

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:** Final rule.

SUMMARY: This final 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: *Effective Date:* This rule is effective September 7, 2010.

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

SUPPLEMENTARY INFORMATION:**A. Background**

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 is revising 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. This 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.

B. Public Comments

The Department of Defense published a proposed rule on July 24, 2009 (74 FR 36639-36640). No comments were received on the proposed rule before the comment period closed.

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, 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 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 199.2(b) is amended by revising the definition of "Rare diseases" as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Rare diseases. TRICARE/CHAMPUS defines a rare disease as any disease or condition that has a prevalence of less than 200,000 persons in the United States.

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Dated: July 26, 2010.

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

[FR Doc. 2010-19308 Filed 8-5-10; 8:45 am]

BILLING CODE 5001-06-P**DEPARTMENT OF DEFENSE****Office of the Secretary****32 CFR Part 199**

[DOD-2009-HA-0094]

RIN 0720-AB32

TRICARE; Diabetic Education**AGENCY:** Office of the Secretary, Department of Defense.**ACTION:** Final rule.

SUMMARY: The Department of Defense is publishing this final rule to clarify TRICARE coverage for diabetic education. This rule introduces new definitions and addresses revisions or

omissions in policy or procedure inadvertently missed in previous regulatory changes pertaining to diabetic education.

DATES: Effective Date: This final rule is effective September 7, 2010.

FOR FURTHER INFORMATION CONTACT: Joy Saly, Medical Benefits and Reimbursement Branch, TRICARE Management Activity, telephone (303) 676-3742. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION: This final rule introduces new definitions and addresses revisions or omissions in policy or procedure inadvertently missed in previous regulatory changes pertaining to diabetic education.

Diabetes self-management training (DSMT) is an interactive, collaborative process involving beneficiaries with diabetes, their physician(s), and their educators. The educational process should provide the beneficiary with the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes required to manage the diabetes successfully.

TRICARE had previously classified DSMT as a counseling service that was not medically necessary. Since all services provided under the TRICARE program must be medically necessary and appropriate, DSMT was excluded from coverage. In developing the TRICARE policy on self-management, however, it was determined that diabetes educational services are consistent with the medically necessary and appropriate provision and it was decided to conform with Medicare's policy on DSMT. As such, TRICARE removed "diabetic self-management training" programs as an excluded benefit effective July 1, 1998. Although the policy change conflicted with existing regulation language, TRICARE determined to move forward with the policy change because TRICARE was expanding and not restricting a benefit, and the change was in line with Medicare's benefit. This final rule corrects the failure to amend the language of the regulation and brings the regulation into conformance with the current policy.

Section 199.4 provides basic program benefits.

Section 199.4(d)(3)(ix) Diabetic self-management training (DSMT) is added as a benefit under other covered services and supplies. This addition brings the regulation into conformance with the current policy.

Section 199.4(g)(39) is revised to remove diabetic self-education programs as an exclusion.

Section 199.6 addresses authorized providers.

Section 199.6(c)(3)(iii)(L) adds Nutritionist to the list of individual professional providers of medical care authorized to provide services to CHAMPUS beneficiaries.

Section 199.6(c)(3)(iii)(M) adds Registered Dietitian to the list of individual professional providers of medical care authorized to provide services to CHAMPUS beneficiaries.

Public Comments

A proposed rule (74 FR 44798-44800) was published on August 31, 2009, and provided a 60-day comment period. No comments were received.

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, require 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 a significant regulatory action.

Public Law 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601)

Public Law (Pub. L.) 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601), requires that each Federal agency prepare 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 have a significant impact on a substantial number of small entities. Therefore, this final rule is not subject to the requirements of the RFA.

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

This rule does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Pub. L. 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35).

Public Law 104-4, Section 202, "Unfunded Mandates Reform Act"

Section 202 of Public Law 104-4, "Unfunded Mandates Reform Act," requires that an analysis be performed to determine whether any Federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. It has

been certified that this final 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, and thus, this final rule is not subject to this requirement.

Executive Order 13132, "Federalism"

E.O. 13132, "Federalism," requires that an impact analysis be performed to determine whether the rule has 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. It has been certified that this final rule does not have federalism implications, as set forth in E.O. 13132.

List of Subjects in 32 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 adding paragraph (d)(3)(ix), and revising paragraph (g)(39) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(ix) *Diabetes Self-Management Training (DSMT).* A training service or program that educates diabetic patients about the successful self-management of diabetes. It includes the following criteria: Education about self-monitoring of blood glucose, diet, and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivates the patient to use the skills for self-management. The DSMT service or program must be accredited by the American Diabetes Association.

Coverage limitations on the provision of this benefit will be as determined by the Director, TRICARE Management Activity, or designee.

* * * * *

(g) * * *

(39) *Counseling.* Counseling services that are not medically necessary in the treatment of a diagnosed medical

condition: For example, educational counseling, vocational counseling, nutritional counseling, and counseling for socioeconomic purposes, stress management, lifestyle modification. Services provided by a certified marriage and family therapist, pastoral, or mental health counselor in the treatment of a mental disorder are covered only as specifically provided in Section 199.6. Services provided by alcoholism rehabilitation counselors are covered only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

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■ 3. Section 199.6 is amended by adding paragraphs (c)(3)(iii)(L) and (M) to read as follows:

§ 199.6 TRICARE-authorized providers.

* * * * *

- (c) * * *
(3) * * *
(iii) * * *

(L) Nutritionist. A nutritionist may provide DSMT via an accredited DSMT program. The nutritionist must be licensed by the State in which the care is provided, and must be under the supervision of a physician who is overseeing the DSMT program.

(M) Registered Dietitian. A dietitian may provide DSMT via an accredited DSMT program. The dietitian must be licensed by the State in which the care is provided, and must be under the supervision of a physician who is overseeing the DSMT program.

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Dated: July 26, 2010.

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

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DEPARTMENT OF DEFENSE

Office of the Secretary

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

32 CFR Part 199

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

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The Department is publishing this final 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. In response to public comment on the proposed rule, this final rule includes a clarification that the benefit encompasses screening based on Health and Human Services guidelines.

DATES: Effective Date: This rule is effective September 7, 2010.

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

SUPPLEMENTARY INFORMATION:

A. 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.

B. Public Comments

The Department of Defense published a proposed rule on July 24, 2009 (74 FR 36638-36639). A single comment was received asking that the language be written more clearly. The final rule includes language in section (g)(37)(viii) that is more precise in terms of which

cancers will be covered and notes that cervical and breast cancer screenings will be provided in accordance with the standards based on the guidelines from the U.S. Department of Health and Human Services.

C. 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 final 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 section, of \$100 million or more in any one year.

Executive Order (EO) 13132

We have examined the impact(s) of the final 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