

suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the **Federal Register**.

(D) *Web-based resources.*

Downloadable educational materials on the effects of tobacco use will be available through the Internet or other electronic media. This service may be made available to overseas Prime beneficiaries in all locations where Web based resources are available. There shall be no requirement to create Web based resources in any geographic area in order to make this service available.

(iii) *Limitations of smoking cessation program.* Eligible beneficiaries are entitled to two quit attempts per year (consecutive 12 month period). A third quit attempt may be covered per year with physician justification and pre-authorization. A quit attempt is defined as up to eighteen face-to-face counseling sessions over a 120 consecutive day period and/or 120 days of pharmacologic intervention for the purpose of smoking cessation. Counseling and pharmacological treatment periods that overlap by at least 60-days are considered a single quit attempt.

* * * * *

(g) *Exclusions and limitations.*

* * * * *

(39) *Counseling.* Educational, vocational, and nutritional counseling and counseling for socioeconomic purposes, stress management, and/or lifestyle modification purposes, except that the following are not excluded:

(i) Services provided by a certified marriage and family therapist, pastoral or mental health counselor in the treatment of a mental disorder as specifically provided in paragraph (c)(3)(ix) of this section and in section 199.6 of this Part.

(ii) Diabetes self-management training (DSMT) as specifically provided in paragraph (d)(3)(ix) of this section.

(iii) Smoking cessation counseling and education as specifically provided in paragraph (e)(28) of this section.

(iv) Services provided by alcoholism rehabilitation counselors 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.

* * * * *

(65) [Reserved]

* * * * *

3. Section 199.21 is amended by:

- a. Revising paragraph (a)(2);
- b. Revising paragraph (h)(2)(i);
- c. Adding a new paragraph (h)(2)(iii);

and

- d. Adding a new (i)(2)(v)(D).

The additions and revisions read as follows:

§ 199.21 TRICARE—Pharmacy Benefits Program.

(a) *General.*

(1) * * *

(2) *Pharmacy benefits program.* (i)

Applicability. The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Geographically, except as specifically provided in paragraph (a)(2)(ii) of this section, this program is applicable to all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)), the TRICARE pharmacy benefits program may be implemented in areas outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the ASD (HA) may also authorize modifications to the pharmacy benefits program rules and procedures as may be appropriate to the area involved.

(ii) *Applicability exception.* The pharmaceutical benefit under the TRICARE smoking cessation program under section 199.4(e)(28) of this Part is available to TRICARE beneficiaries who are not entitled to Medicare benefits authorized under Title XVIII of the Social Security Act. Except as noted in section 199.4(e)(28) of this Part, the smoking cessation program, including the pharmaceutical benefit, is not applicable or available to beneficiaries who reside overseas, including the U.S. territories of Guam, Puerto Rico, and the Virgin Islands, except that under the authority of section 199.17 of this part active duty service members and active duty dependents enrolled in TRICARE Prime residing overseas, including the U.S. territories of Guam, Puerto Rico, and the Virgin Islands, shall have access

to smoking cessation pharmaceuticals through either an MTF or the TMOP program where available.

* * * * *

(h) *Obtaining pharmacy services under the retail network pharmacy benefits program.*

(1) * * *

(2) *Availability of formulary pharmaceutical agents.* (i) *General.* Subject to paragraphs (h)(2)(ii) and (h)(2)(iii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all points of service identified in paragraph (h)(1) of this section.

(ii) * * *

(iii) Pharmaceutical agents prescribed for smoking cessation are not available for coverage when obtained through a retail pharmacy. This includes network and non-network retail pharmacies.

* * * * *

(i) *Cost-sharing requirements under the pharmacy benefits program.*

(1) * * *

(2) * * *

(v) For pharmaceutical agents obtained under the TMOP program there is a:

(A) * * *

(B) * * *

(C) * * *

(D) \$0.00 co-payment for smoking cessation pharmaceutical agents covered under the smoking cessation program.

* * * * *

Dated: August 24, 2011.

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

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD-2011-HA-0035]

RIN 0720-AB49

TRICARE; TRICARE Sanction Authority for Third-Party Billing Agents

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The rule proposes to provide the Director, TRICARE Management Activity (TMA), or designee, with the authority to sanction third-party billing agents by invoking the administrative remedy of exclusion or suspension from the TRICARE program. Such sanctions

may be invoked in situations involving fraud or abuse on the part of third-party billing agents that prepare or submit claims presented to TRICARE for payment.

DATES: Written comments received at the address indicated below by November 21, 2011 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 eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

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: Ms. Joy Saly, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676-3742.

SUPPLEMENTARY INFORMATION:

I. Background

TRICARE has regulatory authority under 32 CFR 199.9 to invoke sanctions in situations involving fraud or abuse on the part of providers of TRICARE services. A provider is defined in 32 CFR 199.2 as, "A hospital or other institutional provider, a physician, or other individual professional provider, or other provider of services or supplies as specified in Sec 199.6 of this part." Third-party billing agents do not meet the definition of a provider as stated in 32 CFR 199.2, nor do TRICARE regulations currently define third-party billing agents.

Title 42 of the CFR subpart C—Exclusions at 42 CFR 402.200(b)(1) provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions provided in Sec. 402.1(e) (and further described in Sec. 402.1(c)). However, TRICARE has to date established no independent regulatory authority to sanction or exclude third-party billing agents.

When TRICARE identifies submission of improper claims by a third-party billing agent not identified by the Centers for Medicare and Medicaid Services (CMS), TRICARE must refer the case to another Federal agency (Defense Criminal Investigative Service, Department of Justice, etc.) for action. In addition, CMS' authority extends only to those third-party billing agents in the United States because Medicare only covers care received in the U.S. or its territories.

II. Department of Defense Inspector General Report on TRICARE Controls Over Claims Prepared by Third-party Billing Agents

The Department of Defense, Office of Inspector General (DoD IG) initiated an audit in February 2008 to review TRICARE controls over claims submitted by third-party billing agents (Department of Defense Inspector General Report No. D-2009-037—"TRICARE Controls Over Claims Prepared by Third-Party Billing Agencies"). The DoD IG published a report on December 31, 2008. The report included a recommendation that the Director, TMA strengthen internal controls by initiating action to obtain statutory or regulatory authority to sanction billing agencies or any entities that prepare or submit improper health care claims to TRICARE contractors.

Statutory authority already exists that provides the Secretary with the authority to administer the TRICARE program to ensure quality of care for program beneficiaries, including sanctioning entities determined to be involved fraud, abuse, or conflict of interest. TRICARE already has regulatory authority to invoke sanctions on providers under 32 CFR 199.9. Based on the existing statutory authority, TMA is pursuing a regulatory change that will provide the authority to ensure both providers and third-party billing agents are held accountable for the submission of correct and proper billings. The regulatory change proposes to implement the DoD IG recommendation by adding third-party billing agents as another entity under the regulation that can be sanctioned in situations where fraud and abuse are identified on the part of third-party billing agents that prepare or submit claims presented to TRICARE for payment.

TRICARE program policy acknowledges a participating provider may arrange for a third-party to act on its behalf in the submission and the monitoring of third-party claims, including TRICARE claims. There must be an agency relationship established in which the third-party billing agent is

reimbursed for the submission and monitoring of claims, but the claim remains that of the provider and the proceeds of any third-party payments, including TRICARE payments, are paid to the provider. TRICARE contractors may deal with these agents in much the same manner as they deal with the provider's accounts receivable department. This proposed rule does not intend to change the current acknowledgment of a provider's right to use a third-party billing agent as a separate billing resource.

This rule seeks to establish that such entities, when acting on behalf of a provider, are held to an equal standard in regard to accuracy and honesty when filing claims for services and supplies under the TRICARE program. As such, these entities should be subject to the same administrative controls applied to providers in ensuring that funds are disbursed appropriately. This rule will allow TRICARE to sanction third-party billing agents to prevent the payment of false or improper billings.

Regulatory Procedures

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

Section (Sec.) 801 of title 5, United States Code, 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 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.

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 is not an economically significant regulatory action, and it has been certified that it 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).

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 proposed rule does not have federalism implications, as set forth in E.O. 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 199.2 is amended by adding to paragraph (b), to appear in alphabetical order, a definition of “Third-party billing agent,” to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Third-party billing agent. Any entity that acts on behalf of a provider to prepare, submit and monitor claims, excluding those entities that act solely as a collection agency.

* * * * *

3. Section 199.9 is amended by adding paragraph (n) to read as follows:

§ 199.9 Administrative Remedies for Fraud, Abuse, and Conflict of Interest.

* * * * *

(n) * * * Third-party billing agents as defined in § 199.2(b) of this part, while not considered providers, are subject to the provisions of this section to the same extent as such provisions apply to providers.

* * * * *

Dated: August 24, 2011.

Patricia L. 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–2011–HA–0058; RIN 0720–AB51]

TRICARE; Changes Included in the National Defense Authorization Act for Fiscal Year 2010; Constructive Eligibility for TRICARE Benefits of Certain Persons Otherwise Ineligible Under Retroactive Determination of Entitlement to Medicare Part A Hospital Insurance Benefits

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department is publishing this proposed rule to implement section 706 of the National Defense Authorization Act (NDAA) for Fiscal Year 2010, Public Law 111–84. Specifically section 706 exempts TRICARE beneficiaries under the age of 65 who become disabled from the requirement to enroll in Medicare Part B for the retroactive months of entitlement to Medicare Part A in order to maintain TRICARE coverage. This statutory amendment and proposed rule only impact eligibility for the period in which the beneficiary’s disability determination is pending before the Social Security Administration. Eligible beneficiaries would still be required to enroll in Medicare Part B in order to maintain their TRICARE coverage for future months, but would be considered to have coverage under the TRICARE program for the months retroactive to their entitlement to Medicare Part A. This proposed rule also amends the eligibility section of the TRICARE regulation to more clearly address reinstatement of TRICARE eligibility following a gap in coverage due to lack of enrollment in Medicare Part B.

DATES: Written comments received at the address indicated below by November 21, 2011 will be accepted.

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

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

Mail: Federal Docket Management System Office, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

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: Ms. Anne Breslin, TRICARE Management Activity (TMA), TRICARE Operations Branch, telephone (703) 681–0039.

SUPPLEMENTARY INFORMATION: Prior to the enactment of section 706 of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111–84), 10 U.S.C. 1086(d) provided that a person who would otherwise receive benefits under section 1086 who is entitled to Medicare Part A hospital insurance is not eligible for TRICARE unless the individual is enrolled in Medicare Part B. When a TRICARE beneficiary becomes eligible for Medicare, Medicare becomes the primary payer and TRICARE is the secondary payer. Retroactive Medicare eligibility determinations therefore caused DoD and Medicare to reprocess claims. Section 706 of the Fiscal Year 2010 National Defense Authorization Act amended 10 U.S.C. 1086(d) to exempt TRICARE beneficiaries under the age of 65 who became Medicare eligible due to a retroactive disability determination from the requirement to enroll in Medicare Part B for the retroactive months of entitlement to Medicare Part A in order to maintain TRICARE coverage. This statutory amendment became effective upon enactment of the Fiscal Year 2010 National Defense Authorization Act on October 28, 2009. Prior to this amendment, beneficiaries who did not purchase Medicare Part B to cover the retroactive period lost their TRICARE eligibility during that period of time. As a result, beneficiaries and providers were then subject to TRICARE