IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866 .

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart federal regulation.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 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

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget 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 counterpart 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 counterpart federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 19, 2000.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 00–13551 Filed 5–30–00; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA57

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Methodology for Coverage of NIH-Sponsored Clinical Trials

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule modifies the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures by adding a provision allowing a waiver of the prohibition in connection with clinical trials sponsored or approved by the National Institutes of Health, if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments, and contribute to the development of such treatments.

DATES: Public comments must be received by July 31, 2000.

ADDRESSES: TRICARE Management Activity (TMA), Program Development Branch, Aurora, CO 80045–6900.

FOR FURTHER INFORMATION CONTACT: Kathleen Larkin, Office of the Assistant Secretary of Defense (Health Affairs)/ TRICARE Management Activity, telephone (703) 681–3628.

SUPPLEMENTARY INFORMATION:

I. Proposed Changes

Introduction and Background

On January 24, 1996, the Department provided notice in the **Federal Register** (61 FR 1899) of an expansion of an existing demonstration to provide coverage for all cancer treatment clinical trials under approved National Cancer Institute (NCI) clinical trials. The demonstration's purpose was to improve beneficiary access to promising new therapies, assist in meeting the National Cancer Institute's clinical trial

goals, and arrival at conclusions regarding the safety and efficacy of emerging therapies in the treatment of cancer. The demonstration was further expanded on June 21, 1999 (64 FR 109) to include cancer prevention clinical trials. Based on the improved beneficiary access to these trials, and the contributions to the development of such treatments, it is in the best interest of the Department and its beneficiaries to continue to provide access through an authorized waiver as outlined in the proposed rule.

This proposed rule implements title 10, United States Code, section 1079(a)(13) which provides for a waiver of the general prohibition on coverage of unproven medical treatments or procedures in connection with clinical trials sponsored or approved by the National Institutes of Health if the Secretary of Defense so determines that a waiver will promote access to promising new treatments and contributes to the development of such treatments.

II. Regulatory Procedures

Executive Order 12866 requires certain regulatory assessments for any significant regulatory action, defined as one which would result in an annual effect on the economy of $100 million or more, or have other substantial impacts.

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 a regulation which would have a significant impact on a substantial number of small entities.

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

Public comments are invited. All comments will be carefully considered. A discussion of the major issues received by public comments will be included with the issuance of the permanent final rule, anticipated approximately 60 days after the end of the comment period.

List of Subjects in 32 CFR Part 199

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

Accordingly, 32 CFR part 199 is proposed to be 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 proposed to be amended by adding new paragraph (e)(21) and revising paragraph (g)(15) introductory text to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(21) *National Institutes of Health clinical trials.* By law, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be waived in connection with clinical trials sponsored or approved by the National Institutes of Health if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. A waiver shall only be exercised as authorized under this paragraph.

(i) *Demonstration waiver.* A waiver may be granted through a demonstration project established in accordance with § 199.1(o).

(ii) *Continuous waiver.* (A) *General.* As a result of a demonstration project under which a waiver has been granted in connection with a National Institutes of Health clinical trial, a determination may be made that it is in the best interest of the government and CHAMPUS beneficiaries to end the demonstration and continue to provide a wiaver for CHAMPUS cost-sharing of the specific clinical trial. Only those specific clinical trials identified under paragraph (e)(21)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

(B) *National Cancer Institute (NCI) Sponsored Cancer Prevention, Screening, and Early Detection Clinical Trials.* A continuous waiver under paragraph (e)(21) of this section has been granted for CHAMPUS cost-sharing for those CHAMPUS-eligible patients selected to participated in NCI sponsored Phase II and Phase III studies for the prevention and treatment of cancer.

(*1*) CHAMPUS will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. CHAMPUS will cost-share all medical care required as a result of participation in NCI-sponsored studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

(*i*) The provider seeking treatment for a CHAMPUS-eligible patient in an NCI approved protocol has obtained preauthorization for the proposed treatment before initial evaluation; and,

(*ii*) Such treatments are NCI sponsored Phase II or Phase III protocols; and,

(*iii*) The patient continues to meet entry criteria for said protocol; and

(*iv*) The institutional and individual providers are CHAMPUS authorized providers.

(*2*) CHAMPUS will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(*3*) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NCI-sponsored clinical trials.

(*4*) The Director, OCHAMPUS, shall issue procedures and guidelines establishing NCI sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NCI sponsored cancer clinical trials.

* * * * *

(g) * * *

(15) *Unproven drugs, devices, and medical treatments or procedures.* By law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproved and cannot be cost-shared by CHAMPUS *except* as authorized under § 199.4(e)(20) of this part.

* * * * *

Dated: May 24, 2000.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 00–13520 Filed 5–30–00; 8:45 am]

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