Substances	Limitations
* * * * *	
Dimethylamine-epichlorohydrin resin: Complying with § 173.60(a) and (b) of this chapter.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
* * * * *	

* * * * *

Dated: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–15901 Filed 6–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Akey, Inc.

DATES: This rule is effective June 25, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Akey, Inc., P.O. Box 607, Lewisburg, OH 45338, has informed FDA of a change of name and address to North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Akey, Inc.'' and by alphabetically adding a new entry for ''North American Nutrition Companies, Inc.'', and in the table in paragraph (c)(2) by revising the entry for ''017790'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338	017790
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
017790	North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338
* * * * * * *	

Dated: May 24, 2002.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–15900 Filed 6–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA28

TRICARE; Revisions to Coverage Criteria for Transplants, Cardiac and Pulmonary Rehabilitation and Ambulance Services

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule implements a number of regulatory revisions relating to TRICARE coverage for transplants and related services, cardiac and pulmonary rehabilitation and ambulance services. The revisions are clarification of TRICARE coverage and time limitations on preauthorizations for solid organ and stem cell transplantation for beneficiaries whose conditions are considered appropriate

for transplantation according to guidelines adopted by the Executive Director, Tricare Management Activity (TMA), or a designee; clarification of TRICARE coverage for ambulance service for organ and stem cell transplant candidates; recognition of certain transplant centers as authorized TRICARE institutional providers according to provisions adopted by the Executive Director, TMA, or a designee; clarification of pediatric consortium programs for organ transplantation according to provisions adopted by the Executive Director, TMA, or a designee; extension of coverage for cardiac rehabilitation for those patients who have had heart valve surgery, heart or heart-lung transplantation; establishment of coverage for pulmonary rehabilitation for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Executive Director, TMA, or a designee; and elimination of payment restrictions for MTF ordered ambulance transfers.

DATES: This final rule is effective July 25, 2002, except 199.4 (e)(18)(i)(F) and (e)(18)(i)(G) are effective December 1, 1991.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Marty Maxey, Medical Benefits and Reimbursement Systems, telephone (303) 676–3627.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

In the **Federal Register** of March 17, 1995 (60 FR 14403), the Office of the Secretary of Defense published for public comment a proposed rule regarding a number of changes relating to organ transplants. We received comments from government agencies that by law CHAMPUS is required to consult with during the rule making process. Following is a summary of the changes included in the proposed rule, an analysis of the comments received and provisions of the final rule.

II. Provisions of the Rule

A. Proposed Changes to Organ Transplantation

1. Coverage for Heart-Lung, Single or Double Lung, and Combined Liver-Kidney Transplantation

Provisions of the Proposed Rule. The proposed rule established coverage for heart-lung, single or double lung and combined liver-kidney transplantation. Section 199.4, paragraph (e)(5) of 32 CFR allows Basic Program benefits to be extended for otherwise covered services or supplies in connection with an organ transplant procedure, provided such transplant procedure generally is in accordance with accepted professional medical standards and is not considered to be experimental or investigational. Based on recommendations from the National Heart Lung and Blood Institute (NHLBI) on heart-lung, single and double lung transplantation and technology assessments from the Agency for Health Care Policy and Research (AHCPR) on heart-lung, single and double lung transplantation and combined liver-kidney transplantation, TRICARE determined it could no longer deny coverage for these transplant procedures as investigational since safety, efficacy and superiority to conventional treatments had been established.

Analysis of Major Public Comments. Several commentors brought to our attention that we incorrectly stated HCFA, renamed the Centers for Medicare and Medicaid Services (CMS), requested the Agency for Health Care Policy and Research (AHCPR) to perform assessments on lung and heart-lung transplantation when it was the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), renamed TRICARE Management Activity, who initiated the requests.

Response: It is hereby noted the commentor's statements are correct.

In the preamble of the proposed rule, we stated 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. A commentor from AHCPR indicated the language should be changed to read: ''The findings of the AHCPR assessment indicated that the combined liver-kidney transplantation may be an effective intervention in improving survival in patients with end-stage renal and hepatic disease, but also discussed that factors related to patient selection and institutional criteria must be considered.''

Response: Although the preamble language of the proposed rule is not included in the final rule, we concur with the comment and note it accordingly.

One commentor felt the proposed rule language regarding liver transplantation coverage for primary liver tumors should be more explicit.

Response: As stated below in the Provisions of the Final Rule, all covered transplant procedures and the patient selection criteria has more appropriately been placed in the TRICARE/CHAMPUS Policy Manual. The information in the TRICARE/CHAMPUS Policy Manual is more explicit than that contained in 32 CFR part 199. The TRICARE/CHAMPUS Policy Manual can be accessed through TRICARE's Web site at *www.tricare.osd.mil.*

A commentor suggested we ask CMS, formerly HCFA, to describe its method of calculating and charging acquisition costs for kidneys because the proposed rule incorrectly states that all kidney recipients pay the ''same standard'' costs.

Response: We contacted CMS, formerly HCFA, and were advised the information regarding kidney acquisition costs is correct. The proposed regulatory language did state standard acquisition costs for live donors is different than that of cadavers.

A commentor believed the transportation cost of a living donor should be considered a TRICARE benefit.

Response: Transportation except by ambulance is specifically excluded under paragraph 199.4(g)(67).

One commentor questioned whether the effective date of July 1, 1983, for liver transplantation is correct.

Response: The July 1, 1983, date is correct.

Another commentor asked whether denying coverage for liver transplantation for those patients with ''active alcohol and other substance abuse'' preclude paying for a liver transplantation for someone with alcoholic cirrhosis? The same question was applied to combined liver-kidney transplantation.

Response: Coverage may be allowed if the patient has documented abstinence prior to transplantation and there is no evidence of other major organ debility. In addition, there must be evidence of ongoing participation in a social support group such as Alcoholics Anonymous; and evidence of a supportive family/social environment. These criteria are detailed in the TRICARE/CHAMPUS Policy Manual and can be accessed through TRICARE's Web site at www.tricare.osd.mil.

Several commentors suggested changing the phrase ''medically necessary and generally accepted practice . . .'' to terms such as ''medically necessary because it represents generally accepted practice . . .'' or ''reasonable and necessary.'' It was also suggested the term ''non-investigational,'' was confusing and should not be used.

Response: The phrase ''medically necessary and generally accepted practice . . .'' has been changed to read ''. . . medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.'' The term ''non-investigational'' has been removed.

Provisions of the Final Rule. When the CHAMPUS final rules on Liver and Heart Transplants were published in 1986, the science of solid organ transplants was relatively new, therefore, detailed guidelines for these transplants were published in paragraph 199.4 (e)(5). The purpose of the Code of Federal Regulations is to provide broad guidelines and policies; the publishing of detailed guidelines in paragraphs 199.4 (e)(5)(v) and (e)(5)(vi) for liver and heart transplants has proved difficult to maintain. For example, one of the contraindications listed in paragraph 199.4 (e)(5)(v)(B) for liver transplants is viral-induced liver disease when viremia is still present. Recent studies show liver transplants for patients with end-stage liver failure resulting from hepatitis B and C is safe, effective and comparable to standard treatment.

Many transplant procedures are no longer considered unproven and are covered under TRICARE. To assist our beneficiaries in obtaining coverage for new transplant procedures in a timely manner, detailed policy and patient selection criteria for each covered transplant has more appropriately been placed in the TRICARE/CHAMPUS Policy Manual. The TRICARE/CHAMPUS Policy Manual contains operational policy necessary to efficiently implement 32 CFR part 199. The TRICARE/CHAMPUS Policy Manual augments 32 CFR part 199 and must be used in conjunction with the CFR for complete policy information. The TRICARE/CHAMPUS Policy Manual can be accessed through TRICARE's Web site at *www.tricare.osd.mil.*

Paragraph (e)(5) continues to allow Basic Program benefits to be extended for otherwise covered services or supplies in connection with an organ or stem cell transplant procedure, provided such transplant procedure generally is in accordance with accepted professional medical standards and is not considered unproven.

Since publication of the proposed rule, a final rule clarifying the exclusion of unproven drugs, devices and medical treatments and procedures was published in the **Federal Register** on January 6, 1997 (62 FR 625). The final rule adopted the use of the term ''unproven'' instead of investigational or experimental, therefore, we have replaced the terms investigational and experimental with the term unproven.

2. Time Limit on Preauthorization for Transplants

Provisions of the Proposed Rule: Wishing to protect beneficiaries and providers from significant financial risks as a result of noncovered care related to organ transplantation and to ensure the prudent expenditure of public funds, the proposed rule established preauthorization requirements for: (1) High dose chemotherapy and stem cell transplantation; (2) all initial and retransplanted solid organs, except kidney and cornea; and (3) advanced life support air ambulance and certified advanced life support attendant for lung or heart-lung candidates.

Analysis of Major Public Comments. One commentor expressed concern regarding the proposed preauthorization time requirement for organ transplants occur ''not fewer than two business days prior to the planned admission.''

Response: The reference to ''not fewer than two business days prior to the planned admission'' was removed prior to publication of the proposed rule in the **Federal Register**.

Provisions of the Final Rule: The paragraph on preauthorization requirements at Paragraph (e)(5)(ii) has been removed from the final rule, as preauthorization procedures are outlined in § 199.7 (f)(1)(ii) and § 199.15 (b)(4)(ii)(C).

3. Coverage of Cardiac Rehabilitation for Those Patients who have had Heart-Valve Surgery, Heart or Heart-Lung Transplantation

Provisions of the Proposed Rule. TRICARE coverage of cardiac rehabilitation for those patients who have had heart-valve surgery, heart or heart-lung transplantation is based on an assessment conducted by the AHCPR on ''Cardiac Rehabilitation Programs: Heart Transplant, Percutaneous Transluminal Coronary Angioplasty, and Heart Valve Surgery Patient'', establishing cardiac rehabilitation programs as safe and effective for these patients.

Analysis of Major Public Comments. One commentor suggested we make reference to AHCPR's assessment on cardiac rehabilitation programs if TMA, formerly OCHAMPUS, used the assessment in arriving at the decision to expand the cardiac rehabilitation benefit.

Response: It is hereby noted that TMA, formerly OCHAMPUS, did use the AHCPR's assessment in arriving at the decision to expand the cardiac rehabilitation benefit to include those patients who have had heart-valve surgery, heart or heart-lung transplantation.

Provisions of the Final Rule. The final rule is consistent with the proposed rule.

4. Recognizing Certain Transplant Centers as Authorized TRICARE Institutional Providers

Provisions of the Proposed Rule. The proposed rule outlined specific requirements for those institutional providers who wish to be certified as a TRICARE approved organ transplant center for heart-lung and single or double lung transplantation.

Analysis of Major Public Comments. One commentor questioned if there is a time period for which the liver transplant center should ''have at least a 70 percent one year actuarial survival rate . . .?'

Response: The transplant center should have a 70 percent actuarial survival rate based on the preceding 12-month period.

Provisions of the Final Rule: When the CHAMPUS final rules on Liver and Heart Transplants were published in 1986, there were not very many institutional providers performing these transplants, therefore, detailed procedures for qualifying as a CHAMPUS-approved heart or liver transplant center were published in 32 CFR, Section § 199.6 (b)(4)(ii) and (b)(4)(iii). As stated above, the purpose of the Code of Federal Regulations is to provide broad guidelines and policies; the publishing of detailed guidelines in § 199.6 (b)(4)(ii) and (b)(4)(iii) for heart and liver transplant centers has proved difficult to maintain. For example, the one year actuarial survival rate for liver transplants is currently over 70 percent, whereas § 199.6 (b)(4)(ii)(A)(*3*) states a liver transplant center must have at least a 50 percent one-year survival rate for ten cases. Publishing the required actuarial survival rates in the CFR does not allow the flexibility of easily updating the survival percentages as they improve, thus assuring our beneficiaries receive transplants at centers meeting the current actuarial survival rates. The certification requirements for transplant centers have more appropriately been placed in the TRICARE/CHAMPUS Policy Manual. The TRICARE/CHAMPUS Policy Manual contains operational policy necessary to efficiently implement the 32 CFR part 199. The TRICARE/CHAMPUS Policy Manual augments the 32 CFR part 199 and must be used in conjunction with the CFR for complete

policy information. The TRICARE/CHAMPUS Policy Manual can be accessed through TRICARE's Web site at *www.tricare.osd.mil.* § 199.6 (b)(4)(ii) provides broad policy guidelines for approving organ transplant centers.

5. Pediatric Consortium Program for Organ Transplantation

Provisions of the Proposed Rule: The proposed rule allows TRICARE to recognize pediatric facilities as authorized transplant centers when they belong to a pediatric consortium program whose combined experience and survival data meet the TRICARE criteria for qualifying as a certified TRICARE organ transplant center.

Analysis of Major Public Comment: Several commentors expressed concern about TRICARE's approach to consortium programs. One commentor asked us to explain the basis for differences between TRICARE and CMS, formerly HCFA, in our decision to certify as an authorized institutional provider those individual facilities that qualify only on the basis of combined experience and survival rates of a consortium. The commentor explained CMS, formerly HCFA, requires the individual facilities of a consortia meet these criteria separately.

Response: We failed to make clear in the language of the proposed rule that the consortium concept is being advocated on the part of pediatric transplantation centers. Our rationale for certifying individual pediatric facilities on the basis of combined experience and survival rates of a consortium is because pediatric facilities performing organ transplants are generally not able to meet TRICARE standards for certification as an authorized transplant center because of the number of transplants performed. Since TRICARE's beneficiary population is younger than Medicare's we needed to develop a process to recognize pediatric facilities as TRICARE authorized transplant centers.

Provisions of the Final Rule: As stated above, the certification requirements for transplant centers, including pediatric organ transplant centers have more appropriately been placed in the TRICARE/CHAMPUS Policy Manual. § 199.6 (b)(4)(iii) provides broad policy guidelines for approving individual pediatric organ transplant centers.

6. Exception to the Ambulance Benefit

Provisions of the Proposed Rule. The proposed rule allows an exception to the requirement that patients be transported to the closest appropriate facility when the patient is an organ transplantation candidate to be transported to a certified TRICARE organ transplant center.

Provisions of the Final Rule. Since publication of the proposed rule, military health care has undergone major reforms from a dual delivery system consisting of direct military treatment and civilian health care, to a fully integrated managed health care system; it is no longer appropriate to restrict coverage/payment of MTF ordered ambulance transfers. Based on this, the payment restrictions for MTF ordered ambulance transfers is being eliminated from the final rule language.

7. Coverage of Pulmonary Rehabilitation

Provisions of the Proposed Rule. The proposed rule extends coverage for pulmonary rehabilitation for beneficiaries whose conditions are considered appropriate according to guidelines adopted by the Executive Director, TMA, or a designee.

Provisions of the Final Rule. The final rule is consistent with the proposed rule.

8. Miscellaneous Provisions

Analysis of Major Comment: One commentor states CHAMPUS is not exempt from the Paperwork Reduction Act on the grounds that hospitals would not find the reporting intrusive. The commentor informs us the law allows no such exception.

Response: The commentor is correct. The TMA is aware of the Paperwork Reduction Act requirements. The Paperwork Reduction Act requirements do not apply in this case as the collection of information is standardized and will affect less than nine entities per year.

III. Regulatory Procedures

Executive Order 12866 requires that a regulatory impact analysis be performed on any major rule. A ''major rule'' is defined as one that would result in the annual effect on the national economy of $100 million or more, or have other substantial impact. 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 final rule is not major rule under the Congressional Review Act. The changes set forth in this final rule are minor revisions to existing regulation. The changes made in this final rule involve an expansion of TRICARE benefits. In addition, this final rule will have minor impact and will not significantly affect a substantial number of small entities. In light of the above, no regulatory impact analysis is required.

The rule has been designated as significant and has been reviewed by the Office of Management and Budget as required under the provisions of Executive Order 12866.

The final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 55).

List of Subjects in 32 CFR Part 199

Claims, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

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

2. Section 199.4 is amended as follows:

a. Revise paragraph (d)(3)(v) introductory text preceding the Note;

b. Remove paragraph (d)(3)(v)(A);

c. Redesignate paragraphs (d)(3)(v)(B) and (d)(3)(v)(D) as (d)(3)(v)(A) through (d)(3)(v)(C);

d. Revise newly designated paragraphs (d)(3)(v)(A) and (d)(3)(v)(C);

e. Revise paragraph (e)(5); and

f. Add paragraphs (e)(18)(i)(F), (e)(18)(i)(G) and (e)(21).

The additions and revisions read as follows:

§ 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(v) *Ambulance.* Civilian ambulance service is covered when medically necessary in connection with otherwise covered services and supplies and a covered medical condition. For the purpose of TRICARE payment, ambulance service is an outpatient service (including in connection with maternity care) with the exception of otherwise covered transfers between hospitals which are cost-shared on an inpatient basis. Ambulance transfers from a hospital based emergency room to another hospital more capable of providing the required care will also be cost-shared on an inpatient basis.

* * * * *

(A) 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)(C)(*1*) of this section transport must be to the closest appropriate facility by the least costly means.

* * * * *

(C) Except as described in paragraph (d)(3)(v)(C)(1)(*1*) of this section, ambulance services 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.

(*1*) Advanced life support air ambulance and certified advanced life support attendant are covered services for solid organ and stem cell transplant candidates.

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

* * * * *

(e) * * *

(5) *Transplants.* (i) *Organ transplants.* Basic Program benefits are available for otherwise covered services or supplies in connection with an organ transplant procedure, provided such transplant procedure is in accordance with accepted professional medical standards and is not considered unproven.

(A) *General.* (*1*) Benefits may be allowed for medically necessary services and supplies related to an organ transplant for:

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

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

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

(*iv*) Blood and blood products.

(*v*) FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.

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

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

(*viii*) 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.

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

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

(*3*) Donor costs are payable when:

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

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

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

(*iv*) 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.)

(*4*) If the donor is not a CHAMPUS beneficiary, TRICARE 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.

(*5*) TRICARE benefits will not be allowed for transportation of an organ donor.

(B) [Reserved]

(ii) *Stem cell transplants.* TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for stem cell transplant according to guidelines adopted by the Executive Director, TMA, or a designee.

* * * * *

(18) * * *

(i) * * *

(F) Heart valve surgery.

(G) Heart or Heart-lung Transplantation.

* * * * *

(21) *Pulmonary rehabilitation.* TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Executive Director, TMA, or a designee.

* * * * *

3. Section 199.6 is amended by revising paragraphs (b)(4)(ii) and (b)(4)(iii) to read as follows:

§ 199.6 Authorized providers.

* * * * *

(b) * * *

(4) * * *

(ii) *Organ transplant centers.* To obtain TRICARE approval as an organ transplant center, the center must be a Medicare approved transplant center or meet the criteria as established by the Executive Director, TMA, or a designee.

(iii) *Organ transplant consortia.* TRICARE shall approve individual pediatric organ transplant centers that meet the criteria established by the Executive Director, TMA, or a designee.

* * * * *

4. Section 199.7 is 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. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy Manual, or until the approved transplant occurs.

* * * * *

5. Section 199.15 is 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. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in the TRICARE/CHAMPUS Policy

Manual, or until the approved transplant occurs.

* * * * *

Dated: June 11, 2002.

L.M. Bynum,

Alternate Federal Register Liaison Officer, Department of Defense.

[FR Doc. 02–15220 Filed 6–24–02; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 341

Deputy Secretary of Defense

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This final regulation announces the authority of the Deputy Secretary of Defense, Dr. Paul Wolfowitz, to act for the Secretary of Defense and to exercise the powers of the Secretary of Defense upon any and all matters concerning which the Secretary of Defense is authorized to act pursuant to law. It further permits the Deputy Secretary to make specific delegations of this authority in appropriate cases.

EFFECTIVE DATE: January 26, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Munson, Directorate of Organizational and Management Planning, Office of the Director, Administration and Management, Office of the Secretary of Defense, 1950 Defense Pentagon, Washington, DC 20301–1950, telephone 703–697–1143.

SUPPLEMENTARY INFORMATION:

Executive Order 12866, ''Regulatory Planning and Review''

It has been determined that 32 CFR part 341 is not a significant regulatory action. The rule does not:

(1) Have an annual effect to the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4)

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities because it does not change existing DoD practices and it primarily affects the internal activities of the Department of Defense.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been certified that this rule does impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995. The reporting and recordkeeping requirements have been submitted to OMB for review.

Federalism (Executive Order 13132)

It has been certified that this rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 341

Organization and functions (Government agencies).

Accordingly, Chapter I, Subchapter R, of title 32 of the Code of Federal Regulations is amended to add part 341 to read as follows:

PART 341—DEPUTY SECRETARY OF DEFENSE

Sec.

341.1 Purpose.

Authority: 10 U.S.C. 301.

§ 341.1 Purpose.

(a) In accordance with the authorities contained in 10 U.S.C. and except as expressly prohibited by law, Deputy Secretary of Defense Paul D. Wolfowitz has full power and authority to act for the Secretary of Defense and to exercise the powers of the Secretary of Defense upon any and all matters concerning which the Secretary of Defense is authorized to act pursuant to law.

(b) The all-inclusive authority reflected herein may not be delegated in toto; however, the Deputy is authorized to make specific delegations, as required.

Dated: June 18, 2002.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 02–15913 Filed 6–24–02; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–02–034]

Safety Zone; Captain of the Port Detroit Zone

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation of regulation.

SUMMARY: The Coast Guard is implementing safety zones for annual fireworks displays in the Captain of the Port Detroit Zone during July 2002. This action is necessary to provide for the safety of life and property on navigable waters during these events. These zones will restrict vessel traffic from a portion of the Captain of the Port Detroit Zone.

DATES: Effective from 12:01 a.m. (Eastern Time) on July 1, 2002 to 11:59 p.m. (Eastern Time) on July 31, 2002.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Brandon Sullivan, U.S. Coast Guard Marine Safety Office Detroit, MI at (313) 568–9580.

SUPPLEMENTARY INFORMATION: The Coast Guard is implementing the permanent safety zones in 33 CFR 165.907 (66 FR 27868, May 21, 2001), for fireworks displays in the Captain of the Port Detroit Zone during July 2002. The following safety zones are in effect for fireworks displays occurring in the month of July 2002:

(1) *City of Wyandotte Fireworks, Wyandotte, MI.* Location: The waters off the breakwall between Oak & Van Alstyne St., Detroit River bounded by the arc of a circle with a 300-yard radius with its center in approximate position 42°12′ N, 083°09′ W on July 2, 2002 from 9:15 p.m. until 10:15 p.m.

(2) *Caseville Fireworks, Caseville, MI.* Location: The waters off the Caseville breakwall, Saginaw River bounded by the arc of a circle with a 300-yard radius with its center in approximate position 43°55′ N, 083°17′ W, on July 3, 2002, from 10 p.m. until 11 p.m.