

and Gas/Electric Operational Communications Standards) (Version 1.8, September 30, 2006);

(ii) Nominations Related Standards (Version 1.8, September 30, 2006) and including the standards contained in NAESB WGQ 2007 Annual Plan Item 7b/NAESB WGQ 2008 Annual Plan Item 4b (August 25, 2008);

(iii) Flowing Gas Related Standards (Version 1.8, September 30, 2006);

(iv) Invoicing Related Standards (Version 1.8, September 30, 2006);

(v) Quadrant Electronic Delivery Mechanism Related Standards (Version 1.8, September 30, 2006) with the exception of Standard 4.3.4;

(vi) Capacity Release Related Standards (Sep. 3, 2008) and including the standards contained in NAESB WGQ 2007 Annual Plan Item 7a/NAESB WGQ 2008 Annual Plan Item 4a (August 25, 2008) and the Standards included in NAESB WGQ 2007 Annual Plan Item 7a/NAESB WGQ 2008 Annual Plan Item 4a/NAESB WGQ 2009 Annual Plan Item 4; and

(vii) Internet Electronic Transport Related Standards (Version 1.8, September 30, 2006) with the exception of Standard 10.3.2.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2008-HA-0025; 0720-AB20]

TRICARE; Changes Included in the National Defense Authorization Act for Fiscal Year 2007; Improvements to Descriptions of Cancer Screening for Women

AGENCY: TRICARE Management Activity, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department is publishing this proposed rule to implement section 703 of the National Defense Authorization Act (NDAA) for Fiscal Year 2007 (FY07), Public Law 109-364. Specifically, that legislation authorizes breast cancer screening and cervical cancer screening for female beneficiaries of the Military Health System, instead of constraining such testing to mammograms and Papanicolaou smears. The rule allows coverage for "breast cancer screening" and "cervical cancer screening" for female beneficiaries of the Military Health System, instead of

constraining such testing to mammograms and Papanicolaou tests. This rule ensures new breast and cervical cancer screening procedures can be added to the TRICARE benefit as such procedures are proven to be a safe, effective, and nationally accepted medical practice. This amends the cancer specific recommendations for breast and cervical cancer screenings to be brought in line with the processes for updating other cancer screening recommendations.

DATES: Written comments will be accepted at the address indicated below until September 22, 2009.

ADDRESSES: You may submit comments, identified by docket number and/or RIN, by any of the following methods:

- *Federal eRulemaking 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, Office of the Chief Medical Officer, TRICARE Management Activity, telephone (703) 681-0064.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Defense updated coverage for screening with the use of the breast MRI for women in a designated high risk category as advised by the American Cancer Society. In the process of providing this additional coverage, it was discovered that because of statutory wording, there was a group of high risk women that are standard beneficiaries under the age of 35 for whom this coverage could not be provided without an amendment in the Code of Federal Regulations (CFR). Amending the CFR will provide coverage for breast MRI screening for all Department of Defense beneficiaries in the high risk category recommended by the American Cancer Society.

II. Regulatory Procedures

Executive Order (EO) 12866 and Regulatory Flexibility Act

E.O. 12866 requires a comprehensive regulatory impact analysis be performed

on any economically 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. 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 that would have a significant impact on a substantial number of small entities. This rule is not an economically significant regulatory action and will not have a significant impact on a substantial number of small entities for purposes of the RFA, thus this proposed rule is not subject to any of these requirements. This rule, although not economically significant, is a significant rule under E.O. 12866 and has been reviewed by the Office of Management and Budget. Amending the CFR will provide coverage for breast MRI screening for all Department of Defense beneficiaries in the high risk category, if necessary. It is critically important that we eliminate any potential gaps in coverage for high risk individuals as quickly as possible.

Paperwork Reduction Act

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).

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.

Executive Order (EO) 13132

We have examined the impact(s) of the proposed rule under E.O. 13132 and it does not have 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—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES

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. In § 199.4:

A. Revise paragraphs (g)(37)(viii) and (ix).

B. Redesignate paragraphs (g)(27)(x) through (g)(37)(xii) as (g)(37)(xi) through (g)(37)(xiii).

C. Add a new paragraph (g)(37)(x).

The revisions and additions read as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) * * *
(37) * * *

(viii) Cancer screenings authorized by 10 U.S.C. 1079.

(ix) Health promotion and disease preventions visits (which may include all of the services provided pursuant to § 199.18(b)(2)) may include all of the services provided pursuant to § 199.18(b)(2) may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (g)(37)(ii) or (g)(37)(viii) of this section.

(x) Physical examinations for beneficiaries ages 5–11 that are required in connection with school enrollment.

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Dated: July 17, 2009.

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–2008–HA–0060]

RIN 0720–AB26

TRICARE; Rare Diseases Definition

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule revises the definition of rare diseases to adopt the definition of a rare disease as promulgated by the National Institutes of Health, Office of Rare Diseases. The rule modification will result in the definition used by the TRICARE program for a rare disease to be consistent with the definition used by

the National Institutes of Health and the Food and Drug Administration. TRICARE has generally been applying the broader National Institutes of Health and Food and Drug Administration definitions when making coverage decisions for treatments; therefore, there will be no practical changes for beneficiaries.

DATES: Written comments received at the address indicated below by September 22, 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:

LCDR James Ellzy, TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681–0064.

SUPPLEMENTARY INFORMATION: On January 6, 1997, the Office of the Secretary of Defense published a final rule in the **Federal Register** (62 FR 627–631) clarifying the TRICARE exclusion of unproven drugs, devices and medical treatments and procedures and adding a definition of rare diseases to be used in the TRICARE Program. TRICARE defined a rare disease as one which affects fewer than one in 200,000 Americans. Upon further review, TRICARE proposes to revise the definition to be in compliance with the definition of other federal agencies. The Office of Rare Diseases was initially established as part of the National Institutes of Health in 1993 to promote research and collaboration on rare and orphan diseases. The Rare Diseases Act of 2002 (Pub. L. 107–280) codified the establishment of the Office of Rare Diseases by adding a section 404F to the Public Health Service Act (42 U.S.C. 283h). This statute defines a rare disease as “any disease or condition that affects less than 200,000 persons in the United

States.” Additionally, Section 526(a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bb(a)(2)), provides, in part, that the term “rare disease or condition” means any disease or condition which affects less than 200,000 persons in the United States. The proposed rule modification will result in the definition used by the TRICARE program for a rare disease to be consistent with the definition used by the National Institutes of Health and the Food and Drug Administration.

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, or a significant regulatory action under the provisions of E.O. 12866.

Section 202, Public Law 104–4, “Unfunded Mandates Reform Act”

It has been certified that his 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,