Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 570

Prisoners.

Thomas R. Kane,

Acting Director, Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons, we propose to revise 28 CFR part 570 as set forth below.

Subchapter D—Community Programs and Release

PART 570—COMMUNITY PROGRAMS

1. Revise the authority citation for 28 CFR part 570 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 751, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161–4166, 5006–5024 (Repealed October 12, 1984, as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

2. In part 570, subpart B is revised to read as follows:

Subpart B—Pre-Release Community Confinement

Sec.
570.20 Purpose.
570.21 Time-frames.
570.22 Designation.

§ 570.20 Purpose.

The purpose of this subpart is to provide the procedures of the Bureau of Prisons (Bureau) for designating inmates to pre-release community confinement or home detention.

(a) *Community confinement* is defined as residence in a community treatment center, halfway house, restitution center, mental health facility, alcohol or drug rehabilitation center, or other community correctional facility (including residential re-entry centers); and participation in gainful employment, employment search efforts, community service, vocational training, treatment, educational programs, or similar facility-approved programs during non-residential hours.

(b) *Home detention* is defined as a program of confinement and supervision that restricts the defendant to his place of residence continuously, except for authorized absences, enforced by appropriate means of surveillance by the probation office or other monitoring authority.

§ 570.21 Time-frames.

(a) *Community confinement.* Inmates may be designated to community confinement as a condition of pre-release custody and programming during the final months of the inmate's term of imprisonment, not to exceed twelve months.

(b) *Home detention.* Inmates may be designated to home detention as a condition of pre-release custody and programming during the final months of the inmate's term of imprisonment, not to exceed the shorter of ten percent of the inmate's term of imprisonment or six months.

(c) *Exceeding time-frames.* These time-frames may be exceeded when separate statutory authority allows greater periods of community confinement as a condition of pre-release custody.

§ 570.22 Designation.

Inmates will be considered for pre-release community confinement in a manner consistent with 18 U.S.C. Section 3621(b), determined on an individual basis, and of sufficient duration to provide the greatest likelihood of successful reintegration into the community, within the time-frames set forth in this part.

[FR Doc. 2011–23684 Filed 9–19–11; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2011–HA–0038]

RIN 0720–AB50

TRICARE; Smoking Cessation Program Under TRICARE

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements Section 713 of the Duncan Hunter National Defense Authorization Act (NDAA) for Fiscal Year 2009 (FY 2009), Public Law 110–417. Section 713 states the Secretary shall establish a smoking cessation program under the TRICARE program. The smoking cessation program under TRICARE shall, at a minimum, include the following: the availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with the limitation on the availability of such pharmaceuticals to the mail-order pharmacy program under the TRICARE program; smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; and access to print and Internet web-based tobacco cessation material. Per the statute, Medicare-eligible beneficiaries are excluded from the TRICARE smoking cessation program.

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:

Federal Rulemaking 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: Barbara (Bobbie) Matthews, Medical

Benefits and Reimbursement Branch, TRICARE Management Activity, telephone (303) 676–3558.

SUPPLEMENTARY INFORMATION:

I. Background

The Duncan Hunter NDAA for FY 2009 (Pub. L. 110–417) provides authority for establishment of a smoking cessation program under the TRICARE program. Prior to enactment of Section 713 of the Duncan Hunter NDAA FY09 (Pub. L. 110–417), all supplies and services related to ''stop smoking'' programs were excluded from TRICARE coverage per the regulation, 32 Code of Federal Regulations (CFR) 199.4(g)(65).

Smoking is the number one cause of *preventable* illness and disease in the United States and yet, the prevalence of smoking among TRICARE beneficiaries exceeds that of the general population. According to the Centers for Disease Control and Prevention (CDC), adverse health effects from smoking account for an estimated 443,000 deaths in the United States each year.

Smoking causes respiratory diseases such as emphysema, bronchitis, and chronic airway obstruction. It also causes several types of cancers including, but not limited to, esophageal, oral cavity, uterine, and lung cancer. In fact, the CDC estimates that 90 percent of lung cancer deaths in men and 80 percent in women are caused by smoking.

Smoking also puts individuals at increased risk for several other types of diseases and adverse health outcomes such as coronary artery disease, chronic obstructive lung diseases, peripheral vascular disease, heart attack, and stroke. In addition, it increases the risk of infertility, preterm delivery, stillbirth, low birth weight, and sudden infant death syndrome.

Smoking and its related adverse effects pose a significant challenge for more than two million TRICARE beneficiaries. Establishment of the TRICARE smoking cessation program attempts to reduce the number of TRICARE beneficiaries who are nicotine dependant, thereby improving the health of the TRICARE beneficiary population and reducing Department of Defense costs, in particular those related to the adverse effects of smoking. For further information on TRICARE and the benefits provided under the TRICARE program, please visit *http://www.tricare.mil.*

II. Section 713 of the Duncan Hunter NDAA for FY 2009

This proposed rule implements Section 713 of the Duncan Hunter NDAA for FY 2009. Section 713 stipulates the following key features for inclusion in the TRICARE smoking cessation program:

(1) The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program if appropriate.

(2) Counseling.

(3) Access to a toll-free quit line that is available 24 hours a day, 7 days a week.

(4) Access to print and Internet web-based tobacco cessation material.

(5) Chain of command involvement by officers in the chain of command of participants in the program who are on active duty.

Additionally, Section 713 of NDAA FY 2009 stated the TRICARE smoking cessation program shall not be made available to Medicare-eligible beneficiaries. The statutory language further stated that refunds of copayments paid by Medicare-eligible beneficiaries are available during fiscal year 2009, subject to the specific availability of appropriations for this purpose. However, this authority was not extended beyond FY 2009; consequently, no action is required by TRICARE regarding this provision.

III. Provisions of Proposed Rule

This proposed rule establishes a smoking cessation program under the TRICARE program. The TRICARE smoking cessation program will be available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In general, the TRICARE smoking cessation program will not be available to TRICARE beneficiaries who reside overseas except that under authority of 32 CFR 199.17 of this part, active duty service members and active duty dependents residing overseas including the U.S. territories of Guam, Puerto Rico, and the Virgin Islands who are enrolled in TRICARE Prime at a military treatment facility may have access to those services that the ASD(HA) has determined may be reasonably provided overseas.

It is the intent of the Department to provide access to smoking cessation pharmaceuticals and web based smoking cessation materials overseas where feasible. However, beneficiaries residing in certain areas overseas may not have easy access to the mail services, equipment or technology needed to receive these smoking cessation benefits and in those areas there is no requirement to make them available. For example, there is no intent by the Department to make the web based services available in areas where there are no web based carriers to provide such a service. Additionally, the laws and our treaties with various countries restrict the mailing of pharmaceuticals into the country. If such laws or treaties do not allow the delivery of the pharmaceuticals through the TRICARE Mail Order Pharmacy (TMOP), it is not the intent of the Secretary to provide the pharmaceutical benefit in those areas through this mechanism.

At this time, it is not the intent of the Department to provide access to the toll free quit line overseas due to the technological barriers and cost involved in providing this service. In addition, it is not the intent of the Department at this time to make face-to-face smoking cessation counseling available overseas through the local economy. However, in accordance with 32 CFR 199.17 of this part should the ASD(HA) determine that it is technologically, economically, or otherwise feasible to provide additional benefits or it becomes impractical to continue the benefits and services overseas, the ASD(HA) may use this authority to add or modify any benefit or service. The use of this authority shall be published in the **Federal Register**.

There will be no requirement for an eligible beneficiary to be diagnosed with a smoking related illness in order to access benefits under the TRICARE smoking cessation program. Benefits under this program will include, at no cost to the beneficiary, pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program; smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; and access to print and internet web-based tobacco cessation materials.

IV. Regulatory Procedures

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

Section 801 of title 5, United States Code, and Executive Orders 12866 and 13563 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.

This proposed 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 Pub. L. 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. 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. 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:

a. Revising paragraph (d)(3)(vi).

b. Adding new paragraph (d)(3)(vi)(C).

c. Adding new paragraph (e)(28).

d. Revising paragraph (g)(39).

e. Removing and reserving paragraph (g)(65).

The revisions and additions read as follows:

§ 199.4 TRICARE—Basic Program Benefits.

* * * * *

(d) *Other benefits.*

* * * * *

(3) *Other covered services or supplies.*

* * * * *

(vi) *Drugs and medicines.* Drugs and medicines that by United States law require a prescription are also referred to as ''legend drugs.'' Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider's license and ordered or prescribed in connection with an otherwise covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

(A) * * *

(B) * * *

(C) Over-the-counter (OTC) drugs (drugs that by United States law do not require a prescription), in general, are not covered. However, insulin is covered for a known diabetic even in states that do not require a prescription for its purchase. In addition, OTC drugs used for smoking cessation are covered when all requirements under the TRICARE smoking cessation program are met as provided in paragraph (e)(28) of this section.

* * * * *

(e) *Special benefit information.*

* * * * *

(28) *Smoking cessation program.* The TRICARE smoking cessation program is a behavioral modification program to assist eligible beneficiaries who desire to quit smoking. The program consists of a pharmaceutical benefit; smoking cessation counseling; access to a toll-free quit line for non-medical assistance; and, access to print and Internet Web-based tobacco cessation materials.

(i) *Availability.* The TRICARE smoking cessation program is available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In addition, pursuant to section 199.17 of this Part, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE smoking cessation program may be implemented in whole or in part in areas outside the 50 states and the District of Columbia for active duty members and their dependents who are enrolled in TRICARE Prime (overseas Prime beneficiaries). In such cases, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the TRICARE smoking cessation program rules and procedures as may be appropriate to the overseas area involved. The use of this authority, not otherwise mentioned below, shall be published in the **Federal Register.**

(ii) *Benefits.* There is no requirement for an eligible beneficiary to be diagnosed with a smoking related illness to access benefits under this program. The specific benefits available under the TRICARE smoking cessation program are:

(A) *Pharmaceutical agents.* Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in section 199.21 of this Part. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary. Smoking cessation pharmaceuticals will not be available at any retail pharmacies. A prescription from a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

(B) *Face-to-face smoking cessation counseling.* Both individual and group smoking cessation counseling are covered. The number and mix of face-to-face counseling sessions covered under this program shall be determined by the Director, TMA; however, shall not exceed the limits established in paragraph (e)(28)(iii) of this section. A TRICARE-authorized provider listed in section 199.6 of this Part must render all counseling sessions.

(C) *Toll-free quit line.* Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific

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.

[FR Doc. 2011–23764 Filed 9–19–11; 8:45 am]

BILLING CODE 5001–06–P

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