

ASD(HD&ASA), guidance regarding this part as it relates to National Guard matters.

Dated: December 22, 2010.

**Patricia L. Toppings,**  
OSD Federal Register Liaison Officer,  
Department of Defense.

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 199

[DoD-2009-HA-0051]

RIN 0720-AB31

#### TRICARE; Coverage of National Cancer Institute (NCI) Sponsored Phase I Studies

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Final rule.

**SUMMARY:** This final rule adds coverage of National Cancer Institute (NCI) sponsored Phase I studies for certain beneficiaries. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe.

**DATES:** *Effective Date:* This rule is effective February 14, 2011.

**FOR FURTHER INFORMATION CONTACT:** Commander James Ellzy, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681-0064.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

This final rule adds the coverage of a subset of National Cancer Institute (NCI) sponsored Phase I trials for certain TRICARE patients. The NCI sponsored clinical treatment trials are conducted in a series of steps called phases. Phase I trials are the first studies conducted in people. They evaluate how a new drug should be given (by mouth, injected into the blood, or injected into the muscle), how often, and what dose is safe. A Phase I trial usually enrolls only a small number of patients, sometimes as few as a dozen. A Phase II trial continues to test the safety of the drug, and begins to evaluate how well the new drug works. Phase II studies usually focus on a particular type of cancer. A Phase III trial tests a new drug, a new combination of drugs, or a new surgical

procedure in comparison to the current standard. A participant will usually be assigned to the standard group or the new group at random. Phase III trials often enroll large numbers of people and may be conducted at many doctors' offices, clinics, and cancer centers nationwide.

This final rule adds coverage only of NCI sponsored Phase I trials with clinical or pre-clinical data providing a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative. Additionally, only those TRICARE patients for whom standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative, would be eligible for these additional trials. TRICARE has covered NCI sponsored Phase II and III trials since 1996. The NCI estimates that Phase I trial participants represent about 3.4 percent of overall Phase II and III participants combined. Based on the history of Department of Defense participation in these studies, it is estimated that there would be a maximum of 1,000 new patients annually enrolling in Phase I trials. It is estimated that the net cost to TRICARE of adding Phase I treatment trials will increase costs by 12.8 percent of the total gross costs (approximately \$150,000 in FY09). Currently, ten States mandate coverage of at least some Phase I trials.

##### B. Public Comments

The DoD published a proposed rule on June 22, 2009 (74 FR 29435-29436). One set of comments was received on the proposed rule. The sole commenter strongly supported the proposed rule and urged the DoD to make it final. We agree with this recommendation and have not made any modifications to the proposed rule.

##### C. Regulatory Procedures

*Executive Order 12866, "Regulatory Planning and Review"*

Section 801 of Title 5, United States Code (U.S.C.), and Executive Order (E.O.) 12866 requires certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy, or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule; however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

*Sec. 202, Public Law 104-4, "Unfunded Mandates Reform Act"*

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)*

The Regulatory Flexibility Act (RFA) requires 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. This final rule will not significantly affect a substantial number of small entities for purposes of the RFA.

*Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)*

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

*Executive Order 13132, "Federalism"*

This final rule has been examined for its impact under E.O. 13132 and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government; therefore, consultation with State and local officials is not required.

##### List of Subjects in 32 CFR Part 199

Claims, Dental Health, Health Care, 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 by:

■ A. Redesignating paragraphs (e)(26)(ii)(B)(2), (3) and (4) as paragraphs (e)(26)(ii)(B)(3), (4) and (5);

■ B. Adding a sentence to the introductory text in paragraph (e)(26)(ii)(B);

■ C. Revising paragraph (e)(26)(ii)(B)(1)(i);

■ D. Revising paragraph (e)(26)(ii)(B)(1)(iv);

■ E. Adding paragraph (e)(26)(ii)(B)(1)(v); and

■ F. Adding a new paragraph (e)(26)(ii)(B)(2) to read as follows:

**§ 199.4 Basic program benefits.**

\* \* \* \* \*

(e) \* \* \*

(26) \* \* \*

(ii) \* \* \*

(B) \* \* \* Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) \* \* \*

(i) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

\* \* \* \* \*

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (iii) of this section.

\* \* \* \* \*

Dated: January 4, 2011.

**Patricia L. Toppings,**

*OSD Federal Register, Liaison Officer,  
Department of Defense.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 146**

[Docket No. USCG-2008-1088]

RIN 1625-AB28

**Notice of Arrival on the Outer Continental Shelf**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard revises its regulations on Outer Continental Shelf (OCS) Activities to enhance maritime domain safety and security awareness on the OCS by issuing regulations which will require notice of arrival for floating facilities, mobile offshore drilling units (MODUs), and vessels planning to engage in OCS activities. This final rule implements provisions of the Security and Accountability for Every Port Act of 2006 and increases overall maritime domain awareness by requiring owners or operators of United States and foreign flag floating facilities, MODUs, and vessels to submit notice of arrival information to the National Vessel Movement Center prior to engaging in OCS activities.

**DATES:** This final rule is effective February 14, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2008-1088 and are available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2008-1088 in the "Keyword" box, and then clicking "Search."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Mr. Kevin Pekarek, Vessel and Facility Operating Standards Division (CG-5222), Coast Guard; telephone 202-372-1386, e-mail [Kevin.Y.Pekarek2@uscg.mil](mailto:Kevin.Y.Pekarek2@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

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**I. Abbreviations**

BOEMRE Bureau of Ocean Energy Management, Regulation and Enforcement.  
CFR Code of Federal Regulations.  
DHS Department of Homeland Security.  
FR **FEDERAL REGISTER.**  
ISM International Safety Management.  
ISSC International Ship Security Certificate.  
MMS Minerals Management Service.  
MODU Mobile Offshore Drilling Unit.  
NAICS North American Industry Classification System.  
NOA Notice of Arrival.  
NOA OCS Notice of Arrival on the Outer Continental Shelf.  
NPRM Notice of Proposed Rulemaking.  
NTTAA National Technology Transfer and Advancement Act, 15 U.S.C. 272 note.  
NVMC National Vessel Movement Center.  
OCS Outer Continental Shelf.  
OCSLA Outer Continental Shelf Lands Act.  
OIRA Office of Information and Regulatory Affairs.  
OMB Office of Management and Budget.  
RFA Regulatory Flexibility Act, 5 U.S.C. 601-612.  
SAFE Port Act Security and Accountability for Every Port Act of 2006, Pub. L. 109-347, 120 Stat. 1884 (2006).  
U.S.C. United States Code.  
U.S.C.A. United States Code Annotated.

**II. Regulatory History**

On June 22, 2009, we published a notice of proposed rulemaking (NPRM) entitled Notice of Arrival (NOA) on the Outer Continental Shelf in the **Federal Register** (74 FR 29439). We received two sets of comments on the proposed rule prior to the close of the comment period. One additional set of comments was received after the close of the