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

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-

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 proposed rule corrects the failure to amend the language of the regulation and brings the regulation into conformance with the current policy.

Sec. 199.4 provides basic program benefits.

Sec. 199.4(d)(3)(xiv) 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.

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

Sec. 199.6 addresses authorized providers.

Sec. 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.

*Sec.*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.

Regulatory Procedures.

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

Section 801 of title 5, United States Code, and Executive Order 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 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 proposed rule will not have a significant impact on a substantial number of small entities. Therefore, this proposed 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 Public Law 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 proposed 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 proposed rule is not subject to this requirement.

Executive Order 13132, ''Federalism''

Executive Order 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 proposed rule does not have federalism implications, as set forth in Executive Order 13132.

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 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, etc. 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 § 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.

* * * * *

3. Section 199.6 is amended by adding paragraphs (c)(3)(iii)(L) and (M).

§ 199.6 TRICARE—authorized providers.

* * * * *

(c) * * *

(3) * * *

(iii) * * *

(L) Nutritionist. A nutritionist may provide diabetes self-management training (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 diabetes self-management training (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.

* * * * *

Dated: August 21, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–20684 Filed 8–28–09; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD–2009–HA–0095]

RIN 0720–AB33

TRICARE; Extended Care Health Option

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department of Defense is publishing this proposed rule to implement the requirements enacted by Congress in Section 732 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 which changes the limit of the Government's share of providing certain benefits under the Extended Care Health Option (ECHO) from $2,500 per month to $36,000 per year, and for other non-legislated changes to the ECHO.

DATES: 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, 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: Michael Kottyan, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676–3520.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1079 of title 10, United States Code (U.S.C.), as amended by Section 701(b) of the National Defense Authorization Act for Fiscal Year 2002 [Pub. L. 107–107], required the Department of Defense to establish a program of extended benefits for eligible dependents. That program, known as the Extended Care Heath Option (ECHO), replaced the Program for Persons with Disabilities (PFPWD) and was implemented on September 1, 2005. The primary purpose of the ECHO is to provide eligible beneficiaries with benefits that are not available through the TRICARE Basic Program. The term ''eligible beneficiary'' means an individual who is a dependent of an Active Duty Service Member (ADSM) or is a Transitional Survivor of a deceased ADSM and who has a qualifying condition. Qualifying conditions include moderate or severe mental retardation, serious physical disability, or an extraordinary physical or psychological condition. The benefits available through the ECHO are intended to assist in the reduction of the disabling effects of an ECHO qualifying condition.

Section 1079(e)(3) and (4) authorized benefits, including training, rehabilitation, special education, assistive technology devices, institutional care in private, nonprofit, public, and State institutions and facilities and, if appropriate, transportation to and from such institutions and facilities in which the beneficiary is receiving institutional care.

Section 1079(f)(2) limited the Government's liability for benefits authorized by Section 1079(e) and (4) to $2,500 per month and required that the beneficiary's sponsor be liable for any amount of the monthly total cost for those benefits that exceeded the Government's limit. Section 1079(e) also authorized the extended benefits program to provide additional benefits including diagnostic services, inpatient and outpatient care, comprehensive home health care, respite care, and other services and supplies as determined appropriate by the Secretary. However, Section 1079(f) did not limit the Government's liability for those additional benefits. By Final Rule published in the **Federal Register** on August 20, 2004, (69 FR 51559) the Department established that those additional benefits accrued to the $2,500 per month limit.

Section 732 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 [Public Law 110–417] (NDAA 2009) changed the limit of the Government's liability for benefits authorized under Section 1079(e)(3) and (4) from $2,500 per month to $36,000 per year, prorated as determined by the Secretary. This rule does not prorate the annual limit of Government liability. Section 732 does not affect other benefits authorized under Section 1079(e).

This proposed rule changes the Government's share of providing all benefits available through the Extended Care Health Option from $2,500 per month to $36,000 per fiscal year. This rule does not change the Government's liability for benefits provided by the ECHO Home Health Care (EHHC) benefit or the EHHC Respite Care benefit.

Additionally, Section 732 changed the sponsor's liability for costs exceeding the limit of the Government's liability from a per-month basis to a per-year basis; this rule includes that change.

The following additional changes contained in this rule are further discussed below: deletes references to the PFPWD, eliminates allocating the allowable cost of durable equipment authorized for purchase through the ECHO, clarifies the monthly reimbursement for benefits received through the ECHO Home Health Care (EHHC), and allows a waiver of the requirement to enroll in the sponsor's branch of Service Exceptional Family Member Program (EFMP) in order to register in the ECHO.

Active Duty Family Members who have a qualifying condition are eligible to receive benefits through the ECHO. Qualifying conditions include moderate or severe mental retardation, a serious physical disability, or an extraordinary physical or psychological condition such that the beneficiary is homebound. Serious physical disabilities include those conditions that preclude an individual from the unaided performance of at least one major life activity such as breathing, cognition, hearing, seeing, and age appropriate ability essential to bathing, dressing, eating, grooming, speaking, stair use, toilet use, transferring, and walking.

The ECHO, as the replacement for the PFPWD, has been fully implemented for several years; it is therefore appropriate to delete references in the regulations to the transition of the PFPWD to the ECHO.

Durable equipment, which is defined as a device or apparatus which does not qualify as ''Durable Medical Equipment'' under the TRICARE Basic Program but which is essential to the efficient arrest or reduction of the functional loss resulting from, or the