



UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

MAY 9 2011

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

Dear Mr. Chairman:

The enclosed report responds to section (sec.) 712 in the National Defense Authorization Act for Fiscal Year 2010 that requires the Secretary of Defense to report on the implementation of policy guidance dated November 7, 2006, regarding deployment-limiting psychiatric conditions and medications, and to establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces. We apologize for the delay in submitting this final report since our interim report stated it would be provided in January 2011. Obtaining core data, and additional data later found to be needed, took more time than expected.

The Department examined indicators of compliance with implementation of the 2006 policy guidance regarding deployment-limiting psychiatric conditions and medications. This final report contains results from this examination. It also examines the policy published on February 5, 2010, Department of Defense (DoD) Instruction 6490.07, "Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees," to determine if the policy elements required by sec. 712(b) have been met.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

A handwritten signature in black ink, appearing to read "Clifford L. Stanley".

Clifford L. Stanley

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member



PERSONNEL AND
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UNDER SECRETARY OF DEFENSE
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MAY 9 2011

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

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The Honorable Lindsay Graham
Ranking Member



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MAY 9 2011

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

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The Honorable Thad Cochran
Vice Chairman



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Committee on Appropriations
United States Senate
Washington, DC 20510

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Vice Chairman



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PERSONNEL AND
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017 9 2011

The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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cc:
The Honorable Adam Smith
Ranking Member



PERSONNEL AND
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UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

The Honorable Joe Wilson
Chairman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

July 9 2011

Dear Mr. Chairman:

The enclosed report responds to section (sec.) 712 in the National Defense Authorization Act for Fiscal Year 2010 that requires the Secretary of Defense to report on the implementation of policy guidance dated November 7, 2006, regarding deployment-limiting psychiatric conditions and medications, and to establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces. We apologize for the delay in submitting this final report since our interim report stated it would be provided in January 2011. Obtaining core data, and additional data later found to be needed, took more time than expected.

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cc:
The Honorable Susan A. Davis
Ranking Member



UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

MAY 9 2011

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cc:
The Honorable Norman D. Dicks
Ranking Member



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE

4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

11/9/2011

The Honorable C. W. Bill Young
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to section (sec.) 712 in the National Defense Authorization Act for Fiscal Year 2010 that requires the Secretary of Defense to report on the implementation of policy guidance dated November 7, 2006, regarding deployment-limiting psychiatric conditions and medications, and to establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces. We apologize for the delay in submitting this final report since our interim report stated it would be provided in January 2011. Obtaining core data, and additional data later found to be needed, took more time than expected.

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The Honorable Norman D. Dicks
Ranking Member

NATIONAL DEFENSE AUTHORIZATION ACT 2010
Section 712 (a) and (b)

Report on the Administration and Prescription of Psychotropic Medications for
Members of the Armed Forces Before and During Deployment



APRIL 2011

Preparation of this study/report cost the
Department of Defense a total of approximately
\$49,811.00 dollars in Fiscal Years 2010-2011.

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Introduction

BACKGROUND

Section 712 of the National Defense Authorization Act for Fiscal Year 2010 (henceforth to be referred to as “Section 712”) contained two requirements. First, the Secretary of Defense shall submit a report on the implementation of policy guidance dated November 7, 2006, regarding deployment-limiting psychiatric conditions and medications. Second, it directed that a policy be established and implemented for the use of psychotropic medications for deployed members of the Armed Forces by October 1, 2010 (Attachment A, Sections 712(a) and (b)). This second requirement was met by a policy published February 5, 2010 (Department of Defense Instruction (DoDI) [DoDI 6490.07], *Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees*). This DoDI did not replace, but incorporated by reference, the November 7, 2006, *Policy Guidance for Deployment-Limiting Psychiatric Conditions*.

The content of both the DoDI 6490.07, published in February 2010, and the November 7, 2006 Policy Guidance (henceforth to be referred to as the “2006 Guidance”) were mapped to the requirements of Section 712(b), to evaluate whether all required policy elements have been sufficiently met (Attachment B). Operational compliance with the requirements set forth by the 2006 Guidance was then evaluated by conducting an analysis to examine key indicators of implementation. The findings from this evaluation are detailed in a subsequent section of this report.

ORGANIZATION OF THE REPORT

This report first provides findings from the 2006 Guidance implementation compliance analysis regarding deployment-limiting psychiatric conditions and medications (Section 712 (a)).

Then it delivers findings from the mapping of existing policy to the requirements of Section 712 (b), to assure that the intent of the requirements is being met. The focus was to gather and evaluate information to determine if there is a need for supplementary policy development, changes in existing policy, and/or changes in operational processes. Adjunct reference information that may impact or have potential bearing on final recommendations is also included. The findings are discussed and the report concludes with recommendations.

Implementation of 2006 Guidance Pertaining to Deployment-limiting Psychiatric Conditions and Medications

OVERVIEW

The 2006 Guidance addresses circumstances of deployment and continued service in a deployed environment for military personnel who experience psychiatric disorders and/or who are prescribed psychotropic medication. It did not alter or replace the accession, retention, and general fitness for duty standards. Thus, the 2006 Guidance did not change the requirement for the mental and physical fitness necessary to plan and execute missions involving combat. It established deployment-limiting medications and those inherently disqualifying for deployment regardless of military occupational specialty or location. Taking into account that the following may not cover all circumstances (e.g., Service specific standards such as medication use in aviators), certain psychiatric medications were indicated as being disqualifying for deployment, as follows:

- Antipsychotics used for psychotic, bipolar and chronic insomnia symptoms
- Lithium and anticonvulsants to control bipolar symptoms
- Medications that require special storage, such as refrigeration
- Medications that require lab or special follow-up monitoring or assessment
- Medications prescribed within 3 months prior to deployment not yet determined to be efficacious or free of side effects
- Medications that may be clinically and operationally problematic such as short half-life benzodiazepines and stimulants (for this medication type, the decision may be made to

deploy personnel on such medications but only if balanced with necessity to function in a deployed setting, susceptibility to withdrawal, ability to procure the meds, and potential for abuse).

The Military Departments disseminated specific-Service notification to implement this 2006 Guidance.

As well, Services are required to follow Combatant Command policy for those deploying to Central Command (CENTCOM) controlled areas. The only Service exception is ship deployments in the Navy that are not covered under CENTCOM deployment regulations. There is no published Navy instruction specific to psychiatric medication or diagnosis limiting conditions for these ship deployments; deployability is determined by the ship's medical department. The Navy follows guidance concerning small arms for all other deployments. If a Service member is not able to carry small arms due to a diagnosed psychiatric condition and/or medication, they cannot deploy. Attachment C, *Psychotropic Medications and Associated CENTCOM Restrictions*, demonstrates how the above medication restrictions referenced in the 2006 Guidance are implemented by CENTCOM into an operational reference guide.

GOALS

Goals accomplished were in-depth analyses, specific to measuring compliance with the 2006 Guidance for deployment-limiting psychotropic medications and diagnoses. The objectives were to: (1) evaluate trend data of key indicators of compliance since the implementation of the 2006 Guidance; (2) note trends that may identify the insufficiency of existing policy in meeting the intent of restricting deployments for those with certain mental conditions and/or those on psychotropic medications; and (3) inform the potential need for further development or revision of policy or implementation processes.

INDICATORS

Indicators that could be ascertained through available administrative medical encounter and deployment data were selected as described in Table 1.

Table 1. Indicators of Compliance for Implementation of Deployment-limiting Psychiatric Medication and Diagnosis Policy

2006 Policy Guidance for Psychiatric Related Deployment Limitations	Indicator for Compliance
<ul style="list-style-type: none"> ▪ 4.1.4.2 <i>Psychotic diagnosis (non-deployable)</i> 	(1) Diagnosis of a psychotic disorder within 3 months of deployment.
<ul style="list-style-type: none"> ▪ 4.1.4.2 <i>Bipolar diagnosis (non-deployable)</i> 	(2) Diagnosis of a bipolar disorder within 3 months of deployment.
<ul style="list-style-type: none"> ▪ 4.2.3.1. <i>Antipsychotics¹ ... [includes Lithium]... used for psychotic, bipolar and chronic insomnia symptoms (non-deployable)</i> 	(3) Antipsychotic medication prescribed within 3 months of deployment.
<ul style="list-style-type: none"> ▪ 4.3.1. <i>Medical readiness follows a military lifecycle process that includes sustainment, pre-deployment, deployment, and post-deployment periods. Psychological readiness must be assessed at each phase of that lifecycle...</i> 	(4) Pre-deployment screening.

POPULATION

The source population was the total service member population between 2006 and 2009. This census data were extracted from the Defense Enrollment Eligibility Reporting System (DEERS). From this population, all Active Duty, and Activated Guard and Reserve Service members in fiscal years 2006 through 2009 deployed to Operation Iraqi Freedom (OIF) or Operation Enduring Freedom (OEF) were identified by the Defense Manpower Data Center (DMDC). Each year's group of Activated Guard and Reserve Component (RC) and Active Component (AC) Service members was then examined separately to allow for comparisons by year and identification of trends across time. Table 2 shows the total number of Service members by component by year included in this examination.

¹ Excludes allowable prescriptions for Seroquel 25 mg.

Table 2. Number of Service Members Designated for Deployment by Fiscal Year

Year	2006	2007	2008	2009
AC	278,638	304,987	296,795	292,837
RC	79,860	70,114	79,726	108,552
Grand Total	358,498	375,101	376,521	401,389

DATA SOURCES

The data came from the corporate Military Health System (MHS) Data Repository (MDR). The Pharmacy Data Transaction System (PDTS) data – contained within the MDR – was used to count the number of Service members receiving a prescription drug filled at a military treatment facility (MTF), the TRICARE mail order pharmacy (TMOP) or a retail pharmacy under contract with TRICARE. The medication restrictions listed on Attachment C were used as the method for identifying and categorizing deployment-limiting psychotropic medications in this evaluation.

The indicators pertaining to mental health diagnoses were examined using data from the direct care Standard Inpatient Data Repository (SIDR) and Standard Ambulatory Data Repository (SADR) encounters, and purchased care TRICARE Encounter Data (TED) claims. The primary diagnosis code and all other diagnosis codes associated with an encounter were used to determine if a mental health condition was present at the time of an encounter with a health care provider. All of these diagnosis codes were then sorted into groups of diagnosis type by adapting the Agency for Healthcare Research and Quality Clinical Classification Software (CCS) diagnosis code system. “The CCS provides a method for classifying mental health ICD-10 diagnoses into clinically meaningful categories, which can be used for aggregate statistical reporting of a variety of types.” (http://www.hcup-us.ahrq.gov/tools_software.jsp). From these categories, indicator-specific sub-groups of diagnoses (bipolar disorders and psychoses) were

identified for data extraction purposes (Refer to Attachment D). The use of one of these codes in a medical encounter, within three months of deployment, was considered reflective of an active condition that is under treatment, regardless of the effectiveness of that treatment.

Contingency Tracking System (CTS) data was received from Defense Manpower Data Center. CTS data contains information relating to deployment to OEF and OIF contingencies.

TRENDS IDENTIFIED

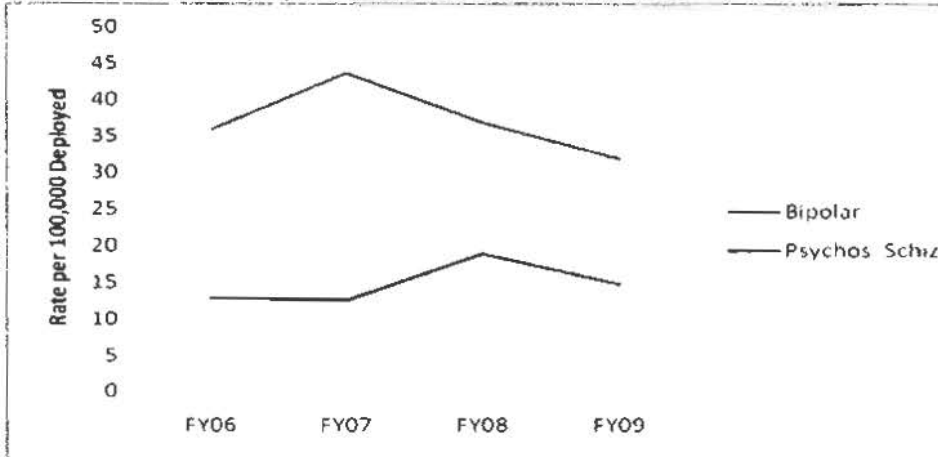
As stated in the Introduction, the 2006 Guidance was signed November 7, 2006. The following data shown for identified trends are reported by fiscal year (FY). Thus, when viewing the findings, it is important to note that the 2006 Guidance was issued, not during FY2006, but instead during the first quarter of FY 2007.

Diagnosis of a psychotic or bipolar disorder within 3 months of deployment.

The 2006 Guidance states, “Psychotic and Bipolar Disorders are considered disqualifying for deployment.” (Paragraph 4.1.4.2) These are, therefore, referenced as deployment-limiting diagnoses. Using policy compliance as a surrogate measure of implementation, the question was whether Service members with deployment limiting conditions were being deployed and if there was a shift in that rate subsequent to policy implementation.

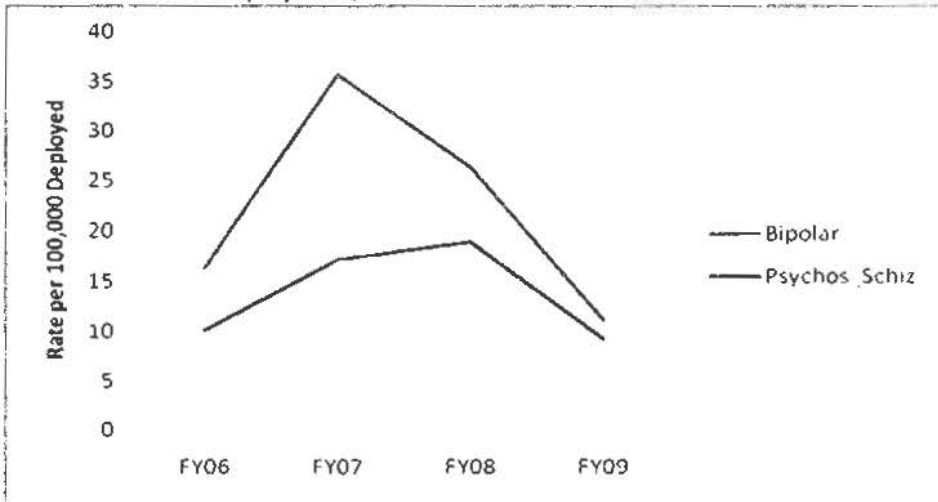
Active Component. The data in Figure 1 were reflective of AC Service members that had been deployed with diagnoses that were, by policy, deployment limited. While not statistically significant, the trend appears to be in a downward direction.

Figure 1. Mental Health Deployment limiting condition rates per 100,000 Active Component Troops Deployed within 3 months of deployment, U.S. Armed Forces 2006-2009



Reserve Component. These data in Figure 2 were reflective of RC Service members that had been deployed with diagnoses that were, by policy, deployment limited. While the rate of decline for psychoses and schizophrenia was not statistically significant, the trend appears to be in a downward direction and may be affected the limited number of cases. The rate of the decline for bipolar disorders (also deployment limiting) was significant with $p=.0026$.

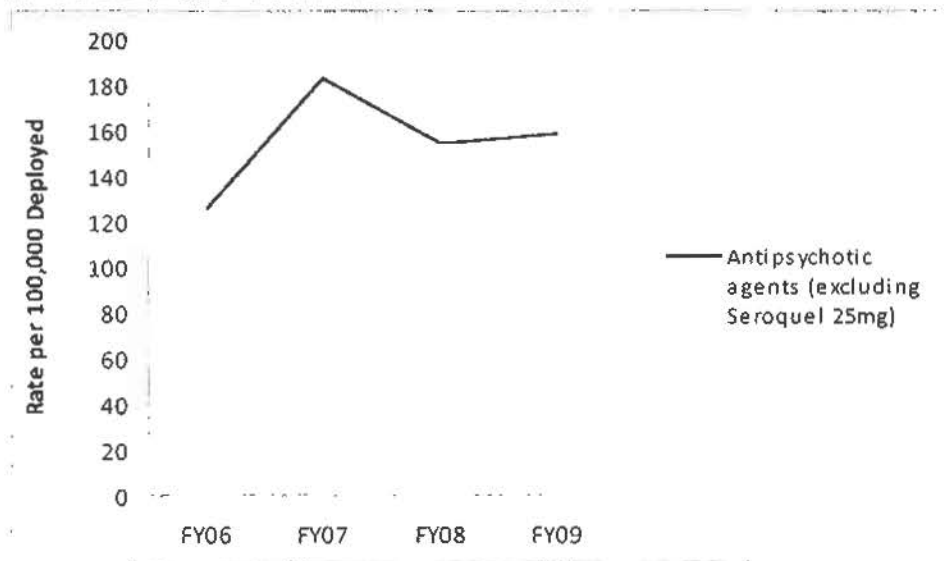
Figure 2. Mental Health Deployment limiting condition rates per 100,000 Reserve Component Troops Deployed within 3 months of deployment, U.S. Armed Forces 2006-2009



Antipsychotic medication prescribed within 3 months of deployment.

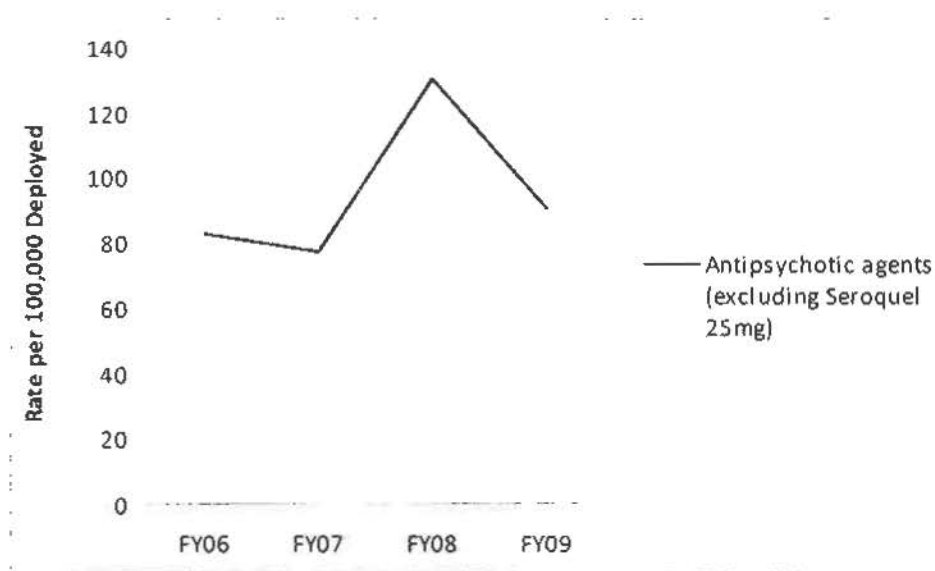
Active Component. Antipsychotics used to control psychotic, bipolar, and chronic insomnia symptoms; and lithium and anticonvulsants to control bipolar symptoms were noted as disqualifying for deployment under paragraph 4.2.3.1. of the 2006 Guidance. The guidance applies only to anti-psychotic medications that are used to control psychotic, bipolar and chronic insomnia symptoms. There is no reference to use of this class of medications for non-psychotropic indications. This may, in part, account for the lack of a significant downward trend for this specific indicator of policy implementation among both the AC and RC as shown in Figures 3 and 4. This trend is also inconsistent with the significant decline in bipolar disorders and decline in psychotic disorders and schizophrenia as noted in Figures 1 and 2.

Figure 3. Deployment-limiting Anti-psychotic Medication rates per 100,000 Active Component Troops Deployed within 3 months of deployment, U.S. Armed Forces 2006-2009



Reserve Component. Results.

Figure 4. Deployment-limiting Anti-psychotic Medication rates per 100,000 Reserve Component Troops Deployed within 3 months of deployment, U.S. Armed Forces 2006-2009



OTHER

Paragraph 4.3.1. of the 2006 Guidance states, “Medical readiness follows a military lifecycle process that includes sustainment, pre-deployment, deployment, and post-deployment periods. Psychological readiness must be assessed at each phase of that lifecycle...” Indicative of this requirement is the rate of pre-deployment screening. Mental health screening has been increasing overall since 2006, with a significant increase in the rate of pre-deployment screening in 2008 and 2009. This increase can be associated with the full implementation of the 2006 Guidance for deployment-limiting psychotropic medications and diagnoses. See Figures 5 and 6 for the total number of Service members undergoing a mental health pre-deployment screening. Because deployment times differ among the services, these count data should not be confused with population incident rates.

Figure 5. Total Pre-deployment Mental Health Screening within 3 months of deployment Service members, AC component, U.S. Armed Forces 2006-2009

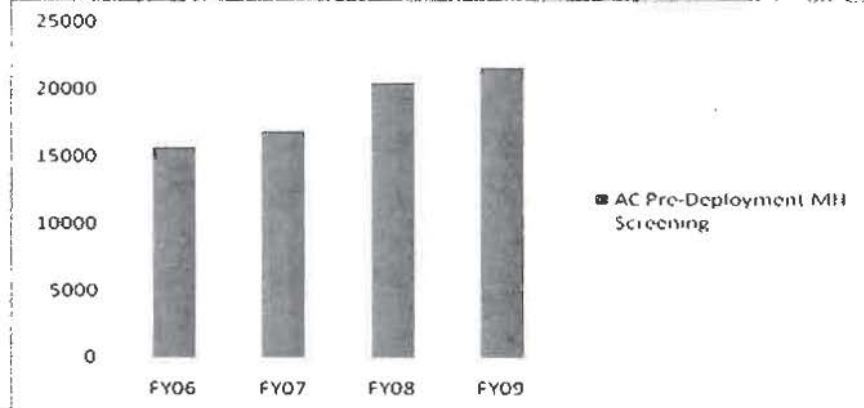
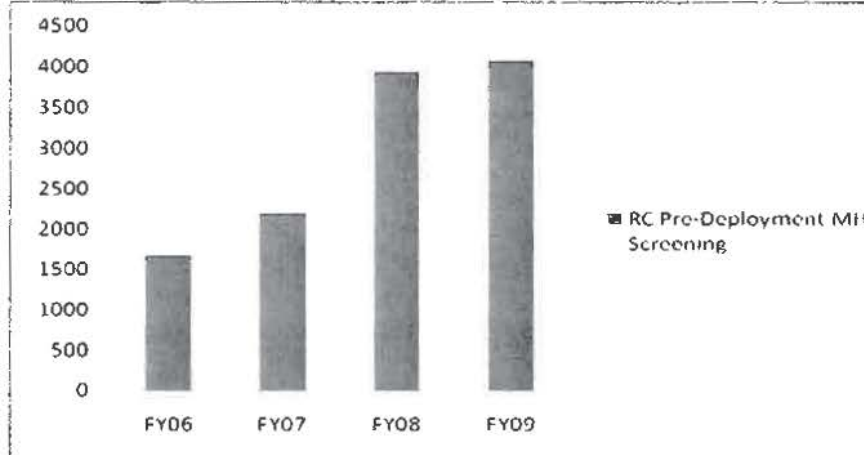


Figure 6. Total Pre-deployment Mental Health Screening within 3 months of deployment Service members, RC component, U.S. Armed Forces 2006-2009



For both the AC and the RC, these data represent a significant and increasing trend over time.

SECTION 712(a) SUMMARY

Examination of the rate of those Service members with a diagnosis of bipolar disorder, a psychotic disorder or schizophrenia within three months of their deployment from 2006 – 2007 indicated a possible downward trend of those Service members deployed with these conditions consistent with the Fiscal Year 2007 (November 2006) issuance of the 2006 Guidance. Over this time period, there was also a significant upward trend in the rate of mental health screenings. Both of these findings lend strong support that the 2006 Guidance requirement that

psychological readiness be assessed at each phase... [In this case the pre-deployment phase]... of the Service member's lifecycle is being implemented.

The finding that there was not a downward trend associated with the issuance of the 2006 Guidance pertaining to anti-psychotic medications called for closer scrutiny beyond the immediate purview of evaluating implementation of this Guidance. Recent attention has been drawn to the increasing use of antipsychotic medications for "off label" uses, as initially studied relative to behavior management of elderly patients. (Kuehn. JAMA, April 28, 2010) Several points of potential relevance to these analyses were identified. For example, the FDA may, over time, expand the indications for a particular drug. Aripiprazone, an antipsychotic medication, was approved for use as an adjunctive therapy for major depression in late 2007. This medication is among the CENTCOM list of anti-psychotic medications deemed non-deployable. Other points of relevance were: the need to evaluate appropriateness of the use of medications vs. only a data-based count of prescriptions; that physicians may not be aware that their prescribing pattern is off label without sufficient evidence; and, the recognition that there are, in fact, evidence-based reasons for which psychotropic medications are frequently used. Last, an important caveat is the recognition of whether or not studies being cited were designed to evaluate appropriateness of the use of the medications.

The Armed Forces Health Surveillance Center (AFHSC) conducted an analysis of prescriptions for mental health-related conditions for the Active Component covering the period of CY2002-2009. This analysis was conducted to examine all of the prescription categories listed in the Army Times article (*Medicating the Military*, March 8, 2010) that could be distinguished in the Pharmacy Service database: pain relievers, muscle relaxants, anti-convulsants, anxiolytics (includes sleep aids), anti-depressants, and anti-psychotics. They found very few instances of an anti-psychotic medications being prescribed within 30 days of deployment (Figure 7).

Figure 7. Adapted from Table 3 of the Armed Forces health Surveillance Center Analysis of Prescriptions for Mental Health-Related Conditions for the Active Component Within 30 Days of Deployment

Anti-Psychotic Prescriptions within 30 Days Prior to Deployment Start				
Service	2006	2007	2008	2009
Army	60	100	61	70
Air Force	5	4	3	1
Marines	4	5	11	5
Navy	4	6	3	5
Total	73	115	78	81

Of those that were targeted for deployment, the authors noted that it was not known, with certainty, whether these deployments actually occurred. They found that sixty-seven percent of these prescriptions were for Seroquel but their findings did not distinguish between a *non*-deployment limiting prescriptions for Seroquel 25 mg. (i.e., when prescribed as a sleep aid for long distance trips that cross various time zones) and prescriptions for Seroquel greater than 25 mg. that are deployment-limiting. Thus, the low percentage of those who had been placed on an anti-psychotic medication within 30 days is likely to be even lower than reported.

Unlike the AFHSC analysis, the 2006 Guidance analysis included the additive total of all prescriptions issued within 3 months, within 2 months and within 1 month of deployment. (Figure 10) Under the Guidance, antipsychotics used to control psychotic, bipolar, and chronic insomnia symptoms are deployment limiting medications. An individual on an antipsychotic medication can be switched to another medication so long as there is sufficient time to demonstrate efficacy or to be free of potentially significantly impairing side effects. The policy guidance defines that period of time as within 3 months of deployment. Therefore an individual receiving an antipsychotic deployment limiting medication within 3 months of deployment cannot meet the stabilization requirements for a different medication if the intent was to switch the patient to another medication shortly before deployment.

Figure 10. Prescription & Unique Beneficiary Count for Antipsychotic Prescriptions 30 Days of Deployment for the Active Component

FY06 #scripts (#people)	FY07 #scripts (#people)	FY08 #scripts (#people)	FY09 #scripts (#people)
417 (349)	628 (556)	547 (456)	550 (464)

Figure 10 also shows both the unique number of Service members receiving a prescription and the total number of prescriptions that were dispensed. It is of highest importance that these numbers be put into perspective for reporting purposes. By referring back to Table 2 (the number of AC Service member deployments that occurred within each of these years), the rate of the number of people who were noted as having a prescription for an anti-psychotic medications 3 months prior to deployment *is very small*: 0.1%, 0.2%, 0.2%, and 0.2%, respectively. As seen in the preceding Figures, these small counts relative to the denominator population of number of deployments, necessitated graphically reporting the findings using a rate of “per 100,000” Service members to enable visual representation of the trends over time.

Service members being deployed to Iraq and Afghanistan are governed by deployment policy published by CENTCOM. While Department of Defense Issuances provide baseline requirements, CENTCOM can establish more stringent deployment requirements if desired. The 2006 Guidance pertains specifically to mental health related conditions. Providers not treating mental health related conditions may not be aware of the CENTCOM pharmaceutical restrictions or may not believe that a medication, unrelated to a deployment limiting mental health diagnosis, is restricted by policy. For instance, in addition to certain types of emotional, behavioral, or mental conditions. Chlorpromazine (a CENTCOM restricted anti-psychotic medication) may also be used to control transient conditions such as nausea, vomiting, or continuous hiccups. While the 2006 Guidance does not address the use of anti-psychotic medications for non-psychiatric indications, the preceding discussion and findings of this analysis suggests that more

research is needed in this area. Additionally, as previously mentioned, more focus is needed on approved uses of medications such as Aripizole, classified as an anti-psychotic, which may be prescribed for depression, a condition that is not categorically deployment-limiting.

Existing Policy Mapped to Requirements in NDAA Section 712 (b)

The Section 712 policy requirement to establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces was to, at a minimum, address the following:

- The circumstances or diagnosed conditions for which such medications may be administered or prescribed.
- The medical personnel who may administer or prescribe such medications.
- The method in which the administration or prescription of such medications will be documented in the medical records of members of the Armed Forces.
- The exam, treatment, or other care that is required following the administration or prescription of such medications.

DoDI 6490.07, *Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees*, was published February 2, 2010. It did not cancel the 2006 Policy Guidance but upholds the 2006 Guidance definitions of psychiatric diagnoses and medications that are deployment-limiting for Service members, as follows:

- Psychotic and/or bipolar diagnosis
- Under treatment with fewer than 3 months of demonstrated stability
- Presence of residual symptoms that impair duty performance
- Pose a substantial risk for deterioration and/or recurrence of impairing symptoms in the deployed environment
- Chronic: requires ongoing treatment with antipsychotics, lithium or anticonvulsants

SECTION 712(b) SUMMARY

By mapping the above listed Section 712 required policy elements to the newly published DoDI 6490.07 and the continuation of the 2006 Policy Guidance as a current policy of reference, it was determined that the congressionally directed requirement to establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces has

been met. (Refer to Attachment B). The benefit of fully incorporating and canceling the 2006 Guidance in a future revision of DoDI 6490.07 has been identified. This would consolidate the policy elements required under Section 712 into one policy document rather than being distributed between the two documents.

Owing to the recent (2010) publication of DoDI 6490.07, sufficient data were not yet available for examination of the effects of implementation and/or compliance with this policy specifically, nor was this a requirement of Section 712. However, the analysis of indicators of compliance with the 2006 Guidance has served to inform indices of compliance and issues inherent to both.

Discussion

In March 2010, shortly after the February 2, 2010 publication of DoDI 6490.07, *Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees*. CENTCOM, issued a message, Subject: Modification Ten to USCENTCOM Individual Protection and Individual/Unit Deployment Policy. Under this message, CENTCOM provided the following guidance: "Psychotropic medications include, but are not limited to, controlled and non-controlled substance anti-depressants, anti-anxiety, quetiapine (Seroquel) for sleep, CII and non-CII stimulants, anti-seizure medications... This term also encompasses the generic equivalents of the above medication categories when used for non-psychotropic indications." While this statement references the use of psychotropic medications for non-psychotropic indications, there is no suggestion in the CENTCOM message that anti-psychotic agents are categorically deployment limiting. Thus, while this message gives guidance for a limited supply of psychotropic medications and the need for service members to seek clinical follow-up in theater to ensure a continued supply of medications, the phrase "but are not limited to" suggests that the list is not all inclusive and could include anti-psychotic medications. While CENTCOM

published a list of restricted medications found in Attachment C, providers outside of the mental health community may not be privy to – or aware of – the CENTCOM restricted medication list. Thus, although the 2006 Guidance contains language specific to mental health conditions and psychotropic medications that are deployment limiting, and DoDI 6490.07 contains language specific to mental health conditions that are deployment-limiting, the use of medications for non-psychiatric reasons, is not addressed in either of these Issuances.

In response to public scrutiny of the Department of Defense policies and Service practices regarding the use of psychotropic drugs, a request was made August 17, 2010 from the Office of the Assistant Secretary of Defense (Health Affairs) to the Defense Health Board (DHB) to address questions related to: the safety and effectiveness of off-label prescribing practices, treatment side effects, potential risks, and possible impairments to combat mission readiness. These issues have arisen as a result of reports suggesting psychotropic drug use increased significantly within the military since the start of Operations Iraqi Freedom and Enduring Freedom. The DHB was asked to address the DoD's concerns with these assertions and to provide recommendations for actions that the DoD might pursue to ensure the health and safety of Service members. The memorandum and associated questions submitted to the DHB can be found in Attachment E. Findings and recommendations were requested for completion by the DHB no later than March 31, 2011, and a report will be submitted to Congress. The findings from this report may provide additional information specific to deployment-limiting psychotropic medications among the Military Departments that will need to be evaluated for potential inclusion in future policy development or revisions.

Examples of additional possible indicators, drawn from the 2006 Guidance, that have future potential use as measures of policy implementation, and/or that warrant further examination are listed on Table 3.

Table 3. Additional Potential Indicators of Compliance for Implementation of Deployment-limiting Psychiatric Medication and Diagnosis Policy

<ul style="list-style-type: none"> ▪ 4.2.2. <i>Caution is warranted in beginning psychotropic medication for deploying personnel</i> 	→ New psychotropic medication prescription within 3 months of deployment
<ul style="list-style-type: none"> ▪ 4.2.3.4 Medication prescribed within 3 months prior to deployment that has yet to demonstrate efficacy or be free of significantly impairing side effects. 	→ Benzodiazepines-anxiolytics prescribed within 3 months of deployment
<ul style="list-style-type: none"> ▪ 4.2.4 Psychiatric medications that may be clinically and operationally problematic during deployment 	→ Benzodiazepines-anxiolytics prescribed within 30 days of deployment

These and other potential indicators and outcomes were outside the scope of this task and current data to evaluate. Examining indicators such as these, as well other outcomes of importance will require a multi-faceted investigative study dedicated both to evaluating these indicators and to validating the efficacy of the outcome intended by policy. For instance, by evaluating Service members who appeared to not meet policy guidelines, was there a greater rate of return for psychiatric related conditions using the air evacuation system, or was the policy guidance too restrictive? Further study is needed to answer these questions.

Conclusion

This report summarizes the actions accomplished to meet the requirement of Section 712. A compliance analysis was completed that indicated implementation of the 2006 Guidance. Existing policy was mapped to the requirements of Section 712 Section (b), and revealed that requirements are met. The Department is committed to continuing the identification, implementation, evaluation and ongoing surveillance of policy elements informed by medical science. Our next steps will include examining the findings and recommendations of the DHB study for potential policy-specific implications that should be included in future revisions of policy pertaining to deployment-limiting psychiatric medications and mental diagnoses. At that time, we will consider the potential usefulness of unifying the policy elements that pertain to deployment-limiting psychiatric medications and mental diagnoses currently found across

multiple policy sources into one document. We will also explore the feasibility of conducting follow-on analyses to examine such issues as the identification of predictors for psychiatric evacuation out of theater which may also inform future revisions of policy pertaining to deployment-limiting indicators.

**NDA 2010 - SEC. 712. ADMINISTRATION AND PRESCRIPTION OF
PSYCHOTROPIC MEDICATIONS FOR MEMBERS OF THE ARMED FORCES
BEFORE AND DURING DEPLOYMENT**

(a) **REPORT REQUIRED.**—Not later than October 1, 2010, the Secretary of Defense shall submit to the congressional defense committees a report on the implementation of policy guidance dated November 7, 2006, regarding deployment-limiting psychiatric conditions and medications.

(b) **POLICY REQUIRED.**—Not later than October 1, 2010, the Secretary shall establish and implement a policy for the use of psychotropic medications for deployed members of the Armed Forces. The policy shall, at a minimum, address the following:

- (1) The circumstances or diagnosed conditions for which such medications may be administered or prescribed.
- (2) The medical personnel who may administer or prescribe such medications.
- (3) The method in which the administration or prescription of such medications will be documented in the medical records of members of the Armed Forces.
- (4) The exam, treatment, or other care that is required following the administration or prescription of such medications.

**EXISTING POLICY AND NATIONAL DEFENSE AUTHORIZATION ACT,
SECTION 712 REQUIRED POLICY ELEMENTS REGARDING THE
ADMINISTRATION AND PRESCRIPTION OF PSYCHOTROPIC MEDICATIONS
BEFORE AND DURING DEPLOYMENT**

Required policy elements	Memorandum, "Policy Guidance for Deployment-Limiting Psychiatric conditions and Medications", William Winkenwerder, Nov 7 2006	DoDI 6490.07, "Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees", February 5, 2010
(1) The circumstances or diagnosed conditions for which medications may be administered or prescribed	<p>2.2 Any condition or treatment for that condition that negatively impacts on the mental status or behavioral capability of an individual must be evaluated to determine the potential impact both to the individual Service member and to the mission.</p> <p>4.2. 1. Discusses circumstances and conditions associated with medication prescription;</p> <p>4.2.3.1. Identifies specific conditions for which antipsychotics, lithium and anticonvulsants are used</p>	<p>This guidance assists healthcare providers to decide whether Service members with psychiatric disorders and/or who are prescribed psychotropic medications should be deployed. Defines medical assessment as "the total of the pre-deployment activities described in section 1 of Enclosure 2 of Instruction and those listed in E4.A1.1 of DoDI 6490.03 (Ref 1) to include:</p> <ul style="list-style-type: none"> -Requirement for all DoD personnel to undergo a medical assessment prior to deployment -Requirements for Force Health Prescription Products
(2) The medical personnel who may administer or prescribe such medications	<p>Not specifically stated; referenced as a "clinician" (e.g., 4.3.1.3 pertaining to personnel diagnosed with a psychiatric disorder in theater)</p>	<p>Ref 1 – Subparagraph, E4.A1.1.3. re: Force Health Prescription Products</p> <p>In PROCEDURES, performance of medical assessments by a trained DoD health-care provider is required (Sec. 1) and trained providers are defined (Sec. 3.e.)</p>
(3) The method in which the administration or prescription of such medications will be documented in the medical records of members of the Armed Forces	<p>4.3.1.1.2. – Notes that any limitations should be documented in the Service-specific profile or military occupational health system & notations documented in the medical record</p> <p>Sec. 4.3.1.1.3. that medications ...implemented ...should be noted</p> <p>Sec. 4.3.1.1.1 any conditions...or prescribed psychotropic medication identified through the PHA (and post-deployment) assessment processes must be documented</p>	<p>Ref 1 – Subparagraph, E4.A1.1.3.4 requires that the provision or issuance of Force Health Prescription Products shall be documented in the medical records of the individuals receiving the prescription product</p> <p>Ref 1 – Subparagraph E4.A2.6. Copies of all ...medical encounter documentation...must be incorporated into the deployment health record.</p>
(4) The exam, treatment, or other care that is required following the administration or prescription of such medications	<p>Not limited to psychotropic meds. Assumption of treatment is implied in Sec. 4.3.1.1.3. that all medications/and or therapeutic conditions ...implemented ...should be noted...[and]...at the conclusion of treatment</p> <p>Also refer to 4.3.1.3 re: personnel diagnosed with a psychiatric disorder in theater</p>	<p>Not specifically stated but references memorandum "Policy Guidance dated Nov 7. 2006."</p>

Deployment Limiting Diagnoses

Mental Health Disorder	ICD-9-CM diagnostic code	Description
Bi-Polar	296.00-296.06	Bipolar I disorder, single manic episode
	296.10-296.16	Manic disorder, recurrent episode
	296.40-296.46	Bipolar I disorder, most recent episode (or current) manic
	296.50-296.56	Bipolar I disorder, most recent episode (or current) depressed
	296.60-296.66	Bipolar I disorder, most recent episode (or current) mixed
	296.7	Bipolar I disorder, most recent episode (or current) unspecified
	296.80-296.81, 296.89	Other and unspecified bipolar disorders
Schizophrenia and other Psychotic Disorders	293.81-293.82	Other specified transient mental disorders due to conditions classified elsewhere
	295.00-295.95	Schizophrenic disorders
	297.0 -297.9	Delusional disorders
	298.0-298.4; 298.8;298.9	Other nonorganic psychoses

**DEFENSE HEALTH BOARD STUDY QUESTIONS PERTAINING TO PRESCRIBING
AND USE OF PSYCHIATRIC MEDICATIONS**



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

AUG 17 2010

HEALTH AFFAIRS

MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD

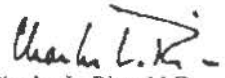
SUBJECT: Question to the Board Regarding Psychotropic Medication Prescription Use and Complementary and Alternative Medicine Use in the Department of Defense

The Department of Defense (DoD) policies and the Service practices regarding the prescription of psychotropic drugs are being scrutinized by lawmakers and the public. Concerns pertaining to the safety and effectiveness of off-label prescribing practices, treatment side effects, potential risks, and possible impairments to combat mission readiness, have arisen as a result of reports suggesting psychotropic drug use has increased significantly within the military since the start of Operations Iraqi Freedom and Enduring Freedom.

We request the Defense Health Board (DHB) consider DoD's concerns with these assertions and provide recommendations for actions DoD might pursue to ensure the health and safety of our Service members. In addition to reviewing the use and prescribing of psychiatric medications, we also request that the DHB review DoD's use of Complementary and Alternative Medicine. Issues should be considered that would augment and ensure patient safety and quality of care, such as provider credentialing and criteria used to inform decisions pertaining to continuation of services provided, including outcome measurements regarding clinical and functional improvement. In order for DoD to provide optimal support to Service members and beneficiaries, these issues should be considered in the context of specific challenges unique to the military, such as increased military operational tempo, separations, and deployment stress that might impact the well-being and psychological health of Service members.

Enclosed are two sets of questions for the DHB to review and advise the Department. We need the Board's findings and recommendations as soon as possible, but no later than March 31, 2011.

My point of contact for this action is Ms. Christine Bader, who may be reached at (703) 681-8448, ext. 1215, or Christine.Bader@ha.osd.mil. Thank you for your continued support to the Board and your commitment to optimizing the health and force-readiness of our military.



Charles L. Rice, M.D.
President, Uniformed Services University of
the Health Sciences
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

Attachments:
As Stated

PRESCRIBING AND USE OF PSYCHIATRIC MEDICATIONS

1. Medications generally included in the category psychiatric medications vary widely in their safety, addictive properties, interactivity with other substances, and overall impact on the patients. We would appreciate your review including that distinction among the medications as some may be disabling, while others may not. Where there are conditions and presumptions, they too would be most helpful.
2. Post Traumatic Stress Disorder
 - a. What medications are commonly recommended for PTSD?
 - b. How efficacious are these medications for this diagnosis?
 - c. How do they work to reduce flashbacks? Isolation? Other symptoms associated with PTSD?
3. Acute Stress Disorder
 - a. What medications are commonly recommended for ASD?
 - b. How efficacious are these medications for this diagnosis?
 - c. How do they work to reduce flashbacks? Isolation? Other symptoms associated with ASD?
4. Psychotropic Medications
 - a. Which psychotropic medications may be considered safe for use in a deployed combat environment? Some of these drugs have side effects of fatigue or tiredness that would impede an individual's combat readiness; what determinations should be made regarding the appropriate use of these medications?
 - b. Which psychotropic medications may be considered safe for other operational environments, such as flight duty, undersea (submarine/diving) duty, weapons handling, and nuclear duty?
 - c. Some medications (according to some studies) carry the potential for increased suicide risk; under what conditions might suicide or violent behavior occur?
 - d. If these medications are prescribed and used, what monitoring procedures would be recommended? And would that monitoring be different from that conducted for other medications? If yes, how?
 - e. Should warriors receive counseling/therapy with prescribed psychotropic medications? Should this be required for all instances of prescribed psychotropic medications? If not, in what situations or illnesses should psychotherapy be required?
 - f. In many of our primary care clinics, warriors may receive care for depression and anxiety. Care provided may involve treatment for substance misuse, chronic pain, concussion and post traumatic stress. We would welcome the Board's assessment of the draft tool kit for primary care providers attending patients with these health issues.
 - g. Some psychotropic medications have the potential for abuse (e.g., narcotics, benzodiazepines, stimulants, etc.), what documentation procedures would you recommend for prescribing and for discontinuation? Should we require specific

justification in the medical record when prescribing medications with addictive properties for a person with personal/family history of abuse or dependence, compared to those without such history?

- h. How do the private sector and other public sector health systems identify patients whose prescription medication use develops into drug dependence or drug seeking behaviors? What treatment courses or protocols are followed in such instances? If none exist, should military medicine have policies and systems in place in MHS pharmacies, primary care and specialty clinics to allow for the identification of such patients as well as treatment courses and protocols? If yes, what are your recommendations for those courses and protocols?
 - i. What procedures have other public and private sector systems and practices have in place to ensure that off-label prescription medication use is consistent with current standards of practice? How might these procedures be applied in the Military Health System?
 - j. What programs for quality improvement in psychotropic medication practices of prescribing providers exist in other public sector and private sector health systems and how might they be adapted for use in the DoD?
 - k. How do the private sector and other public sector health systems address drug-drug interactions involving over the counter medications or dietary supplements? What might the Military Health System consider in the way of policies or protocols to monitor and prevent these occurrences?
5. Best Practice Standards
- a. Do best practice standards exist for treatment of multiple and various symptoms related to mental health that could be reasonably compared to the experiences of our warriors?
 - b. Do best practice standards exist for prescribing of medications for the multiple and various symptoms related to mental health that could be reasonably compared to the experiences of our warriors?
 - c. If such best practice standards for either treatment or prescribing of medications do not exist, how would you recommend such standards be determined? We recognize that limited scientific evidence exists for the use of multiple psychotropic medications; how should the Department ensure such use is done safely?
 - d. How are Clinical Practice Guidelines used in other public sector and private sector health systems; are such guidelines mandatory with notations of any deviation in the individual's medical record? Are the guidelines encouraged to be used? By what means are they encouraged?

Note: Questions regarding complementary and alternative medication practices, which followed this section, were not included in this Attachment.