under the criteria of the Regulatory Flexibility Act. Since this rule involves routine matters that will only affect air traffic procedures and air navigation, it does not warrant preparation of a Regulatory Flexibility Analysis because the anticipated impact is so minimal.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, *Airspace Designations and Reporting Points,* dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6002 Class E airspace areas extending upward from the surface of the earth.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW OK E2 Gage, OK [Revoked]
ASW OK E5 Gage, OK [Revoked]

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Issued in Fort Worth, TX on January 8, 2001.

Robert N. Stevens,

Acting Manager, Air Traffic Division, Southwest Region.

[FR Doc. 01–1549 Filed 1–30–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ACE–33]

Amendment to Class E Airspace; Albia, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Albia, IA.

EFFECTIVE DATE: 0901 UTC, March 22, 2001.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2525.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on November 9, 2000 (65 FR 67254). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on March 22, 2001. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on January 5, 2001.

H.J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 01–2038 Filed 1–30–01; 8:45 am]

BILLING CODE 4910–13–M

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 Phase II and Phase III Clinical Trials Sponsored by the National Institutes of Health

AGENCY: Office of The Secretary; DoD.

ACTION: Final rule.

SUMMARY: This final rule allows the Department of Defense to waive normal requirements so that covered beneficiaries can participate in Phase II and Phase III clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute (NIH NCI). This waiver authority is expected to promote beneficiary access to promising new treatments and contribute to the development of such treatments.

EFFECTIVE DATE: March 2, 2001.

ADDRESSES: TRICARE Management Activity (TMA), Program Operations Directorate, Program Development, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041–3206.

FOR FURTHER INFORMATION CONTACT: Patricia Collins, Office of the Assistant Secretary of Defense (Health Affairs)/ TRICARE Management Activity, telephone (703) 681–0039. Questions regarding payment of specific claims under CHAMPUS should be addressed to the appropriate regional TRICARE/ CHAMPUS contractor.

SUPPLEMENTARY INFORMATION:

I. Overview of the Rule

Introduction and background

This final 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-National Cancer Institute. This waiver is contingent upon the Secretary of Defense's determination that a waiver will promote access to promising new treatments and contribute to the development of such treatments. 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. The Department of Defense and the National Institutes of Health National Cancer Institute (NCI) established a partnership in 1994 for the purpose of conducting a demonstration project that allowed patients with breast cancer to be considered for NCI-sponsored bone marrow transplant clinical trials. This program expanded in 1996 to include all cancers and NCI-Sponsored Phase II and III cancer treatment clinical trials. The partnership was further expanded as of June 21, 1999 to include cancer prevention and treatment. Between January 1996 and January 2000, approximately 270 beneficiaries have participated in NCI-approved clinical trials under the waiver. The Department of Defense hopes that this permanent benefit will heighten the awareness among our cancer patients that clinical trials are a promising treatment option and encourage them to consider this.

Public Comments: The proposed rule was published in the **Federal Register** on May 31, 2000 (65 FR 34627). No public comments were received.

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

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 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

Administrative practice and procedure, Claims, Fraud, Health care, Health insurance, Military personnel.

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 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 National Cancer Institute 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) of this part.

(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 National Cancer Institute 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 waiver for CHAMPUS cost-sharing of the specific clinical trial. Only those specific clinical trials identified under paragraph (e)(2)(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)(20) of this section has been granted for CHAMPUS cost-sharing for those CHAMPUS-eligible patients selected to participate 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 pre-authorization 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)(21) of this part.

* * * * *

Dated: January 25, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–2763 Filed 1–30–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC82

Special Regulations; Areas of the National Park System: Delay of Effective Date

AGENCY: National Park Service, Interior.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' 66 FR 7701 (Jan. 24, 2001), this document temporarily delays for 60 days the effective date of the rule entitled Special Regulations; Areas of the National Park System, published in the **Federal Register** on January 22, 2001, (66 FR 7259). That rule concerns the restrictions on snowmobiles and other winter activities in Yellowstone and Grand Teton National Parks as well as the John D. Rockefeller, Jr., Memorial Parkway.

DATES: The effective date of the Special Regulations; Areas of the National Park System, published in the **Federal Register** on January 22, 2001, (62 FR 7259), is delayed for 60 days, from February 21, 2001 to a new effective date of April 22, 2001.

FOR FURTHER INFORMATION CONTACT: Kym Hall, Regulations Program Manager,