

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.

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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