplant center must calculate survival rates using the Kaplan-Meier (product-limit) technique utilizing the definitions and rules below. Each applicant facility must identify its Kaplan-Meier actuarial survival percentage at one year. Heart transplant facilities must also identify its Kaplan-Meier actuarial survival percentage at two year point. Each applicant facility must also submit calculations to support the reported actuarial survival percentage.

(*1*) Each applicant facility will report all transplantation experience from its inception at the facility, unless this section otherwise prescribes a starting date for the reporting of specific transplantation experience.

(*2*) CHAMPUS recognizes the team experience gained in retransplantation. Therefore, retransplantation experience must be reported and calculated in the same manner as first transplantation experience.

(*3*) All experience and survival rates must be reported as of a point in time that is no more than 90 days prior to the submission of the application for CHAMPUS certification. That date is referred to as the fiducial date.

(*4*) Calculations assume survival only to (and censoring on) the date of last ascertained survival.

(*5*) Patients who are not thought to be dead are considered ''lost to follow-up'' if they were:

(*i*) Operated more than 120 days before the fiducial date, but have no ascertained survival within 60 days of the fiducial date; or

(*ii*) Operated from 61 to 120 days before the fiducial date, but ascertained survival is less than 60 days from date of transplantation; or

(*iii*) Operated within 60 days of the fiducial date, but not ascertained to have survived as of the fiducial date.

(*6*) Survival must be calculated with the assumption that each patient in the ''lost to follow-up'' category died on or one day after the date of last ascertained survival.

(*7*) Clearly defined and well justified secondary or alternate treatment of ''lost to follow-up'' may also be submitted, but primary attention will be given to the results using definitions and procedures specified above.

(*8*) Facilities seeking certification for lung and/or heart-lung transplantation must report all lung and heart-lung transplantation experience beginning January 1, 1987. When facility experience is reported and the actuarial survival is calculated, lung and heart-lung transplantation experience must be combined to arrive at a single one year survival percentage.

(I) *Combined liver-kidney transplants.* If the facility is authorized as a CHAMPUS (or Medicare) approved liver transplant center as outlined in paragraphs (b)(4)(ii)(B) and (b)(4)(ii)(E) of this section, the facility may be considered to be a CHAMPUS approved center to perform combined liver-kidney transplantations.

(J) *Organ transplant consortia.* CHAMPUS shall approve individual organ transplant centers which meet the above provisions in paragraph (b)(4)(ii)(B) of this section, and would otherwise qualify as a CHAMPUS-authorized transplant center by:

(*1*) Using the combined experience and actuarial survival data of a consortium of which a single transplant team rotates among member hospitals for purposes of meeting the certification requirements outlined in paragraphs (b)(4)(ii)(E), (b)(4)(ii)(F), (b)(4)(ii)(G), (b)(4)(ii)(H), and (b)(4)(ii)(I) of this

section, for liver, heart, lung, heart-lung and combined liver-kidney when,

(*i*) The hospitals are under common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute;

(*ii*) The hospitals share resources by using the same personnel or services in their transplant programs. The individual physician members of the transplant team practice in all of the hospitals;

(*iii*) The same organ procurement organization, immunology, and tissue typing services are used by all the hospitals; and

(*iv*) The hospital submits its individual and combined experience and survival data to the CHAMPUS authorizing authority, and

(*v*) If one of the hospitals is a pediatric transplant program, in addition to the requirements previously listed the following apply;

(*A*) Although pediatric surgeons and pathologists are not required to practice in the adult hospital and vice versa, it can be documented that they otherwise function as members of the transplant team.

(*B*) The facility must have other solid organ transplant program(s) that meet CHAMPUS criteria for certification based on actuarial survival rates and experience.

(*C*) The surgeon responsible for the transplant is commonly involved in the type of surgery (i.e., related to hepatology, cardiology and pulmonary medicine) with children of the age and size in whom the transplant is being performed, and

(*D*) If the program involves heart transplant, the facility must have an active pediatric cardiovascular medical and surgical program with a minimum of 150 cardiac catheterizations performed per year on patients in the pediatric range. A surgical case load of 200 operations per year should be performed in combined adult and pediatric programs: Of these, at least 100 operation per year (three of four should use extracorporeal circulation) should be on pediatric patients. In programs serving only a pediatric population, at least 100 cardiac surgical procedures (three of four should use extracorporeal circulation) should be performed per year.

* * * * *

4. Section 199.7 is proposed to be amended by revising paragraph (f)(1)(ii) to read as follows:

§ 199.7 Claims submission, review, and payment.

* * * * *

(f) * * *

(1) * * *

(ii) *Time limit on preauthorization.* Approved preauthorizations are valid for specific periods of time, appropriate for the circumstances presented and specified at the time the preauthorization is approved. In general, preauthorizations are valid for 30 days. If the preauthorized service or supplies are not obtained or commenced within the specified time limit, a new preauthorization is required before benefits may be extended. Special rules apply for organ, stem cell transplantation, and air ambulance (in conjunction with lung or heart-lung transplantation preauthorizations) (refer to § 199.4(e)(5)(ii)).

* * * * *

5. Section 199.15 is proposed to be amended by revising paragraph (b)(4)(ii)(C) to read as follows:

§ 199.15 Quality and utilization review peer review organization program.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(C) An approved preauthorization shall state the number of days, appropriate for the type of care involved, for which it is valid. In general, preauthorizations will be valid for 30 days. If the services or supplies are not obtained within the number of days specified, a new preauthorization request is required. Special rules apply for organ, stem cell transplantation, and air ambulance (in conjunction with lung or heart-lung transplantation preauthorizations (refer to § 199.4(e)(5)(ii)).

* * * * *

Dated: March 13, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–6561 Filed 3–16–95; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 18

RIN 1018–AD21

Marine Mammals; Incidental Take During Specified Activities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Fish and Wildlife Service (Service) hereby proposes to extend for an additional 42 months through December 15, 1998, the effectiveness of the final regulations that authorize and govern the incidental, unintentional take of small numbers of polar bear and walrus during year-round oil and gas industry operations (exploration, development, and production) in the Beaufort Sea and adjacent northern coast of Alaska.

DATES: Comments on this proposed rule must be received by May 16, 1995.

ADDRESSES: Written comments should be submitted by mail to Supervisor, Office of Marine Mammals Management, Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, AK 99503. Comments may also be hand delivered to the same address during normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday, or sent by FAX to 907/786–3816. Comments and materials received in response to this proposed action will be available for public inspection at this address during the normal working hours identified above.

FOR FURTHER INFORMATION CONTACT: Dave McGillivary, Supervisor, Office of Marine Mammals Management, Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, AK 99503, 907/786–3800, or Jeff Horwath, in the Service's Division of Fish and Wildlife Management Assistance, Arlington, Virginia, at 703/358–1718.

SUPPLEMENTARY INFORMATION: Under provisions of section 101(a)(5)(A) of the Marine Mammal Protection Act of 1972, as amended (MMPA), the taking of small numbers of marine mammals may be allowed incidental to specified activities other than commercial fishing if the Director of the Service finds, based on the best available scientific evidence available, that the cumulative total of such taking over a 5-year period will have a negligible effect on these species and will not have an unmitigable adverse impact on the availability of these species for subsistence uses by Alaskan Natives. If these findings are made, the Service is required to establish specific regulations for the activity that set forth: Permissible methods of taking; means of effecting the least practicable adverse impact on the species and their habitat and on the availability of the species for subsistence uses; and requirements for monitoring and reporting.

On December 17, 1991, BP Exploration (Alaska), Inc., for itself and on behalf of 14 other energy related entities (hereafter collectively referred to as ''Industry'') petitioned the Service