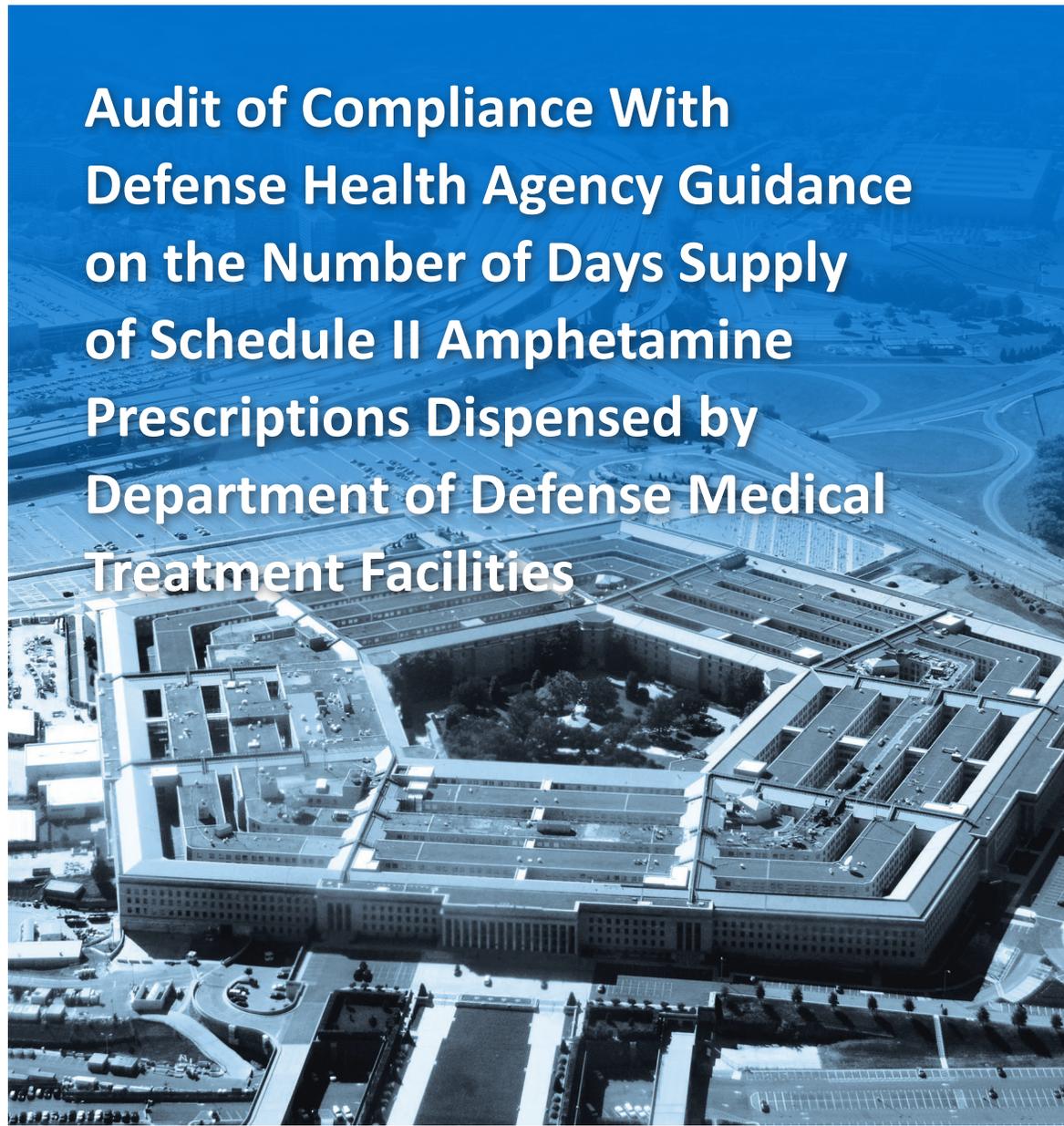




INSPECTOR GENERAL

U.S. Department of Defense

APRIL 6, 2021



Audit of Compliance With Defense Health Agency Guidance on the Number of Days Supply of Schedule II Amphetamine Prescriptions Dispensed by Department of Defense Medical Treatment Facilities





Results in Brief

Audit of Compliance With Defense Health Agency Guidance on the Number of Days Supply of Schedule II Amphetamine Prescriptions Dispensed by Department of Defense Medical Treatment Facilities

April 6, 2021

Objective

The objective of this audit was to determine whether DoD medical treatment facilities (MTFs) dispensed the appropriate number of days supply for Schedule II amphetamines, in accordance with Defense Health Agency (DHA) guidance.

Background

Amphetamines are stimulants that speed up the body's systems. They are prescribed commonly to treat attention-deficit hyperactivity disorder and narcolepsy. Controlled drugs are categorized by Schedule I through V and are classified according to their abuse potential and psychological effects. Many amphetamines, such as Adderall and Ritalin, are Schedule II, which means that they have a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Using amphetamines can lead to addiction. According to the Drug Enforcement Administration, stimulants can be diverted from legitimate channels and are also clandestinely manufactured exclusively for the illicit market.

On December 20, 2019, the DHA issued guidance for the Military Departments, the DHA, and the MTFs, stating that medications to treat attention-deficit hyperactivity disorder may be filled for quantities up to a 90-day supply with no refills. According to the Acting Chief of the DHA Pharmacy Operations Division, the DHA allowed the Military Departments until April 14, 2020, to implement the 90-day supply requirement. Also, the DHA guidance states that active

duty service members requiring resupply of medication while deployed will be enrolled in the TRICARE Deployment Prescription Program. The Program fills and mails the maintenance medications to the deployed active duty member. Each Military Department has its own guidance on the number of days that medications can be prescribed for deployed active duty service members.

Finding

Overall, most DoD MTFs dispensed the appropriate number of days supply for Schedule II amphetamines. Specifically, according to data from the Military Health System Data Repository, from April 15, 2020, through August 13, 2020, DoD MTFs dispensed 89,356 Schedule II amphetamines, of which 86,074 (or 96 percent) were equal to or less than a 90-day supply, as required by the DHA guidance. Therefore, the majority of MTFs complied with DHA guidance, reducing the chances of drug addiction and diversion.

However, 65 MTFs, mostly located on Navy and Air Force installations, dispensed a total of 2,967 Schedule II amphetamine prescriptions that were for a 100-day supply. Of these prescriptions, 1,281 (or 43 percent) were for active duty service members, leaving 1,687 (or 57 percent) for family members of active duty service members, and retired service members and their family members. Therefore, this indicates that the majority of prescriptions for 100-day supply are not for deployed active duty service members. This occurred because the Navy and at least one MTF did not revise their guidance to conform to DHA guidance to dispense only up to a 90-day supply of Schedule II amphetamines to conform to DHA guidance. For example, Navy guidance allows for up to a 100-day supply of stimulant medications to include amphetamines. As a result, although several MTFs only dispensed 10 more days supply than the DHA guidance, these MTFs dispensed Schedule II amphetamines to beneficiaries in a manner that was inconsistent with DHA policy and may have increased the risk of overdose and diversion from legal sources to the illicit market.



Results in Brief

Audit of Compliance With Defense Health Agency Guidance on the Number of Days Supply of Schedule II Amphetamine Prescriptions Dispensed by Department of Defense Medical Treatment Facilities

Recommendation

We recommend that the Director of the DHA ensure that DoD MTFs and the Navy Bureau of Medicine and Surgery revise their guidance to limit Schedule II amphetamines prescriptions used to treat attention-deficit hyperactivity disorder to no more than a 90-day supply, except for applicable deployments.

Management Comments and Our Response

The DHA Director agreed with the recommendation. The Director stated that the DHA procedural instruction is in place on pharmacy operations, which supersedes any Service policy publications for DHA-specific functions including clinical and health delivery services. The Director stated that Service policy publications will continue to address Service readiness activities and deployed and operational units and settings. The Director also stated that the Navy Bureau of Medicine and Surgery will update its Service policy to reflect DHA policy at MTFs. The Director further stated that there are advantages to dispensing these medications in the original unopened 100-count bottles; however, initial standardization efforts led to the selection of the 90-day supply guidance.

Comments from the Director partially addressed the recommendation; therefore, the recommendation is unresolved. We agree that the DHA procedural instruction should supersede any Service policy publications for DHA-specific functions including clinical and health delivery services. However, DoD MTF personnel were not consistently following the DHA procedural instruction; therefore, until MTF guidance is revised, MTFs may continue prescribing over the limit of a 90-day supply regardless of whether DHA guidance supersedes the MTF guidance. Additionally, we recognize the potential advantages of dispensing unopened 100-count manufacturer bottles. However, we used a 90-day supply as the standard for our testing because the DHA established a 90-day supply as the DoD standard. If the DHA changed the policy to a 100-day supply, we would have used that standard for our testing instead of the 90-day supply. We request that the Director reconsider the DHA's position on ensuring that MTFs revise their guidance to limit Schedule II amphetamines prescriptions to no more than a 90-day supply and provide additional comments to the report.

Please see the Recommendations Table on the next page for the status of recommendation.

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Director, DHA	1	None	None

Note: The following categories are used to describe agency management’s comments to individual recommendations.

- **Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **Closed** – OIG verified that the agreed upon corrective actions were implemented.





**INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
4800 MARK CENTER DRIVE
ALEXANDRIA, VIRGINIA 22350-1500**

April 6, 2021

MEMORANDUM FOR DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Audit of Compliance with Defense Health Agency Guidance on the Number of Days Supply of Schedule II Amphetamine Prescriptions Dispensed by Department of Defense Medical Treatment Facilities (Report No. DODIG-2021-073)

This final report provides the results of the DoD Office of Inspector General's audit. We previously provided copies of the draft report and requested written comments on the recommendations. We considered management's comments on the draft report when preparing the final report. These comments are included in the report.

This report contains a recommendation that is considered unresolved because the Director's response did not meet the intent of the recommendation present in the report. Therefore, as discussed in the Recommendation, Management Comments, and Our Response section of this report, the recommendation remains open. We will track the recommendation until an agreement is reached on the actions that you will take to address the recommendation, and you have submitted adequate documentation showing that all agreed-upon actions are completed.

DoD Instruction 7650.03 requires that recommendations be resolved promptly. Therefore, please provide us within 30 days your response concerning specific actions in process or alternative corrective actions proposed on the recommendation. Send your response to audityorktown@dodig.mil.

If you have any questions, please contact me at [REDACTED]

A handwritten signature in black ink, reading "Theresa S. Hull".

Theresa S. Hull
Assistant Inspector General for Audit
Acquisition, Contracting, and Sustainment

Contents

Introduction

Objective.....	1
Background.....	1
Review of Internal Controls.....	3

Finding. The DoD Generally Dispensed Schedule II Amphetamines in Accordance With DHA Guidance, but Improvements Are Needed..... 4

Dispensed Schedule II Amphetamine Pharmaceuticals.....	4
Guidance Allowed More Than a 90-Day Supply.....	6
Conclusion.....	7
Management Comments on the Finding and Our Response.....	7
Recommendations, Management Comments, and Our Response.....	8

Appendix

Scope and Methodology.....	10
Use of Computer-Processed Data.....	10
Prior Coverage.....	10

Management Comments

Defense Health Agency Comments.....	11
-------------------------------------	----

Acronyms and Abbreviations..... 14

Introduction

Objective

The objective of this audit was to determine whether DoD medical treatment facilities (MTFs) dispensed the appropriate number of days supply for Schedule II amphetamines, in accordance with Defense Health Agency (DHA) guidance. See the Appendix for the scope and methodology.

Background

DoD Medical Treatment Facilities

According to the DHA, the Military Health System (MHS) is the most comprehensive military health care enterprise in the world. The MHS provides direction, resources, health care providers, and other means necessary to foster, protect, sustain, and restore health to active duty service members, retirees, and their family members. Currently, the MHS consists of 50 military hospitals, 425 clinics, and 246 dental clinics, serving 9.6 million service members, military retirees, and their families.

In 2013, the Secretary of Defense established the DHA as part of the DoD effort to reform the MHS. The DHA supports the delivery of health care services to DoD beneficiaries and integrates clinical and business processes across the MHS. Section 702 of the National Defense Authorization Act of 2017 directed the DHA to assume authority, direction, and control of all the MTFs from the Military Services by October 1, 2018.¹

An MTF is any fixed facility of the DoD that is outside of a deployed environment and used primarily for health care and any other location used for purposes of providing health care services as designated by the Secretary of Defense.² On August 13, 2018, section 711 of the National Defense Authorization Act of 2019 amended the transition date for the DHA to assume authority, direction, and control of all MTFs from the Military Services to the DHA to no later than September 30, 2021.³

¹ Public Law 114-328, "National Defense Authorization Act for Fiscal Year 2017," section 702, "Reform of Administration of the Defense Health Agency (DHA) and Military Medical Treatment Facilities," December 23, 2016.

² Public Law 116-92, "National Defense Authorization Act for Fiscal Year 2020," section 711, "Modification Of Organization Of Military Health System," December 20, 2019.

³ Public Law 115-232, "John S. McCain National Defense Authorization Act for Fiscal Year 2019," section 711, "Improvement of Administration of the Defense Health Agency and Military Medical Treatment Facilities," August 13, 2018.

As of October 25, 2019, the DHA assumed authority, direction, and control over the MTFs within the continental United States, as well as Alaska, Hawaii, and Puerto Rico, with management of these facilities being executed through Direct Support agreements in effect between the DHA and the Military Departments.

Schedule II Amphetamines

Amphetamines are stimulants that speed up the body's systems. They are commonly prescribed to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy (excessive daytime sleepiness). According to the National Institutes of Health, stimulants increase alertness, attention, and energy. Many amphetamines are Schedule II, which means that they have a high potential for abuse and have an acceptable medical use.⁴ Schedule II pharmaceutical products are available only through prescriptions, which are not allowed to be refilled. Schedule II amphetamines, such as dextroamphetamine-amphetamine (brand name, Adderall) and methylphenidate (brand names, Concerta or Ritalin), have a high potential for abuse, with abuse potentially leading to severe psychological or physical

• *Using amphetamines can lead to addiction.*

dependence. Using amphetamines can lead to addiction. According to the Drug Enforcement Administration, stimulants can be diverted from

legitimate channels and are also clandestinely manufactured exclusively for the illicit market.

According to the Drug Enforcement Administration, amphetamine abuse is often associated with a pattern of binge use. Smoking, snorting, or injecting amphetamines produces a sudden sensation known as a "rush" or a "flash." During heavy use, all other interests become secondary to recreating the initial euphoric rush. The Drug Enforcement Administration also states that an overdose, unless medical intervention occurs, can result in high fever, convulsions, cardiovascular collapse, and even death.

DoD Guidance on Amphetamines

The DoD and Military Departments have their own guidance on the number of days supply for Schedule II amphetamines. On December 20, 2019, the DHA issued guidance for the Military Departments, DHA, and MTFs. The guidance states that medications to treat ADHD may be filled for quantities up to a 90-day supply

⁴ In 1970, the Controlled Substances Act created five drug schedules, or classifications, that group drugs based on risk of abuse or harm. Schedule I drugs are considered unsafe for use, even under medical supervision. Schedule II drugs are defined as drugs with a high potential for abuse, with abuse potentially leading to severe psychological or physical dependence. These drugs are considered dangerous. Other substances classified as Schedule III and Schedule IV drugs are considered to have a lower potential for abuse and a lower risk of dependence than Schedule I and II drugs. Prescriptions for controlled substances such as amphetamines must be issued for a legitimate medical purpose by practitioners acting in the usual course of their professional practice.

with no refills.⁵ A DHA pharmacy official stated that the DHA issued its guidance in December 2019, and gave the Military Departments until April 14, 2020, to implement the 90-day supply limits. According to DHA guidance, active duty personnel requiring resupply of maintenance medication while deployed will be enrolled in the TRICARE Deployment Prescription Program and provided contact information for updating their mailing address once at the deployed site. A DHA pharmacy official stated that the TRICARE Deployment Prescription Program will only be used if it is practical for the deployed active duty member.

Army Guidance

Army guidance allows physicians to prescribe up to a 90-day supply for a medication and a 180-day supply for deployments.⁶

Air Force Guidance

Air Force guidance allows up to a 90-day supply for a medication. Pharmacies will dispense prescription medication to deploying personnel in a quantity sufficient to last for the duration of the deployment plus transit time unless otherwise prohibited by Federal law, combatant command guidance, or provider judgment.⁷

Navy Guidance

Navy guidance states that Schedule II medications are normally limited to a reasonable quantity (usually a 30-day supply); however, the Navy Bureau of Medicine and Surgery authorizes up to a 100-day supply of stimulant medications. Deploying members may receive a deployment supply of Schedule II medications, following guidance of the area of responsibility.⁸

The Navy Bureau of Medicine and Surgery authorizes up to a 100-day supply of stimulant medications.

Review of Internal Controls

DoD Instruction 5010.40 requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls.⁹ We identified a control weakness associated with the DHA not effectively preventing MTFs from dispensing more than a 90-day supply of Schedule II amphetamines. We will provide a copy of the final report to the senior official responsible for internal controls in the DHA and Military Departments.

⁵ Defense Health Agency Procedural Instruction, 6025.31, "Military Medical Treatment Facility Pharmacy Operations," December 20, 2019.

⁶ Army Regulation 40-3, "Medical, Dental, and Veterinary Care," April 23, 2013.

⁷ Air Force Instruction 44-102, "Medical Care Management," March 17, 2015.

⁸ Change 163, Manual of the Medical Department, U.S. Navy, NAVMED P-117, March 5, 2018.

⁹ DoD Instruction 5010.40, "Managers' Internal Control Program Procedures," May 30, 2013.

Finding

The DoD Generally Dispensed Schedule II Amphetamines in Accordance With DHA Guidance, but Improvements Are Needed

Overall, DoD MTFs dispensed the appropriate number of days supply for Schedule II amphetamines. Specifically, according to data from the Military Health System Data Repository (MDR), from April 15, 2020, through August 13, 2020, DoD MTFs dispensed 89,356 Schedule II amphetamines, of which 86,074 (or 96 percent) were equal to or less than a 90-day supply, as required by the DHA guidance. Therefore, the majority of MTFs complied with DHA guidance, reducing the chances of drug addiction and diversion.

However, 65 MTFs, mostly located on Navy and Air Force installations, dispensed a total of 2,967 Schedule II amphetamine prescriptions that were for a 100-day supply. Of these dispensed prescriptions, 1,281 (or 43 percent) were for active duty service members, leaving 1,687 (or 57 percent) for family members of active duty service members, and retired service members and their family members. Therefore, this indicates that the majority the 100-day supply of dispensed prescriptions were not for deployed active duty service members. This occurred because the Navy Bureau of Medicine and Surgery and at least one MTF did not revise their guidance to conform to DHA guidance to dispense up to a 90-day supply of Schedule II amphetamines. For example, Navy Bureau of Medicine and Surgery guidance allows for up to a 100-day supply of stimulant medications. As a result, although several MTFs only dispensed 10 more days supply than the DHA guidance, these MTFs dispensed Schedule II amphetamines to beneficiaries in a manner that was inconsistent with DHA policy and may have increased the risk of overdose and diversion from legal sources to the illicit market.

Dispensed Schedule II Amphetamine Pharmaceuticals

Overall, DoD MTFs dispensed the appropriate number of days supply for Schedule II amphetamines. Specifically, according to the MDR, from April 15, 2020, through August 13, 2020, DoD MTFs dispensed 89,356 Schedule II amphetamines of which 86,074 (or 96 percent) were equal to or less than a 90-day supply. Table 1 shows that 96 percent of dispensed Schedule II amphetamines were equal to or less than a 90-day supply. Also, of the 89,356 dispensed Schedule II amphetamines, only 302 (less than 1 percent) were for more than a 100-day supply. Of the 302 dispensed, 216 (or 72 percent) were for active duty service members, which could be for deployments. Therefore, the vast majority of MTFs complied with DHA guidance.

Table 1. Number of Times Schedule II Amphetamines Were Dispensed at DoD MTFs From April 15, 2020, Through August 13, 2020

Days Supply by Range	No. of Prescriptions Dispensed	Percent of Total
0 to 30	30,185	33.78
31 to 60	8,261	9.25
61 to 90	47,628	53.30
Subtotal (0 to 90 days)*	86,074	96.33
91 to 99	13	0.01
100 (no range)	2,967	3.32
101 to 180	242	0.27
181 to 300	55	0.06
301 to 365	5	0.01
Total	89,356	100

* These dispensed prescriptions were in accordance with DHA guidance.
Source: The DoD OIG.

Some MTFs Dispensed 100-Day Supply Prescriptions

Sixty-five MTFs, mostly located on Navy and Air Force installations, dispensed a total of 2,967 Schedule II amphetamines prescriptions that were for a 100-day supply. Of these dispensed prescriptions, 1,281 (43 percent) were for active duty service members, leaving 1,686 (57 percent) for family members of active duty service members, and retired service members and their family members. This indicates that many of dispensed prescriptions for a 100-day supply were not for deployed active duty service members. We did not determine how many of the 2,967 dispensed prescriptions were prescribed to treat ADHD because the MDR data did not contain diagnosis information. Table 2 shows the number of Schedule II amphetamine prescriptions that were dispensed for 100-day supply and the number of MTFs that dispensed them by Military Department.

Table 2. Number of MTFs by Military Department That Had a 100-Day Supply of Schedule II Amphetamines From April 15, 2020, Through August 13, 2020

Military Department	Military Department MTFs	No. of 100-day Supply Prescriptions	Percent of Total
Army	6	95	3
Air Force	14	1,129	38
Navy	45	1,743	59
Total	65	2,967	100

Source: The DoD OIG.

For example, an MTF on Nellis Air Force Base, Nevada, had 316 Schedule II amphetamine prescriptions dispensed from April 15, 2020, through August 13, 2020. Of those dispensed prescriptions, 223 (or 71 percent) were for family members of service members, and retired service members and their family members. As another example, an MTF on Joint Expeditionary Base—Little Creek (a Navy installation), Virginia, had dispensed 467 Schedule II amphetamine prescriptions from April 15, 2020, through August 13, 2020. Of those dispensed prescriptions, 280 (or 60 percent) were for family members of service members, retired service members and their family members. Therefore, most of the dispensed prescriptions were not for deploying active duty service members.

Guidance Allowed More Than a 90-Day Supply

The Navy and at least one MTF did not revise their guidance to conform to DHA guidance to dispense up to a 90-day supply of Schedule II amphetamines. The DHA published DHA Procedural Instruction 6025.31 on December 20, 2019, limiting Schedule II amphetamine prescriptions to treat ADHD to a 90-day supply. DHA Pharmacy Operations personnel allowed MTFs until April 14, 2020, to implement the new number of days supply limits. According to DHA Pharmacy Operations personnel, the DHA ultimately settled on a 90-day supply limit because it is the civilian standard from an insurance coverage perspective.

Additionally, installation guidance at Nellis Air Force Base allowed for a 100-day supply.

However, Navy Bureau of Medicine and Surgery guidance authorizes up to a 100-day supply of stimulant medications, and deploying members may receive a

deployment supply of Schedule II medications, following guidance of the area of responsibility. Additionally, installation guidance at Nellis Air Force Base allowed for a 100-day supply. The 99th Medical Group guidance at Nellis Air Force Base, dated November 25, 2017, states:

Schedule II controlled substances may be dispensed for a maximum 30-day supply and are not refillable.

Medication for the treatment of Attention Deficit Hyperactivity Disorder and narcolepsy may be dispensed for a maximum of a 100-day supply with no refills.

During our visit to Nellis Air Force Base, Nevada, we asked a pharmacy technician why the MTF was dispensing some Schedule II amphetamine prescriptions in a 100-day supply. The pharmacy technician stated that it was easier to provide a 100-day supply because the medicine came from the supplier in packages of 100 tablets, making it easier to dispense.

Other MTFs also may have not revised their guidance to only allow only up to a 90-day supply of Schedule II amphetamines. The DHA should ensure that MTFs and the Navy Bureau of Medicine and Surgery revise their guidance to limit Schedule II amphetamine prescriptions used to treat ADHD to no more than a 90-day supply, except for applicable deployments.

Conclusion

The DoD was generally compliant with DHA guidance to limit Schedule II amphetamines to treat ADHD to only quantities up to a 90-day supply with no refills, reducing the chances of drug addiction and diversion. Although several MTFs only dispensed 10 more days supply than the DHA guidance, these MTFs dispensed Schedule II amphetamines to beneficiaries in a manner that was inconsistent with DHA policy and may have increased the risk of overdose and diversion from legal sources to the illicit market.

Management Comments on the Finding and Our Response

Defense Health Agency Comments

The DHA Director partially disagreed with the conclusion of the report. The Director stated that one metric not measured in this audit was the percent of prescriptions with less than or equal to a 90-day supply over time. The Director stated that their data indicates that monthly MTF compliance with the new DHA guidance improved from 96.6 to 98.1 percent over the April through August timeframe. The Director also stated that the statement of dispensing 10 more days of Schedule II amphetamines potentially causing increased risk of overdose is problematic.

The Director stated that in dealing with chronic medical conditions, such as ADHD, quantities of medication on hand are generally considered as increasing medication adherence versus a source of product for diversion. Additionally, the Director stated that the report fails to take into consideration the potential advantages of dispensing unopened 100-count manufacturer bottles, including increased

adherence, decreased risk of pharmacy staff diversion, decreased risk of counting errors, and increased efficiency. The different days' supply of 90 and 100 for chronic medications have their own advantages, but the need to standardize caused one to be chosen over the other, according to the DHA.

Our Response

We agree that the DoD was generally compliant with DHA guidance to limit quantities of Schedule II amphetamines to treat ADHD to a 90-day supply with no refills, reducing the chances of drug addiction and diversion. However, we disagree with the DHA that stating dispensing 10 more days of Schedule II amphetamines potentially causes increased risk of overdose in the report is problematic. Amphetamines are known for being abused and diverted from legitimate channels to the illicit market, according to the Drug Enforcement Administration. Additionally, we recognize the potential advantages of dispensing unopened 100-count manufacturer bottles. However, we used a 90-day supply as the standard for our testing because the DHA established a 90-day supply as the DoD standard. If the DHA changed the policy to a 100-day supply, we would have used that standard for our testing instead of the 90-day supply.

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Director of the Defense Health Agency ensure that DoD medical treatment facilities and the Navy Bureau of Medicine and Surgery revise their guidance to limit Schedule II amphetamines prescriptions used to treat attention-deficit hyperactivity disorder to no more than a 90-day supply, except for applicable deployments.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA procedural instruction is in place on pharmacy operations, which supersedes any Service policy publications for DHA-specific functions including clinical and health delivery services. The Director stated that Service policy publications will continue to address Service readiness activities and deployed and operational units and settings. The Director also stated that the Navy Bureau of Medicine and Surgery will update its Service policy to reflect DHA policy at MTFs. The Director stated that as DHA continues to review policy guidance, potential changes to days supply guidance may be made. Future guidance may increase or decrease this number and MTF pharmacists must continue to exercise professional judgement in allowing deviations from the established policy.

Our Response

Comments from the Director partially addressed the recommendation; therefore, the recommendation is unresolved. We agree that the DHA procedural instruction should supersede any Service policy publications for DHA-specific functions including clinical and health delivery services. However, DoD MTF personnel were not consistently following the DHA procedural instruction; therefore, until MTF guidance is revised, MTFs may continue prescribing over the limit of a 90-day supply regardless of whether DHA guidance supersedes the MTF guidance. We request that the Director reconsider the DHA's position on ensuring that MTFs revise their guidance to limit Schedule II amphetamines prescriptions to no more than a 90-day supply and provide additional comments to the report.

Appendix

Scope and Methodology

We conducted this performance audit from January 2020 through February 2021 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.

Our initial objective was to determine whether the DHA properly accounted for and safeguarded pharmaceuticals at selected DoD MTFs in accordance with DHA and Military Department guidance. However, the Coronavirus Disease–2019 pandemic impacted the scope and methodology of our audit. Due to travel restrictions, we were unable to proceed with our planned site visits. Therefore, we revised our audit objective to determine whether the DoD MTFs dispensed the appropriate number of days supply for Schedule II amphetamine pharmaceuticals, in accordance with DHA guidance.

To complete the revised audit objective, we extracted data from the MDR to determine the number of Schedule II amphetamine prescriptions that MTFs filled from October 1, 2017, through August 13, 2020. Because the DHA set implementation of the 90-day supply for Schedule II amphetamine prescriptions for April 14, 2020, we reviewed prescriptions that MTFs dispensed from April 15, 2020, through August 13, 2020. We analyzed the data to determine whether the MTFs dispensed the prescriptions in more than a 90-day supply. We reviewed pharmacy operations regulations on dispensing Schedule II amphetamines at MTFs. We corresponded with DHA pharmacy personnel on policies related to amphetamines.

Use of Computer-Processed Data

In August 2020, we used computer-processed data from the MDR to identify all Schedule II amphetamine prescriptions that were listed as filled by MTF pharmacies. To test the reliability of the data, we compared relevant MDR data fields to source documents from MTF pharmacies and patient medical records. We identified only minor inaccuracies that did not affect the conclusions made in the report. Therefore, we determined that the data were reliable to make conclusions for the audit objective.

Prior Coverage

No prior coverage has been conducted on DoD MTFs dispensing the appropriate number of days supply of Schedule II amphetamines.

Management Comments

Defense Health Agency Comments



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

March 12, 2021

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: Department of Defense Inspector General Draft Report D2020-D000AW-0011.000

This is the Department of Defense (DoD) response to the Department of Defense Inspector General Draft Report on Project No. D2020-D000AW-0011.000.

Thank you for the opportunity to review and comment on the Draft Report. Overall, I concur with the findings contained in the Draft Report. The management of dispensing prescriptions of Schedule II amphetamines to our beneficiaries is of importance to the DoD in areas of patient safety and diversion prevention. The DoD supports enhanced ability to implement prescription return/take-back and disposal programs to aid in the removal of unwanted, unused, and expired controlled substances. My specific responses to the conclusion and recommendation 1 are attached.

My points of contact on this issue are [REDACTED] (Functional) who can be reached at [REDACTED] or via e-mail at [REDACTED] or [REDACTED] (Audit Liaison) at [REDACTED] or via email at [REDACTED].

PLACE. RONALD.J. [REDACTED] Digitally signed by
JOSEPH. [REDACTED] in SCE RONALD.JOSEPH. [REDACTED]

RONALD J. PLACE
LTG, MC, USA
Director

Attachments:
As stated

Defense Health Agency Comments (cont'd)

**DEPARTMENT OF DEFENSE INSPECTOR GENERAL DRAFT REPORT ON
PROJECT NO. D2020-D000AW-0011.000 "AUDIT OF COMPLIANCE WITH DEFENSE
HEALTH AGENCY GUIDANCE ON THE NUMBER OF DAYS SUPPLY SCHEDULE II
AMPHETAMINE PRESCRIPTIONS DISPENSED BY DEPARTMENT OF DEFENSE
MEDICAL TREATMENT FACILITIES"**

RESPONSE TO RECOMMENDATION

Conclusion: The DoD was generally compliant with DHA guidance to limit Schedule II amphetamines to treat ADHD to only quantities up to a 90-day supply with no refills, reducing the chances of drug addiction and diversion. Although several MTFs only dispensed 10 more days supply than the DHA guidance, these MTFs dispensed Schedule II amphetamines to beneficiaries in a manner that may have increased the risk of overdose and diversion from legal sources to the illicit market.

DHA Response:

DHA Partially Concur.

One metric not measured in this audit was the percent of prescriptions with less than or equal to a 90-day supply over time. Our data indicates that monthly MTF compliance with the new DHA guidance improved from 96.6% to 98.1% over the April through August timeframe. Additionally, the statement of dispensing 10 more days of Schedule II amphetamines potentially causing increased risk of overdose is problematic. In dealing with chronic medical conditions such as Attention Deficit Hyperactivity Disorder (ADHD), quantities of medication on hand are generally considered as increasing medication adherence versus a source of product for diversion. Additionally, it fails to take into consideration the potential advantages of dispensing unopened 100-count manufacturer bottles, including increased adherence, decreased risk of pharmacy staff diversion, decreased risk of counting errors, and increased efficiency. The different days' supply of 90 and 100 for chronic medications have their own advantages, but the need to standardize caused one to be chosen over the other.

Recommendation: We recommend that the Director of the Defense Health Agency ensure that DoD medical treatment facilities and the Bureau of Navy Medicine and Surgery revise their guidance to limit Schedule II amphetamines prescriptions used to treat attention-deficit hyperactivity disorder to no more than a 90-day supply, except for applicable deployments.

DHA Response:

DHA Concur.

Defense Health Agency Procedural Instruction (DHAPI) 6025.31 "Military Medical Treatment Facility Pharmacy Operations" is in place. DHAPI 6025.31 supersedes any Service policy publications for DHA-specific functions including clinical/health delivery services. Service policy publications will continue to address Service readiness activities and deployed/operational units and settings. BUMED will update its Service policy to reflect DHA policy at MTFs. As stated above, there are advantages to dispensing these medications in the original unopened 100-count bottles, however, initial standardization efforts led to the selection of the 90-day

Defense Health Agency Comments (cont'd)

supply guidance in DHAPI 6015.31. As DHA continues to review policy guidance, potential changes to days supply guidance may be made. Future guidance may increase or decrease this number and MTF pharmacists must continue to exercise professional judgement in allowing deviations from the established policy.

DoD recommends closure.

Acronyms and Abbreviations

- ADHD** Attention-Deficit Hyperactivity Disorder
- DHA** Defense Health Agency
- MDR** Military Health System Data Repository
- MHS** Military Health System
- MTF** Medical Treatment Facility

Whistleblower Protection

U.S. DEPARTMENT OF DEFENSE

Whistleblower Protection safeguards DoD employees against retaliation for protected disclosures that expose possible waste, fraud, and abuse in government programs. For more information, please visit the Whistleblower webpage at <http://www.dodig.mil/Components/Administrative-Investigations/Whistleblower-Reprisal-Investigations/Whistleblower-Reprisal/> or contact the Whistleblower Protection Coordinator at Whistleblowerprotectioncoordinator@dodig.mil

For more information about DoD OIG reports or activities, please contact us:

Congressional Liaison

703.604.8324

Media Contact

public.affairs@dodig.mil; 703.604.8324

DoD OIG Mailing Lists

www.dodig.mil/Mailing-Lists/

Twitter

www.twitter.com/DoD_IG

DoD Hotline

www.dodig.mil/hotline



DEPARTMENT OF DEFENSE | OFFICE OF INSPECTOR GENERAL

4800 Mark Center Drive
Alexandria, Virginia 22350-1500
www.dodig.mil
DoD Hotline 1.800.424.9098

