THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 22 2009

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

The overall goal of the tobacco use cessation program is to improve the success, health, and quality of life for those beneficiaries desiring to stop smoking. The plan describes the current status of the TRICARE smoking cessation benefit, and includes information that will be used to broadly implement a more comprehensive, evidence-based tobacco use treatment and prevention program.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 22 2009

The Honorable Ben Nelson
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

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S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 22 2009

The Honorable Daniel K. Inouye
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

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Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Vice Chairman

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 22 2009

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

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Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John M. McHugh
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 22 2009

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

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Thank you for your continued support of the Military Health System.

Sincerely,

Best,
Ward

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Joe Wilson
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 2 2 2009

The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is submitted in response to Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, which requires the Department of Defense to provide a report on the plan to implement a smoking cessation program under TRICARE for all non-Medicare eligible beneficiaries. Specifically, the program is to include pharmaceutical and counseling treatment interventions for participants, access to patient educational materials, and provision for the involvement of officers in an active duty beneficiary's chain of command. Section 713 authorizes the Department to establish new or modify existing regulatory guidance as necessary to implement the program.

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Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Jerry Lewis
Ranking Member

# DEPARTMENT OF DEFENSE

## Smoking Cessation Program

A Report to Congress on the Implementation Plan for a Comprehensive, Evidence-Based Program for all Non-Medicare Eligible Beneficiaries Covered Under TRICARE

TRICARE Smoking Cessation Program

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Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 requires the Department of Defense to submit a plan on the implementation of a Smoking Cessation Program for all non-Medicare eligible beneficiaries covered under TRICARE. Specifically, the program must include the following interventions designed for the treatment of nicotine dependency secondary to smoking:

- Smoking cessation pharmaceuticals, which are available to the beneficiary, at no cost, through the TRICARE Mail Order Pharmacy if appropriate.
- Counseling services.
- Access to a toll-free quit line that is available to the beneficiary 24 hours a day, 7 days a week.
- Access to print and Internet web-based tobacco cessation materials.

Section 713 further requires the program to provide for the involvement of officers in the chain of command of an Active Duty Service member. The Department is also required to submit a follow-up report to Congress by October 2009 addressing the status, number of participants, rate of success, and recommendations pertaining to the program.

The Department is also authorized to establish new or change existing regulations as necessary to implement the TRICARE Smoking Cessation Program. The Department will implement best practices of other nationally recognized tobacco use cessation programs into the TRICARE Smoking Cessation Program.

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## EXECUTIVE SUMMARY

Smoking and its related adverse effects pose a significant challenge for more than two million of TRICARE's 9.4 million beneficiaries, and costs the Department of Defense in excess of $1 billion per year in direct medical costs and indirect productivity costs combined. The prevalence of tobacco use remains significant in the United States and is the number one cause of preventable illness and disease. Among TRICARE beneficiaries, the rate of smoking is higher than in the general population. Due to its numerous adverse effects, smoking, and its resultant nicotine dependency, is recognized as a chronic condition, requiring a sustained effort of repeated interventions to overcome the threat of relapse and achieve a healthier quality of life.

This report provides the comprehensive approach to the design and implementation of a TRICARE Smoking Cessation Program for all eligible beneficiaries. The information contained in this report describes the overall programmatic structure and multi-component interventions used to assist eligible TRICARE beneficiaries in their smoking cessation efforts.

## INTRODUCTION

Smoking leads to nicotine dependency – a strong chemical addiction affecting over 45 million Americans. Published tobacco research from the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services shows that cigarette smoking continues as a major health risk and is the leading cause of preventable disease and premature death in the United States. In fact, one out of every five deaths each year among Americans results from a smoking-related illness.

Despite these alarming statistics, the smoking rate within the TRICARE beneficiary population exceeds the general population's rate by two to four percentage points, depending on the age group, and is roughly ten percent higher overall. CDC statistics show that 70 percent of current adult smokers in the United States desire to quit smoking. However, the withdrawal symptoms associated with nicotine dependency often lead to relapse, making tobacco use cessation difficult. This type of dependency is known and described as a chronic relapsing condition requiring multiple attempts to quit smoking and repeated treatment.

Because of the significant health and financial costs of nicotine dependency, a comprehensive treatment program designed to facilitate abstinence and prevention is vital to improve and maintain the health and quality of life for eligible TRICARE beneficiaries. The Department's health promotion policy is to encourage military personnel, retirees, and their families to live healthy lives through an integrated, coordinated and comprehensive health promotion program. (Title 32 of the Code of Federal Regulations (CFR) 85.4(a)).

## TRICARE PROGRAM IMPLEMENTATION

### *Comprehensive Structure*

The comprehensive structure of the TRICARE Smoking Cessation Program will incorporate multiple, evidence-based intervention strategies. This type of design is recommended as a best practice by other national smoking cessation programs and is proven to be effective in decreasing the rate of smoking. The key programmatic elements include:

- Recommendations from the Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guideline on effective tobacco use cessation interventions;

- Cessation treatment coverage;
- Resources for patient education aimed to facilitate smoking cessation and prevention and access to a 24/7 quit line;
- Regulatory, policy, and contractual changes necessary for program implementation; and
- Mechanisms for program evaluation.

Cessation treatment coverage and patient education/quit line are interventions specifically required by Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009. These interventions will be covered in the subsequent sections of this report. The results and recommendations from ongoing TRICARE initiatives (demonstration projects, programs, counter-marketing efforts, educational campaigns, and research initiatives) aimed to facilitate smoking cessation will be considered in the final program implementation and also addressed in this report. The Department will also strive to implement the best practices of other national tobacco control programs into the TRICARE program, as encouraged by Congress in the Joint Explanatory Statement for Section 713, and will discuss such efforts in this report.

TRICARE currently has some aspects of the overall smoking cessation program in place, as will be addressed in other areas of this report. These include web sites maintained by our Managed Care Support Contractors and the TRICARE Management Activity that provide educational information and programs operated in wellness centers at our military treatment facilities (MTFs). Other aspects that do not require regulatory change will be implemented as quickly as possible. However, certain program issues requiring further guidance to be established or modified to accomplish program implementation have also been identified in this report. Where necessary, changes will be made in regulation (32 CFR 199), policy, and contractual provisions, as applicable, to fully implement the TRICARE cessation treatment benefits. Since regulation changes take time to become fully implemented, modifications to the TRICARE Operations Manual will be initiated concurrently and, where possible, implemented simultaneously with the rule change.

*Key Elements*

1. *Clinical Practice Guideline (CPG)*

The Department of Veterans Affairs/DoD CPG on the management of tobacco use plays a significant role in the overall design of the TRICARE smoking

cessation program and allows for quality patient care consistent with Military Health System (MHS) goals. This guideline is evidence-based – targeted specifically to VA/DoD beneficiaries – and functions to incorporate the best practices for smoking cessation and prevention. The guideline also provides methods and strategies to decrease variations in clinical practice, thereby improving the rate of successful cessation for those desiring to quit smoking. This CPG provides critical interventions highly recommended and proven to facilitate smoking cessation and prevention by focusing on the importance of repeated screenings for tobacco use; emphasizing the need for easy access to effective evidence-based cessation treatment, including counseling and pharmacotherapy; and strongly encouraging patient education.

When considering the method and desired effect of implementation, the CPG offers a comprehensive approach to designing a program aimed to assist TRICARE eligible cessation specialists in delivering effective and tailored treatments that will improve and maintain the health and quality of life for eligible TRICARE beneficiaries.

2a. *Cessation Treatment Coverage (Counseling Services)*

Section 713 requires the TRICARE cessation treatment benefit to include counseling services. The CPG highly recommends that smokers desiring to quit receive some form of counseling. The CPG provides that counseling services may be delivered in multiple formats, such as individual counseling, group counseling, or proactive telephone counseling. Further, the CPG advises that counseling may be more effective when different formats are combined, and this is encouraged in Section 713. The TRICARE cessation treatment benefit is also required to include access to proactive telephone counseling through a toll-free quit line available 24 hours a day, seven days a week.

Currently, services and supplies related to "stop smoking" regimens are prohibited by regulation, as provided in 32 CFR 199.4(g) (65). Therefore, a regulation change to remove this limitation is necessary. Additionally, the TRICARE Manuals that implement this new benefit will also have to be revised to reflect this new benefit and how it will be implemented. However, these changes to the Manuals can become final only after the related regulation has been changed.

The CPG highly recommends that counseling should be provided by clinical providers to increase the rate of smoking cessation. The Department is engaged in ascertaining what qualifications a provider needs in order to provide these counseling services and then determining if the provider classification is one that may be reimbursed under our current regulations or whether additional

changes must be made to add them as authorized TRICARE providers and to determine the proper method of billing for these counseling services. The Department is also determining the mechanisms for payment of counseling services delivered through a telephone quit line as compared to those services provided by the beneficiary's primary care physician.

We do not currently anticipate limiting the number of counseling sessions available via the Internet or quit line. There will, however, be limits set on the number of face-to-face counseling sessions per quit attempt and the number of quit attempt initiations per year; these numbers will be established based on current evidence-based smoking cessation guidelines. The beneficiary and primary care physician will determine if smoking cessation treatment is the best course of action and, if so, the TRICARE cessation benefit will be designed to fully assist the beneficiary in his or her efforts for smoking cessation.

2b. *Cessation Treatment Coverage (Pharmaceuticals)*

Section 713 specifically requires the TRICARE smoking cessation treatment coverage to include pharmaceuticals at no cost to the beneficiary and authorizes the Department to restrict their availability to the TRICARE Mail Order Pharmacy (TMOP) program if appropriate. Both the U.S. Surgeon General's guidelines and the VA/DoD CPG state counseling and medication are effective when used by themselves for treating tobacco dependence. However, the combination of counseling and medication is more effective than either alone. Thus, providers should encourage all individuals making a quit attempt to use both counseling and medication. The DoD Uniform Formulary will be modified as recommended by the DoD Pharmacy and Therapeutics Committee to include smoking cessation medications. These medications will be available to beneficiaries through the TMOP and, when applicable, through MTF pharmacies. Although the Department is currently anticipating excluding availability of these medications through the retail pharmacy system, this decision has not been finalized. A final determination will be made once all factors surrounding the viability of utilizing the retail pharmacy system have been fully analyzed. In addition, most smoking cessation medications are currently available as Over the Counter (OTC) medications, and therefore cannot be procured by beneficiaries through the TMOP or retail pharmacy system. Changes to current regulations will also be required to enable beneficiaries to obtain these OTC medications at no cost through these venues.

3. *Patient Education and Access to 24 hours 7 days a week (24/7) Quitline*

Section 713 requires the TRICARE program to include a method by which beneficiaries participating in the program can have access to smoking cessation

materials in both printed and Web-based format. In addition, it requires access to a toll-free quit line, 24 hours a day, 7 days a week. These two elements are presented together as there is significant overlap between the Web-based services available and the quit lines. Many of these resources provide Web-based educational materials and interactive quit plans that are supported by telephonic interaction and counseling.

Currently, there are many Web-based cessation programs that incorporate methods proven to be effective in assisting smokers to stop their tobacco use. Some of these Internet sites also provide educational materials, online group and individual counseling, and support for medication usage. For example, the Department of Health and Human Services provides an online cessation program consistent with the VA/DoD CPG for effective treatment methods. This online cessation program is found at http://www.smokefree.gov. The American Lung Association has a similar program available at http://www.ffsonline.org. In addition to its own award-winning Web site, www.ucanquit2.org, which is directed at junior enlisted personnel, TRICARE will publish a comprehensive listing of Web sites focusing on smoking cessation (see Appendix A).

There are currently a significant number of quitline services available across the United States. The North American Quitline Consortium provides a compendium of services available and an interactive map to direct beneficiaries to the local quitline resources in their area. The American Cancer Society provides quitline contact information by state listings. They can be found at www.cancer.org/docroot/PED/PED_10_3x_Find_support.asp?sitearea=&level= . The American Lung Association provides an interactive map to access resources; their Web address is www.lungusa.org/site/c.dvLUK9O0E/b.22931/k.8550/Smoking_Cessation_Support.htm. The U.S. Department of Health and Human Services offers 1-800-QUITNOW resources across the country. Their Web site http://1800quitnow.cancer.gov/ puts beneficiaries in touch with local resources and support counselors. Though few of these resources currently offer 24/7 access, TRICARE is currently working to provide access to quitline services around the clock as required in Section 713.

4. *Involvement of Chain of Command Officers*

Section 713 requires the Department to provide for the involvement of officers in the efforts of an Active Duty participant to quit smoking. Smoking compromises military readiness and fitness levels within the Uniformed Services. Per 32 CFR, Section 85.6, each Military Department has implemented a smoking cessation program as part of its health promotion plan and must integrate the activities of the medical and personnel departments. Therefore, the critical

involvement of the chain of command should continue and be enhanced with the implementation of TRICARE's smoking cessation program as required under Section 713,

It should also be noted that although rates of smoking among Active Duty Service members, and particularly young and veteran beneficiaries, have increased, many resources are available to this specific population. A list of Internet Web-based sites available for military members is found at Appendix A.

5. *Program Evaluation*

Section 713 requires the Department to submit a report to Congress by October 2009 addressing the status, number of participants, rate of success, and recommendations pertaining to the program, as implemented. The Department has several ongoing measures testing the effectiveness of implementing a comprehensive smoking cessation program. These measures include the "Healthy Choices for Life" demonstration program, the "Tobacco Free Me" pilot project, and counter-advertising campaign for young military smokers, "Quit Tobacco--Make Everyone Proud." The results and recommendations from these demonstrations and projects are currently being evaluated, and they will be considered in the final implementation of the program.

The Department is also coordinating with the VA on a research initiative project conducted by the Institute of Medicine to identify ways that both Departments can work together to promote tobacco use prevention and cessation among the military and veteran populations. To achieve this goal, a committee consisting of professional health care experts from the private sector will review each Department's policies and practices to recommend effective research approaches to smoking cessation for their specific population.

## APPENDIX A: SMOKING CESSATION PROGRAMS

*Service Specific*

- U.S. Army Center for Health Promotion and Preventable Medicine. Directorate of Health Promotion and Wellness. Available at: http://chppm-www.apgea.**army**.mil/dhpw/

- Navy Health Promotion Program. Available at: http://www-nehc.med.navy.mil/hp/

- Navy and Marine Corps Public Health Center. Available at: http://www-nmcphc.med.navy.mil/hp/tobacco/personal_health.htm

- Air Force Institute for Operational Health. Available at: http://www.airforcemedicine.afms.mil/

- Quit Tobacco – Make Everyone Proud. Available at: http://www.ucanquit2.org

- Coast Guard Tobacco Cessation Program. Available at: http://www.uscg.mil/worklife/tobacco_cessation.asp

*Other*

- http://www.Smokefree.gov

- 1-800-QuitNow

- North American Quitline Consortium

## APPENDIX B – SMOKING CESSATION SERVICES

- American Cancer Society. Available at: http://www.cancer.org
- American Lung Association. Available at http://www.lung.usa.
- CDC Smoking & Tobacco Use: Quit Smoking. Available at, www.cdc.gov/tobacco