Signed: April 15, 2009.

John J. Manfreda,

Administrator.

Approved: May 26, 2009.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. E9–14548 Filed 6–19–09; 8:45 am]

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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: Proposed rule.

SUMMARY: This proposed 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: Written comments received at the address indicated below by August 21, 2009 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Colonel John Kugler, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681–0064.

SUPPLEMENTARY INFORMATION: This proposed 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 proposed rule adds coverage only of NCI sponsored Phase I trials with clinical or preclinical 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 DoD participation in these studies, it is estimated that there would be a maximum of one thousand 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.

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 proposed 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 proposed 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 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 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 end of the introductory text in paragraph (e)(26)(ii)(B);

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

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

E. Adding new 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*) * * *

(*ii*) 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 (e)(26)(ii)(B)(*2*)(*iii*) of this section.

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Dated: May 15, 2009.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–14441 Filed 6–19–09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[USCG–2009–0400]

RIN 1625–AA08

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend special local regulations for annual regattas and marine parades in the Captain of the Port Sault Sainte Marie zone. This action is necessary to protect and separate the public from the hazards of these events. This proposed rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after regattas or marine parades.

DATES: Comments and related materials must reach the Coast Guard on or before July 22, 2009.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2009–0400 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: LCDR Christopher Friese, Prevention Dept. Chief, Sector Sault Sainte Marie, 337 Water St., Sault Sainte Marie, MI 49783; 906–635–3220.

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–0400), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name, mailing address, and an e-mail address or other contact information in the body of your document to ensure that you can be identified as the submitter. This also allows us to contact you in the event further information is needed or if there are questions. For example, if we cannot read your submission due to technical difficulties and you cannot be contacted; your submission may not be considered. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on ''Search for Dockets,'' and enter the docket number for this rulemaking (USCG–2008–XXXX) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

C. Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the