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Aaron Siegel,

Alternate 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-0175]

RIN 0720-AB38

TRICARE; Elimination of Co-payments for Authorized Preventive Services for Certain TRICARE Standard Beneficiaries

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of Defense is publishing this final rule to implement section 711 of the National Defense Authorization Act (NDAA) for Fiscal Year 2009 (FY 2009), Public Law 110-417. Section 711 eliminates copayments for authorized preventive services for TRICARE Standard beneficiaries other than Medicare-eligible beneficiaries. This rule also realigns the covered preventive services listed in the Exclusions section of the regulation to the Special Benefits section in the regulation.

DATES: *Effective Date:* This final rule is effective January 27, 2012. *Applicability Date:* 32 CFR 199.4(f)(12) applies for dates of service on or after October 14, 2008, for preventive services listed in paragraph (e) (28) of this section.

FOR FURTHER INFORMATION CONTACT: Ann Fazzini, Medical Benefits and Reimbursement Branch, TRICARE Management Activity, telephone (303) 676-3803. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1079(b) and 1086(b) of Title 10, United States Code (U.S.C.), as amended by Section 711 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2009 (Pub. L. 110-417), required the Department of Defense to eliminate copayments for those authorized preventive services named in the law for TRICARE Standard beneficiaries other than Medicare-eligible beneficiaries.

This language requires all copayments to be eliminated for authorized

preventive services for certain TRICARE Standard beneficiaries who would otherwise pay copayments and that certain TRICARE Standard beneficiaries pay nothing for the preventive services during a year even if the beneficiary has not paid the amount necessary to cover the beneficiary's deductible for the year. The language does not expand coverage of preventive services not otherwise authorized by law under the TRICARE preventive care benefit.

The proposed rule published in the **Federal Register** on September 27, 2010, (75 FR 59173) clarified and realigned the preventive services currently listed in the Exclusions section of the TRICARE regulation to the Special Benefits section in the regulation. This realignment does not remove from coverage any preventive services currently covered under the program nor does it create a new entitlement to preventive or other services not otherwise authorized in title 10, Chapter 55, United States Code. We performed this realignment because Title 32 Code of Federal Regulations (CFR) § 199.4(g), "Exclusions and limitations," states in subparagraph (37) that preventive care is excluded, and then lists those services that are not excluded. We believe including covered preventive services in the Exclusions section created confusion for those seeking information about preventive services under the TRICARE program. A person seeking information about what preventive services are covered would most likely not look for that information in a section labeled "Exclusions." We remedied this confusion by removing the list of covered preventive services from this section and placing the list in the "Special Benefit Information" section of 32 CFR 199.4(e). We also realigned those services currently in the "Exclusions" section that are not truly preventive but are more evaluative in nature in the "Special Benefit Information" section of 32 CFR 199.4(e) and added a definition of "evaluative" services in 32 CFR 199.2. However, based upon public comments received, we have removed the evaluative services definition and label from the Final Rule language, instead opting to simply list separately those covered benefits that while preventive in nature are authorized independently from the statutory lists of specifically authorized preventive services contained in Chapter 55 of title 10, United States Code. See Section III. Public Comments below.

II. Section 711 of the Duncan Hunter NDAA for FY 2009

Section 711 of the NDAA 2009 waives certain copayments for authorized preventive services for TRICARE Standard beneficiaries by amending subparagraphs 1079(b) and 1086(b) of Title 10, United States Code.

It is important to note that the language in Section 711 includes in the list of preventive services for which a cost share is not applicable an "annual physical exam." By law, only well-child visits for beneficiaries under 6 years of age are covered, as are physical examinations for beneficiaries 6 years of age or older if conducted as part of health promotion and disease prevention visits when provided in connection with otherwise authorized immunizations and or cancer screenings, resulting in elimination of copayments for these specific physical examinations for TRICARE Standard beneficiaries. See Title 10, U.S.C. 1079(a)(2). Routine annual examinations, other than as described above, are not covered by the TRICARE program.

III. Public Comments

The proposed rule was published in the **Federal Register** (75 FR 59173) on September 27, 2010 for a 60-day public comment period. We received seven comments from six respondents on the proposed rule.

Five respondents expressed support of this rule change because it will provide better overall coverage for beneficiaries, will increase awareness of disease states and prevention, is a step toward healthier lifestyles and better health choices, and in the long run will save the government money. We agree, and are pleased to promulgate this rule.

One respondent stated agreement that a military beneficiary seeking information about what preventive services are covered would most likely not look for that information in a section labeled "Exclusions." We agree and are pleased we are able to remedy this confusion.

Two respondents requested minimal changes to make the regulation better understood and to eliminate confusing verbiage. We appreciate the comments and believe that the new evaluative services category may have been misleading. Adding the new evaluative services language in 32 CFR 199.4, the "Special Benefit Information" section, may have had the unintended result of implying that we were expanding benefit coverage of preventive services beyond what was otherwise authorized by law or otherwise creating a new type

of benefit that did not previously exist. We have carefully reviewed the preventive services provision from a historical perspective. In general, the TRICARE program has been and continues to be a benefit program based upon medical necessity. At the time the current regulation at 32 CFR 199.4(g)(37) was written, certain services, when not medically necessary and not designed to treat a specific illness or injury, were commonly referred to as preventive in nature. The term "preventive care" was used rather broadly and not limited to those preventive services specifically authorized in statute. The regulation at 32 CFR 199.4(g)(37) was thus written to exclude from coverage care which fell under this broad type of definition and was not deemed to be medically necessary. A number of exceptions were then listed under the exemption to indicate situations when the services were no longer considered preventive in nature but rather covered as medically necessary (e.g., tetanus shots following an accidental injury) or otherwise authorized by statute (e.g., physical examinations for beneficiaries ages 5–11 that are required in connection with school enrollment). The TRICARE program has evolved over time as has the practice of medicine. Certain preventive health care services are now specifically authorized by statute. As a result, we believe it is necessary to distinguish the statutorily authorized preventive health care services from the broader category of services, which are based upon a medical necessity determination or are otherwise authorized by statute. Continuing to utilize the term "preventive care" in the historically broad sense as well as to refer to specific statutorily covered preventive services is certain to lead to confusion. As a result, this rule realigns statutorily authorized preventive care as well as care otherwise authorized by statute from the Exclusions section to the Special Benefits section. We have eliminated reference to the specific examples of medically necessary care that were highlighted under the exceptions to the general preventive care exclusion in 32 CFR 199.4(g)(37)(iii)–(vi) as realigning these specific routine types of medically necessary care to the special benefits section is confusing and unnecessary. Eliminating the individual reference to these medically necessary services in no way conveys a change in TRICARE benefit coverage. We are modifying the remaining regulatory text in 32 CFR 199.4 (e) (28) to include preventive services and in paragraph (e)(29)

including those other special services that are otherwise authorized by law. We believe these changes will clarify our intent regarding preventive and other special benefits, which will be further clarified in the TRICARE Policy Manual.

One respondent suggested that we expand this service/coverage to include other health insurance providers and Medicare-eligible patients. We appreciate this comment and want to assure the respondent the changes we are implementing do not add to or subtract from the covered preventive services beneficiaries are now receiving, but are primarily to address the elimination of copayments for certain preventive services. We are not certain what the respondent means by "other health insurance providers," but we believe this refers to other payers. This law is specific to the Department of Defense TRICARE Program and has no effect on other payers. TRICARE beneficiaries who are also eligible for Medicare are specifically excluded from the elimination of copayments under this provision. In these situations, Medicare is the primary payer and TRICARE is the secondary payer for services, and in most cases, TRICARE pays the Medicare copayments or cost-shares so that the beneficiary has no out-of-pocket expenses for these services. We would also note that to the extent our Medicare-eligible beneficiaries have no copayments or cost-shares for covered preventive services under Medicare, there are no out-of-pocket expenses for TRICARE to reimburse. We will ensure this is clarified in the TRICARE Policy Manual.

Two respondents recommended waiving any co-pays for preventive office visits. We appreciate this comment and the opportunity to clarify that the regulation lists health promotion and disease prevention visits as a covered preventive care benefit (32 CFR 199.4(e) (28) (iv)), for which there is no copayment, when a beneficiary receives at least one of the preventive services listed (e.g., immunizations or cancer screening examinations) during the office visit. We will ensure this is clarified in the TRICARE Policy Manual.

One respondent stated support for the elimination of cost-sharing for TRICARE beneficiaries for secondary prevention, such as eye examinations for those with diabetes, as this would be an important extension of the health enhancement and cost containment goals of the FY2009 NDAA. The respondent stated that FY2009 was retroactive, meaning that beneficiaries did not necessarily know that their co-pays would be eliminated when they received a

qualifying preventive service, and that it should be done prospectively, ideally for more than one fiscal year at a time. We appreciate the respondent's support to expand this benefit to secondary prevention. However, we cannot address this as it is outside the scope of the law. Benefits may not be implemented until granted by Congress. We have attempted to alleviate the financial burden for those services already received by including a provision in the regulation that allows requests for reimbursement of copayments paid by beneficiaries on or after the applicability date of October 14, 2008. The elimination of copayments for these preventive services is effective October 14, 2008, and will continue for successive years until it is revised or eliminated by law.

One respondent stated this rule provides an important opportunity to review TRICARE's coverage policies for pediatric health promotion and disease prevention services to ensure that cost-sharing is not imposed for any of these vital services. While we appreciate the respondent's suggestion regarding review of our coverage policies for pediatric preventive services, we cannot address this as it is outside the scope of the law. As to the comment relating to the reimbursement to providers of these preventive services, they will be eligible to be paid 100% of the TRICARE allowed amount, and will see no reduction in their payment levels for these services.

IV. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

It has been certified that this amendment to 32 CFR part 199 does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders.

It has been certified that this rule is not economically significant, and has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

Section 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 to 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 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 rule has been examined for its impact under E.O. 13132, and 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 199.4 is amended by adding paragraphs (e)(28), (e)(29), and (f)(12), and revising paragraph (g)(37) to read as follows.

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(28) *Preventive care.* The following preventive services are covered:

(i) Cervical, breast, colon and prostate cancer screenings according to standards issued by the Director, TRICARE Management Activity, based on guidelines from the U.S. Department of Health and Human Services. The standards may establish a specific schedule that includes frequency, age specifications, and gender of the beneficiary, as appropriate.

(ii) Immunizations as recommended by the Centers for Disease Control and Prevention (CDC).

(iii) Well-child visits for children under 6 years of age as described in paragraph (c)(3)(xi) of this section.

(iv) Health promotion and disease prevention visits (which may include all of the services provided pursuant to § 199.18(b)(2)) for beneficiaries 6 years of age or older may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (e)(28)(i) and (ii) of this section.

(29) *Physical examinations.* In addition to the health promotion and disease prevention visits authorized in paragraph (e)(28)(iv) of this section, the following physical examinations are specifically authorized:

(i) Physical examinations for dependents of Active Duty military personnel who are traveling outside the United States. The examination must be required because of an Active Duty member's assignment and the travel is being performed under orders issued by a Uniformed Service. Any immunizations required for a dependent of an Active Duty member to travel outside of the United States is covered as a preventive service under paragraph (e)(28) of this section.

(ii) Physical examinations for beneficiaries ages 5-11 that are required for school enrollment and that are provided on or after October 30, 2000.

(iii) Other types of physical examinations not listed above are excluded including routine, annual, or employment-requested physical examinations and routine screening procedures that are not part of medically necessary care or treatment or otherwise specifically authorized by statute.

(f) * * *

(12) *Elimination of cost-sharing for certain preventive services.*

(i) Effective for dates of service on or after October 14, 2008, beneficiaries, subject to the limitation in paragraph (f)(12)(iii) of this section, shall not pay

any cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section. The beneficiary shall not be required to pay any portion of the cost of these preventive services even if the beneficiary has not satisfied the deductible for that year.

(ii) Beneficiaries who paid a cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section on or after October 14, 2008, may request reimbursement until January 28, 2013 according to procedures established by the Director, TRICARE Management Activity.

(iii) This elimination of cost-sharing for preventive services does not apply to any beneficiary who is a Medicare-eligible beneficiary. For purposes of this section, the term "Medicare-eligible" beneficiary is defined in 10 U.S.C. 1111(b) and refers to a person eligible for Medicare Part A.

(iv) Appropriate copayments and deductibles will apply for all services not listed in paragraph (e)(28) of this section, whether considered preventive in nature or not.

(g) * * *

(37) *Preventive care.* Except as stated in paragraph (e)(28) of this section, preventive care, such as routine, annual, or employment-requested physical examinations and routine screening procedures.

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■ 4. Section 199.17 is amended by adding paragraphs (m)(1)(ii)(D) and (m)(2)(iii) to read as follows:

§ 199.17 TRICARE program.

* * * * *

(m) * * *

(1) * * *

(ii) * * *

(D) As stated in § 199.4(f)(12), TRICARE Standard beneficiaries who are not Medicare-eligible beneficiaries, shall have no cost sharing requirements for preventive care listed under § 199.4 (e)(28)(i) through (iv).

* * * * *

(2) * * *

(iii) As stated in § 199.4(f)(12), TRICARE Standard beneficiaries who are not Medicare-eligible beneficiaries, shall have no cost sharing requirements for preventive care listed under § 199.4 (e)(28)(i) through (iv).

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Dated: December 21, 2011.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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