rulemaking, effective on August 31, 2009.

Authority and Signature.

**Megan Uzzell,**

*Acting Assistant Secretary for Policy.*

[FR Doc. E9–20923 Filed 8–28–09; 8:45 am]

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 199

**[DoD–2008–HA–0090; RIN 0720–AB23]**

## TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

**AGENCY:** Office of the Secretary, Department of Defense.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Defense is publishing this proposed rule to revise the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device.'' This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act. Additionally, this rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed in TRICARE regulations. As it is determined that reliable evidence demonstrates that previously unproven drugs, devices, and medical treatments or procedures have proven medical effectiveness, TRICARE has removed them from the list and authorized medically necessary care. This revision removing the partial list is necessary as the list will never be completely current, and is only a partial list of examples. The removal of this partial list does not change or eliminate any benefits that are currently available under the TRICARE program.

**DATES:** Written comments received at the address indicated below by October 30, 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:** René L. Morrell, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676–3618.

**SUPPLEMENTARY INFORMATION:** This proposed rule revises the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device.'' This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). Additionally, this proposed rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under § 199.4(g)(15).

### Off-Label Uses of Devices

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 or procedures and adding the TRICARE definition of unlabeled or off-label drugs. This rule also added the provision for coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are prescribed or administered by a health care practitioner and are used for indications or treatments not included in the approved labeling. We are now modifying the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device'' to be consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) However, this proposed rule does not present new agency policy. Rather, it corrects an error and omission from the current rule. Coverage is limited to those indications for which there is reliable evidence, as defined in section 199.2, sufficient to establish that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity.

### Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

By law, TRICARE can only cost-share medically necessary supplies and services. Any drug, device, and medical treatment or procedure, the safety and efficacy of which have not been established, as described in § 199.4(g)(15), is unproven and cannot be cost-shared by TRICARE except as authorized under § 199.4(e)(26). The current regulation and program policy provide a partial list of examples of unproven drugs, devices, and medical treatments or procedures that are excluded from benefits. The intent of this partial list was to provide information on specific examples of emerging drugs, devices, and medical treatments or procedures determined to be unproven by TRICARE based on review of current reliable evidence. Due to the rapid and extensive changes in medical technology it is not feasible to maintain this list in the regulation. Removal of this partial list of examples does not change the exclusion of unproven drugs, devices, and medical treatments or procedures. Removal of the partial list of examples does not change the process TRICARE follows in determining for purposes of benefit coverage when a drug, device, and medical treatment or procedure has moved from the status of unproven to proven medical effectiveness. The intent of this revision is to ensure that benefit determinations are made based on current reliable evidence rather than relying on outdated regulatory and policy provisions.

### Regulatory Procedures

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

Section 801 of Title 5, 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 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 significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized.

*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 32 CFR 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 removing the definition of *Unlabeled or Off-Label Drugs* and adding a new definition of *Off-Label Use of a Drug or Device* in alphabetical order to read as follows:

**§ 199.2 Definitions.**

* * * * *

(b) * * *

* * * * *

*Off-Label Use of a Drug or Device.* A use other than an intended use for which the drug or device is legally marketed under the Federal Food, Drug, and Cosmetic Act. This includes any use that is not included in the approved labeling for an approved drug or approved device; any use that is not included in the cleared statement of intended use for a device that has been determined by the Food and Drug Administration (FDA) to be substantially equivalent to a legally marketed predicate device and cleared for marketing; and any use of a device for which a manufacturer or distributor would be required to seek pre-market review by the FDA in order to legally include that use in the device's labeling.

* * * * *

3. Section 199.4 is amended by revising the third paragraph of the Note to paragraph (g)(15)(i)(A), and removing paragraph (g)(15)(iv) as follows:

**§ 199.4 Basic program benefits.**

* * * * *

(g) * * *

(15) * * *

(i) * * *

(A) * * *

**Note:** * * * CHAMPUS will consider coverage of off-label uses of drugs and devices that meet the definition of *Off-Label Use of a Drug or Device* in Section 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity, and also requires demonstrations from reliable evidence, as defined in § 199.2, that the off-label use of the drug or device is safe, effective and in accordance with nationally accepted standards of practice in the medical community.

* * * * *

Dated: August 21, 2009.

**Patricia L. Toppings,**

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

[FR Doc. E9–20683 Filed 8–28–09; 8:45 am]

**BILLING CODE 5001–06–P**

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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:** Proposed rule.

**SUMMARY:** The Department of Defense is publishing this proposed 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:** Written comments received at the address indicated below by October 30, 2009 will be accepted.

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

*The Web site: http://www.regulations.gov.* Follow the instructions for submitting comments.

*Mail:* Federal Docket Management System Office, Room 3C843 Pentagon, 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:** 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 proposed 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 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 diabetes self-management training as a counseling service that was not medically necessary. Since all services provided under the TRICARE program must be medically necessary and appropriate, diabetes self-management training 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 diabetes self-management training. As such, TRICARE removed ''diabetic self-