United States Government Accountability Office

Report to Congressional Committees

January 2016

DOD AND VA HEALTH CARE

Actions Needed to Help Ensure Appropriate Medication Continuation and Prescribing Practices

GAO-16-158

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GAO Highlights

Highlights of GAO-16-158, a report to congressional committees

Why GAO Did This Study

Medication continuation, when clinically appropriate, is critical for transitioning servicemembers with PTSD or TBI who have been prescribed psychiatric, pain, or sleep medications. Adverse health effects may occur if these medications are inappropriately discontinued.

The National Defense Authorization Act for Fiscal Year 2015 included a provision for GAO to assess transitions of care, particularly medication continuation for servicemembers with PTSD or TBI transitioning to VHA. GAO examined (1) the extent to which DOD and VHA developed and monitored recommended medication practices for PTSD and TBI; (2) the extent to which psychiatric, pain, and sleep medications on DOD's formulary are on VA's formulary, and how differences might affect medication continuation; and (3) key efforts VHA has to help ensure medication continuation, and the extent it is monitoring these efforts. GAO reviewed documents and analyzed DOD and VHA data from fiscal years 2012 through 2015; and interviewed DOD and VHA officials from headquarters and five Army and DOD facilities, selected for variation in size and location. GAO focused on the Army as the largest number of its servicemembers served in recent conflicts.

What GAO Recommends

GAO recommends that the Army monitor prescribing practices of medications discouraged under the PTSD guideline and that VHA clarify its medication continuation policy. DOD and VHA concurred with the recommendations.

View GAO-16-158. For more information, contact Debra Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

The Department of Defense (DOD) and the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) have collaborated to develop clinical practice guidelines for post-traumatic stress disorder (PTSD) and mild traumatic brain injury (TBI). The mild TBI guideline does not include recommendations based on scientific evidence regarding the use of medications to treat symptoms because of a lack of available research; however, the PTSD guideline discourages the use of benzodiazepines (a sedative) and states that the use of antipsychotics to treat PTSD lacks support, based on available research. VHA monitors the prescribing of benzodiazepines and antipsychotics to treat PTSD nationally and by VA medical centers (VAMC) and requires VAMCs to implement improvement plans if their prescribing is significantly higher than the average of all VAMCs. GAO found that DOD relies on each military service to review the medication prescribing practices of its providers and that the Army does not monitor the prescribing of medications to treat PTSD on an ongoing basis. Without such monitoring, the Army may be unable to identify and address practices that are inconsistent with the guideline. Federal internal control standards require agencies to have control activities to establish performance measures, implement ongoing monitoring to assess performance, and ensure that the findings of reviews are promptly resolved.

As of August 2015, VA's formulary included 57 percent of the psychiatric, pain, and sleep medications on DOD's formulary. These medications are prescribed to treat symptoms common among servicemembers and veterans with PTSD or mild TBI, and most of the DOD prescriptions in fiscal year 2014 for these medications (88 percent) were on both formularies. In addition, DOD and VHA officials GAO interviewed agreed that the differences did not affect the continuation of medications for servicemembers transitioning from DOD to VHA.

VHA has two key efforts to help ensure continuation of medications for transitioning servicemembers, including those with PTSD or mild TBI, but a lack of clarity of one effort may limit its effectiveness. VHA's nonformulary request process is one key effort that helps ensure newly transitioned veterans avoid medication discontinuations due to differences between the DOD and VA formularies. VHA monitors nonformulary requests. VHA data show that 81 percent of requests submitted from fiscal years 2012 through 2014 were approved, and 98 percent of requests were adjudicated within VHA's required time frame of 96 hours. The other key effort is VHA's 2015 policy instructing its providers not to discontinue mental health medications initiated by DOD providers due to formulary differences. However, VHA providers GAO interviewed had varying interpretations of which medications are covered by this policy, and VHA officials acknowledged that the definition of a mental health medication could be subjective. Federal internal control standards state that agencies should establish control activities, such as developing clear policies. Because VHA's policy lacks clarity, VHA providers may be inappropriately discontinuing mental health medications due to formulary differences, which could increase the risk of adverse health effects for transitioning servicemembers.

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Abbreviations

DOD	Department of Defense
MTF	military treatment facility
PTSD	post-traumatic stress disorder
TBI	traumatic brain injury
VA	Department of Veterans Affairs
VAMC	VA medical center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

January 5, 2016

Congressional Committees

Post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI) are two of the most prevalent injuries occurring as a result of military operations in Afghanistan and Iraq. Servicemembers diagnosed with PTSD or TBI, which is classified as mild, moderate, or severe, are treated with various therapies to manage their symptoms. These therapies may include psychiatric, pain, and sleep medications to manage symptoms such as irritability, insomnia, and headaches. If these medications are abruptly changed or discontinued, adverse health effects may occur. For example, a servicemember with PTSD whose symptoms of outbursts and self-destructive behavior have been stabilized with a psychiatric medication may experience a return of symptoms or withdrawal effects if the medications are suddenly stopped. A servicemember could also experience the onset of new side effects when initiating a new medication.

Effective medication management, which includes ensuring that medication regimens are continued when clinically appropriate, is critical for servicemembers with PTSD or TBI who transition their health care from the Department of Defense (DOD) to other health care systems, including the one operated by the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA). In particular, some stakeholders have raised concerns that VHA providers may change or discontinue servicemembers' medications upon transition to VHA because the VA formulary includes fewer medications than the DOD formulary. Further, some stakeholders have recommended that DOD and VA have a single formulary to better ensure medication continuation for transitioning servicemembers.

The Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 included a provision for us to assess the transition of care, particularly with respect to medications, for

servicemembers with PTSD or TBI as they transition from DOD to VHA.[1] This report examines

1. the extent to which DOD and VHA have developed and monitored recommended medication practices for PTSD and TBI;
2. the extent to which psychiatric, pain, and sleep medications on DOD's formulary are also on VA's formulary, and how, if at all, any differences have affected the continuation of medications for servicemembers transitioning from DOD to VHA; and
3. key efforts, if any, VHA has in place to help ensure the continuation of medications for servicemembers transitioning from DOD to VHA, and the extent to which VHA is monitoring these efforts.

To determine the extent to which DOD and VHA have developed and monitored recommended medication practices for PTSD and TBI, we reviewed documents and interviewed officials from DOD, the Department of the Army, and VHA. We focused our review of DOD's monitoring efforts on the Army because, compared to the other military services, it has the largest number of servicemembers who served in military operations in Iraq and Afghanistan, placing them at increased risk for having PTSD or TBI. We further focused our review on mild TBI because these patients are typically treated on an outpatient basis while patients with more severe TBI are treated in inpatient settings and medication discontinuation in outpatient settings may be especially challenging. We reviewed documents, such as the VA/DOD clinical practice guidelines for management of PTSD and mild TBI, and department policies and program documents related to medication treatments and monitoring efforts, including reports summarizing the prescribing of medications to treat servicemembers and veterans with PTSD. We interviewed officials from DOD, Army, and VHA headquarters to obtain information about recommended medication practices for patients with PTSD or mild TBI and monitoring efforts to help ensure that providers are following these practices. Specifically, for DOD, we interviewed officials from the Office of the Assistant Secretary of Defense for Health Affairs (Health Services Policy and Oversight), the Defense and Veterans Brain Injury Center within the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, and the Defense Health Agency Pharmacy Operations Division. For the Army, we interviewed officials from the Office

[1]Pub. L. No. 113-291, § 731, 128 Stat. 3292, 3422 (Dec. 19, 2014).

of the Surgeon General Behavioral Health Service Line and Traumatic Brain Injury Program, Medical Command Evidence-Based Practice Office, and the Pharmacovigilance Center. For VHA, we interviewed officials from the National Center for PTSD; Office of Mental Health Operations; Office of Quality, Safety, and Value Evidence-Based Clinical Practice Guidelines Program; Pharmacy Benefits Management Services; Pain Management Program; and Polytrauma System of Care at the Richmond, Virginia VA Medical Center (VAMC). We interviewed pharmacists, psychiatrists, and other providers who treat patients with PTSD or mild TBI about the recommended medication practices and related monitoring at three VAMCs located in Washington, D.C.; Boise, Idaho; and Tuscaloosa, Alabama; and two Army military treatment facilities (MTF) located in Fort Hood, Texas and Fort Carson, Colorado.[2] We selected the VAMCs and Army MTFs for variation in size and geographic location. As part of our review, we examined the extent to which the Army's and VHA's efforts were consistent with the standards for internal control in the federal government—specifically those related to control activities and monitoring.[3]

To determine the extent to which the psychiatric, pain, and sleep medications on DOD's formulary are also on VA's formulary and how, if at all, any differences have affected the continuation of medications for servicemembers transitioning from DOD to VHA, we conducted a comparison of the two formularies and interviewed DOD and VHA officials and stakeholders for their perspectives on any differences. We selected these three categories of medications because they are used to treat symptoms that are common among patients with PTSD or mild TBI. DOD's Pharmacy Operations Division identified the psychiatric, pain, and

[2]We interviewed pharmacists about recommended medication practices and related monitoring because pharmacists are responsible for reviewing prescriptions for clinical appropriateness and may also be responsible for reviewing the utilization of certain medications.

[3]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

sleep medications on DOD's formulary as of August 2015.[4] We compared the active pharmaceutical ingredients on this list with those on the VA formulary as of August 2015, as provided by VHA.[5] Because we focused on transitions of care from DOD to VHA, we did not determine which medications on VA's formulary were not on DOD's formulary. To provide further context to our formulary comparison, we analyzed DOD's utilization of the medications on its formulary. We obtained data from DOD on the number of prescriptions filled by DOD for active duty servicemembers in fiscal year 2014, the most recent year of complete data available, for each of the psychiatric, pain, and sleep medications on its formulary. We spoke with knowledgeable DOD officials about the formulary and prescription data, including their methodology for identifying pain, psychiatric, and sleep medications, and as a result, DOD made several modifications to its final list of medications. We also spoke with DOD and VHA officials about our methodology for comparing the formularies. On the basis of these discussions, we determined the data to be sufficiently reliable for the objectives of our report.

We also interviewed DOD and VHA officials about the reasons for, and potential implications of, identified formulary differences. In addition, we reviewed analyses conducted by VHA and other organizations on the possible implications of formulary differences, including the extent to which differences may have affected medication continuation.[6] We also obtained the perspectives of providers and pharmacists from our selected VAMCs and Army MTFs, as well as case managers who help manage

[4]These medications included nonopioid pain management agents, narcotic analgesics, nonsteroidal anti-inflammatory agents, antianxiety agents, antidepressants, attention-deficit hyperactivity disorder agents, and sedative hypnotics, among others, that are commonly used to treat pain, psychiatric, and sleep disorders. DOD's Pharmacy Operations Division excluded psychiatric, pain, and sleep medications that were available over-the-counter, were bulk medications used by pharmacists for compounding, or were provided through certain routes of administration, such as intravenous pain medications.

[5]According to DOD and VHA officials, different formulations (such as dosage form) and different routes of administration do not always correspond to clinically significant differences. However, in some cases, different formulations may be prescribed for different clinical indications and may have significant implications for patients. We determined that medications on the DOD and VA formularies were not the same in cases where the VA formulary was limited to formulations with a different clinical indication.

[6]For example, we reviewed VHA's 2015 study of servicemembers transitioning from DOD to VHA with psychiatric, pain, or sleep medications. We also reviewed multiple estimates of the costs associated with developing a common DOD and VA formulary.

and transition the health care of servicemembers and veterans with complex needs. In addition, we interviewed seven stakeholder groups—American Legion, Iraq and Afghanistan Veterans of America, Military Officers Association of America, three Vet Centers (associated with the three VAMCs included in our review), and the Military Compensation and Retirement Modernization Commission.[7]

To identify the key efforts, if any, VHA has in place to help ensure the continuation of medications for servicemembers transitioning from DOD to VHA and to determine the extent to which VHA is monitoring these efforts, we interviewed VHA officials and reviewed related VHA documentation and data. Specifically, to determine how VHA providers prescribe medications that are not on VA's formulary to servicemembers transitioning from DOD, we reviewed VHA policy documents and interviewed VHA officials, providers and pharmacists from our three selected VAMCs, and the Veterans Integrated Service Networks (VISN) for the VAMCs in our review.[8] We obtained data, from fiscal years 2012 through 2014, from VHA on medications that were not on VA's formulary that VHA providers requested, and we analyzed the data to determine the percentage of such requests that were approved and the extent to which these requests were adjudicated in a timely manner.[9] We also obtained data on VHA's prescription rates for fiscal year 2014 for the top five psychiatric, pain, and sleep medications prescribed by DOD that were not on VA's formulary to determine the extent to which VHA prescribes

[7]Vet Centers provide confidential counseling and referral services to veterans and their families through a nationwide system of community-based centers that VA established separately from other facilities.

The Military Compensation and Retirement Modernization Commission, established by the National Defense Authorization Act for Fiscal Year 2013, as amended, was charged with conducting a review of the retirement and military compensation systems—including military health benefits—and making recommendations to modernize these systems. In January 2015, the commission issued a report to the President and Congress that included a recommendation that DOD and VA establish a single formulary for pain and psychiatric medications and any other types of medications identified as critical for transitioning servicemembers. See Military Compensation and Retirement Modernization Commission, *Final Report of the Military Compensation and Retirement Modernization Commission* (Arlington, VA: Jan. 29, 2015).

[8]Each VISN is responsible for managing and overseeing VAMCs within a defined geographic area. At the time of our review, there were 21 VISNs.

[9]Our review included all medications not on VA's formulary that were requested by VHA providers and was not limited to psychiatric, pain, and sleep medications.

medications that are not on the formulary. Based on our discussions with VHA, VISN, and VAMC officials about how prescription data and requests for medications not on the VA formulary are collected, analyzed, and reported, we determined the data to be sufficiently reliable for the objectives of our report. In addition, we interviewed VHA officials to identify policies related to continuation of medications for transitioning servicemembers and reviewed those policies, including the extent to which VHA monitors their effectiveness. As part of our review, we examined the extent to which VHA's policies and monitoring efforts were consistent with the standards for internal control in the federal government—specifically those related to control activities and monitoring.[10]

We conducted this performance audit from May 2015 to December 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

DOD and VHA Health Care

DOD and VHA provide health care, including medications for psychiatric, pain, and sleep conditions, to servicemembers and veterans through their respective health care systems. DOD provides health care to active duty servicemembers; Reserve and National Guard members on active duty; and other beneficiaries, such as family members and retired servicemembers, through TRICARE, its health care program.[11] TRICARE beneficiaries can obtain comprehensive health care services—including outpatient and inpatient care, mental health care, and prescriptions for medications—through a direct-care system of MTFs operated by the

[10]GAO/AIMD-00-21.3.1.

[11]Reserve and National Guard members on active duty for more than 30 consecutive days are covered by TRICARE. They also may be eligible for TRICARE coverage prior to active duty, and, after active duty, they may be eligible to purchase TRICARE coverage when they return to inactive status.

Departments of the Army, Navy, and Air Force, or through a purchased-care system of civilian health care providers.[12] Prescription medications can be obtained through MTF pharmacies, retail pharmacies, and the TRICARE mail-order pharmacy. DOD is required by law to make all clinically appropriate medications available to servicemembers, and, with the exception of certain classes of medications, such as weight-loss medications, DOD makes all Food and Drug Administration-approved prescription medications available.[13] DOD's formulary process is administered by DOD's Pharmacy and Therapeutics Committee, and the formulary includes a list of medications that all MTFs must provide and medications that an MTF may elect to provide on the basis of the types of specialized services that the MTF offers (such as cancer medications).[14] DOD classifies certain medications as "nonformulary" on the basis of its evaluation of their cost and clinical effectiveness, and DOD's nonformulary classification applies to all MTFs and DOD's purchased-care system. Nonformulary medications are available to beneficiaries at a higher cost, unless the provider can establish medical necessity.

Veterans who served in active military duty, and were discharged or released under conditions other than dishonorable are generally eligible for VHA health care.[15] In general, veterans must enroll in VHA health care to receive VHA's medical benefits—a set of services that includes a full range of hospital and outpatient services, mental health care, and

[12]DOD's direct-care system of MTFs included 55 hospitals and 373 ambulatory care clinics in 2014.

[13]See 10 U.S.C. § 1074g(a)(3); 32 C.F.R. §§ 199.4(g), 199.21(h)(3)(iii).

[14]DOD's Pharmacy and Therapeutics Committee is responsible for evaluating the clinical and cost effectiveness of medications for inclusion on DOD's formulary and its membership includes representatives from the military services.

[15]Any veteran who has served in a combat theater after November 11, 1998, and who was discharged or released from active military duty on or after January 28, 2003, has up to 5 years from the date of the veteran's most recent discharge or release from active duty service to enroll in VHA and receive health care services. See 38 U.S.C. § 1710(e)(1)(D),(e)(3). For those veterans who do not enroll during their enhanced eligibility period, eligibility for enrollment and subsequent care is based on other factors such as compensable service-connected disability, VA pension status, catastrophic disability determination, or financial circumstances. Reserve and National Guard members also may be eligible for VHA health care if they were called to active duty by federal order and completed the full period for which they were called, or when they demobilize from combat operations, even if they have not separated from military service.

prescription medications.[16] VHA provides health care services at various types of facilities, including VAMCs and community-based outpatient clinics.[17] Veterans may obtain prescription and over-the-counter medications through VAMC or community-based outpatient clinic pharmacies, VHA's mail-order pharmacy, or through certain non-VHA pharmacies. VA's formulary provides access to medications for eligible beneficiaries. VHA manages VA's formulary and makes decisions about whether to add medications to the formulary on the basis of clinical and cost effectiveness and, like DOD, provides access to nonformulary medications when providers establish medical necessity. Because VHA only fills prescriptions written by VHA providers or providers VHA has authorized its patients to see, VHA generally has direct control over the medications that are prescribed to its patient populations.

PTSD and Mild TBI

PTSD is a trauma and stressor-related disorder that can occur after a person is exposed to a traumatic or stressful event such as a death or serious injury; its onset may be delayed. As defined in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders, to be diagnosed with PTSD, patients must have experienced four types of symptoms that continue for more than 1 month after the event:

- **persistently re-experiencing the event** such as through flashbacks and traumatic nightmares;
- **persistently avoiding trauma-related stimuli** such as places or situations that are reminders of the event;
- **negative changes in cognitions and mood** that began or worsened after the event, such as persistent negative beliefs about oneself or the world; and
- **changes in arousal and reactivity** that may include aggressive or self-destructive behavior and insomnia.[18]

[16]VA's enrollment system includes eight categories for enrollment, with priority generally based on service-connected disability, low income, and other recognized statuses, such as former prisoner of war. See 38 U.S.C. § 1705; 38 C.F.R. § 17.36.

[17]According to VHA, as of June 30, 2015, there were 167 VAMCs.

[18]American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, 5th ed., (DSM-5)* (Arlington, VA: 2013).

The symptoms cause significant distress or impairment—for example, in the patient's social relationships and work life—and the duration of symptoms varies, according to the *Diagnostic and Statistical Manual of Mental Disorders*. That is, some patients with PTSD have symptoms for less than 3 months while others may experience symptoms for longer than a year and sometimes for many years. In addition to providing medication therapy, DOD and VHA provide psychotherapy, which has been shown to be effective in the treatment of PTSD in clinical research studies, as well as other types of therapies.[19]

Mild TBI (also known as a concussion) is caused by a blow or jolt to the head that temporarily disrupts the normal function of the brain. The diagnosis is based on several factors including that the patient has an alternation of consciousness that may last from a moment up to 24 hours or has a loss of memory for the events immediately before or after the injury that lasts for a day or less.[20] There are many causes of this condition—such as blasts and car accidents—and, while not all patients with mild TBI have symptoms, those that do typically experience symptoms immediately following the event. Headache is the most common symptom, and other common symptoms include dizziness, fatigue, irritability, and insomnia. A very small proportion of patients with mild TBI have symptoms that persist beyond 6 months, although symptoms may last longer after repeated mild TBIs.[21] In addition to providing medication therapy for certain symptoms, DOD and VHA provide other services for the treatment of mild TBI symptoms which may include physical and occupational therapy and neuropsychological care. Servicemembers that are diagnosed with mild TBI as a result of combat also have a higher risk of experiencing PTSD. Additionally, servicemembers with either PTSD or mild TBI often experience other co-

[19]Effective psychotherapy for PTSD includes cognitive elements (e.g., identifying and modifying trauma-related beliefs) and/or exposure elements (e.g., the repetitive review of traumatic memories and trauma-related situations) or stress inoculation training (e.g., breathing retraining and muscle relaxation). Other types of therapies include complementary or alternative therapies such as relaxation therapy.

[20]Department of Veterans Affairs and Department of Defense, *VA/DOD Clinical Practice Guideline for Management of Concussion/mild Traumatic Brain Injury* (Washington, D.C.: April 2009).

[21]Ibid.

occurring conditions, such as chronic pain, which may be related to their combat-related injuries.[22]

Medication Management and Continuation during Transitions of Care

As we previously have reported, the length of time that servicemembers take to transition their health care from DOD to VHA or another health care system varies.[23] Some servicemembers may not transition their care to VHA at all and instead seek care from other health care systems and providers. Of those transitioning to VHA, some servicemembers separate from the military and have their first appointment at VHA the following week. Others may take more time to transition to VHA, waiting months or years before scheduling their first appointment.[24]

Effective transitions of care, including for servicemembers transitioning from DOD to VHA, should include education and counseling about medication adherence, medication lists at discharge, and a plan for how to get medications during transitions, according to the National Transitions of Care Coalition—a nonprofit organization that produces tools and resources to assist with such transitions. As we previously have reported, DOD and VHA have established several programs to assist servicemembers, such as those with PTSD or mild TBI, with care transitions, including help with medication management.[25] For example, Army nurse case managers have procedures both to assess if servicemembers receiving care at MTFs have sufficient supplies of medications until their initial VAMC appointment and to share servicemembers' medication lists with VA liaisons.[26] VA liaisons, who are nurses or social workers stationed at MTFs, in turn, have procedures to ensure that VHA providers receive servicemembers' medication lists and

[22]Ibid.

[23]GAO, *DOD and VA Health Care: Medication Needs during Transitions May Not Be Managed for All Servicemembers,* GAO-13-26 (Washington, D.C.: Nov. 2, 2012).

[24]We have reported on concerns regarding VHA's ability to ensure and accurately monitor access to timely medical appointments. See for example, GAO, *VA Health Care: Reliability of Reported Outpatient Medical Appointment Wait Times and Scheduling Oversight Need Improvement,* GAO-13-130 (Washington, D.C.: Dec. 21, 2012).

[25]For more information on DOD and VHA programs that provide assistance with care transitions and medication management, see GAO-13-26.

[26]Army nurse case managers provide services to servicemembers with case management needs, which may include servicemembers with PTSD or mild TBI.

that transitioning servicemembers have adequate supplies of medications until their initial appointments.[27] Another example is DOD's inTransition Program. The inTransition Program is a confidential personal coaching program that helps servicemembers with mental health conditions as they move between health care systems or providers. The inTransition Program coaches are social workers who encourage transitioning servicemembers with mental health needs to continue their medications.[28] The continuation of medication therapy, that is, prescribing the same medications when a servicemember separates from DOD and transitions to other health care systems including VHA, is another important element of effective care transitions. Continuing clinically appropriate medications during this transition is especially important for servicemembers and veterans with mental health or pain conditions, such as PTSD, whose symptoms may have been stabilized as a result of medications that DOD providers have prescribed. The treatment of symptoms with medications can enable patients with mental health conditions to return to near-normal functioning and can enhance the effectiveness of psychotherapy.

DOD and VHA Have Developed Medication Treatment Recommendations for PTSD and Mild TBI and VHA Monitors the Prescribing of Certain Medications for PTSD

[27]As of April 2015, 43 VA liaisons were stationed at 21 Army and other MTFs.

[28]Beginning in April 2015, servicemembers who received mental health services are automatically enrolled in the inTransition Program unless they choose to opt out. Prior to April 2015, servicemembers were referred to the program by DOD providers.

DOD and VHA Have Collaborated to Develop Clinical Practice Guidelines for Medication Treatment for PTSD and Mild TBI

DOD and VHA have jointly developed clinical practice guidelines related to PTSD and mild TBI, which include recommendations for the treatment of symptoms among servicemembers and veterans with these conditions.[29] Each guideline includes a discussion of, and recommendations on, management of care for servicemembers and veterans with these conditions, such as screening and diagnosis, types of treatment interventions, and assessing treatment responses. The PTSD clinical practice guideline includes evidence-based recommendations to assist DOD and VHA clinicians in their decision making about which medications to prescribe to treat the symptoms of PTSD.[30] The mild TBI clinical practice guideline also includes recommendations related to medications for treating the symptoms of the condition; these recommendations are based on expert opinions, rather than evidence-based research, because of the lack of published studies on mild TBI medication treatments.[31] The guidelines state that the recommendations should not prevent providers from using their own clinical expertise in the care of an individual patient and should never replace sound clinical judgment. In addition to providing guidance for clinical decision making, the guidelines are intended to help improve the quality and continuum of care and the health outcomes for servicemembers and veterans with PTSD and mild TBI.

The PTSD guideline recommends that patients with PTSD be offered certain types of antidepressants and discourages the use of benzodiazepines, a type of sedative.[32] According to the guideline, the use

[29]Department of Veterans Affairs and Department of Defense, *VA/DOD Clinical Practice Guideline for Management of Post-Traumatic Stress* (Washington, D.C.: October 2010) and Department of Veterans Affairs and Department of Defense, *Clinical Practice Guideline for mild Traumatic Brain Injury*.

[30]The guideline is based on a review of research outcomes available at the time of publication. The evidence-based recommendations provide information regarding treatments that have been consistently shown in controlled research to be effective or ineffective for treating PTSD. The guideline also includes evidence-based recommendations for nonmedication treatments.

[31]The expert opinions were obtained from DOD and VHA clinical experts who updated the guideline. They represented various clinical specialties such as neurology, internal medicine, and psychiatry. The mild TBI guideline describes several challenges regarding the development of strong evidence-based studies on which to build recommendations for treating patients with mild TBI, including that the symptoms are common to other conditions and occur frequently in the larger population.

[32]DOD and VHA officials said that they plan to issue an updated version of the PTSD guideline by the end of 2016 or beginning of 2017.

of selective serotonin reuptake inhibitors or serotonin norepinephrine reuptake inhibitors (types of antidepressants) are strongly recommended because there is good evidence that they are effective in reducing the core symptoms of PTSD and are generally well tolerated by servicemembers and veterans with PTSD.[33] In contrast, the guideline states that the use of benzodiazepines should be discouraged because of their lack of effectiveness in treating PTSD and because the risks may outweigh potential benefits.[34] The guideline also states that there is evidence to suggest that benzodiazepines may worsen recovery and, once they are initiated, they can be very difficult to discontinue due to significant withdrawal symptoms.

Additionally, the guideline states that the use of antipsychotics (atypical and conventional) to treat PTSD is not supported because the existing evidence is insufficient to warrant their use.[35] The guideline specifically recommends against the use of one atypical antipsychotic (risperidone) to supplement the use of antidepressants in treating PTSD, based on evidence from a VA study.[36] This study showed that risperidone did not reduce the symptoms of PTSD and its use did not justify the risk for adverse events.[37]

The mild TBI guideline provides general guidance on medications for treating the condition's symptoms and on those medications that warrant

[33]The PTSD guideline assigns a grade to each recommendation reflecting the strength of evidence. For example, the recommendation for the selective serotonin reuptake inhibitors or serotonin norepinephrine reuptake inhibitors is assigned an "A" because good evidence was found that use improves health outcomes and benefits substantially outweigh harm. Certain other antidepressants (e.g., tricyclic antidepressants) are assigned a "B" because there is at least fair evidence that they are effective.

[34]Benzodiazepines also induce sleep and, as a result, may be prescribed to treat insomnia.

[35]Atypical antipsychotics, also called second-generation antipsychotics, refer to those that were more recently developed than conventional antipsychotics.

[36]J.H. Krystal, R.A. Rosenheck, J.A. Cramer, J.C. Vessicchio, K.M. Jones, J.E. Vertrees, R.A. Horney, G.D. Huang, and C. Stock, "Adjunctive Risperidone Treatment for Antidepressant-Resistant Symptoms of Chronic Military Service-Related PTSD: A Randomized Trial," *Journal of the American Medical Association*, vol.306, no.5 (2011).

[37]The PTSD guideline includes several other recommendations. For example, the guideline states that there is either insufficient evidence for, or the existing evidence does not support, the use of certain anticonvulsants.

particular caution, including antipsychotics and benzodiazepines.[38] According to the guideline, there is insufficient evidence for recommending the use of one medication over another to treat the symptoms of mild TBI. As a result, the guideline provides general recommendations about medications, such as ibuprofen or naproxen—nonsteroidal anti-inflammatory medications—that may be used to treat common symptoms, such as tension headaches that occur periodically. Because some patients with mild TBI may experience seizures and confusion, the guideline cautions against the use of medications that can increase a patient's susceptibility to seizures, including antipsychotics, and medications that can cause confusion, such as benzodiazepines. Further, the use of medications to treat the condition itself (brain injury) is not recommended since the Food and Drug Administration had not approved any medications for this purpose as of April 2009, as stated in the guideline.[39]

The PTSD and mild TBI guidelines also include clinical guidance for treating insomnia and pain in servicemembers and veterans with these conditions. The guidelines emphasize that, when possible, initial treatment for insomnia should begin with nonmedication options, and recommend treatments, such as good sleep hygiene practices and cognitive behavioral therapy. Should medications also be needed, the guidelines state that insomnia may be treated with the use of certain sleep medications that are not benzodiazepines, such as zolpidem.[40] For pain, the guidelines recommend individualized treatment plans tailored to the types of pain the patient is experiencing. If medications are included in the treatment plans, the guidelines recommend, for example, that non-steroidal anti-inflammatory medications be used to treat pain resulting from injuries to the bones and muscles. The PTSD guideline further recommends that providers prescribe low doses of opioids or other centrally acting pain medications (which reduce the transmission of pain

[38]DOD and VHA officials said that they plan to issue an updated version of the mild TBI guideline by the end of 2015 or beginning of 2016.

[39]DOD and VHA officials confirmed that, as of November 2015, the Food and Drug Administration has not approved a medication to treat mild TBI since the current guideline was issued.

[40]The PTSD guideline also includes recommendations for the use of the antidepressant trazodone to help manage insomnia and the blood pressure medication prazosin for the treatment of nightmares.

through the brain), if required, and only in the short term, because they can cause confusion, and then transition their patients to the use of non-steroidal anti-inflammatory medications.[41]

VHA Monitors the Prescribing of Medications to Treat PTSD, but DOD and the Army Do Not; None Monitor Mild TBI Medications Given Lack of Specific Medication Recommendations in Mild TBI Clinical Guideline

VHA monitors the prescribing of medications that are included in the PTSD guideline, but DOD and the Army do not monitor such prescribing among servicemembers. As part of its Psychotropic Drug Safety Initiative, which began in 2013, VHA tracks the prescribing of benzodiazepines, antipsychotics, and other psychiatric medications to treat veterans with PTSD.[42] VHA tracks the prescribing of these medications quarterly at the VAMC, VISN, and national levels. Specifically, VHA tracks the percentage of veterans with PTSD who have been prescribed: (1) a benzodiazepine, (2) an antipsychotic (atypical and conventional) without a separate diagnosis of severe mental illness, and (3) medications from certain classes of psychiatric medications for 60 days or more.[43]

As part of the Psychotropic Drug Safety Initiative, VHA requires each VAMC to develop and implement a plan to improve on any measure for which the individual VAMC was performing significantly below the average of all VAMCs. This requirement encompasses measures focused on reducing prescriptions for benzodiazepines, antipsychotics, and other classes of psychiatric medications to treat veterans with PTSD. If a VAMC does not have any measures that meet the criteria, VHA still requires the

[41]In 2010, DOD and VHA jointly developed a clinical practice guideline for the use of opioids to treat chronic pain conditions. It includes recommendations for determining the appropriateness of opioid therapy, starting and adjusting dosages, assessing patient adherence and response to the therapy, and discontinuing the therapy. See Department of Veterans Affairs and Department of Defense, *VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (Washington, D.C.: May 2010). DOD and VHA officials said that they plan to issue an updated version of the opioid therapy guideline by the end of 2016 or beginning of 2017.

[42]The overall goal of the initiative is to improve the safety and efficacy of care for veterans by ensuring the use of evidence-based medication treatments for veterans with mental health conditions.

[43]The classes of psychiatric medications are antidepressants, antipsychotics, benzodiazepines, mood stabilizers, and antianxiety medications. VHA tracks the percentage of veterans prescribed medications from three or more of these five classes at the same time. VHA also tracks the prescribing of psychiatric medications in other populations as part of the Psychotropic Drug Safety Initiative. For example, VHA tracks the percentage of elderly veterans prescribed a benzodiazepine. In total, VHA is tracking 34 measures through the initiative.

VAMC to implement a plan to reduce prescriptions for psychiatric medications based on at least one measure, such as the percentage of veterans with PTSD who have been prescribed a benzodiazepine. In 2015, 22 VAMCs had developed plans to decrease the percentage of veterans with PTSD who are prescribed benzodiazepines and 26 had developed plans to decrease the percentage of veterans with PTSD who are prescribed antipsychotics (without a diagnosis of severe mental illness). Specifically, one VAMC created a clinical reminder in its electronic medical record that is activated when a veteran with PTSD (without a diagnosis of severe mental illness) is prescribed an atypical antipsychotic. To order the prescription, the VHA provider must justify why the medication is needed. This VAMC decreased the percentage of veterans with PTSD who had been prescribed antipsychotics by almost half, from 21.8 percent in 2013 to 11.5 percent in 2015. In addition to continually monitoring these measures, VHA officials told us that they review VAMCs' improvement plans twice a year and provide VAMCs feedback. As part of the initiative, VHA provides patient-level data to VAMCs—such as information about each patient with PTSD who is prescribed a benzodiazepine along with the name of the provider who prescribed the medication—so that VAMCs can prioritize patients where prescribing practices can be improved. In 2013, VHA also began tracking annually the percentage of veterans with PTSD who are prescribed antidepressants and other medications including prazosin—a medication recommended for PTSD patients who experience nightmares—nationally and by VISN, and the results are shared with VISN pharmacy executives, who are responsible for tracking pharmacy and patient outcome data.

In addition, VHA has begun a program, known as Academic Detailing, to make resources available to providers to assist them in incorporating evidence-based recommendations in the treatment of veterans with mental health conditions, including PTSD. In 2014, VHA developed a guide for clinicians on treating PTSD patients that summarizes key recommendations for medication treatment included in the PTSD guideline and provides other information, such as guidance on how to discontinue benzodiazepines by tapering their dosage over time.[44] As part of the program, pharmacists meet one-on-one with providers that have a high proportion of patients who had been prescribed certain medications

[44]Department of Veterans Affairs, *A VA Clinician's Guide to Managing Posttraumatic Stress Disorder: Improving Quality of Life Through the Use of Evidence-Based Medicine* (Washington, D.C.: June 2014).

(e.g., benzodiazepines, opioids) for whom there are significant safety concerns, including risk for abuse, to identify and address any treatment gaps, according to a VHA official. Each VISN is responsible for implementing an Academic Detailing program and was required to have a program in place by September 30, 2015. VHA officials told us that as of October 2015, 6 of the 21 VISNs had fully implemented such a program.

In contrast to VHA, neither DOD nor the Army monitors the prescribing of medications to treat servicemembers with PTSD in accordance with the guideline recommendations, on an ongoing basis. DOD officials told us that DOD relies on each military service to review the medication prescribing practices of its providers and helps facilitate medication reviews by generating reports for all MTFs that include a list of patients who are prescribed multiple psychiatric and pain medications.[45] DOD officials also told us that they track the prescriptions of certain medications included in the PTSD guideline, such as antipsychotics, by individual military service but do not track prescriptions according to PTSD diagnosis on an ongoing basis. We found that the Army also does not monitor the prescribing of medications that are included in the guideline recommendations on an ongoing basis. Instead, Army officials told us they have emphasized the importance of the PTSD recommendations in their recently issued policies and provider training. Specifically, the Army issued a PTSD policy in 2012, reissued it in 2014, and provided related training on the medication recommendations in the guideline. The policy and training stated that prescribing benzodiazepines to patients with PTSD should be avoided and that prescribing atypical antipsychotics to patients with PTSD warrants caution, given concerns with potential adverse health effects.[46]

The Army issued a policy in 2012 that required MTFs to review their prescribing practices for atypical antipsychotics, but the policy did not apply to benzodiazepines, and it expired in 2014. Army officials stated that they issued the policy on atypical antipsychotics given concerns that these medications could be prescribed without sufficient clinical rationale

[45]According to DOD officials, DOD updates these reports monthly, and the reports include a list of servicemembers who have been prescribed four or more psychiatric and pain medications from seven categories, including antipsychotics.

[46]The policy states that if these medications are prescribed to servicemembers with PTSD, Army providers should document their clinical rationale for prescribing and obtain informed consent from patients.

by providers in the treatment of PTSD but said that they do not plan to re-issue it. Providers and pharmacists we interviewed from one Army MTF told us that they are continuing to conduct these reviews because they identified a higher-than-expected prescribing rate and believe improvements can be made with additional efforts, such as further education of providers. In contrast, providers and pharmacists we interviewed from another Army MTF said that they were no longer conducting the reviews because the policy expired. Army officials told us that they are focusing their monitoring efforts on the extent to which the clinical outcomes among servicemembers with PTSD improve over time. These officials added that they do not have the same level of concern about atypical antipsychotic prescribing for patients with PTSD as they did 5 years ago because they believe recent efforts to raise awareness about prescribing antipsychotics for PTSD have been effective.[47] After we asked Army officials about the effects of the policy, they responded by conducting an analysis, which showed that the proportion of servicemembers with PTSD (without a separate diagnosis of severe mental illness) prescribed atypical and other antipsychotics decreased by almost half, from 19 percent in fiscal year 2010 to 10 percent in fiscal year 2014. Army officials stated that they could repeat their analysis, if needed, but did not identify any specific plans to do so. They added that they could similarly track the percentage of servicemembers with PTSD prescribed a benzodiazepine using the same data source.

Although a decrease in the proportion of servicemembers prescribed atypical antipsychotics is important, the Army's lack of ongoing monitoring of the prescribing of these medications may increase the risk that the PTSD guideline recommendations are not effectively followed. Federal internal control standards require federal agencies to have control activities in place to establish and review performance measures over time and then implement ongoing monitoring to assess the quality of performance and ensure that the findings of reviews are promptly resolved.[48] Without ongoing monitoring of Army providers' prescribing of antipsychotics and benzodiazepines to servicemembers with PTSD, the

[47]As part of this effort, officials told us that the Army plans to track PTSD outcomes throughout its behavioral health clinics using a new electronic system, beginning in fiscal year 2016.

[48]GAO/AIMD-00-21.3.1.

Army may be unable to identify and address prescribing practices that are inconsistent with the guideline and do not have a clinical justification.

Neither VHA nor DOD and the Army monitor the prescribing of medications to treat mild TBI because the mild TBI guideline does not include specific medication recommendations. According to a VHA official, VHA does not conduct such monitoring because mild TBI is associated with a wide range of symptoms, and, thus, treatment regimens need to be individualized based on each patient's symptoms. In addition, this official added that, in contrast to the PTSD guideline, the mild TBI guideline does not recommend the use of a particular medication over another and there are no strict contraindications for certain medications. DOD officials told us that the individual military services have processes in place to review the prescribing practices of its providers. Army officials stated that the Army has procedures in place that may include the review of medication prescribing decisions, including for mild TBI, such as peer reviews that are part of the Army's privileging process.[49] Army officials explained that each department within an Army MTF is responsible for developing standards for their specialty and monitoring, for example, whether providers follow related evidence-based medical practices, which may include prescribing medications.[50] Army officials also stated that they are currently focusing their TBI monitoring efforts on tracking the clinical outcomes of TBI patients and have begun to pilot this effort in the TBI clinics at seven Army MTFs.

[49]Privileging is the process that defines the scope and limits of practice for a physician and is based on several factors, including a physician's clinical competence and recommendations from peers.

[50]Several VHA providers also told us that peer reviews, part of VHA's privileging process, may include the review of medication prescribing decisions, including for mild TBI.

VA's Formulary Included More than Half of the Psychiatric, Pain, and Sleep Medications on DOD's Formulary; Officials Agree That Differences Do Not Affect Medication Continuation

Our review found that VA's formulary included more than half of the psychiatric, pain, and sleep medications on DOD's formulary. These medications are prescribed to treat symptoms that are common among servicemembers and veterans with PTSD or mild TBI.[51] DOD and VHA officials we spoke with agreed that the formulary differences did not affect the continuation of medications for servicemembers transitioning from DOD to VHA. (See app. I for a complete list of the psychiatric, pain, and sleep medications on the DOD and VA formularies, as well as information on DOD prescriptions for these medications.) We also found that the vast majority of these medications that were actually prescribed by DOD in fiscal year 2014 were on both formularies.[52] (See table 1.) Additionally, we found the most agreement between the formularies for psychiatric medications, with the medications on VA's formulary representing 98 percent of the prescriptions that had been filled by DOD in fiscal year 2014.

Table 1: Summary Comparison of the Psychiatric, Pain, and Sleep Medications on the Department of Defense (DOD) and Department of Veterans Affairs (VA) Formularies

Medication type	Percentage of medications on both the DOD and VA formularies as of August 2015	Percentage of prescriptions filled by DOD for active duty servicemembers in fiscal year 2014 for medications on both the DOD and VA formularies as of August 2015[a]
Psychiatric	67%	98%
Pain	49	90
Sleep	22	75
Total	**57**	**88**

Source: GAO analysis of DOD and Veterans Health Administration data. I GAO-16-158

[a]This represents the most current data available for prescriptions filled by DOD for active duty servicemembers at the time of our review.

VHA officials told us that clinical considerations and cost are factors in determining whether to include a medication on the formulary.

[51]We compared the medications on the DOD and VA formularies as of August 2015.

[52]These medications include those that were prescribed by DOD and filled by active duty servicemembers. Fiscal year 2014 was the most recent fiscal year of data available at the time of our review.

Specifically, they said they first consider which medications are the safest and most effective for treating each condition, and then they select the most cost-effective options. As a result of this process, the VA formulary includes fewer medications than DOD's. For example, VHA officials told us that VA's formulary did not include the pain medication piroxicam because the formulary already included safer alternatives. VHA officials also said the VA formulary only included two sleep medications because of concerns about the appropriateness of some sleep medications for the treatment of insomnia. Further, VHA officials and providers noted that sleep problems are often a symptom of other conditions, including those related to mental health, and, therefore, treating the underlying condition may also treat the insomnia. Rather than including more of these medications on the VA formulary, VHA has developed evidence-based clinical recommendations for treating insomnia, which includes off-label use of other types of medications, such as antidepressants; over-the-counter medications, such as antihistamines; and nonmedication treatments.[53]

DOD and VHA officials told us they do not believe that the differences between the formularies affected the extent to which VHA providers continued medications prescribed by DOD providers, when clinically appropriate. In support of this position, officials noted the results of VHA's 2015 study on this issue.[54] Specifically, VHA conducted this study to assess the extent to which differences in the DOD and VA formularies affected medication continuation and found that VHA providers infrequently changed or discontinued medications for nonclinical reasons, including formulary differences.[55] As part of the 2015 study, VHA

[53]For example, VHA recommends that the medication diphenhydramine (an antihistamine) be prescribed to treat insomnia. Diphenhydramine is an over-the-counter medication that is included on VA's formulary. Department of Veterans Affairs, *Chronic Insomnia: VA Clinician's Guide to Managing Insomnia* (Washington, D.C.: Aug. 2014). Off-label use includes the use of a medication for a condition for which the medication was not approved by the Food and Drug Administration. Although a medication may not be Food and Drug Administration-approved for a certain condition, prescribing a drug off-label may be clinically appropriate.

[54]Department of Veterans Affairs, *Pilot Evaluation of Medication Continuation for Veterans Transitioning from the Department of Defense Health Care System to the Department of Veterans Affairs Health Care System* (Washington, D.C.: Feb. 2015).

[55]Nonclinical reasons also included changes for which the reason was not documented by the provider. VHA did not provide data on the number of changes in the nonclinical category that were due to missing documentation.

pharmacists reviewed DOD and VHA data on a sample of 729 servicemembers who transitioned from DOD to VHA in 2013 with a psychiatric, pain, or sleep medication to determine whether their medications were changed by VHA providers upon transition. For the 167 servicemembers whose medications were changed or discontinued, VHA pharmacists reviewed the individual medical records to determine the reasons why. VHA determined that 24 servicemembers (3 percent of the 729 servicemembers reviewed) had psychiatric, pain, or sleep medications that were changed or discontinued for nonclinical reasons, which could include formulary differences, upon transitioning to VHA.

Consistent with the findings of the 2015 VHA study, providers, pharmacists, and case managers we interviewed at three VAMCs and two Army MTFs, as well as military and veterans' stakeholder groups, were generally unaware of specific instances of medications being changed or discontinued for nonclinical reasons, including formulary differences. Although VHA providers and pharmacists said that this type of change could occur, they most commonly said that medications are changed for clinical reasons, such as side effects, the medication not working, interactions with other medications, and general disagreement with the prior treatment approach. Additionally, several VHA providers we interviewed said most of the psychiatric, pain, and sleep medications they would want to prescribe are already on the VA formulary, and we found that the majority of the medications providers said were not on the formulary have recently been added. For example, duloxetine, an antidepressant added to VA's formulary in 2015, was a commonly mentioned nonformulary medication during our interviews with providers.

Given the differences in the formularies, some stakeholders have suggested that DOD and VA establish a single formulary. The advantages and disadvantages of doing so would depend, in part, on the resulting formulary—that is, whether VA adopts all of the medications on DOD's formulary or, instead, VA and DOD agree to a new list of

medications.[56] When we discussed the concept of a single formulary with officials, VHA officials expressed concern that adopting DOD's formulary could diminish elements of their formulary process that they believe are important from a clinical and cost perspective. Specifically, VHA officials told us that adopting DOD's formulary would result in including medications that VHA has determined to be less safe than other alternatives. For example, the DOD formulary includes a recently Food and Drug Administration-approved extended release opioid medication associated with a greater risk of overdose, if used incorrectly, due to the larger amount of the active ingredient present in the medication, compared to some other pain medications (such as immediate release opioids). VHA officials told us they decided not to include this medication on the formulary, given its ongoing efforts to improve the safety of opioid prescribing.[57] In addition, the Congressional Budget Office estimated that VA's costs would increase if it were to adopt the psychiatric, pain, and sleep medications on the DOD formulary.[58] VHA officials explained that they are able to control pharmacy costs by requiring providers to prescribe the most cost-effective medications, unless there is a clinical reason to prescribe something else. Clinical reasons could include medication continuation or concerns about particular side effects for certain patients.

A single formulary could also be achieved by DOD and VA collaboratively selecting which medications to include. This approach could result in cost savings for DOD if the new formulary excluded higher cost medications. Although VHA officials told us they would be supportive of this approach, DOD officials said they are not because they view it as a reduction of the

[56]After we provided a draft of our report to the agencies for comment, a bill was signed into law that requires the Secretary of DOD and the Secretary of VA to establish a joint uniform formulary that will include psychiatric, pain, and sleep disorder medications and medications for other conditions critical for the transition of a servicemember from treatment furnished by DOD to treatment furnished by VA. The law also requires that the Secretaries, no later than July 1, 2016, issue a report to certain congressional committees on the joint uniform formulary, including a list of the medications selected for inclusion on the formulary. See National Defense Authorization Act for Fiscal Year 2016, Pub. L. No. 114-92, § 715, 129 Stat. 726 (Nov. 25, 2015).

[57]Under VHA's Opioid Safety Initiative, which began in 2012, VAMCs with high rates of opioid prescribing are required to implement plans to assess the appropriateness and decrease the prescribing rates when clinically possible.

[58]Congressional Budget Office, *Cost Estimate: H.R. 1735 National Defense Authorization Act for Fiscal Year 2016* (Washington, D.C.: May 11, 2015).

benefit that they currently provide, and believe it is important to have a more comprehensive formulary to better accommodate prescriptions written by civilian health care providers. In addition, DOD officials told us that current law requires them to include all clinically appropriate Food and Drug Administration-approved medications. DOD officials told us that including more medications on the formulary is beneficial because individual patients respond differently to different medications.

VHA Has Two Key Efforts to Help Ensure Continuation of Medications, but Lack of Clarity of One Effort May Limit Its Effectiveness

VHA's Nonformulary Request Process Helps Ensure Continuation of Medications and Most Requests Are Adjudicated within 96 Hours and Approved

VHA's nonformulary request process is one key effort that helps newly transitioned veterans, including those with PTSD or mild TBI, avoid medication discontinuations that could occur as the result of differences in the DOD and VA formularies, according to providers we interviewed and VHA documents we reviewed. Data provided by VHA show that the most commonly DOD-prescribed psychiatric, pain, and sleep medications not on the VA formulary are prescribed by VHA providers through this process.[59] According to VHA policy, providers may request a medication not on the VA formulary by submitting a nonformulary request, which is reviewed by a pharmacist. The pharmacist, in turn, either approves or denies the request based on whether the provider has demonstrated that there is a clinical necessity for the medication. To be approved, requests

[59]For example, VHA providers wrote over 24,000 prescriptions for the sleep medication eszopiclone in fiscal year 2014. Eszopiclone was one of the most commonly prescribed sleep medications by DOD providers in fiscal year 2014 and, as of August 2015, is not on the VA formulary.

for nonformulary medications must meet one of several clinical criteria.[60] For example, a request will be approved if the provider has documented that the veteran has had an allergic reaction to a formulary medication. The pharmacist who reviews the request must approve or deny it within 96 hours, and a provider may appeal a request that a pharmacist initially denied.

VHA monitors the rates in which VAMCs approve nonformulary requests and the extent to which they adjudicate the requests within the required timeframe of 96 hours. VAMCs report data quarterly to VHA on the number of nonformulary requests that their pharmacists approved and denied, the number of denied requests that providers subsequently appealed, and the number of appealed requests that were overturned. VHA does not collect data on the reasons why pharmacists deny nonformulary requests. VHA officials told us they do not collect such data because the only reason for a denial is that the provider did not establish clinical justification for the medication.

VAMCs also report to VHA the number of nonformulary requests that pharmacists adjudicated outside of VHA's required 96-hour timeline. For nonformulary requests that take longer than 96 hours to adjudicate, VAMCs are required to report the reasons for the delayed adjudication. For example, some of the reasons that VAMCs have reported include that a request was referred to a specialist (e.g., a physician or another pharmacist) for additional review and that the required documentation to determine the appropriateness of the request (e.g., lab value) was unavailable at the time of the request.[61] VHA officials combine data from VAMCs within each of the VISNs to report nonformulary request data quarterly to VISN pharmacists. VHA officials told us they examine the

[60]Department of Veterans Affairs, Veterans Health Administration, *VHA Formulary Management Process,* VHA Handbook 1108.08 (Washington, D.C.: Feb. 26, 2009). VHA issued a policy in January 2015 that established an exception for approving certain nonformulary requests for newly transitioned veterans. Specifically, if a provider documents that a nonformulary request is for a DOD-prescribed mental health medication for a newly transitioned veteran, then additional clinical documentation is not required for approval.

[61]In 2015, VHA officials narrowed the standard reasons for delayed adjudication that they track and discontinued tracking reasons provided as free-text, because they were unable to consistently categorize the provided reasons. These officials told us they believe that these revisions will be more useful for determining strategies to help reduce identified delays in adjudication.

data, among other things, to identify outliers across VISNs related to the number of nonformulary requests that take longer than 96 hours to adjudicate, and they discuss these results during quarterly meetings with VISN pharmacists who are responsible for overseeing the request process with their respective VAMCs. For example, in 2013, VHA officials identified a VISN with a relatively high number of nonformulary requests with delayed adjudication and discussed this outlier at a meeting with VISN pharmacists. This discussion led the VISN to implement several changes that ultimately resulted in a lower number of requests with delayed adjudication. Specifically, the VISN created an automated nonformulary request form that tracks how long each request takes from submission to adjudication. This change allows a provider that submits a nonformulary request, as well as the pharmacists that review the request, to be aware of requests that approach the required 96-hour timeframe for adjudication.

VHA's nonformulary request data show that pharmacists approved the majority of the nonformulary requests that providers submitted from fiscal years 2012 through 2014. Specifically, they approved 81 percent of the 2.1 million total nonformulary requests, or about 1.7 million, during this time period. (See table 2.) Of the 19 percent of requests that were denied (about 399,000), providers appealed 1 percent of these (about 4,600), and most were overturned (61 percent). Providers we interviewed from all three VAMCs told us that pharmacists approved the majority of nonformulary requests they submitted.

Table 2: Adjudication Results of VA Medical Center (VAMC) Nonformulary Medication Requests, Fiscal Years 2012 through 2014

Nonformulary medication request result	Total	2012	2013	2014
Number of nonformulary requests	2,113,973	771,319	664,152	678,502
Number and percent of nonformulary requests that VAMCs approved	1,715,394	630,789	535,160	549,445
	81.1%	81.8%	80.6%	81.0%
Number and percent of nonformulary requests that VAMCs adjudicated within 96 hours	2,069,280	751,424	651,461	666,395
	97.9%	97.4%	98.1%	98.2%
Number and percent of denied nonformulary requests that providers appealed	4,602	1,814	1,323	1,465
	1.2%	1.3%	1.0%	1.1%
Number and percent of appeals in which VAMCs overturned denied formulary requests	2,814	1,131	760	923
	61.1%	62.3%	57.4%	63.0%
Number and percent of appeals that VAMCs adjudicated within 96 hours	4,192	1,651	1,226	1,315
	91.1%	91.0%	92.7%	89.8%

Source: GAO analysis of Veterans Health Administration data. I GAO-16-158

Further, the vast majority of nonformulary requests that providers submitted from fiscal years 2012 through 2014 were adjudicated within 96 hours. Of the approximately 2.1 million nonformulary requests that providers submitted to pharmacists during this time, 98 percent were adjudicated within 96 hours. Providers we interviewed from the three VAMCs in our review told us that pharmacists adjudicated the majority of their nonformulary requests within the required timeframe, and several providers said they frequently received decisions on their requests within 1 or 2 hours of submitting them and sometimes sooner if they spoke directly with a pharmacist about the request. The VHA data also showed that the vast majority of requests that providers appealed were adjudicated within the required timeline of 96 hours (91 percent) from fiscal years 2012 through 2014. Of the nonformulary requests that took longer than 96 hours to adjudicate, three pain medications and one psychiatric medication were among the most frequently requested medications by providers.[62] However, the extent to which requests for these four medications were ultimately approved or denied is unknown because VHA officials do not separately track the results of nonformulary requests for specific medications, including those taking longer than 96 hours to adjudicate.

[62]The three pain medications were lidocaine patches, a gel formulation of the medication diclofenac, and pregabalin (which is currently only available as the brand name Lyrica, and is not on the DOD formulary) and the one psychiatric medication was duloxetine. VHA added duloxetine to the VA formulary in March 2015. Of the nonformulary requests that took longer than 96 hours to adjudicate, sleep medications were not among the top medications requested.

VHA Issued a Policy to Help Ensure Continuation of Certain Medications for Transitioning Servicemembers, but It Lacks Clarity

VHA issued a policy in January 2015 that instructs providers not to discontinue mental health medications initiated by DOD providers due to differences in the DOD and VA formularies; another key effort to help ensure medication continuation.[63] VHA officials said that the reason for issuing this policy was to provide added assurance that patients with mental health conditions—who are among the most vulnerable—would not have their mental health medications changed or discontinued for nonclinical reasons upon transitioning from DOD to VHA. However, the policy lacks clarity regarding which types of medications should be considered mental health medications and, therefore, are not to be discontinued. Specifically, the policy is unclear on whether providers should continue (when clinically appropriate) all of the medications prescribed by DOD providers for patients with mental health conditions or only the psychiatric medications (such as antidepressants) that were prescribed specifically to treat their mental health condition.

As pain and sleep medications treat symptoms that are commonly experienced by patients with mental health conditions, such as PTSD, VHA providers and pharmacists we interviewed had varying interpretations of whether these medications would be considered mental health medications under the new policy. For example, VHA providers had different interpretations about whether they should continue eszopiclone, a medication for the treatment of insomnia which is on DOD's formulary, but not VA's. Some VHA providers said they would have to switch medications for patients who transition from DOD on this medication to one on the VA formulary, unless there is a clinical reason not to do so. Other VHA providers said that the policy could cover other types of medications prescribed to patients with mental health conditions, such as sleep medications. In addition, in our review of VHA's 2015 study of transitioning servicemembers, we found that among the 24 servicemembers whose medications were changed or discontinued for nonclinical reasons, more than half of them (13 of 24) had a pain or sleep medication changed.

[63]The DOD providers that the policy refers to are those authorized by DOD, including MTF providers and civilian providers who have contracts with DOD to provide care to servicemembers through TRICARE. According to the policy, medications should also not be changed or discontinued for other nonclinical reasons, such as the cost of the medication. See Department of Veterans Affairs, Veterans Health Administration, *Continuation of Mental Health Medications Initiated by Department of Defense Authorized Providers*, VHA Directive 2014-02 (Washington D.C.: Jan. 20, 2015).

VHA officials acknowledged that the definition of a mental health medication could be subjective and that they intended the policy to be broad and to apply to any medication that is prescribed to treat a mental health condition. Therefore, they stated that pain and sleep medications should be considered mental health medications under the policy. However, they also noted that some pain and sleep medications are not intended for long term use, so providers may choose to discontinue prescribing them for clinical reasons.

Given that VHA's policy lacks clarity regarding which types of medications should be considered mental health medications, VHA providers may be inappropriately changing or discontinuing mental health medications due to formulary differences. Such changes could lead to adverse health effects, such as exacerbation of symptoms or new side effects. This lack of clarity in VHA's policy is inconsistent with federal internal control standards, which state that agencies should establish control activities, such as developing clear policies, in order to accomplish the agency's objectives.

VHA officials told us that they are planning to conduct another study of transitioning servicemembers to determine if the new policy is having the intended effect. Specifically, VHA officials told us that they plan to review the prescriptions of about 5,000 servicemembers who transitioned from DOD to determine whether their medications were continued at VHA when clinically appropriate.[64] VHA officials told us that they have been working with DOD officials to obtain the data needed to conduct this study.

Conclusions

Servicemembers and veterans diagnosed with PTSD or mild TBI may experience significant difficulties and impairments in their social relationships and work life. VHA and DOD have jointly developed a clinical practice guideline for PTSD patients that includes evidence-based recommendations to aid clinicians in their decision making about which medications to prescribe to treat the symptoms of PTSD. However, the

[64]VHA officials added that they would also like to review, on a more consistent basis, whether providers are continuing medications when clinically appropriate, by using real-time data from DOD on transitioning servicemembers' prescriptions. VHA officials told us that they have begun discussions with DOD officials about the feasibility of obtaining such data.

Army does not have a mechanism in place to monitor on an ongoing basis whether MTFs are prescribing medications that are consistent with these recommendations.

Ensuring that medication regimens are continued when clinically appropriate is critical for servicemembers transitioning their health care from DOD to VHA, including those with PTSD and mild TBI. We did not find evidence that the differences in the DOD and VA formularies for these medications result in the inappropriate discontinuation of medications. Although VA's formulary includes just over half of the medications on the DOD formulary, those on both formularies represent the most commonly DOD-prescribed psychiatric, pain, and sleep medications. However, we found that VHA's new policy to ensure the continuation of mental health medications lacks clarity on the types of medications considered mental health medications, and, as a result, VHA providers may be inappropriately changing or discontinuing mental health medications due to formulary differences, potentially increasing the risk of adverse health effects for transitioning servicemembers.

Recommendations for Executive Action

We recommend that the Secretary of Defense direct the Secretary of the Army to implement processes to review and monitor Army MTF prescribing practices for medications discouraged under the PTSD guideline and address identified deviations.

We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to clarify which types of medications are covered by VHA's January 2015 policy on medication continuation.

Agency Comments

DOD provided written comments on a draft of this report, which we have reprinted in appendix II. In its comments, DOD agreed with our conclusions and generally concurred with our recommendation. DOD stated that any policy that it may issue related to the monitoring of prescribing practices would be directed toward all of the military services. DOD also provided technical comments, which we have incorporated in the report as appropriate.

VA also provided written comments on a draft of this report, which we have reprinted in appendix III. In its comments, VA agreed with our conclusions and concurred with our recommendation. VA stated that it will issue written guidance to its providers clarifying which types of medications are covered by its 2015 policy on medication continuation,

with an estimated completion date of March 2016. VA also provided technical comments, which we have incorporated in the report as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Defense, the Secretary of Veterans Affairs, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

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Appendix I: Formulary Comparison

We found that the Department of Veterans Affairs (VA) formulary included 57 percent of the psychiatric, pain, and sleep medications on the Department of Defense (DOD) formulary, as of August 2015, and these medications represented the most frequently prescribed psychiatric, pain, and sleep medications on the DOD formulary in fiscal year 2014. (See table 3.)

Table 3: Comparison of the Psychiatric, Pain, and Sleep Medications on the Department of Defense (DOD) and Department of Veterans Affairs (VA) Formularies

Medication on DOD's formulary as of August 2015[a]	Medication on VA's formulary as of August 2015	Percentage of prescriptions, by medication type, filled by DOD for active duty servicemembers, fiscal year 2014[b]
Psychiatric	√	
Trazodone[c]	√	8.5
Amphetamine dextroamphetamine[c]	√	8.2
Bupropion[c]	√	7.1
Sertraline[c]	√	6.9
Diazepam[c]	√	6.8
Fluoxetine	√	6.5
Venlafaxine	√	6.4
Citalopram	√	6.0
Clonazepam	√	4.6
Topiramate	√	4.2
Amitriptyline	√	3.8
Escitalopram	√	3.5
Methylphenidate	√	2.6
Quetiapine	√	2.5
Alprazolam	√	2.1
Duloxetine	√	2.1
Mirtazapine	√	1.9
Lorazepam	√	1.9
Paroxetine	√	1.9
Buspirone	√	1.7
Aripiprazole	√	1.5
Nortriptyline	√	1.3
Valproate[d]	√	1.2
Modafinil		1.1
Lamotrigine	√	1.0
Atomoxetine		0.7

Medication on DOD's formulary as of August 2015[a]	Medication on VA's formulary as of August 2015	Percentage of prescriptions, by medication type, filled by DOD for active duty servicemembers, fiscal year 2014[b]
Risperidone	√	0.6
Levetiracetam	√	0.6
Doxepin	√	0.5
Lithium	√	0.3
Lisdexamfetamine		0.3
Oxcarbazepine	√	0.3
Dextroamphetamine	√	0.2
Olanzapine	√	0.2
Zonisamide	√	0.2
Ziprasidone	√	0.1
Carbamazepine	√	0.1
Armodafinil		0.1
Fluvoxamine		0.1
Imipramine	√	0.1
Haloperidol	√	< 0.1
Guanfacine		< 0.1
Chlorpromazine	√	< 0.1
Desipramine	√	< 0.1
Chlordiazepoxide	√	< 0.1
Clomipramine	√	< 0.1
Clozapine	√	< 0.1
Nefazodone		< 0.1
Clorazepate		< 0.1
Oxazepam		< 0.1
Protriptyline		< 0.1
Paliperidone[e]		< 0.1
Dexmethylphenidate		< 0.1
Perphenazine amitriptyline[f]	√	< 0.1
Olanzapine fluoxetine[e,f]		< 0.1
Fluphenazine	√	< 0.1
Perphenazine	√	< 0.1
Pimozide	√	< 0.1
Thiothixene	√	< 0.1
Phenelzine	√	< 0.1
Amitriptyline chlordiazepoxide[f]	√	< 0.1
Clonidine	√	< 0.1

Medication on DOD's formulary as of August 2015[a]	Medication on VA's formulary as of August 2015	Percentage of prescriptions, by medication type, filled by DOD for active duty servicemembers, fiscal year 2014[b]
Loxapine	√	< 0.1
Tranylcypromine	√	< 0.1
Trifluoperazine	√	< 0.1
Methamphetamine		< 0.1
Thioridazine		< 0.1
Isocarboxazid		< 0.1
Desvenlaxafine		< 0.1
Amoxapine		0.0
Ethosuximide		0.0
Ethotoin		0.0
Felbamate	√	0.0
Maprotiline		0.0
Meprobamate		0.0
Methsuximide		0.0
Rufinamide		0.0
Trimipramine		0.0
Vigabatrin		0.0
Subtotal psychiatric (79)		**100%**
Subtotal (percent) on both formularies	**53 (67%)**	
Pain		
Ibuprofen[c]	√	19.7
Naproxen[c]	√	17.1
Hydrocodone acetaminophen[c]	√	16.2
Oxycodone acetaminophen[c]	√	13.2
Tramadol[c]	√	9.0
Celecoxib		4.7
Gabapentin	√	3.8
Lidocaine[e]		3.5
Meloxicam	√	2.3
Oxycodone	√	2.1
Acetaminophen codeine	√	2.0
Butalbital acetaminophen caffeine	√	1.4
Diclofenac	√	1.2
Indomethacin	√	0.9
Piroxicam		0.5
Hydromorphone	√	0.4

Medication on DOD's formulary as of August 2015[a]	Medication on VA's formulary as of August 2015	Percentage of prescriptions, by medication type, filled by DOD for active duty servicemembers, fiscal year 2014[b]
Morphine	√	0.3
Ketorolac[e]		0.3
Etodola[c]	√	0.2
Tramadol acetaminophen[f]	√	0.1
Fentanyl	√	0.1
Buprenorphine[e]		0.1
Nabumetone		0.1
Hydrocodone ibuprofen		0.1
Oxymorphone		0.1
Meperidine[e]		0.1
Methadone	√	0.1
Codeine	√	0.1
Tapentadol		< 0.1
Oxaprozin		< 0.1
Diclofenac misoprostopol[f]	√	< 0.1
Butalbital aspirin caffeine	√	< 0.1
Ketoprofen		< 0.1
Sulindac	√	< 0.1
Naproxen esomeprazole		< 0.1
Butorphanol[e]		< 0.1
Codeine butalbital acetaminophen caffeine[f]	√	< 0.1
Diflunisal		< 0.1
Salsalate	√	< 0.1
Tolmetin		< 0.1
Flurbiprofen[e]		< 0.1
Pentazocine naloxone		< 0.1
Butalbital acetaminophen		< 0.1
Codeine butalbital aspirin caffeine[f]	√	< 0.1
Hydrocodone		< 0.1
Fenoprofen		< 0.1
Oxycodone aspirin[f]	√	< 0.1
Meclofenamate		< 0.1
Levorphanol		< 0.1
Ibuprofen oxycodone[f]	√	< 0.1
Choline magnesium salicylate		0.0
Codeine carisoprodol aspirin		0.0

Medication on DOD's formulary as of August 2015[a]	Medication on VA's formulary as of August 2015	Percentage of prescriptions, by medication type, filled by DOD for active duty servicemembers, fiscal year 2014[b]
Dihydrocodeine acetaminophen caffeine		0.0
Dihydrocodeine aspirin caffeine		0.0
Morphine naltrexone[g]		0.0
Subtotal pain (55)		**100%**
Subtotal (percent) on both formularies	**27 (49%)**	
Sleep	√	
Zolpidem[c]		67.8
Eszopiclone	√	19.5
Temazepam[c]		7.3
Triazolam		2.7
Zaleplon		2.6
Doxepin[e]		0.1
Flurazepam		0.1
Estazolam		< 0.1
Suvorexant[g,h]		0
Subtotal sleep (9)		**100%**
Subtotal (percent) on both formularies	**2 (22%)**	
Total (143)		
Total (percent) on both formularies	**82 (57%)[i]**	

Source: GAO analysis of DOD and Veterans Health Administration (VHA) data. I GAO-16-158

[a]DOD identified the psychiatric, pain, and sleep medications for this comparison. DOD did not include psychiatric, pain, or sleep medications on the DOD formulary that were available over-the-counter, were bulk medications used by pharmacists for compounding, or were provided through certain routes of administration, such as intravenous pain medications, typically administered in an inpatient setting. We conducted this analysis by active ingredient and did not account for differences in drug formulation, such as the dosage form (e.g., liquid or tablet), route of administration (e.g., oral or nasal), modified release formulation (e.g., extended or immediate release), salt form (e.g., hydrochloride or sulfate), or strength of the medication.

[b]This represents the most current data available for prescriptions filled by DOD for active duty servicemembers at the time of our review.

[c]We compared the specific formulations of medications available on the DOD and VA formularies for these 12 medications. We found that DOD's formulary included formulations not available on VA's formulary for 5 medications: diazepam, naproxen, oxycodone acetaminophen, tramadol, and zolpidem. DOD and VHA officials agreed that these differences were not generally clinically significant and would only have implications for specific patients.

[d]Valproate includes valproic acid and divalproex because these medications all have the same active ingredient.

[e]In instances where the formulations available on the VA formulary were for a different clinical indication or would typically be administered in an inpatient setting, we have not marked the medication as being on the VA formulary.

[f]VA generally does not include combination medications on its formulary. However, VHA officials told us that providers can prescribe several medications together, which can be equivalent to the combination medication. In cases where the VA formulary includes the individual medications that

make up a particular combination medication, we have marked it as being on the VA formulary. VHA officials noted that providers might be more likely to prescribe certain nonformulary combination medications using VHA's nonformulary request process rather than prescribe the individual ingredients.

[g]In fiscal year 2014 DOD did not fill any prescriptions for active duty servicemembers for morphine naltrexone and suvorexant because these medications were not available on the market at that time. DOD officials confirmed that the other 14 medications on the DOD formulary with zero prescriptions were on the market in fiscal year 2014.

[h]As of October 2015, DOD had removed suvorexant from its formulary.

[i]VA's formulary included 64 percent of the medications on DOD's formulary if the 16 medications for which DOD did not fill any prescriptions for active duty servicemembers in fiscal year 2014 are excluded from the calculation.

For a sample of psychiatric, pain, and sleep medications included on both the DOD and VA formularies and that were frequently prescribed by DOD providers in fiscal year 2014, we also compared the specific formulations that were available on each formulary. We conducted this supplemental analysis because DOD and Veterans Health Administration (VHA) officials told us that prescribing different formulations of the same medication may have clinical significance for certain medications or certain patients. Specifically, we reviewed differences in the medication formulations according to their available dosage form (e.g., liquid or tablet), modified release formulation (e.g., extended or immediate release), salt form (e.g., hydrochloride or sulfate), strength, and also their route of administration (e.g., oral or nasal).[1] We selected the five psychiatric and five pain medications most frequently prescribed and filled by DOD for active duty servicemembers in fiscal year 2014 that were on both DOD and VA formularies. For sleep, the VA formulary only included two medications, so we reviewed the formulations for both.

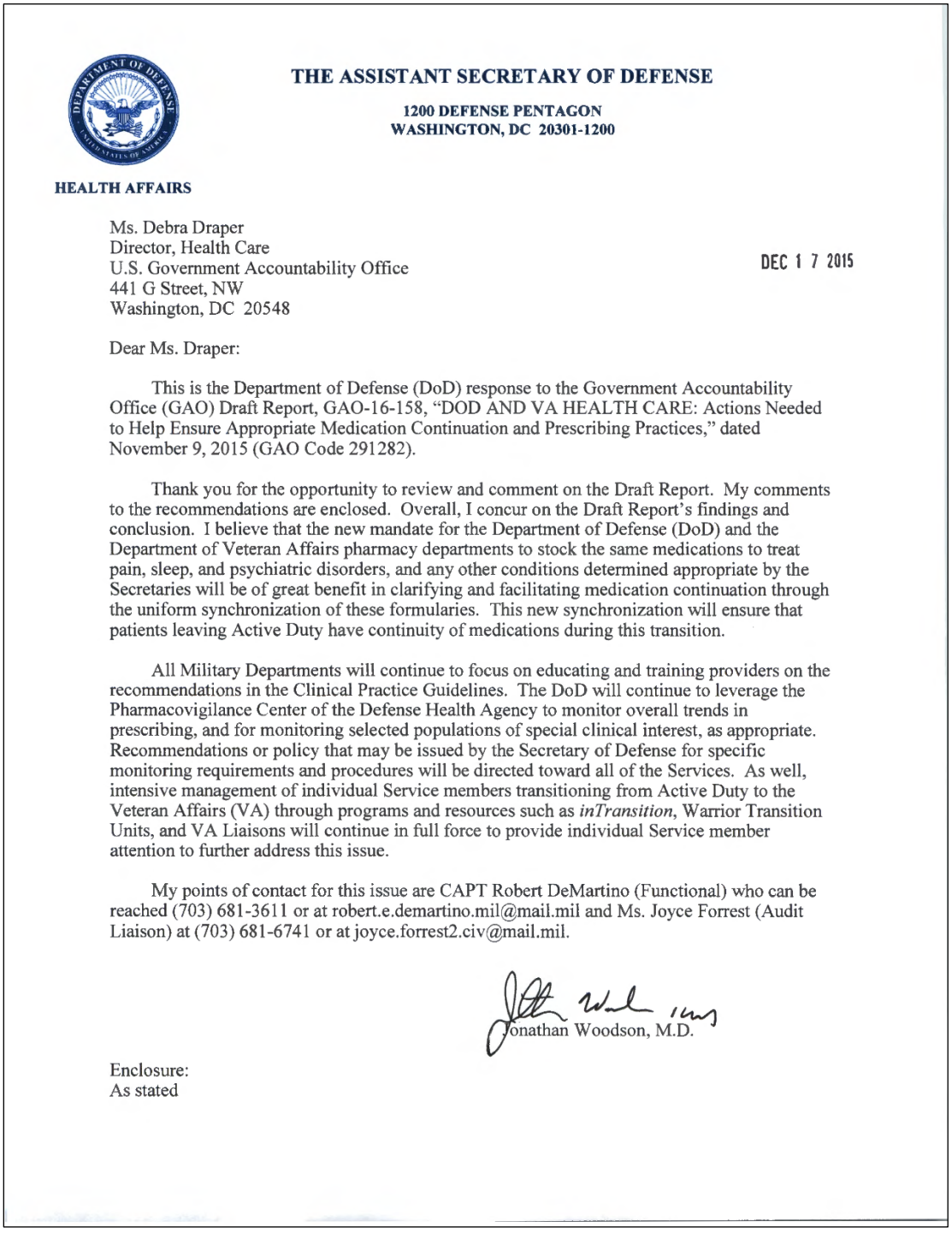
We found that the VA formulary included all of the formulations that were on the DOD formulary for 7 of these 12 medications. The formulation differences for the remaining 5 psychiatric, pain, and sleep medications resulted from differences in dosage form and modified release formulation. That is, 2 of the 5 medications were available on the DOD formulary but not the VA formulary in the liquid form, and the remaining 3 medications were available on the DOD formulary but not on the VA formulary in the extended release form.[2] For example, the DOD and VA

[1]Extended release medications are formulated to release the active ingredient slowly over time. For example, extended release medications may be taken every 12 or 24 hours, as opposed to more frequently.

[2]In addition, for one of the pain medications, the VA formulary also did not include a form with a coating that helps with digesting the medication.

formularies both include immediate release formulations of the sleep medication zolpidem, but the DOD formulary also includes the extended release version. We obtained the perspectives of DOD and VHA officials regarding the clinical significance of the formulation differences that we observed, and they agreed that these differences were not generally clinically significant and would only have implications for specific patients, such as certain patients who cannot swallow pills and who would benefit from the liquid forms. In addition, DOD and VHA officials both said that the primary difference between immediate release and extended release medications would be the frequency with which the patient needs to take the medication, but there could be differences in their effectiveness for certain patients. VHA officials noted that the formulations of medications that are not included on the VA formulary are often those for which there is a limited need in their patient population, but, in situations where these specific formulations are clinically indicated, they would utilize the nonformulary request process to prescribe that medication. DOD officials agreed that some of the formulations not available on VA's formulary are often not clinically indicated.

Appendix II: Comments from the Department of Defense



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Ms. Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

DEC 17 2015

Dear Ms. Draper:

This is the Department of Defense (DoD) response to the Government Accountability Office (GAO) Draft Report, GAO-16-158, "DOD AND VA HEALTH CARE: Actions Needed to Help Ensure Appropriate Medication Continuation and Prescribing Practices," dated November 9, 2015 (GAO Code 291282).

Thank you for the opportunity to review and comment on the Draft Report. My comments to the recommendations are enclosed. Overall, I concur on the Draft Report's findings and conclusion. I believe that the new mandate for the Department of Defense (DoD) and the Department of Veteran Affairs pharmacy departments to stock the same medications to treat pain, sleep, and psychiatric disorders, and any other conditions determined appropriate by the Secretaries will be of great benefit in clarifying and facilitating medication continuation through the uniform synchronization of these formularies. This new synchronization will ensure that patients leaving Active Duty have continuity of medications during this transition.

All Military Departments will continue to focus on educating and training providers on the recommendations in the Clinical Practice Guidelines. The DoD will continue to leverage the Pharmacovigilance Center of the Defense Health Agency to monitor overall trends in prescribing, and for monitoring selected populations of special clinical interest, as appropriate. Recommendations or policy that may be issued by the Secretary of Defense for specific monitoring requirements and procedures will be directed toward all of the Services. As well, intensive management of individual Service members transitioning from Active Duty to the Veteran Affairs (VA) through programs and resources such as *inTransition*, Warrior Transition Units, and VA Liaisons will continue in full force to provide individual Service member attention to further address this issue.

My points of contact for this issue are CAPT Robert DeMartino (Functional) who can be reached (703) 681-3611 or at robert.e.demartino.mil@mail.mil and Ms. Joyce Forrest (Audit Liaison) at (703) 681-6741 or at joyce.forrest2.civ@mail.mil.

Jonathan Woodson, M.D.

Enclosure:
As stated

GAO DRAFT REPORT DATED NOVEMBER 9, 2015
GAO-16-158 (GAO CODE 291282)

"ACTIONS NEEDED TO HELP ENSURE APPROPRIATE MEDICATION CONTINUATION AND PRESCRIBING PRACTICES"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATIONS

RECOMMENDATION 1: The Government Accountability Office (GAO) recommends that the Secretary of Defense direct the Secretary of the Army to implement processes to review and monitor Army Military Treatment Facility prescribing practices for medications discouraged under the post-traumatic stress disorder guideline and address identified deviations.

COMMENTS: There are many factors that need to be considered in a policy decision of this nature, and the Veterans Affairs (VA) policy approach outlined in the GAO report may not be optimal for the Army population needs. Furthermore, there are no universal definitions for what would constitute overly high or inappropriate prescribing practices in any specific health care setting. Instead, there is strong evidence that the Army's overall long-running strategies for improving behavioral health care have already worked and are working to reduce antipsychotic prescribing. The Army's data showed that the decline in antipsychotic use started before Army's 2012 policy memo, and arguably, what the Army established goes well beyond what is routinely considered standard of practice in other health care settings. Therefore, it is unlikely that the Army policy, in formal effect from 2012 to 2014, alone explains the large observed decline in antipsychotic medication use.

All Military Departments will continue to focus on educating and training providers on the recommendations in the Clinical Practice Guidelines. Furthermore, the Department of Defense (DoD) will continue to leverage the Defense Health Agencies, such as the Pharmacovigilance Center, to monitor overall trends in prescribing, as well as for monitoring selected populations of special clinical interest, as appropriate. Additionally, any recommendation or policy that may be issued from the Secretary of Defense for specific monitoring procedures should be directed toward all of the Services, and, only after appropriate review of the scientific evidence by all Services to support such a recommendation.

DoD RESPONSE: The DoD concurs, with comments as provided, above.

RECOMMENDATION 2: The GAO recommends that the Secretary of VA direct the Under Secretary for Health to clarify which types of medications are covered by the Veterans Health Administration's January 2015 policy on medication continuation.

COMMENTS: The GAO should note that, beginning June 1, under the National Defense Authorization Act for Fiscal Year 2016, SEC. 715. JOINT UNIFORM FORMULARY FOR TRANSITION OF CARE, both DoD and VA department pharmacies will be mandated to stock the same medications to treat pain, sleep, and psychiatric disorders and any other conditions determined appropriate by the Secretaries. The new synchronization will ensure that patients leaving Active Duty have continuity of medications during this transition.

DoD RESPONSE: The DoD concurs, with comment, as stated, above.

Appendix III: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

December 7, 2015

Ms. Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Draper:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "DOD AND VA HEALTH CARE: Actions Needed to Help Ensure Appropriate Medication Continuation and Prescribing Practices" (GAO-16-158). VA agrees with GAO's conclusions.

The enclosure specifically addresses GAO's recommendations and provides an action plan for each, and provides technical comments to the draft report. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Robert L. Nabors II
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Response to
Government Accountability Office (GAO) Draft Report
"DOD AND VA HEALTH CARE: Actions Needed to Help Ensure Appropriate Medication Continuation and Prescribing Practices"
(GAO-16-158)

Recommendation 2: We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to clarify which types of medications are covered by VHA's January 2015 policy on medication continuation.

VA Comment: Concur. The Veterans Health Administration (VHA) will provide clarification to VA clinicians about which types of medications are covered by VHA's January 2015 policy on medication continuation. This will be accomplished by communicating the clarification on national conference calls and by issuing written guidance from the Office of the Deputy Under Secretary for Health for Operations and Management. Target Completion Date: March 2016

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Janina Austin, Assistant Director; Jennie F. Apter; Pamela Dooley; Joshua D. Ferencik; Jacquelyn Hamilton; Toni Harrison; Katie McConnell; and Daniel Ries made key contributions to this report.

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