is estimated to vary from 0.5 hour to 4 hours per response, with an average of 1.25 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Because reports are filed 4 times per year, 54,000 responses annually are expected. Thus, the total annual respondent burden of the survey is estimated at 67,500 hours (13,500 respondents times 4 times 1.25 hours average burden). This estimate is the same as the burden hours currently carried for this collection in the OMB inventory.

Comments regarding the burden estimate or any other aspect of this collection of information should be addressed to: Director, Bureau of Economic Analysis (BE–1), U.S. Department of Commerce, Washington, DC 20230, fax: 202–606–5311; and the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project 0608–0004, Attention PRA Desk Officer for BEA, via the Internet at *pbugg@omb.eop.gov*, or by fax at 202–395–7245.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding the economic impact of the rule. As a result, no final regulatory flexibility analysis was prepared.

List of Subjects in 15 CFR Part 806

International transactions, Economic statistics, U.S. investment abroad, Penalties, Reporting and recordkeeping requirements.

Dated: May 26, 2006.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

■ For the reasons set forth in the preamble, BEA is amending 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

■ 1. The authority citation for 15 CFR part 806 continues to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp., p. 173); E.O. 12518 (3 CFR, 1985 Comp., p. 348).

§ 806.14 [Amended]

■ 2. Section 806.14 (e) is amended by removing ''$30,000,000'' and adding ''$40,000,000'' in its place.

[FR Doc. E6–9608 Filed 6–19–06; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket No. DoD–2006–HA–0143]

RIN 0720–0057

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE; Coverage of Phase II and Phase III Clinical Trials Sponsored by the National Institutes of Health National Cancer Institute

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The 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.

DATES: This rule is effective July 20, 2006.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement System, 16301 East Centretech Parkway, Aurora, CO 80011–9066

FOR FURTHER INFORMATION CONTACT: Debra Hatzel, Medical Benefits and Reimbursement Systems, TMA, telephone (303) 676-3572. Questions regarding payment of specific claims under TRICARE should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. 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.

Clinical trials are the major avenue for discovering, developing, and evaluating new cancer therapies, and clinical trial participants are among the first to receive new cancer prevention or treatment methods before they are widely available. Many significant medical discoveries in this field have occurred as a direct result of clinical trial participation. For example, because of survival improvements seen in an NCI-sponsored clinical trial, early initiation of hormonal therapy has become the standard of care in node-positive prostrate cancer patients. Even when they do not lead to new therapies, clinical trials often answer important questions and help move research forward so that others may prevent or survive this disease.

Cancer treatment trials may include testing new drugs, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods such as gene therapy. Studies that involve drugs or invasive procedures are categorized by phase. Phase I trials evaluate new cancer drugs to determine what dose is safe, how a new agent should be administered (by mouth, injected into a vein, or injected into the muscle), and how frequently the treatment should be given. After safety parameters have been established, Phase II trials are conducted to assess the effectiveness of an agent or intervention against a specific type of cancer. Phase III trials compare effective treatments from Phase II studies to conventional cancer treatments. Clinical trials offer high quality care for cancer prevention and treatment, and no patient ever receives a placebo (substance with active ingredients) when effective care exists.

The Department of Defense (DoD) and the National Cancer Institute (NCI) established a partnership in 1994 to conduct a demonstration project that allowed patients with breast cancer to participate in NCI-sponsored bone marrow transplant clinical trials. This demonstration project expanded in 1996 to include all cancers and NCI-sponsored Phase II and III cancer treatment clinical trials. The DoD–NCI demonstration partnership was further

expanded on June 21, 1999 to include clinical trials related to prevention, screening and early detection of cancer. Because of the inherent safety risks and unproven clinical benefits associated with toxicology studies, Phase I clinical trials were not included in this demonstration.

Between January 1996 and July 2004, approximately 350 TRICARE beneficiaries have participated in NCI-approved clinical trials conducted in doctors' offices, community hospitals and clinics, cancer centers, other medical centers, and veterans' and military hospitals across the United States. Healthcare costs for the DoD–NCI demonstration have ranged from $5.8 million to $16 million per year, and research has indicated that patient-care costs associated with cancer clinical trials are only slightly higher than the costs associated with treating similar patients outside of trials.

The Department of Defense hopes that his permanent benefit will heighten the awareness among our cancer patients that clinical trials are a promising treatment option and encourage them to consider Phase II and Phase III clinical trial participation. Participation in clinical trials related to prevention, screening, and early detection of cancer will contribute to the growing base of medical knowledge in these areas and may lead to more effective treatments in the future. Phase I trials will continue to be excluded from coverage; also, TRICARE will continue to deny coverage for any items or services that are already covered under the investigational protocol. Only those supplies and services that TRICARE otherwise would have covered during the normal course of treatment (to include costs for screening tests to determine clinical trial eligibility) will be eligible for cost-sharing. This continues the coverage policy which was previously established for the DoD–NCI cancer trials demonstration.

This final rule was previously published in the **Federal Register** on January 31, 2001 (66 FR 8365–8366). The rule was withdrawn on February 7, 2001 (66 FR 9199) because it was determined that it should not have been published in accordance with the Regulatory Review Plan. We are reissuing this final rule with only minor changes (''CHAMPUS'' changed to ''TRICARE'' where appropriate; minor changes to paragraph numbers to reflect current regulations); however, we are repeating the entire final rule here for the benefit of the public.

II. Public Comments

The proposed rule was published in the **Federal Register** on May 31, 2000 (65 FR 34627). No public comments were received. The final rule is consistent with the proposed rule.

III. Regulatory Procedures

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one which would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. This is not a significant regulatory action under EO 12866 and has been reviewed by the Office of Manpower and Budget.

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. We certify that this final rule will not significantly affect a substantial number of small entities.

This 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, Healthcare, Health insurance, 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 by adding new paragraph (e)(26) and revising paragraph (g)(15) introductory text to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(26) *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 Sec. 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 specified clinical trials identified under paragraph (e)(26)(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)(26) of this regulation 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*) TRICARE 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. TRICARE 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*) TRICARE 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, TRICARE (or designee), 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 paragraph 199.4(e)(26) of this part.

* * * * *

Dated: June 9, 2006.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 06–5432 Filed 6–19–06; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–06–074]

RIN 1625–AA09

Drawbridge Operation Regulations; Welch Causeway (SR 699) Bridge, Gulf Intracoastal Waterway, Mile 122.8, Madeira Beach, Pinellas County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations governing the operation of the Welch Causeway (SR 699) Bridge, Gulf Intracoastal Waterway mile 122.8, Madeira Beach, Pinellas County, Florida. This rule is needed to provide vehicular traffic relief during heavy vehicular traffic periods as well as meeting the reasonable needs of mariners during the construction of nearby bridges. This bridge will open on the hour and half hour, Friday, 2 p.m. until 6 p.m., Saturday, Sunday and Federal holidays from 10 a.m. until 6 p.m. until October 29, 2006.

DATES: This rule is effective from June 20, 2006 until October 29, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD07–06–074 and are available for inspection or copying at Commander (dpb), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 432, Miami, FL 33131, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Project Officer, Seventh Coast Guard District, Bridge Branch, at (305) 415–6743.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NRPM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM was impracticable and contrary to the public interest, because the rule is needed to provide for vehicular traffic relief during construction of bridges and provides provisions for vessels to transit through the area on a twice an hour schedule during heavy vehicular traffic periods.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after **Federal Register** publication. This rule provides for scheduled bridge openings for vessels to transit through the bridge.

Background and Purpose

The Welch Causeway (SR 699) bridge, Gulf Intracoastal Waterway mile 122.8, Madeira Beach, Pinellas County, Florida currently opens on signal; except that, from 9:30 a.m. to 6 p.m. on Saturdays, Sundays, and Federal holidays, the draw need be opened only on the hour, 20 minutes after the hour, and 40 minutes after the hour. This bridge is in close proximity to other bridges currently under construction. The bridge provides vehicular access on and off the coastal barrier islands.

Florida State Representative Rice's office, on behalf of the citizens of Madeira Beach, requested the Coast Guard change the current operation of the bridge to two openings per hour during certain periods, while other bridge construction projects were underway. The bridge will be required to only open on the hour and half-hour Fridays from 2 p.m. until 6 p.m. and Saturdays, Sundays and Federal holidays from 10 a.m. until 6 p.m. Public vessels of the United States, tugs with tows and vessels in distress shall be passed as necessary.

Discussion of Rule

The regulation was requested by Florida Representative Rice's office on behalf of the residents of Madeira Beach and will provide temporary relief for vehicular traffic while other bridge construction projects are underway, while continuing to provide for the reasonable needs of navigation. The bridge will be required to only open on the hour and half-hour on Fridays from 2 p.m. until 6 p.m. and on Saturdays, Sundays and Federal holidays from 10 a.m. until 6 p.m. The draw shall open as necessary for the passage of tugs with tows, public vessels of the United States and vessels in distress.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary, because the rule will allow for bridge openings during the construction of nearby bridges.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities, because the regulations provide for bridge openings, and for the reasonable needs of navigation.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If this rule would affect your small business, organization, or governmental