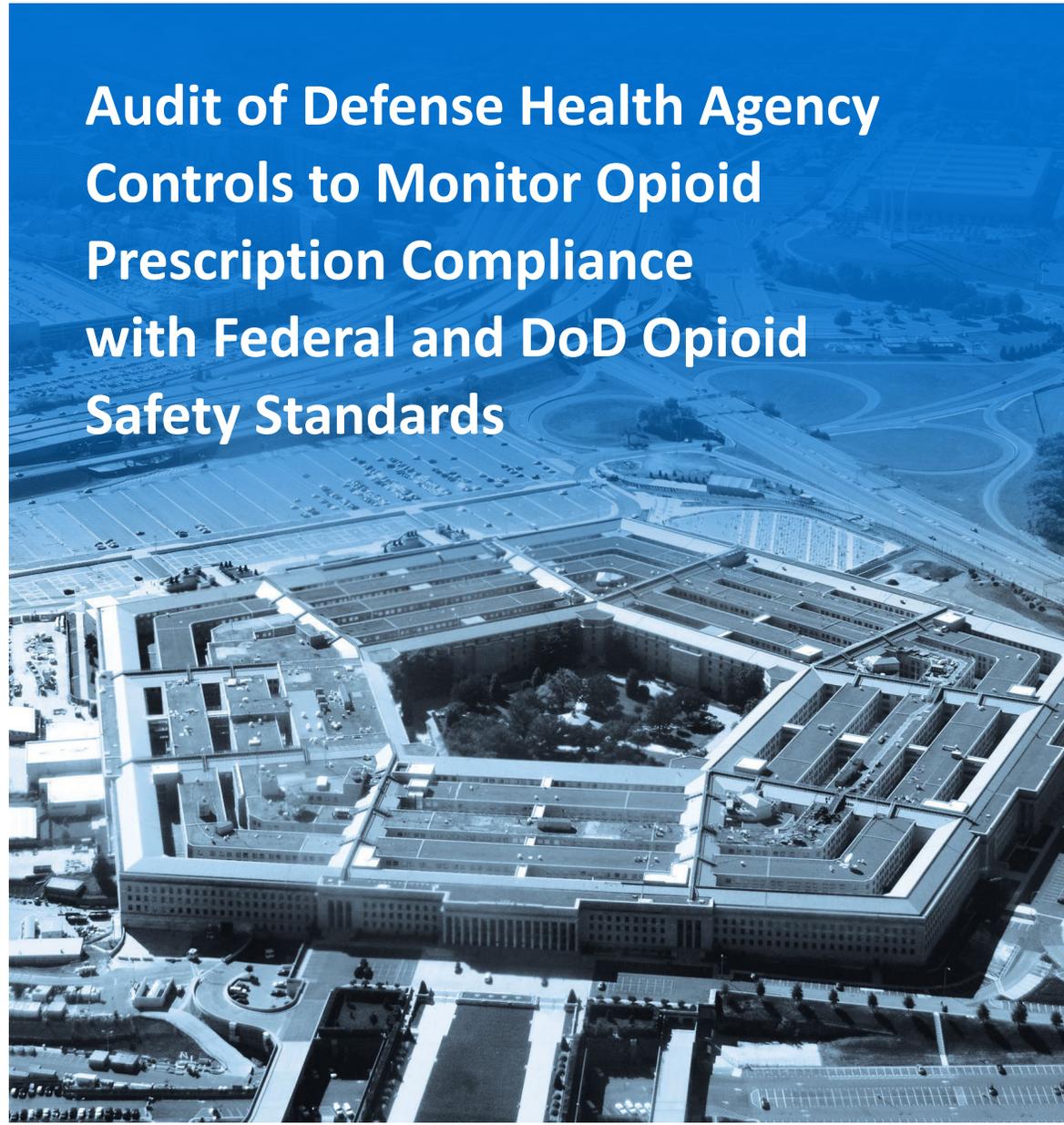




INSPECTOR GENERAL

U.S. Department of Defense

DECEMBER 7, 2023



Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards

INTEGRITY ★ INDEPENDENCE ★ EXCELLENCE





Results in Brief

Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards

December 7, 2023

Objective

The objective of this audit was to determine whether the Defense Health Agency (DHA) had controls in place to monitor opioid prescriptions and ensure compliance with Federal and DoD opioid safety recommendations and requirements.

Findings

Although the DHA established policies and programs to monitor opioid prescriptions, potential overprescribing patterns remained, providers did not follow or meet Federal and DoD opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed through established DHA programs. We obtained military health system and pharmacy data to determine the number of at-risk beneficiaries and reviewed a nonstatistical sample of 19 at-risk beneficiaries. We found that:

- 53,910 of the 3.4 million beneficiaries who received opioid prescriptions between January 1, 2018, and December 31, 2021, were on long-term opioid therapy and received average daily doses higher than the recommended amount;
- providers for 8 of the 9 sample beneficiaries for which we received medical documentation did not follow or meet opioid safety requirements; and
- DoD medical treatment facility (MTF) and Managed Care Support Contractor (MCSC) personnel did not monitor or review 14 sampled beneficiaries through the Prescription Monitoring Program.

Findings (cont'd)

Providers did not follow or meet opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed because the DHA did not have effective controls in place to ensure MTFs and MCSCs consistently implemented Federal opioid safety recommendations and DHA opioid safety policies and programs to monitor at-risk beneficiaries.

In addition, the DHA, MTFs, and MCSCs did not provide us with adequate medical documentation to support whether the DHA and providers followed or met Federal and DoD opioid safety recommendations and requirements for 10 of the 19 sampled beneficiaries. This occurred because the DHA did not have an effective process in place to request and obtain beneficiary medical documentation from the MTFs and MCSCs for at-risk beneficiaries.

As a result, the DHA, MTFs, and MCSCs may not identify or review the tens of thousands of potentially at-risk beneficiaries to determine whether they need additional medical assistance, leaving those individuals at increased risk of being overprescribed opioids. Furthermore, there is an increased risk of drug diversion, whether intentional or unintentional. Opioid misuse can lead to addiction, overdose incidents, or death, and overprescribing remains a serious health and safety issue for beneficiaries and a potential readiness issue for the DoD.

Recommendations

To address the findings in this report, we made eight recommendations. Among other recommendations, we recommend that the DHA Director develop and implement procedures to review compliance with its opioid safety policies and programs. The DHA Director should also coordinate with the TRICARE Pharmacy contractor to ensure that the algorithms used to identify at-risk beneficiaries are adequate.



Results in Brief

Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards

Management Comments and Our Response

The DHA Director agreed or partially agreed with six of the eight recommendations. The Director's comments and actions taken were sufficient to close one recommendation. In addition, the Director's comments addressed the specifics for five other recommendations; therefore, those recommendations are resolved but open.

Although the Director agreed to implement procedures to review MTFs, the Director disagreed with implementing procedures to review whether MCSC personnel and

network providers were following and meeting Federal and DoD opioid safety recommendations and requirements. In addition, while the Director addressed existing processes in place to review MCSC compliance with PMP requirements, the Director did not address how the DHA will implement procedures to review MTF compliance with PMP requirements. Therefore, the two remaining recommendations are unresolved. We request that the Director provide additional comments for those recommendations in response to the final report.

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

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Director, Defense Health Agency	1.b, 2.c	1.a, 2.a, 2.b, 3.a, 3.c	3.b

Please provide Management Comments by January 8, 2024.

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** – DoD OIG verified that the agreed upon corrective actions were implemented.





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

December 7, 2023

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS
DIRECTOR, DEFENSE HEALTH AGENCY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY
AUDITOR GENERAL, DEPARTMENT OF THE NAVY
AUDITOR GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards (Report No. DODIG-2024-036)

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 two recommendations that are considered unresolved because management officials did not fully address the recommendations. Therefore, the recommendations remain open. We will track these recommendations until management has agreed to take actions that we determine to be sufficient to meet the intent of the recommendations and management officials submit adequate documentation showing that all agreed-upon actions are completed. Therefore, please provide us within 30 days your response concerning specific actions in process or alternative corrective actions proposed on the recommendations.

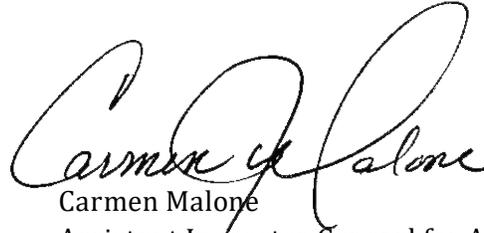
This report contains five recommendations that are considered resolved and open. Therefore, we will close the recommendations when you provide us documentation showing that all agreed-upon actions to implement the recommendations are completed. Therefore, please provide us within 90 days your response concerning specific actions in process or completed on the recommendations.

Management comments and associated actions addressed one recommendation in this report. Therefore, we consider that recommendation closed.

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 unresolved recommendations. Please provide us within 90 days your response concerning specific actions in process or completed on the resolved recommendations. Send your response to [REDACTED].

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

FOR THE INSPECTOR GENERAL:

A handwritten signature in black ink, appearing to read "Carmen Malone". The signature is fluid and cursive, with the first name "Carmen" and last name "Malone" clearly distinguishable.

Carmen Malone
Assistant Inspector General for Audit
Acquisition, Contracting, and Sustainment

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Introduction

Objective

The objective of this audit was to determine whether the Defense Health Agency (DHA) had controls in place to monitor opioid prescriptions and ensure compliance with Federal and DoD opioid safety recommendations and requirements. See Appendix A for our scope, methodology, and prior audit coverage related to the objective.

Background

According to the National Institute on Drug Abuse, opioids are a class of drugs that include the illegal drug heroin; synthetic opioids, such as fentanyl; and legally prescribed pain relievers, such as oxycodone, hydrocodone, and morphine. In addition, the National Institute on Drug Abuse states that prescription opioids are used mostly to treat moderate to severe pain and their use is generally safe when taken for a short time and as prescribed by a doctor. Some patients experience a worsening of their pain or increased sensitivity to pain because of opioid therapy.

Because opioids produce euphoria in addition to pain relief, opioids can be misused. Misuse of prescription drugs includes taking a medication in a manner or dose other than as directed by a doctor, such as use in greater amounts, more often, or longer than directed; using someone else's prescription; or taking medication to feel euphoria or "get high."

Repeated misuse of prescription opioids can lead to a substance use disorder, a medical illness that ranges from mild to severe and from temporary to chronic. Addiction is the most severe form of substance use disorder. A disorder develops when continued misuse of a drug changes the user's brain and causes health problems and failure to meet responsibilities at work, school, or home. Misuse of prescription opioids is also a risk factor for transitioning to heroin use and can lead to addiction, overdose, and death. The Centers for Disease Control and Prevention (CDC) noted in 2020 that overdoses involving opioids killed nearly 69,000 people in the United States.

Defense Health Agency and the DoD TRICARE Program

The Office of the Assistant Secretary of Defense for Health Affairs is responsible for all policies, programs, and activities regarding DoD health and force health protection. The DHA, a major element of the Office of the Assistant Secretary of Defense for Health Affairs, supports the delivery of integrated, affordable, and high-quality health services to DoD beneficiaries and is responsible for driving greater standardization of clinical and business processes across the Military Health System (MHS). According to DHA personnel, the DHA Pharmacy Operations Division (POD) is responsible for overseeing the pharmacy benefits for the DoD medical treatment facilities (MTFs) and TRICARE mail order pharmacies; however, the DHA POD does not prescribe any medications. Furthermore, the DHA POD works with DHA Medical Affairs on policy development, and is part of the MHS Pain Management Clinical Support Service.

According to DHA personnel, the MHS Pain Management Clinical Support Service is a collaborative group that consists of the DHA POD, as well as DHA Medical Affairs, and the Uniformed Services University of the Health Sciences. The goal of the group is to develop standard policies and procedures for the DHA. The current DHA Deputy Assistant Director, Medical Affairs and Chief Medical Officer, is responsible for equipping MHS staff with evidence-based, patient-centered solutions and leading the dissemination of the latest clinical guidance, policies, and procedures across the MHS.

TRICARE is the DoD's worldwide healthcare program and TRICARE-eligible beneficiaries include active duty Service members and their families, retired Service members and their families, and National Guard and Reserve members and their families. TRICARE brings together military and civilian healthcare resources and is managed by the TRICARE Health Plan, an office in TRICARE, in two stateside regions—TRICARE East and TRICARE West. The TRICARE Health Plan Director reports to and operates under the authority, direction, and control of the DHA Director. The TRICARE Health Plan Director has visibility of both the contract and direct care assets, and coordinates with the Services to develop an integrated health plan.

For the TRICARE East and TRICARE West regions, TRICARE awarded contracts in 2016 to two Managed Care Support Contractors (MCSCs). The MCSCs are required to assist the MHS in operating an integrated healthcare delivery system combining resources of the military's direct medical care system and the contractor's managed-care support to provide health, medical, and administrative support services to TRICARE-eligible beneficiaries. The contractor's managed care is required to be composed of individual and institutional providers that produce the best quality clinical outcomes, which are both safe and medically necessary, for TRICARE beneficiaries. Furthermore, the contractor's Chronic Care/Disease Management program is required to incorporate nationally recognized, evidence-based guidelines and protocols, including DoD and Department of Veterans Affairs (VA) guidelines when available and appropriate.

TRICARE Pharmacy Contract

The DHA awarded the TRICARE Pharmacy (TPharm) contract in 2014 to provide comprehensive pharmacy benefit management services, mail order and specialty fulfillment services, and beneficiary education services to maximize patient safety.¹ The TPharm contractor is required to administer the retail pharmacy network. In addition, the TPharm contractor administers the MHS Prescription Drug Monitoring Program (PDMP) and is responsible for validating and registering credentialed MHS providers and pharmacists, as well as their delegates.

The TPharm contractor is also responsible for updating the MHS PDMP data and ensuring data integrity. Providers and pharmacists at all MHS locations are required to register in the MHS PDMP. Furthermore, the TPharm contractor is required to:

- participate in prescription monitoring initiatives to identify beneficiaries who exhibit possible unsafe controlled medication usage and to restrict specific individuals to appropriate levels of use for their medical situation;
- support prescription and use monitoring intended to identify potential abuse situations and restrict access to prevent further abuse;
- administer the Prescription Monitoring Program (PMP), which is a quarterly review of all beneficiaries who received prescriptions using TRICARE benefits; and

¹ The TPharm contract is currently in its fifth iteration.

- perform automated reviews using predefined algorithms to identify beneficiaries with a higher use of controlled substances (Schedule II-V) than parameter thresholds.²

Federal Law and Other Guidance on Prescribing Opioids

Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (the Controlled Substances Act) establishes Federal policy regulating the use of certain drugs, including opioids.³ The CDC, VA, and DoD have issued additional guidance and procedural instructions specific to prescribing opioids.

The Controlled Substances Act

The Controlled Substances Act created five drug schedules, or classifications, that group drugs based on risk of abuse or harm. Schedule I drugs have no currently accepted medical use and a high potential for abuse. Schedule II drugs are drugs with a high potential for abuse that can potentially lead to severe psychological or physical dependence. Opioids classified as Schedule II drugs include hydrocodone, oxycodone, morphine, and fentanyl.

Schedule III and Schedule IV drugs have a lower potential for abuse and a lower risk of dependence than Schedule I and II drugs. Opioids such as Tramadol are classified as Schedule IV. Schedule V drugs are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. According to Public Law, opioid prescribing guidelines are not intended to be used for the purposes of restricting, limiting, delaying, or denying access to a prescription issued for a legitimate medical purpose by practitioners acting in the usual course of their professional practice.⁴

Centers for Disease Control and Prevention Guidance for Prescribing Opioids

In 2016, the CDC published a guideline to improve communication between healthcare providers and patients about the risks and benefits of opioid therapy for chronic pain; improve safety and effectiveness of pain treatment; and reduce

² According to the TRICARE Operations Manual, chapter 28, the PMP performs automated reviews using predefined algorithms to identify beneficiaries above parameter thresholds based on criteria such as morphine milligram equivalent, number of prescribers and prescriptions, and dangerous drug combinations. An algorithm is broadly defined as a step-by-step procedure for solving a problem or accomplishing some end. Morphine milligram equivalent is the amount of milligrams of morphine an opioid dose is equal to when prescribed and is used to account for differences in opioid drug type and strength.

³ Title II of Public Law 91-513, October 27, 1970, codified, as amended, at title 21, United States Code, chapter 13, subchapter 1.

⁴ Public Law 115-271, "Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act," October 24, 2018.

the risks associated with long-term opioid therapy (LOT), including opioid use disorder and overdose.⁵ The guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline notes that when opioids are started, providers should prescribe the lowest effective dosage, and they should avoid increasing dosage to greater than or equal to 90 morphine milligram equivalent (MME) per day or carefully justify a decision to increase dosage to greater than or equal to 90 MME per day.⁶ The guideline also states that patients should receive appropriate pain treatment based on careful consideration of the benefits and risks of treatment. According to the Diagnostic and Statistical Manual of Mental Disorders, opioid use disorder is a problematic pattern of opioid use that causes significant impairment or distress. The guideline further defines LOT as use of opioids on most days for greater than 3 months.⁷

Department of Veterans Affairs/DoD Clinical Practice Guideline

The VA/DoD clinical practice guideline for opioid therapy for chronic pain recommends against prescribing opioid doses more than 90 MME per day to treat chronic pain.⁸ The guideline states that beneficiaries who are prescribed higher doses of opioids are at higher risk for opioid overdose and related death. In addition, the guideline recommends that providers evaluate beneficiaries' prescribed doses more than 90 MME per day for tapering to a reduced dose or discontinuing opioid use.

Defense Health Agency Procedural Instruction 6025.04, "Pain Management and Opioid Safety in the Military Health System"

In June 2018, the DHA issued DHA Procedural Instruction (DHA-PI) 6025.04 to enable, among other capabilities, clinical communities to provide evidence-based pain management based on clinical practice guidelines to effectively treat acute

⁵ "CDC Guideline for Prescribing Opioids for Chronic Pain—United States," March 18, 2016.

The CDC issued updated guidance "CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States," November 4, 2022. The guidance we used for this audit is the 2016 CDC guideline.

⁶ "CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States," November 4, 2022, replaced the 2016 guideline to avoid increasing dosage to greater than or equal to 90 MME per day. The new guideline is to avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. The new guidance also states that additional dosage increases beyond 50 MME per day are progressively more likely to yield diminishing returns in benefits for pain and function relative to risks to patients as dosage increases further.

⁷ The CDC guideline is not applicable for beneficiaries who are in active cancer treatment, palliative care, or end-of-life care.

⁸ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain," Version 3.0, February 2017.

DoD beneficiaries are patients who are entitled to or eligible for medical benefits and therefore authorized treatment in an MTF or under DoD sponsorship.

and chronic pain, and minimize use of opioids with appropriate prescribing only when indicated.⁹ The Instruction states that the DHA Director will monitor implementation of the Instruction to achieve the stated purpose and ensure systems and tools are in place to collect data and measure compliance with the Instruction. Further, the Instruction noted that the Joint Commission would begin enforcing new pain assessment and management standards at accredited hospitals on January 1, 2018.¹⁰

The new standards require that DoD leadership, such as directors or commanders, maximize patient safety by engaging in pain management and safe opioid prescribing and monitoring. In addition, the Instruction requires the DHA Director to ensure that systems and tools are in place to collect data and measure Instruction compliance and monitor Instruction implementation to enable clinical communities to:

- effectively treat acute and chronic pain,
- promote non-pharmacologic treatment, and
- minimize use of opioids when appropriate and prescribe only when indicated.

DHA-PI 6025.04 established the MHS Stepped Care Model and DoD MTF personnel are required to follow guidance in the Instruction to execute the model. The DHA designed the model to be a comprehensive standardized pain management model for the MHS to provide safe, consistent, and quality care for patients with pain, with an emphasis on non-pharmacologic treatments. The DHA affirmed the Stepped Care Model to implement the Joint Commission's standards.

The MHS Stepped Care Model involves the beneficiary meeting with different specialists, such as a primary care manager, pain manager, physical therapist, or addiction specialist.¹¹ Figure 1 illustrates the MHS Stepped Care Model, the separate levels of care, clinical indicators, and escalation and de-escalation criteria.

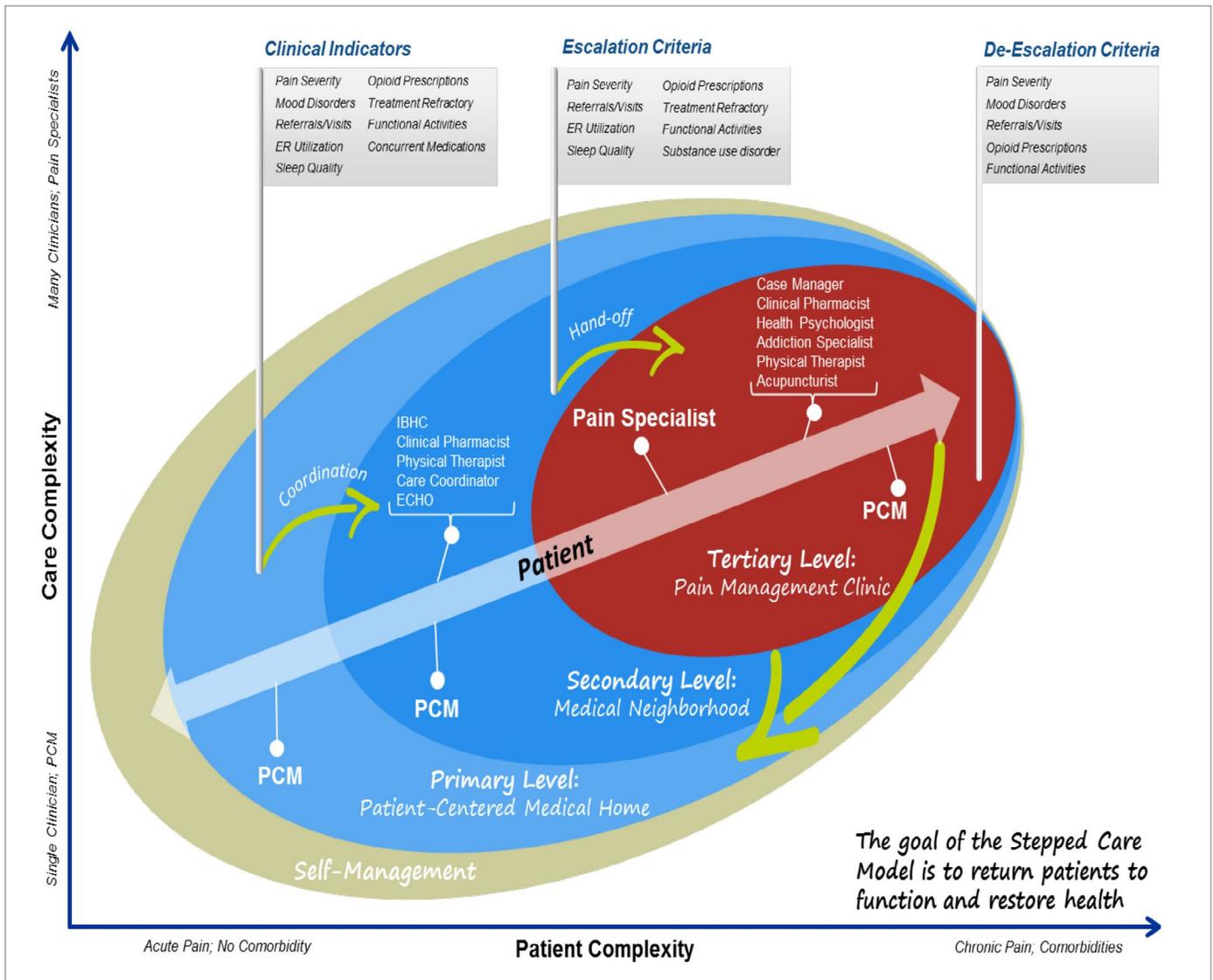
⁹ DHA-PI 6025.04, "Pain Management and Opioid Safety in the Military Health System," June 8, 2018.

¹⁰ The Joint Commission is an independent, not-for-profit organization that is a standards-setting and accrediting body in healthcare.

Accreditation is the objective evaluation process of organizational compliance to performance standards designed to inspire and improve quality and safety for those they serve. An accredited hospital is certified as meeting nationally accepted standards through a recognized accreditation program.

¹¹ A primary care manager is a military or civilian network provider who is responsible for providing all routine, non-emergency, and urgent health care for patients under their care.

Figure 1. Stepped Care Model of the Military Health System



Source: The DHA.

TRICARE Operations Manual, Chapter 28, 2018 and 2020 Updates

The DHA added Chapter 28, "Prescription Monitoring Program," to the TRICARE Operations Manual in January 2018.¹² Chapter 28 establishes the Beneficiary PMP, which is a quarterly review of all beneficiaries who receive prescriptions using TRICARE benefits. The goal of the program is to identify beneficiaries who may need additional medical assistance. Chapter 28 of the TRICARE Operations Manual assigns responsibilities to the MCSCs and the TPharm contractor to implement use and quality controls designed to identify possible drug abuse situations.

¹² TRICARE Operations Manual 6010.59-M, April 1, 2015, Chapter 28, Section 1, "Prescription Monitoring Program (PMP)," Revision C-19, January 24, 2018.

In July 2020, the DHA revised Chapter 28 of the TRICARE Operations Manual to reinforce the Beneficiary PMP requirements established in the January 2018 revision, and establish the Provider PMP.¹³ The Provider PMP applies only to the MCSCs and is a quarterly review of all providers who prescribe controlled substances prescriptions, such as opioids, for beneficiaries using TRICARE benefits.

Defense Health Agency Procedural Instruction 6010.02 “Military Health System Prescription Drug Monitoring Program”

The 2019 National Defense Authorization Act required the Secretary of Defense to establish and maintain the MHS PDMP to be comparable to prescription drug monitoring programs operated by states and applicable to designated controlled substance prescriptions under the pharmacy benefits program. The DHA issued DHA-PI 6010.02 in October 2021, establishing the procedures for registration and use of the MHS PDMP.¹⁴

The MHS PDMP is an electronic database that collects prescription data on controlled medications dispensed to TRICARE beneficiaries within the MHS and is used to track controlled substance prescription information. Providers and pharmacists are required to conduct an MHS PDMP search to the greatest extent possible when there is a suspicion of patient abuse, misuse, or diversion. Furthermore, before prescribing DEA Schedule II-IV controlled substances, providers should check the MHS PDMP when the patient is new to the provider, when a new or renewal is being prescribed for an acute condition, and no less frequently than every 3 months.

The Instruction also requires the creation of an MTF-established PMP. DHA-PI 6010.02 notes that, due to variations in MTF size and scope, each MTF must have procedures in place to review PMP reports and document the reviews.

Defense Health Agency Administrative Instruction 6025.08 “Pain Management and Opioid Safety in Military Medical Treatment Facilities”

In February 2023, the DHA issued Administrative Instruction (AI) 6025.08 to cancel and replace DHA-PI 6025.04.¹⁵ The new Instruction assigns responsibilities to the DHA Deputy Assistant Director, Medical Affairs. The new guidance also adds

¹³ TRICARE Operations Manual 6010.59-M, April 1, 2015, Chapter 28, Section 1, “Prescription Monitoring Program (PMP),” Revision C-66, July 2, 2020.

¹⁴ DHA-PI 6010.02, “Military Health System Prescription Drug Monitoring Program,” October 15, 2021. The scope of the audit was January 1, 2018, through December 31, 2021; therefore, this Instruction was only applicable for the last few months of the audit scope.

¹⁵ DHA-AI 6025.08, “Pain Management and Opioid Safety in Military Medical Treatment Facilities,” February 13, 2023.

the requirement for Directors of MTFs and Dental Treatment Facilities to use the PMP to provide accountability and oversight of MTF and Dental Treatment Facility provider opioid prescribing practices as required by DHA-PI 6010.02. Further, the new guidance expands the population of patients that the directors must monitor for opioid safety. Specifically, as of February 2023, the Enterprise Solutions Board is required to monitor the outcome of patients taking at least 50 MME per day, rather than the previous guidance to monitor patients taking at least 90 MME per day.¹⁶

The new guidance also modifies the definition of patients considered to be on LOT. The previous guidance defined a LOT patient as having received 90 days of continuous opioid therapy with no greater than a 30-day break in use. The new definition includes patients with 90 days or more of opioid therapy within a 180-day period regardless of any break in use.

Military Health System Data Repository and the Pharmacy Data Warehouse

The Military Health System Data Repository (MDR) is a centralized data repository that captures, validates, integrates, distributes, and archives DHA corporate health care data. One of the key benefits of the MDR is that it serves as the central point for data collection. The MDR receives and validates data from the DoD worldwide network of more than 260 health care facilities.

The DHA is responsible for development and implementation of a pharmacy data warehouse (PDW), formerly known as the Pharmacy Data Transaction Service. The data stored within the PDW is a subset of MDR data. Designed to be a comprehensive, historical, and central database for prescription medications dispensed to TRICARE beneficiaries, the PDW contains detailed data for every transaction for all MHS points of service, including MTFs, TRICARE Retail Pharmacies, TRICARE Mail Order Pharmacies, and Overseas Theaters of Operation.

¹⁶ The Enterprise Solutions Board is a clinical and clinical operations decision-making body for the Assistant Director, Health Care Administration. The Deputy Assistant Director, Health Care Operations, chairs the Enterprise Solutions Board.

Finding

Additional Controls Are Needed to Monitor Opioid Prescriptions

Although the DHA established policies and programs to monitor opioid prescriptions, potential overprescribing patterns remained, providers did not follow or meet Federal and DoD opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed through established DHA programs. Specifically, we obtained MDR PDW data to determine the number of at-risk beneficiaries and reviewed a nonstatistical sample of 19 at-risk beneficiaries.¹⁷ We found that:

- 53,910 of the 3.4 million beneficiaries who received opioid prescriptions between January 1, 2018, and December 31, 2021, were on LOT and received average daily doses higher than the 90 MME recommended in CDC and VA/DoD guidelines;¹⁸
- providers for 8 of the 9 sample beneficiaries for which we received medical documentation did not follow or meet Federal and DoD opioid safety recommendations and requirements;¹⁹ and
- MTF and MCSC personnel did not monitor or review 14 sample beneficiaries for opioid safety through the PMP.²⁰

¹⁷ We selected a nonstatistical sample of 19 beneficiaries who were on LOT and received average daily doses higher than the 90 MME recommended in CDC and VA/DoD guidelines. See Appendix A for additional detail regarding our universe and sample beneficiary selection.

¹⁸ We obtained MDR PDW data and identified that the DoD dispensed 16.2 million opioid prescriptions to 3.4 million beneficiaries, excluding prescriptions written to cancer and hospice patients and beneficiaries with dates of birth that indicated the beneficiary was at least 100 years old, as of December 31, 2021. We excluded beneficiaries over 100 years old because there could be various reasons that a patient over 100 years old would receive opioids that are outside of the scope of our review, similar to cancer and hospice patients, and may not be representative of overprescribing or potential opioid complications compared to other beneficiaries.

¹⁹ The DHA, MTFs, and MCSCs only provided medical documentation for 9 of the 19 sample beneficiaries; therefore, we only reviewed 9 beneficiaries to determine whether providers met Federal and DoD opioid safety recommendations and requirements. Specifically, recommendations and requirements provided in: "CDC Guideline for Prescribing Opioids for Chronic Pain—United States," March 18, 2016; "VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain," Version 3.0, February 2017; TRICARE Operations Manual 6010.59-M, April 1, 2015, Chapter 28, Section 1, "Prescription Monitoring Program (PMP)," Revision C-19, January 24, 2018; DHA-PI 6025.04, "Pain Management and Opioid Safety in the Military Health System," June 8, 2018; and DHA-PI 6010.02, "Military Health System Prescription Drug Monitoring Program," October 15, 2021.

²⁰ Although we did not receive medical documentation for 10 of our 19 sample beneficiaries, we did receive PMP reports for the entire scope of the audit. Therefore, we did review all the PMP reports for the 19 beneficiaries to determine whether they were identified as candidates and reviewed for opioid safety.

Providers did not follow or meet opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed, because the DHA did not have effective controls in place to ensure MTFs and MCSCs consistently implemented Federal opioid safety recommendations or DHA opioid safety policies and programs to monitor at-risk beneficiaries.

In addition, the DHA, MTFs, and MCSCs did not provide us with adequate medical documentation to support whether the DHA and providers followed or met Federal and DoD opioid safety recommendations and requirements for 10 of the 19 sampled beneficiaries. This occurred because the DHA did not have an effective process in place to request and obtain beneficiary medical documentation from the MTFs and MCSCs for at-risk beneficiaries.

As a result, the DHA, MTFs, and MCSCs may not identify or review the tens of thousands of potentially at-risk beneficiaries or determine whether they need additional medical assistance, leaving those individuals at increased risk of being overprescribed opioids. Furthermore, there is an increased risk of drug diversion, whether intentional or unintentional.²¹ Opioid misuse can lead to addiction, overdose incidents, or death, and overprescribing remains a serious health and safety issue for beneficiaries and a potential readiness issue for the DoD.

Current Opioid Safety Policies and Programs Did Not Prevent Overprescribing or Ensure Providers Followed or Met Opioid Safety Recommendations and Requirements

The DHA updated opioid safety policies and developed new programs to monitor opioid prescriptions; however, potential overprescribing patterns remained, providers did not follow or meet Federal and DoD opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed through established DHA programs. We obtained MDR PDW data and reviewed a sample of 19 at-risk beneficiaries.

²¹ Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.

Opioid Prescribing Beyond Opioid Safety Recommendations and Requirements

We obtained prescription data from the MDR PDW between January 1, 2018, and December 31, 2021, and identified that the DoD dispensed 16.2 million opioid prescriptions to 3.4 million beneficiaries.²² We identified that 53,910 of these 3.4 million beneficiaries were on LOT for more than 90 consecutive days and received average daily doses higher than the 90 MME per day recommended in CDC and VA/DoD guidelines.

The “CDC Guideline for Prescribing Opioids for Chronic Pain” and the “VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain” state that providers should avoid increasing opioid dosage to 90 MME per day or carefully justify a decision to increase dosage to 90 MME per day. DHA-PI 6025.04 states that patients taking greater than 90 MME per day are at an increased risk for death from opioids. If a provider prescribes a patient more than 90 MME per day, the CDC and VA/DoD guidelines recommend tapering, or stepping down, opioid use to a reduced dose or discontinuation. In addition, DHA-PI 6025.04 identified LOT patients as those who have had 90 days of continuous opioid therapy with no greater than a 30-day break in use.²³ These patients are at higher risk for opioid-related complications. The length of time a patient is considered to be under continuous opioid therapy is calculated as the number of consecutive days a person is prescribed opioids including gaps of up to 29 days. Opioid usage following a gap of 30 days or longer constitutes a separate period of opioid therapy.

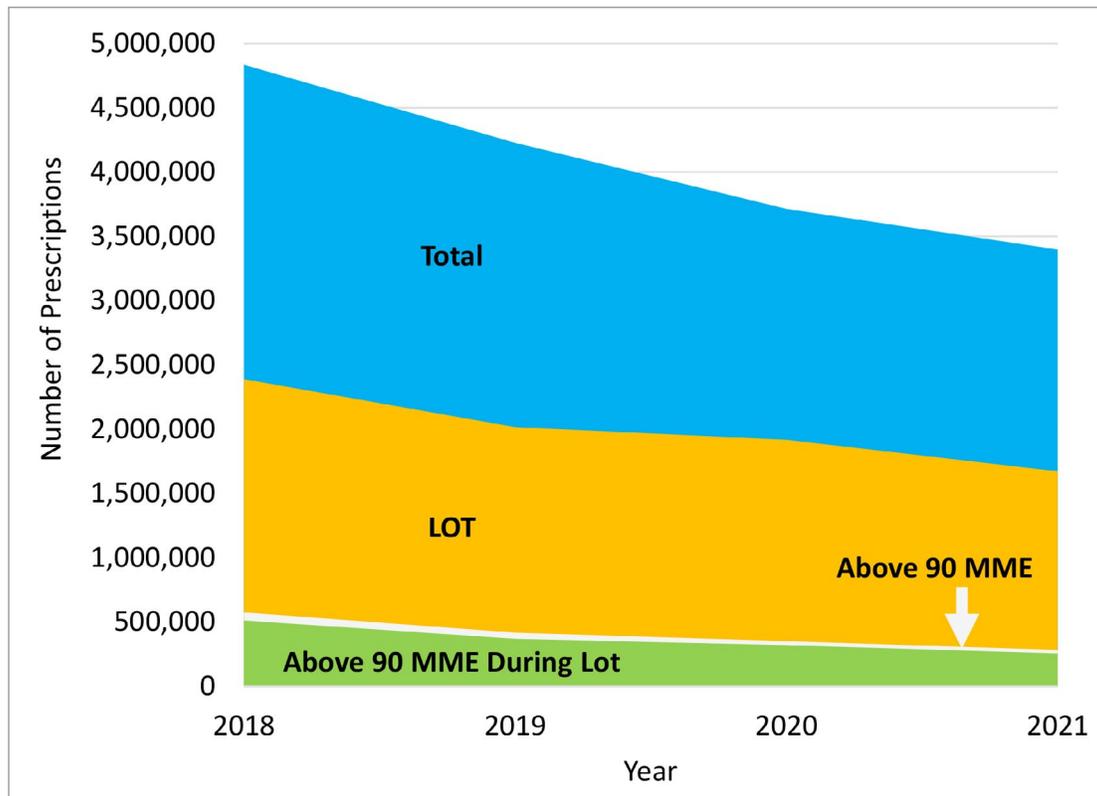
Of the 16.2 million prescriptions dispensed between January 1, 2018, and December 31, 2021, the DoD dispensed 1.5 million prescriptions above 90 MME per day during LOT.²⁴ Figure 2 lists the number of prescriptions dispensed above 90 MME per day during LOT for each year of the audit scope.

²² We excluded any prescriptions written to cancer and hospice patients and prescriptions written to patients with dates of birth that indicated the patient was at least 100 years old as of December 31, 2021.

²³ DHA-PI 6025.04, “Pain Management and Opioid Safety in the Military Health System,” June 8, 2018. DHA-AI 6025.08, “Pain Management and Opioid Safety in Military Medical Treatment Facilities,” which replaced DHA-PI 6025.04 on February 13, 2023, lowers the threshold from 90 MME per day to 50 MME per day for what it considers to increase a patient’s risk for death from opioids.

²⁴ The audit team utilized patients above 90 MME per day during LOT as a starting point to identify patients potentially at higher risk for opioid complications and not as a standard of care.

Figure 2. Prescriptions Dispensed Above 90 MME During Long-Term Opioid Therapy



Legend

LOT Long-Term Opioid Therapy

MME Morphine Milligram Equivalent

Source: The DoD OIG.

As illustrated in Figure 2, updating opioid safety policies and developing new programs to monitor opioid prescriptions and providers for compliance with opioid safety standards may have helped reduce the frequency with which opioids are prescribed beyond safety recommendations. However, there are still a significant number of beneficiaries with opioid prescriptions above 90 MME per day and on LOT that may be at risk of opioid complications if not adequately monitored, as identified in Table 1. Furthermore, DHA-AI 6025.08 reduces the opioid safety standard to 50 MME per day, which is just over half of the current safety standard of 90 MME per day.

With the decrease to 50 MME per day, the number of prescriptions exceeding the safety standards is likely to increase, which means more DHA oversight will be necessary. Table 1 lists the number of beneficiaries who received opioid prescriptions above 90 MME per day during LOT for each year of the audit scope.

Table 1. Beneficiaries with Prescriptions Above 90 MME During Long-Term Opioid Therapy

Category	2018	2019	2020	2021	Total
Total Beneficiaries	1,598,778	1,442,982	1,194,957	1,162,985	3,409,500
Above 90 MME	70,200	51,138	38,121	33,158	126,055
LOT	238,204	199,407	184,443	164,665	349,238
Above 90 MME During LOT	36,733	27,794	22,847	19,350	53,910

Legend

LOT Long-Term Opioid Therapy

MME Morphine Milligram Equivalent

Note: The total column includes unique beneficiaries who received 90 MME per day during LOT between January 1, 2018, through December 31, 2021. Some beneficiaries received 90 MME per day during LOT in multiple years and are included in each year’s column; however, they are only included once in the total column.

Source: The DoD OIG.

From the universe of 53,910 beneficiaries who were on LOT and received average daily doses higher than 90 MME, we selected a nonstatistical sample of 19 beneficiaries. See Appendix A for additional detail regarding our sample beneficiary selection. We then determined whether the DHA and providers met Federal and DoD opioid safety recommendations and requirements to comply with areas such as informed consent, PDMP checks, providing care in the MHS Stepped Care Model, follow-up appointments to evaluate continued use, urine drug testing, and pursuit of tapering or reduced dosing. We also determined whether the DHA, MTFs, and MCSCs were monitoring these beneficiaries through the PMP. See Appendix B for a complete list of the 19 sample beneficiaries.

Providers Did Not Follow or Meet Opioid Safety Recommendations and Requirements

Providers for eight of nine beneficiaries we reviewed did not follow or meet Federal and DoD opioid safety recommendations and requirements.²⁵ Specifically, providers did not:

- document that they completed informed consent for one of nine beneficiaries, as required by DHA-PI 6025.04 and recommended by the VA/DoD Clinical Practice Guideline;
- perform PDMP checks, at least every 3 months, for eight of nine beneficiaries, as recommended by CDC guidance;

²⁵ While we selected 19 at-risk beneficiaries, the DHA was not able to provide the requested documentation for 10 of the beneficiaries. Therefore, we assessed the documentation we received for nine beneficiaries against opioid recommendations and requirements to determine whether monitoring was occurring. We discuss the lack of adequate documentation later in the report.

- provide or refer one of nine beneficiaries for care from a Pain Management Clinic or Pain Specialist, known as the tertiary level of the MHS Stepped Care Model, as required by DHA-PI 6025.04;
- follow up with two of nine beneficiaries at least every 3 months to evaluate benefits and potential harms of continued opioid use, as recommended by CDC guidance and the VA/DoD Clinical Practice Guideline;
- monitor three of nine beneficiaries through urine drug testing at least annually, as required by DHA-PI 6025.04 and recommended by CDC guidance and the VA/DoD Clinical Practice Guideline; or
- pursue tapering opioid use to a reduced dose or taper to discontinuation for one of nine beneficiaries, as recommended by CDC guidance and the VA/DoD Clinical Practice Guideline.

Providers Did Not Complete Informed Consent

For one of nine beneficiaries, providers did not document that they completed informed consent covering the risks and benefits of opioid therapy. The VA/DoD Clinical Practice Guideline states that before initiating opioid therapy, the beneficiary and providers must complete an individualized assessment of potential opioid-related harms relative to realistic treatment goals. In addition, the Clinical Practice Guideline recommends implementing risk mitigation strategies upon initiation of LOT, starting with an informed consent conversation covering the risks and benefits of opioid therapy as well as alternative therapies.

The DHA-PI 6025.04 requires providers educate all patients who receive an opioid prescription on the risks associated with opioids and document this informed consent in the patient's electronic health record. However, providers did not document that they educated one sample beneficiary on the risks and benefits of opioid therapy.

For example, Beneficiary N received opioid prescriptions from January 2018 through December 2021. The medical documentation we received

The medical documentation for Beneficiary N did not include informed consent forms, discussion of informed consent for opioids, or medication risks before the 2021 encounters.

for Beneficiary N shows only two encounters in 2021 where providers discussed medication risks, benefits, costs, interactions, and alternatives with the beneficiary. The medical documentation for Beneficiary N did not include any informed consent forms, further discussion of informed consent related to opioids, or additional medication risks before the two 2021 encounters. In addition, the DHA and MCSCs did not provide any additional evidence to support that providers educated Beneficiary N on the risks and benefits of opioid therapy between

January 2018 and the first discussion of informed consent in 2021. Therefore, providers for Beneficiary N did not follow the VA/DoD Clinical Practice Guideline recommendation or meet DHA-PI requirements related to informed consent.

In addition, DHA-PI 6025.04 states that the DHA will distribute standardized informed consent forms and patient education products to beneficiaries receiving opioid prescriptions at MTFs. DHA-PI 6025.04 further states that patients on LOT are at risk for opioid use disorder or other opioid-related adverse events, or receiving renewals of opioid prescriptions for acute pain will be educated through informed consent by their provider.

Although the DHA established the requirement to provide standardized informed consent forms in June 2018 with DHA-PI 6025.04, the DHA did not incorporate the forms into the policy document and did not provide forms to the MTFs through other means. Therefore, the MTFs were unable to distribute the standardized informed consent forms to beneficiaries receiving opioid prescriptions. The DHA included the standardized informed consent form in the updated DHA-AI 6025.08, which the DHA released in February 2023.

Providers Did Not Perform PDMP Checks

For eight of nine beneficiaries, providers did not perform PDMP checks at least every 3 months. The CDC recommends clinicians review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put the patient at high risk for overdose. The CDC further recommends clinicians review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

For example, Beneficiary D received opioid prescriptions from May 2018 through January 2021. In the medical documentation provided for Beneficiary D, we only identified one MTF-state located PDMP search performed by providers during the timeframe Beneficiary D received opioid prescriptions. Outside of that one instance, the documentation did not have any mention of MHS PDMP or MTF-state located PDMP searches.

The documentation we received only supported one PDMP search for Beneficiary D from May 2018 until January 2021.

We followed up with MTF personnel to obtain any additional documentation for this Beneficiary, and the Medical Record Administrator responded and confirmed that there was no

additional documentation in the patient's records. Therefore, the documentation we received only supported one PDMP search for Beneficiary D from May 2018 until January 2021, and providers did not follow the CDC recommendation for PDMP checks at least every 3 months for Beneficiary D.

Providers Did Not Provide or Refer a Beneficiary for Care from a Pain Management Clinic or Pain Specialist

For one of nine beneficiaries, providers did not provide or refer the beneficiary for care from a pain management clinic or pain specialist, known as the tertiary level of the MHS Stepped Care Model. According to DHA-PI 6025.04, patients require care at the tertiary level of the MHS Stepped Care Model if they:

- take over 90 MMEs of opioids daily,
- are on LOT, or
- had pain for longer than 6 months.

All 19 of our sample beneficiaries were taking over 90 MMEs of opioids daily and were on LOT during the scope of the audit. For example, Beneficiary A received opioid prescriptions from January 2018 through December 2021.

Beneficiary A received opioid prescriptions from providers who were not pain care specialists and had appointments with an MTF clinic, not a pain management clinic.

Beneficiary A received opioid prescriptions from two providers who were not pain care specialists and had regular appointments with an MTF primary care clinic, which is not a pain management clinic. Therefore, Beneficiary A's providers did not meet the DHA-PI 6025.04 requirement to provide care at the tertiary level of the Stepped Care Model.

Providers Did Not Follow Up with Beneficiaries to Evaluate Benefits and Harms of Continued Opioid Use

For two of nine beneficiaries, providers did not follow up with the beneficiaries to evaluate the benefits and potential harms of continued opioid use at least every 3 months or within 1 to 4 weeks of dose escalation.²⁶ The CDC recommends clinicians evaluate benefits and harms of continued therapy with patients at least

²⁶ Dose escalation is an increase in the dosage of medications.

every 3 months. The CDC also recommends clinicians evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. The VA/DoD Clinical Practice Guideline states that, after initiating opioid therapy, frequent visits contribute to the appropriate use and adjustment of the planned therapy, and recommends follow up at least every 3 months or more frequently due to the balance of benefits and harms.

For example, Beneficiary R received opioid prescriptions from January 2018 through November 2021. From January 2018 until May 2021, Beneficiary R maintained follow-up appointments with their provider at least every 3 months. However, Beneficiary R had three different providers from June 2021 until December 2021. The majority of Beneficiary R's prescriptions during that timeframe were from one provider, and the initial encounter in June 2021 with that provider indicated follow up should occur in 6 weeks. However, this was the only encounter record we received for that provider.

Furthermore, we did not receive any supporting documentation for encounters after August 2021. MTF personnel stated that they provided all documentation for the beneficiary. In addition, Beneficiary R had two dose escalations on June 30, 2021 and August 11, 2021. The documentation provided did not show any follow up within 1 to 4 weeks of the two dose escalations. Therefore, from June 2021 until December 2021, Beneficiary R did not maintain follow-up visits every 3 months as recommended by the VA/DoD Clinical Practice Guideline and CDC guidance; or follow up within 1 to 4 weeks of dose escalation as recommended by CDC guidance.

Providers Did Not Monitor Beneficiaries with Urine Drug Testing

For three of nine beneficiaries, providers did not monitor opioid use with urine drug testing at least annually. The CDC recommends clinicians use urine drug testing before starting opioid therapy and consider urine drug testing at least

annually to assess for prescribed medications, as well as other controlled prescription drugs and illicit drugs. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain recommends clinicians obtain urine drug testing before initiating or continuing LOT and periodically thereafter. In addition, DHA-PI 6025.04 requires providers to monitor patients who are on LOT or at risk for opioid use disorder, with urine drug testing. Monitoring requires the ability to screen for potential accompanying drug use or diversion while also allowing for confirmation of the screening test result.

For example, Beneficiary N did not complete any urine drug tests or screens from June 2018 through December 2021. The medical documentation we received for Beneficiary N, which covered dates of service from April 19, 2019, through May 31, 2021, includes one order for urinalysis

Beneficiary N did not complete any urine drug tests or screens from June 2018 through December 2021.

on June 12, 2020, that was subsequently canceled. The documentation provided for Beneficiary N did not include any other urine drug tests or screens during the timeframe Beneficiary N received opioid prescriptions. Beneficiary N continued to receive opioid prescriptions through December 2021, which was 1 year and 6 months after the canceled urinalysis test order. Therefore, providers did not follow the CDC or VA/DoD recommendation, and did not meet the DHA-PI requirement, to complete urine drug testing at least annually for Beneficiary N.

Providers Did Not Pursue Tapering Opioid Use

For one of nine beneficiaries, providers did not pursue tapering opioid use to a reduced dose or to discontinuation. The CDC recommends clinicians optimize other therapies and work with patients to taper opioids to lower dosages or to taper to discontinuation if benefits do not outweigh harms of continued opioid therapy. The CDC further recommends that clinicians regularly inquire about the patient's preference to taper opioids to a reduced dose or discontinuation. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain recommends providers perform a comprehensive assessment that recognizes the increased risk of high dose opioid therapy for patients prescribed more than 90 MME. High doses alone pose an increased risk of overdose, overdose death, adverse effects, or the development of opioid use disorder. Therefore, providers should pursue tapering to a reduced dose or tapering to discontinuation when a patient does not benefit from the opioid dosage or when significant risk factors, in addition to the prescribed opioid dose, are present.

MTF and MCSC providers did not pursue tapering or discontinuing Beneficiary R's opioid dose despite multiple overdoses.

For example, MTF and MCSC providers did not pursue tapering or discontinuing Beneficiary R's opioid dose despite multiple overdoses. The MTF emergency department admitted the beneficiary

on back-to-back days in June 2018 after multiple opioid overdoses. The clinical notes of the emergency department visit indicated that the beneficiary also overdosed in September 2017. In response to the emergency department visits, the MTF Behavioral Health department completed a safety evaluation of the patient. The MTF Behavioral Health department diagnosed the beneficiary with uncomplicated opioid abuse and recommended the beneficiary follow up with their primary care manager to consider tapering opioid use. The MTF Behavioral Health department communicated directly to the beneficiary's primary care manager.

Despite these recommendations and the beneficiary's history of opioid misuse, the beneficiary maintained a daily MME of 90 throughout the scope of the audit and providers did not attempt to taper the beneficiary's opioid prescriptions. Therefore, the beneficiary remained at risk of adverse effects and overdose.²⁷

MTF and MCSC Personnel Did Not Monitor Beneficiaries for Opioid Safety Through the PMP

MTF and MCSC personnel did not monitor or review 14 of 19 beneficiaries for opioid safety through the PMP. The goal of the PMP is to identify beneficiaries who may need additional medical assistance. According to TRICARE Operations Manual, Chapter 28, the PMP performs automated reviews using predefined algorithms based on criteria such as MME, number of prescribers and prescriptions, and dangerous drug combinations to identify beneficiaries with a higher use of controlled substances than parameter thresholds within the algorithms.

The TPharm contractor is required to generate a list of all beneficiaries surpassing these parameters and provide the lists to the MCSCs. The MCSCs are then required to designate a reviewer who is responsible for conducting a medical review of the beneficiaries on the list to validate the beneficiaries' opioid use with a medical diagnosis and appropriateness of care. The MCSC is then required to develop a support plan if the reviewer identifies any inconsistencies between diagnosis and the care provided. TRICARE Operations Manual, Chapter 28, requires each of the MCSCs to review 20 beneficiary cases per quarter from the list. Based on the outcome of the review, the MCSC may place the beneficiary on restrictions, such as restricting the beneficiary to receive opioid prescriptions only from one specific provider.

²⁷ According to updated MDR PDW data, this beneficiary continued receiving opioid prescriptions as of February 2023; however, we could not determine whether there has been an attempt to taper the beneficiary's opioid prescriptions after our audit scope.

The MTFs were not required to participate in the PMP until DHA-PI 6010.02 established the requirement in October 2021. DHA-PI 6010.02 required MTFs to have procedures in place to review PMP reports, document PMP report reviews and actions taken, and develop support plans to meet the needs of the MTF and its beneficiaries. The DHA did not establish a number of beneficiaries who MTFs are required to review from the list. The DHA only required MTFs to have procedures in place to review beneficiaries on the list and document the reviews. DHA personnel also stated that there were no standard reports that identified whether MTF beneficiaries were reviewed.

Of the 19 beneficiaries in our sample, 5 beneficiaries were not listed on any PMP reports during the scope of the audit. For example, Beneficiary L was on LOT for 1,541 consecutive days and received average daily doses of 959 MME, over 10 times higher than the 90 MME recommended by the CDC and VA/DoD guidelines. Beneficiary L was not listed as a candidate on any PMP reports during the scope of the audit.

Of the 14 beneficiaries who were listed on the PMP reports, MTF and MCSC personnel reviewed 5 beneficiaries and took no action on 3 and placed 2 beneficiaries on restrictions. However, for 9 of the 14 beneficiaries on the PMP reports, MTF and MCSC personnel did not conduct a medical review to identify whether the beneficiaries needed additional medical assistance. For example, Beneficiary E received average daily doses of 494 MME, over 5 times higher than the 90 MME recommended by the CDC and VA/DoD guidelines, and providers prescribed this beneficiary several hundred, and as high as 1,080, pills per prescription. In total, three providers prescribed Beneficiary E over 19,000 pills between January 1, 2018, and December 31, 2021.²⁸

In total, three providers prescribed Beneficiary E over 19,000 pills between January 1, 2018, and December 31, 2021.

While Beneficiary E was listed as a candidate through the PMP on two quarterly PMP reports, MTF personnel did not conduct a medical review to determine whether Beneficiary E needed additional medical assistance. Both appearances occurred before October 2021 when the DHA required MTF participation in the PMP. Table 2 lists the number of sample beneficiaries by prescription dispense locations who were not listed on PMP reports, or were listed on PMP reports but MTF or MCSC personnel did not review.

²⁸ Significant opioid prescriptions with a lack of oversight controls from compliance with safety policies and programs, increases the risk for potential unlawful activity and the distribution of opioids without a legitimate medical purpose. We will determine whether any referrals to the Defense Criminal Investigative Service or elsewhere are appropriate after we receive the results of the DHA's reviews of individual beneficiaries in this report.

Table 2. Sample Beneficiaries Identified on PMP Reports

Prescription Dispense Category	Total Sample Beneficiaries in Category	Beneficiaries on PMP Reports	Beneficiaries Not on PMP Reports	Beneficiaries on PMP Reports, but Not Reviewed
MTF Only	7	5	2	3
Retail Only	6	5	1	3
MTF and Retail	6	4	2	3

Source: The DoD OIG.

The DHA Did Not Have Oversight Controls in Place to Ensure Compliance with Opioid Safety Policies and Programs

Providers did not follow or meet opioid safety recommendations or requirements and MTF and MCSC personnel did not monitor beneficiaries for opioid safety because the DHA did not have oversight controls in place to ensure MTF and MCSC personnel and providers complied with DHA policies and monitoring programs. In addition, as of March 2023, the DHA had not performed any reviews of MTFs to ensure providers were complying with the DHA-PI 6025.04 requirements, such as informed consent, the MHS Stepped Care Model, urine drug testing, and opioid tapering or reduced dosing.

The DHA also has not performed any reviews to ensure providers are meeting CDC and VA/DoD clinical practice guideline recommendations for opioid safety. Specifically, the DHA receives PMP reports from the contractors, but it does not conduct any of its own reviews or monitoring of opioid safety at the beneficiary level. The DHA should review the nine at-risk beneficiaries to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers’ beneficiaries to identify additional instances where they did not follow recommendations or meet requirements. In addition, the DHA should implement procedures to review whether MTF and MCSC personnel are following and meeting Federal and DoD opioid safety recommendations and requirements. Specifically, the DHA should ensure providers:

- complete informed consent covering the risks and benefits of opioid therapy and ensure MTFs are distributing DHA standardized informed consent forms to beneficiaries receiving opioid prescriptions;
- perform PDMP checks at least every 3 months;

- provide or refer beneficiaries for care in the tertiary level of the MHS Stepped Care Model;
- follow up with beneficiaries to evaluate the benefits and potential harms of continued opioid use at least every 3 months and within 1 to 4 weeks of dose escalation;
- monitor beneficiaries' opioid use through urine drug testing at least annually; and
- pursue tapering opioid use to a reduced dose or to discontinuation, where appropriate.

In addition, the DHA only required the MCSCs to review a low number of beneficiaries every quarter who were listed as candidates on the PMP reports and did not require MTFs to participate in the PMP until October 2021. We obtained

However, the MCSCs were only required to review 20 candidates once every quarter.

PMP reports with thousands of quarterly candidates; however, the MCSCs were only required to review 20 candidates once every quarter. Therefore, MCSCs may miss opportunities to identify and intervene with at-risk beneficiaries.

We also identified that 9 of the 19 sample beneficiaries were listed as candidates through the PMP on multiple occasions, but the MCSCs did not review these candidates. While we understand the MCSCs may not be able to review every candidate every quarter, when the risk of overdose or other opioid complications is present, the DHA should consider requiring a higher number of reviews. In addition, by not requiring MTFs to participate in the program until October 2021, MTF personnel may not have identified or reviewed many potential at-risk beneficiaries who received care at MTFs to determine whether they needed additional medical assistance.

Furthermore, as part of the requirement for MTFs to participate in the PMP, the DHA required MTFs to have policies and procedures in place to review candidates and make decisions for restrictions. DHA Compliance personnel developed a MHS PDMP checklist, which they planned to use to determine whether MTFs have policies and procedures in place for the PMP, as required by DHA-PI 6010.02. DHA Compliance personnel stated that they intended to inspect

all MTFs for compliance. However, as of March 2023, the DHA had not performed these reviews and indicated the reason for not doing so was related to a lack of personnel. Therefore, there was no assurance that the MTFs were complying with CDC and VA/DoD clinical practice guideline recommendations and DHA-PI requirements or making appropriate decisions to provide medical assistance to at-risk beneficiaries. The DHA should determine whether the five sample beneficiaries who were not listed on PMP reports should have been identified as candidates through the PMP and, based on the results, coordinate with the TPharm contractor to determine whether the algorithms used to identify candidates on the PMP are adequate to identify all at-risk beneficiaries on LOT and receiving high MME. If the DHA determines that the algorithms are not adequate, the DHA should coordinate with the TPharm contractor to adjust the algorithms to ensure they identify all at-risk beneficiaries on LOT and receiving high MME. The DHA should also increase the number of required PMP candidate reviews for the MCSCs, while also implementing standard PMP processes and review requirements for all MTFs to include the number of candidates to review. Further, the DHA should implement procedures to periodically review MTF and MCSC compliance with the PMP requirements in DHA Instructions and the TRICARE Operations Manual.

The DHA Did Not Provide Adequate Medical Documentation to Support Whether Providers Met Federal and DoD Opioid Safety Recommendations and Requirements

The DHA, MTFs, and MCSCs did not provide adequate medical documentation for 10 of the 19 beneficiaries to support whether the DHA and providers complied with Federal and DoD opioid safety recommendations and requirements. Specifically, for these 10 beneficiaries, either DHA, MTF, or MCSC personnel did not provide documentation in response to our request or the documentation provided was not sufficient.

The DHA Did Not Provide Medical Documentation for At-Risk Sample Beneficiaries

We sent our first request for documentation related to the 19 at-risk beneficiaries to the DHA on August 17, 2022. During the next 5 months we coordinated with DHA, MTF, and MCSC personnel attempting to obtain medical documentation for these beneficiaries to support the six areas we identified that would demonstrate

The DHA, MTFs, and MCSCs did not provide documentation for 10 of the 19 beneficiaries to support our audit.

monitoring of at-risk beneficiaries. See Appendix C for a history of our coordination efforts to obtain documentation for these 19 at-risk beneficiaries. However, the DHA, MTFs, and MCSCs did not provide documentation for 10 of the 19 beneficiaries to support our audit.²⁹

As a result, we could not determine whether providers for these 10 beneficiaries met:

- VA/DoD Clinical Practice Guideline recommendations and DHA-PI 6025.04 requirements to complete informed consent;
- CDC recommendations to perform PDMP checks at least every 3 months;
- DHA-PI 6025.04 requirements to provide care in the tertiary level of the MHS Stepped Care Model;
- CDC and VA/DoD Clinical Practice Guideline recommendations to follow up with the beneficiary at least every 3 months and within 1 to 4 weeks of any dose escalation;
- CDC and VA/DoD Clinical Practice Guideline recommendations and DHA-PI 6025.04 requirements to monitor the beneficiary through urine drug testing at least annually; or
- CDC and VA/DoD Clinical Practice Guideline recommendations to pursue tapering opioids to a reduced dose or discontinuation.

For example, Beneficiary H was on LOT for 1,522 days and received average daily doses of 758 MME, over eight times higher than the 90 MME recommended by

Four providers prescribed Beneficiary H over 65,000 tablets between January 1, 2018, and December 31, 2021, an average of more than 44 tablets per day.

the CDC and VA/DoD guidelines. In addition, the majority of Beneficiary H's opioid prescriptions were for 12 to 15 day supplies of 622 tablets per prescription, with a high of 792 tablets on one prescription for 17 days. In total, four providers prescribed Beneficiary H over 65,000 tablets between January 1, 2018, and December 31, 2021, which is an average of more than 44 tablets per day during that time frame.

²⁹ We obtained prescription data for all 19 beneficiaries and the DHA Pharmacy Operations Division provided us with all beneficiary and provider PMP reports during the scope of the audit. Therefore, for these 10 beneficiaries, we were able to review PMP reports to determine whether the beneficiary and providers were listed on the reports.

We coordinated with personnel from the DHA Pharmacy Operations Division (POD), DHA Healthcare Operations, and DHA Healthcare Administration to determine whether this opioid regimen was appropriate for any beneficiary. However, none of them commented on the appropriateness of the beneficiary's average daily doses of 758 MME for 4 years or 65,000 tablets.

These 10 beneficiaries were at risk for opioid-related complications and, without documentation, we could not determine whether providers for these beneficiaries followed or met Federal and DoD opioid safety recommendations and requirements and whether providers justified a need to prescribe long-term opioids to these beneficiaries at significantly high doses and pill quantities.

In addition, 8 of these 10 beneficiaries continued to receive prescriptions from MTF or network providers after the scope of our audit, and 5 were still receiving prescriptions as of February 2023.³⁰ For example, Beneficiary O continued to receive a total of 30 additional opioid prescriptions between January 1, 2022, through February 28, 2023.

The DHA Did Not Have Effective Processes in Place to Request Medical Documentation

The lack of adequate documentation provided by the DHA occurred because the DHA did not have an effective process in place to request and obtain beneficiary medical documentation from the MTFs and MCSCs to monitor at-risk beneficiaries and perform reviews to determine whether providers are following or meeting Federal and DoD opioid safety recommendations and requirements. As noted in Appendix C, we attempted to obtain medical documentation for the 19 sample beneficiaries from DHA, MTF, and MCSC personnel through various attempts over several months. With these repeated attempts, we were provided various reasons from DHA, MTF, and MCSC personnel as to why the documentation could not be provided in a timely manner or at all.

DHA POD personnel stated that on several occasions, we would have to obtain the documentation directly from the MTFs, as the DHA did not have the ability to obtain medical documentation from the MTFs despite the DHA's administrative responsibility and control over MTFs. In addition, MTF personnel questioned why the DHA could not access the information themselves.

³⁰ The data we received did not include any additional prescriptions for Beneficiary H.

During a meeting in December 2022, DHA personnel stated that the DHA did not have a process in place to request beneficiary-level medical documentation. Further, DHA personnel identified that TRICARE contracts allow the MCSCs 45 to 60 days to fulfill each request for documentation. However, DHA personnel stated that they needed to submit a formal request to the contractor to obtain the documentation, and in multiple instances DHA personnel or MTF personnel could not determine whether a beneficiary had received care from outside providers or the appropriate way to request or obtain the requested documentation.

DHA personnel stated that the DHA did not have a process in place to request beneficiary-level medical documentation.

The DHA considered any subsequent attempt to obtain additional documentation as an additional request, which would require us to wait an additional 45 to 60 days. Therefore, if we requested documentation and then requested additional follow-up information, the DHA could have taken 90 to 120 days to fully respond to our request.

In addition, DHA, MTF, and MCSC personnel noted that several of these beneficiaries were also either VA beneficiaries, had other health insurance, or were also covered under Medicare (Part A or B), and TRICARE MCSCs did not pay for the provider encounter claims. Therefore, DHA, MTF, and MCSC personnel stated that they could not obtain medical documentation even though these beneficiaries received opioid prescriptions at MTFs or through network pharmacies.

Without an effective process to obtain the necessary documentation in a timely manner to show adequate monitoring was occurring, the DHA, MTFs, and MCSCs could not verify the health and wellbeing of these 10 beneficiaries and whether they would continue to remain at risk of being overprescribed opioids. Our original request was for medical documentation for 19 at-risk beneficiaries. We submitted our request in August 2022, and we did not start receiving documentation until November 2022 for only a few beneficiaries due to the lack of effective processes in place to request the documentation. After only receiving medical documentation for nine beneficiaries, we submitted a final request for documentation on January 5, 2023, with a suspense date of January 17, 2023.

Despite the final request for documentation, the DHA was still unable to obtain documentation for any of the remaining 10 sample beneficiaries due to the lack of effective processes to obtain the documentation. Waiting 45 to 60 days for a response to each request for medical documentation puts patient safety at risk when beneficiaries are on LOT and receiving average daily doses higher than

the 90 MME recommended in CDC and VA/DoD guidelines. In addition, the lack of an effective process for obtaining medical documentation has the potential

The lack of an effective process for obtaining documentation has potential to negatively impact reviewing and monitoring of at-risk beneficiaries who could have opioid complications.

to negatively impact timely reviewing and monitoring of all at-risk beneficiaries who could have opioid complications.

We identified that 53,910 of the 3.4 million beneficiaries who received opioid prescriptions between January 1, 2018, and December 31, 2021, were on LOT and received average daily

doses higher than the recommended 90 MME. Under the new DHA-AI, the amount that the Enterprise Solutions Board is required to monitor in order to improve opioid safety within DoD Clinical Communities reduced from 90 MME to 50 MME. As a result, the Enterprise Solutions Board may be required to monitor more beneficiaries. The DHA should review the 10 beneficiaries with insufficient medical documentation to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages and determine whether the beneficiaries need additional medical assistance. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers' beneficiaries to identify additional non-compliance. In addition, the DHA should review the MCSC contracts to determine whether 45 to 60 days is reasonable to provide documentation for at-risk beneficiaries and develop and implement standard operating procedures that outline how personnel should request documentation for at-risk beneficiaries to ensure compliance with monitoring these beneficiaries. Furthermore, the DHA should develop and implement a process to obtain medical documentation for DoD beneficiaries from MTFs and other agencies or health insurance providers to support routine monitoring and medical reviews of at-risk beneficiaries.

Conclusion

The DHA established several policies and programs, such as the MHS PDMP, PMP, and MHS Stepped Care Model. These updates to policies, manuals, and programs were developed to monitor whether beneficiaries are being overprescribed and whether providers are following and meeting Federal and DoD opioid safety

recommendations and requirements. However, patterns of potential overprescribing remain, providers did not follow or meet Federal and DoD opioid safety recommendations and requirements, and beneficiaries were not monitored or reviewed through established DHA programs.

As a result, the DHA, MTFs, and MCSCs may not identify or review the tens of thousands of potentially at-risk beneficiaries and determine whether they need additional medical assistance, leaving those individuals at increased risk of being overprescribed opioids. Furthermore, there is an increased risk of drug diversion, whether intentional or unintentional. Opioid misuse can lead to addiction, overdose incidents, or death, and overprescribing remains a serious health and safety issue for beneficiaries and a potential readiness issue for the DoD.

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Director of the Defense Health Agency:

- a. Review the nine at-risk beneficiaries to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers' beneficiaries to identify additional instances where they did not follow recommendations or meet requirements.**

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA will review medical documentation for the nine beneficiaries, provide feedback to the prescribing providers on opioid health practices as clinically indicated, and, if applicable, perform an additional review of three medical charts for each provider to determine trends in practice.

Our Response

Comments from the DHA Director addressed the specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once we obtain documentation to support that the DHA conducted

a review of the nine beneficiaries and, based on the results of the review, provided feedback and performed additional reviews for each provider to determine trends in practice.

- b. Implement procedures to review whether DoD medical treatment facility and Managed Care Support Contractor personnel are following and meeting Federal and DoD opioid safety recommendations and requirements. Specifically, the Defense Health Agency should ensure providers:**
- 1. Complete informed consent covering the risks and benefits of opioid therapy and ensure DoD medical treatment facilities are distributing Defense Health Agency standardized informed consent forms to beneficiaries receiving opioid prescriptions.**
 - 2. Perform Prescription Drug Monitoring Program checks at least every 3 months.**
 - 3. Provide or refer beneficiaries for care in the tertiary level of the Military Health System Stepped Care Model.**
 - 4. Follow up with beneficiaries to evaluate the benefits and potential harms of continued opioid use at least every 3 months and within 1 to 4 weeks of dose escalation.**
 - 5. Monitor beneficiaries' opioid use through urine drug testing at least annually.**
 - 6. Pursue tapering opioid use to a reduced dose or to discontinuation, where appropriate.**

Defense Health Agency Comments

The DHA Director partially agreed with the recommendation, stating that the DHA agrees to implement procedures for items 1, 2, 3, 4, and 6 to review whether MTF providers are following and meeting Federal and DoD opioid safety recommendations, as medically appropriate. However, the Director disagreed with implementing procedures for item 5 to monitor urine drug testing at least annually. The Director stated that the VA/DoD Clinical Practice Guidelines that were current during the scope of the review had a strong recommendation for urine drug testing; however, a 2022 revised VA/DoD Clinical Practice Guideline downgraded urine drug testing to a weak recommendation with no specifications of testing frequency.

The Director added that the CDC guidelines that were current during the scope of the review included a recommendation for clinicians to use urine drug testing before starting opioid therapy and to consider urine drug testing at least annually. The Director stated that the updated 2022 CDC guidelines only recommend that clinicians consider the benefits and risks of toxicology testing to assess prescribed medications and other substances. The Director noted that the DHA agrees that urine drug testing should be included as a risk mitigation intervention when based on clinical and shared decision making with the patient but not based on a specific timeframe.

The Director disagreed with MCSC personnel meeting Federal and DoD opioid safety recommendations and requirements. The Director stated that the MCSCs will not be able to uniformly comply with the recommendation as MCSC network providers are not “owned” by the MCSCs or the DHA and are not held to DoD opioid safety recommendations or requirements. Network providers are held to the standard of care that is widely held across the provider’s specialty and state medical board requirements. The Director noted that there are few Federal requirements related to opioid safety. The Director provided the following additional responses for items 1 through 6 regarding network providers.

1. Network providers are held to the standard of care that is widely held across the provider’s specialty and state medical board requirements. In addition, 12 states do not have a law requiring informed consent before prescribing opioids to adults.
2. According to the CDC, “State requirements vary, but [the] CDC recommends checking at least once every 3 months and consider checking prior to every opioid prescription.” Some states vary the frequency and MME for which providers must check the PDMP.
3. While a network provider would generally not refer to the tertiary level of the MHS, they would have the option to refer to a pain specialist.
4. Despite being widely accepted, the CDC guidelines are not law. The CDC guidelines are recommendations; therefore, they are not enforceable for the MCSC networks.
5. A Federal requirement to monitor opioid use annually through urine drug testing does not exist; therefore, this is not enforceable for the MCSC networks.
6. While recommended, a Federal requirement for tapering or discontinuing opioid use when appropriate does not exist; therefore, this is not enforceable for the MCSC networks.

Our Response

Comments from the DHA Director partially addressed the recommendation; therefore, the recommendation is unresolved. We appreciate the Director's planned actions to implement procedures to review whether MTF personnel are following the Federal and DoD opioid safety recommendations and requirements in items 1, 2, 3, 4, and 6, and acknowledge the change to urine drug testing recommendations in item 5. We agree that urine drug testing should be included as a risk mitigation intervention and would request the DHA Director provide when this requirement will be established and how it will be monitored. However, we disagree with the Director's comments regarding implementing procedures to review whether MCSC personnel and network providers are following and meeting the Federal and DoD opioid safety recommendations and requirements in items 1 through 6. The DHA has the responsibility to monitor TRICARE beneficiaries for opioid safety and ensure they are receiving medically necessary and high quality care. The MCSC contracts require safe care of the highest quality that produces the best quality of clinical outcomes for TRICARE beneficiaries. In addition, the MCSCs are required to manage and implement a clinical quality management and patient safety program for all TRICARE beneficiaries. Furthermore, the MCSC contracts require the contractor's Chronic Care/Disease Management program to incorporate nationally recognized, evidence-based guidelines and protocols, including DoD and Department of Veterans Affairs (VA) guidelines when available and appropriate.

While we understand many states have different opioid safety requirements and recommendations, we do not believe that allowing network providers to meet only the minimum Federal or State safety requirements aligns with the MCSC's contracted objective to provide safe and high quality care for TRICARE beneficiaries. Therefore, within 30 days of this report, we request that the DHA Director provide additional comments that describe the specific actions that the DHA will take to implement procedures to review whether MCSC personnel and network providers are following and meeting Federal and DoD opioid safety recommendations and requirements, or provide rationale explaining why this critical oversight should not be performed.

Recommendation 2

We recommend that the Director of the Defense Health Agency:

- a. Determine whether the five sample beneficiaries who were not listed on PMP reports should have been identified as candidates through the PMP and, based on the results, coordinate with the TRICARE Pharmacy contractor to determine whether the algorithms used to identify candidates on the Prescription Monitoring Program are adequate to identify all at-risk beneficiaries on long-term opioid therapy and**

receiving high morphine milligram equivalents. If the DHA determines the algorithms are not adequate, the DHA should coordinate with the TRICARE Pharmacy contractor to adjust the algorithms to ensure they identify all at-risk beneficiaries on long-term opioid therapy and receiving high morphine milligram equivalents.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA is working to implement the recommendation. The Director also stated that the DHA plans to work with the TPharm contractor to update the identification methodology to align with industry standards, state prescription monitoring boards, and Centers for Medicaid and Medicare Services guidelines. This effort will allow for the identification of additional at-risk beneficiaries on LOT and receiving high MME. The Director noted that once the contract modification is executed, it will take an additional 90 to 120 days to update the methodology. The Director stated that the TPharm contractor made the following updates to the MME review process:

- From January 2018 through April 2018, flag the beneficiary if they were prescribed an average daily dose above 120 MME for the most recent 3 months of the reporting period.
- From April 2018 to present, flag the beneficiary if they were prescribed an average daily dose above 90 MME for the 6-month reporting period and an average daily dose above 200 MME any time during the first and last 90 days of the reporting period.

The Director added that the DHA reviewed the five sample beneficiaries and determined the beneficiaries were under the updated MME review thresholds.

Our Response

Comments from the DHA Director addressed the specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides us with documentation to support that the DHA updated the PMP identification methodology to align with industry standards, state prescription monitoring boards, and Centers for Medicaid and Medicare Services guidelines to allow for the identification of additional at-risk beneficiaries on LOT and receiving high MME.

- b. Increase the number of required Prescription Monitoring Program candidate reviews for the Managed Care Support Contractors, while also implementing standard Prescription Monitoring Program processes and review requirements for all DoD medical treatment facilities to include the number of candidates to review.**

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA is working to implement the recommendation to increase the number of required PMP candidate reviews sent by the TPharm contractor for the MCSCs from 100 to 300. The Director noted that once the contract modification is executed, it will take an additional 90 to 120 days to increase the number of candidate reviews for MCSCs to 300. In addition, the Director stated that the TRICARE Manuals will be updated to incorporate each MCSC to review 20 candidates of the 300 sent each quarter for enrollment in the PMP. The target completion date for the update is 6 to 9 months following the execution of the contract modification with the TPharm contractor.

The Director also stated that the DHA Healthcare Delivery Compliance Inspection program will incorporate updated DHA POD compliance guidance to DHA PI 6010.02, dated October 15, 2021, which includes standard PMP process and review requirements and will apply to all MTFs. The Director added that the target completion date is September 30, 2026, in accordance with the proposed incremental implementation plan of the overarching DHA Healthcare Delivery Compliance Program.

Our Response

Comments from the DHA Director addressed the specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides us the executed contract modification to increase the required number of PMP candidate reviews, documentation to support that the contractor is complying with the updated contract requirement, and updated DHA POD compliance guidance to support that the DHA implemented standard PMP process and review requirements for all MTFs.

- c. **Implement procedures to review DoD medical treatment facility and Managed Care Support Contractor compliance with the Prescription Monitoring Program requirements in Defense Health Agency Instructions and the TRICARE Operations Manual.**

Defense Health Agency Comments

The DHA Director disagreed with the recommendation, stating that the MCSCs have an existing process in place based on the requirements of the TRICARE Operations Manual to perform a medical review of approximately 100 provider charts each quarter and evaluate those charts against industry standards of care. If the MCSCs determine the provider is outside of standard care, the providers are educated and trained, and then the MCSCs perform a follow-up review of additional charts to ensure the providers implement the corrections.

The Director stated that in addition to education and training, the MCSCs make appropriate referrals to the contractors' Quality or Program Integrity departments if there are concerns with care warranting further review and investigation. These medical reviews of provider prescribing practices include cross referencing the beneficiary PMP program. In addition, the Director stated that TRICARE Health Plan subject matter experts provide ongoing oversight and monitoring of the MCSCs PMP, including quarterly MCSC presentations and reviews of quarterly provider PMP reports, which describe medical reviews, determination and actions, and samples of education materials. Furthermore, the Director stated that if TRICARE Health Plan subject matter experts are concerned about the MCSCs' findings, TRICARE Health Plan will connect with the MCSC on the finding in question.

Our Response

Comments from the DHA Director partially addressed the recommendation; therefore, the recommendation is unresolved. Although the Director addressed existing processes in place to review MCSC compliance with PMP requirements, the Director did not address how the DHA will implement procedures to review MTF compliance with the PMP requirements in DHA instructions. We request that the DHA Director provide additional comments on the final report that describe the specific actions that the DHA will take to implement procedures to review MTF compliance with the PMP requirements in DHA instructions.

Recommendation 3

We recommend that the Director of the Defense Health Agency:

- a. **Review the 10 beneficiaries with insufficient medical documentation to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages and determine whether the beneficiaries need additional medical assistance. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers' beneficiaries to identify additional non-compliance.**

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA will conduct a review of the medical documentation for the 10 beneficiaries, provide feedback to the prescribing providers on opioid health practices, and, if applicable, perform an additional review of three medical charts for each provider to determine trends in practice. The Director added that as previously noted in responses to recommendations 1.a and 1.b, DHA providers are not required to implement 100 percent of all clinical recommendations and best practices from various policies and guidelines. They are allowed and expected to use their clinical judgment to align provided care with the patient's treatment goals.

Our Response

Comments from the DHA Director addressed the specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides us with documentation to support that the DHA conducted a review of the 10 beneficiaries and, based on the results of the review, provided feedback and performed additional reviews for each provider to determine trends in practice.

- b. **Review the Managed Care Support Contractor contracts to determine whether 45 to 60 days is reasonable to provide documentation for at-risk beneficiaries and develop and implement standard operating procedures that outline how personnel should request documentation for at-risk beneficiaries to ensure compliance with monitoring these beneficiaries.**

Defense Health Agency Comments

The DHA Director disagreed with the recommendation, stating that the TRICARE Operations Manual requires the MCSCs to provide responses within 60 days after receiving the TPharm report identifying at-risk beneficiaries. The Director stated that the MCSC contracts are performance-based contracts. The Government is not able to dictate how the MCSCs conduct their business, including how the MCSC will request documentation or how they will monitor beneficiaries, as that would be considered a proprietary MCSC best business practice. The Director added that while this information on how MCSCs will fulfill the requirement to request documentation and monitor individual cases is a best business practice, the information may or may not be found in the MCSC's Provider Agreements, which detail the contractual relationship between the MCSC and their network providers.

The Director also stated that according to the TRICARE Operations Manual, chapter 28, section 2, paragraph 2.6, the MCSCs are required to provide responses within 60 days after receiving the TPharm report identifying at-risk beneficiaries, which means that the contractor must get the medical records, review them, and provide a response within 60 days. The Director noted that tightening this timeline would be difficult to accomplish without a significant contract modification, with minimal gain. Furthermore, the DHA Director stated that while this Contract Data Requirement List is evaluated by the TPharm program, the MCSCs routinely meet the 60-day requirement to conduct medical reviews and provide documentation for at-risk beneficiaries.

The Director further added that according to the TRICARE Operations Manual, chapter 28, section 2, paragraphs 2.4 and 2.5, the MCSC provides six different responses based on the 20 beneficiary cases they prioritize and review, including no action, support plan with restrictions, support plan without restrictions, restrictions only, further monitoring needed, and not reviewed.

Our Response

Although the DHA Director disagreed with the recommendation, the comments addressed the specifics of the recommendation. Specifically, the DHA reviewed the MCSC contracts and determined that the timeline to provide documentation within 60 days is reasonable and decreasing the timeframe would result in minimal benefit. In addition, the DHA determined that the contracts are performance-based contracts and that the DHA cannot dictate how the MCSCs request documentation. Therefore, the recommendation is closed, and no further comments are required.

- c. **Develop and implement a process to obtain medical documentation for DoD beneficiaries from DoD medical treatment facilities and other agencies or health insurance providers to support routine monitoring and medical reviews of at-risk beneficiaries.**

Defense Health Agency Comments

The DHA Director partially agreed with the recommendation, stating that the DHA has policies in place for the release of information containing Protected Health Information that complies with DoD Instructions related to the Health Insurance Portability and Accountability Act Privacy Rule and other applicable laws and regulations. Specifically, responsibilities and procedures for obtaining release of medical record information are addressed in DHA Procedures Manual 6025.02, “DoD Health Record Lifecycle Management, Volume 1: General Principles, Custody and Control, and Inpatient Records,” and “DoD Health Record Lifecycle Management, Volume 2: Outpatient Record Components and Dental Records.”

The Director stated that this recommendation has multiple legal and privacy implications given that the DHA has no authority over records generated outside the TRICARE program. The Director noted that the DHA will engage relevant stakeholders and experts regarding medical records, Health Insurance Portability and Accountability Act, and the Office of General Counsel to determine the extent that the DHA can execute the recommendation to develop and implement a process to obtain medical documentation.

Our Response

Comments from the DHA Director addressed the specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides us with documentation to support that the DHA engaged with relevant stakeholders to determine how to execute the recommendation and, based on that determination, implemented procedures to obtain medical documentation for beneficiaries from MTFs and other agencies or health insurance providers.

Appendix A

Scope and Methodology

We conducted this performance audit from May 2022 through July 2023 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.

The DoD OIG Data Analytics Team (DAT) obtained a universe of MHS opioid prescription data from the MDR. The DAT refined the universe to be more relevant and useful to our objective by removing prescriptions with a missing universal patient identifier, liquid opioids, opioids that could not be converted to MMEs, and cancer and hospice patients. The DAT also removed any duplicate records and prescriptions to patients over 100 years of age. The final universe for this audit contains 16,175,350 records for opioid prescriptions dispensed January 1, 2018, through December 31, 2021, from 651,448 unique National Provider Identifiers written to 3,409,500 unique patient identifiers.³¹

Identifying Potentially Overprescribed Beneficiaries

The DHA requested a definition of our use of “potential overprescribing” throughout the report. However, neither the DHA nor the CDC define overprescribing. The United Kingdom’s National Health Service states that overprescribing refers to situations where patients are prescribed medicines that they do not need or want, where potential harm outweighs the benefit of the medication, when a better alternative is available but not prescribed, or where the medicine is appropriate for a condition but not the individual patient. Overprescribing can also refer to prescribing a medication in excess or more often than necessary.

DHA Procedural Instruction 6025.04 requires the Enterprise Solutions Board to monitor the following outcome measures for patients.

- The percentage of patients at MTFs who are prescribed greater than 90 MME per day. These patients are at increased risk for death from opioids. The VA/DoD and CDC clinical practice guidelines recommend against these doses.

³¹ The National Provider identifier is a unique 10-digit number used to identify health care providers, while the unique patient identifier is a 10-digit universal patient identifier assigned by the DHA.

- The median MME per day for LOT patients at MTFs. These patients are at an increased risk of opioid complications, but that risk can be mitigated through lower opioid doses.

The dosage and duration thresholds stated in these DHA guidelines served as the baseline in the DoD OIG's calculation of those patients potentially overprescribed based upon the DHA's own documentation of the increased risk to these patients.

Sample Selection

We coordinated with the DAT to identify examples of beneficiaries who had potentially been overprescribed opioids. Specifically, beneficiaries with a median 90-day average MME greater than 90 MME and who were on LOT. The DAT provided 19 sample beneficiaries who could be grouped into the three following mutually exclusive categories.

1. Beneficiaries with prescriptions filled only at MTFs.
2. Beneficiaries with prescriptions filled only at retail locations.
3. Beneficiaries with prescriptions filled at MTF and retail locations.

Additionally, the sample included beneficiaries with both a large number of overlapping prescriptions, beneficiaries with multiple providers from each of the three categories, beneficiaries under 30 years of age, beneficiaries who overdosed during opioid therapy, and beneficiaries who were prescribed opioids from unusual provider types, such as clinical pharmacists, pediatric providers, and providers in medical genetics. To identify overdoses, the DAT identified International Classification of Diseases codes within the MDR that indicated an overdose diagnosis.

Review of Documentation and Interviews

To accomplish our audit objective, we interviewed officials from the DHA POD, DHA Compliance, TRICARE Health Plan, MTF personnel, and MCSC personnel responsible for monitoring opioid prescriptions on behalf of beneficiaries.

To assess reliability of the MHS MDR prescription data, the DAT provided us with a statistically representative sample of 105 prescriptions to verify against actual prescription documentation. The 105 sample prescriptions consisted of 25 prescriptions dispensed at MTF pharmacies, 73 prescriptions dispensed at network pharmacies, and 7 dispensed at VA pharmacies. We then provided a list of the 105 sample opioid prescriptions to DHA personnel on July 11, 2022, to request supporting documentation for each prescription. The DHA provided supporting documentation for all 25 sample opioid prescriptions dispensed at

MTF facilities by August 10, 2022. The DHA provided supporting documentation for 71 of the 73 prescriptions dispensed at network pharmacies on October 14, 2022.³² The VA provided supporting documentation for all seven prescriptions dispensed at VA pharmacies on October 17, 2022. We evaluated the statistically representative sample of the population and found the data to be reliable.

In addition to reviewing a statistically representative sample to evaluate the reliability of the data, we submitted our first request for documentation for the 19 nonstatistically selected, potentially at-risk beneficiaries on August 17, 2022.³³ On September 8, 2022, the DHA informed us that it did not have the ability to obtain the requested documentation from the MTFs for the beneficiaries with MTF primary care managers. However, the DHA would continue to coordinate the collection of documentation from the MCSCs. On October 27, 2022, the DHA submitted a tasker to all Markets and MTFs to provide the requested documentation.

Between November 2, 2022, and November 30, 2022, we coordinated with individual Market and MTF POCs to obtain documentation for 5 of the 19 beneficiaries. Between December 1, 2022, and December 11, 2022, we received documentation from the MCSCs for 4 of the 19 beneficiaries. We sent a final request for documentation to the DHA for the remaining 10 beneficiaries on January 5, 2023, with a final suspense date of January 17, 2023, 5 months after the initial request. We did not receive any additional documentation in response to this request and therefore determined that the documentation was not available to demonstrate whether providers met Federal and DoD opioid safety recommendations and requirements for these 10 beneficiaries. Therefore, because the DHA could not obtain beneficiary medical documentation, we determined that the DHA did not have adequate controls to monitor opioid prescriptions for these beneficiaries. Furthermore, we did not determine the medical necessity of the prescriptions or review the underlying diagnosis that led to the prescription or appropriateness of the prescription, only whether monitoring of the at-risk beneficiaries occurred.

³² Supporting documentation for two of the prescriptions was not available because the dispensing pharmacies had closed.

³³ The audit team requested 4 years of medical records from January 1, 2018, through December 31, 2021. Some of the 19 sample beneficiaries had prescriptions before or after these dates. Any conclusions drawn in the report were specific to the prescriptions and medical documentation within this timeframe. However, additional information on prescriptions or medical records outside of this timeframe was included in certain examples within the report. The report clearly identifies these instances.

The DHA, through the MTFs and TRICARE contractors, provided medical records for 9 of the 19 beneficiaries, such as prescription logs, encounter summaries, provider notes, or urine drug test results.³⁴ For these beneficiaries, we reviewed the medical records to determine whether the DHA had effective controls to monitor opioid prescriptions from providers to ensure compliance with Federal and DoD opioid safety standards. Specifically, to determine whether the DHA had effective controls to monitor opioid prescriptions, we assessed various aspects of guidance to determine whether the control was effective. Table 3 lists the criteria we identified relevant to our review and the documentation we requested to support whether personnel complied with the criteria.

Table 3. Opioid Safety Standard Criteria and Documentation Requested

Criteria Reference	Documentation Requested
DHA-PI 6025.04 requires all patients who receive an opioid prescription to be educated on the risks associated with opioids. This education should be documented in the electronic health record by the prescribing provider	Informed consents associated with opioid therapy
DHA-PI 6010.02 (established late in the audit scope – 10/15/2021) recommends providers to review the PDMP when a patient is new and a Class II through Class IV controlled substance is prescribed, and at certain intervals, including no less frequently than every 3 months when prescribing controlled substances	Evidence of PDMP (or similar) checks by prescribing physicians
DHA-PI 6025.04 states that all patients who are taking more than 90 MME of opioids daily, are on LOT (greater than 90 days of continuous use), or have had greater than 6 months of pain require care in the tertiary level of the Stepped Care Model. DHA-PI 6025.04 identifies the tertiary level of the Stepped Care Model as care from a Pain Management Clinic and Pain Specialist	Any evidence that the patient consulted with a pain care specialist or any evidence that other practitioners, such as occupational therapists and behavioral specialists, were consulted
CDC recommends clinicians evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently	Summary level view of patient prescription history and appointment history
DHA-PI 6025.04 requires patients on LOT or at risk for opioid use disorder to be monitored with urine drug testing	Evidence of all urine drug tests associated with opioid therapy

³⁴ Documentation provided for three of the nine beneficiaries did not cover the entire scope of January 1, 2018, through December 31, 2021, but we determined it was sufficient to support the audit conclusions.

Table 3. Opioid Safety Standard Criteria and Documentation Requested (cont'd)

Criteria Reference	Documentation Requested
<p>“VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain” states that for patients currently prescribed ≥ 90 MME, a comprehensive assessment that recognizes the increased risk of high dose OT should be performed. Tapering to a reduced dose or tapering to discontinuation should be pursued when clinically meaningful functional benefit is not demonstrated or when significant risk factors in addition to the prescribed opioid dose are present</p>	<p>Any evidence associated with attempted tapering or discontinuation of opioid therapy</p>

Source: The DoD OIG.

We also reviewed PMP and similar reports, during the scope of our review, to determine whether the MCSCs referred the sample beneficiaries or prescribing providers to the proper entities for review. Additionally, we reviewed any adjudications of these referrals.

After we completed initial reviews of the 19 sample beneficiaries using the criteria outlined in Table 4 above, we coordinated with DHA personnel to obtain further information and discuss any monitoring deficiencies we identified.

Criteria

We evaluated the monitoring processes, opioid prescriptions, and documentation according to the following Federal and DoD criteria.

- “CDC Guideline for Prescribing Opioids for Chronic Pain – United States,” March 18, 2016
- “VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,” Version 3.0, February 2017
- TRICARE Operations Manual 6010.59-M, April 1, 2015, Chapter 28, Section 1, “Prescription Monitoring Program (PMP),” Revision C-19, January 24, 2018
- DHA-PI 6025.04 “Pain Management and Opioid Safety in the Military Health System,” June 8, 2018
- DHA-PI 6010.02 “Military Health System Prescription Drug Monitoring Program,” October 15, 2021

Internal Control Assessment and Compliance

We assessed internal controls and compliance with laws and regulations necessary to satisfy the audit objective. In particular, we assessed internal controls related to the DHA and its oversight of MTFs and contractors, and their monitoring of opioid prescription compliance with applicable opioid safety standards. However, because our review was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

Use of Computer-Processed Data

We relied on computer-processed data from the MDR PDW to obtain a sample of prescription transactions to test data reliability and select beneficiaries who were listed to continuously receive opioid prescriptions that were potentially non-compliant with opioid safety standards. Our universe consisted of dispensed opioid prescriptions at MTFs, at Retail pharmacies, and at both, with dates between January 1, 2018, and December 31, 2021. This universe totaled 16,175,350 prescriptions.

To assess reliability of the data, the DAT provided us a statistically valid sample of 105 prescriptions to verify against actual prescription documentation. In verifying the data we compared the MDR Data to the actual prescription to compare the following data elements.

- upid – 10-digit universal patient identifier assigned by the DHA
- deanum – the national unique identifier for the prescriber
 - From MDR: Prescriber ID value will be one of the following
 - SSN – Prescriber’s Social Security Number
 - DEA – Prescriber’s Drug Enforcement Agency Number
 - NPI – Prescriber’s National Provider Identifier
- datedisp – date that prescription was dispensed
- National Drug Code (NDC) – the unique numeric identifier for drug
- daysupply – the number of days that prescription supplies
- decqty – the quantity of units dispensed in the prescription

We could not verify at least one data element for 11 of the 105 sample prescriptions due to unavailable or contradicting supporting documentation; however, we determined that the errors were in the tolerable range of deviation. Only two prescriptions had no documentation available because the associated pharmacies closed. Therefore, we determined that the data were sufficiently reliable for the purposes of the DAT’s calculations.

Use of Technical Assistance

We received assistance from the DAT to obtain a universe of TRICARE opioid prescriptions dispensed between January 1, 2018, and December 31, 2021, from the MDR PDW. The DAT used the universe of opioid prescriptions to develop a sample of 105 prescription transactions to test for data reliability.

The DAT then identified 19 nonstatistically selected, at-risk beneficiaries who received opioids. These 19 beneficiaries received opioids over the 90 MME recommendation for longer than 90 days. Three of the beneficiaries had at least one overdose encounter in their data record. The DAT then provided an update specific to these 19 at-risk beneficiaries to identify whether they received any more prescriptions after our scope ended between January 2022 and February 2023.

Prior Coverage

During the last 5 years, the DoD Office of Inspector General (DoD OIG) and Department of Health and Human Services (HHS) OIG issued eight reports discussing opioids and opioid prescriptions.

Unrestricted DoD OIG reports can be accessed at <http://www.dodig.mil/reports.html/>. Unrestricted HHS OIG reports can be accessed at <https://oig.hhs.gov/reports-and-publications/>.

DoD OIG

Report No. DODIG-2021-073, “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

The DoD OIG determined that most DoD MTFs dispensed the appropriate number of days supply for Schedule II amphetamines. However, 65 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 prescriptions, 1,281 (43 percent) were for active duty service members, leaving 1,687 (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.

Memorandum to the Director of the Defense Health Agency, “Data Analysis of Opioid Prescriptions to DoD Beneficiaries,” June 2, 2020

Of the 466,793 providers who prescribed opioids during the 2-year period the DoD OIG reviewed, 18.4 percent prescribed opioids at least once to beneficiaries who were on long-term therapy and had at least 3 months of opioid prescriptions. Furthermore, the DoD OIG calculated that 17 percent of providers wrote at least one opioid prescription during a 90-day period for a beneficiary whose 90-day average MME was greater than or equal to 90 MME.

DODIG-2020-048 “Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities,” January 10, 2020

The DoD OIG determined that MTFs potentially overprescribed opioids from 2015 through 2017. This occurred because the DHA and Military Departments did not have policies and processes in place to identify and monitor beneficiaries who were prescribed more than 90 MME per day.

DODIG-2019-091 “Evaluation of the DoD’s Management of Opioid Use Disorder for Military Health System Beneficiaries,” June 10, 2019

While the DoD had policies and programs in place to manage the treatment of opioid use disorder for MHS beneficiaries, the DOD OIG determined that the Marine Corps Substance Abuse Counseling Center counselors made substance use disorder diagnoses in violation of DoD and Navy Bureau of Medicine and Surgery policies. Additionally, the DoD did not implement DoD-wide standard outcome and process measures specific to opioid use disorder, such as the percentage of opioid use disorder patients who initiated treatment within 14 days of diagnosis.

HHS OIG

Report No. OEI-02-20-00320, “Opioid Use in Medicare Part D Continued to Decline in 2019, but Vigilance is Needed as COVID-19 Raises New Concerns,” August 2020

HHS OIG found that about 1 in 4 Medicare Part D beneficiaries received opioids in 2019, a decrease from the prior 3 years. Spending for opioids in Part D also decreased to \$2.8 billion, the lowest amount in 10 years. However, nearly 267,000 beneficiaries received high amounts of opioids in 2019, with almost 34,000 of them at serious risk of opioid misuse or overdose. About 140 prescribers ordered opioids for large numbers of these beneficiaries at serious risk.

Report No. OEI-02-19-00130, "Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look," May 2020

Among other findings, the HHS OIG found that Most Part D beneficiaries at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year. In addition, 11 percent of beneficiaries at serious risk in 2017 had an overdose or adverse effect from an opioid in 2017 or 2018 and about one-quarter of beneficiaries at serious risk in 2017 received a prescription through Part D for naloxone, a drug that reverses opioid overdoses. Finally, about half of beneficiaries at serious risk in 2017 were diagnosed with opioid use disorder or other conditions related to the misuse of opioids.

Report No. A-09-18-01005, "Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Actions to Address the Opioid Epidemic," July 2019

The HHS OIG identified actions that selected States took related to their oversight of opioid prescribing and their monitoring of opioid use. Specifically, the HHS OIG identified that the States created policies and procedures and passed laws and regulations related to opioids; used opioid-related data to perform data analytics, as well as performing outreach to providers and patients; and implemented a number of opioid-related prevention, detection, and treatment programs.

Appendix B

Sample Beneficiaries

Beneficiary	Prescription Fill Location	Highest Median 90-Day Avg MME Identified	Intox Length (Days)	# of Opioid Scripts	# of Providers	Documentation Received?
A	MTF	150	1,523	178	2	Yes
B	MTF	195	163	21	2	Yes
C	MTF	222	1,236	43	5	No
D	MTF	153	1,016	101	17	Yes
E	MTF	893	636	28	4	No
F	MTF	135	104	15	7	No
G	Retail	313	619	38	3	Yes
H	Retail	799	1,522	110	4	No
I	Retail	1,317	1,522	149	19	No
J	Retail	265	1,541	101	13	Yes
K	Retail	628	1,553	104	6	No
L	MTF and Retail	1,277	1,541	267	2	No
M	MTF and Retail	242	1,538	100	2	No
N	MTF and Retail	181	633	73	11	Yes
O	MTF and Retail	973	1,514	164	9	No
P	MTF and Retail	468	1,531	192	14	No

Sample Beneficiaries (cont'd)

Beneficiary	Prescription Fill Location	Highest Median 90-Day Avg MME Identified	Intox Length (Days)	# of Opioid Scripts	# of Providers	Documentation Received?
Q	MTF	165	1,519	122	8	Yes
R	Retail	107	661	46	6	Yes
S	MTF and Retail	291	1,518	93	15	Yes

Legend

MME Morphine Milligram Equivalent

MTF Medical Treatment Facility

Source: The DoD OIG.

Sample Beneficiary Reviews

Of the 19 total sample beneficiaries, we received supporting medical documentation to perform our review for 9 beneficiaries. Of the nine beneficiaries we reviewed, providers did not meet Federal and DoD opioid safety recommendations or requirements for eight beneficiaries.

Beneficiary	Informed Consent Completed	PDMP Checks at Least Every 3 Months	Care in the Tertiary Level of the MHS Stepped Care Model	Follow-up Appointments at Least Every 3 Months and Within 1 to 4 Weeks of Dose Escalation	Urine Drug Testing at Least Annually	Tapering Pursued
A	Yes	No	No	Yes	Yes	Yes
B	Yes	Yes	Yes	Yes	Yes	Yes
D	Yes	No	Yes	Yes	No	Yes
G	Yes	No	Yes	Yes	Yes	Yes
J	Yes	No	Yes	No	Yes	Yes

Sample Beneficiaries (cont'd)

Beneficiary	Informed Consent Completed	PDMP Checks at Least Every 3 Months	Care in the Tertiary Level of the MHS Stepped Care Model	Follow-up Appointments at Least Every 3 Months and Within 1 to 4 Weeks of Dose Escalation	Urine Drug Testing at Least Annually	Tapering Pursued
N	No	No	Yes	Yes	No	Yes
Q	Yes	No	Yes	Yes	Yes	Yes
R	Yes	No	Yes	No	No	No
S	Yes	No	Yes	Yes	Yes	Yes

Legend

MHS Military Health System

PDMP Prescription Drug Monitoring Program

Source: The DoD OIG.

Appendix C

Coordination Efforts to Obtain Medical Documentation for Sample Beneficiaries

Date	Coordination Efforts
8/17/2022	We submitted our initial documentation request to DHA POD personnel.
8/30/2022	DHA POD personnel told us that the Patient Administration Division could provide contact information for the MTF beneficiaries but could not obtain the documentation for us. They stated that we would need to communicate directly with the MTFs to obtain the documentation. DHA POD personnel also told us they were still waiting to hear back on an estimated timeframe for documentation for the MCSC beneficiaries and that they suspect a suspense of 30 to 60 days.
9/7/2022	The DHA POD provided us with a spreadsheet identifying Primary Care Manager information for the 19 beneficiaries and stated: (1) for the MTF beneficiaries, we would need to communicate directly with the MTFs to obtain the documentation, and (2) for the MCSC beneficiaries, the POC requested the end of September as a suspense date.
9/8/2022	We held a phone call with the Chief of DHA POD, along with other DHA POD personnel and the DHA Audit Liaison Officer, to discuss the documentation request: (1) The Chief of DHA POD stated that the DHA POD did not have the ability to obtain the documentation from the MTFs. (2) We agreed to send the documentation request to the DHA Audit Liaison Officer to attempt to coordinate the request with the appropriate MTF personnel. (3) DHA POD personnel stated they would continue coordinating the request for the MCSC beneficiaries.
9/12/2022	We sent the documentation request again to DHA POD personnel and the DHA Audit Liaison Officer.
9/20/2022	DHA POD personnel provided a spreadsheet on 9/20/2022 containing some testimonial evidence related to 5 sample beneficiaries. We replied stating that the request was for documentation, not answers to questions. Then, DHA POD personnel told us on 9/27/22 that the request for documentation would take approximately 60 days to fulfill. DHA POD personnel also noted that, according to the TRICARE Operations Manual, the contractor is required to transmit 95 percent of requested documentation within 45 calendar days and 98 percent of requested documentation within 60 calendar days.
10/7/2022	DHA POD personnel stated on 10/7/2022 that they had not heard back from the DHA Patient Administration team to confirm when the documentation for the MCSC beneficiaries would be available. Their assumption was that the 45 to 60 days was based on a formal request to the contractor on September 27, 2022, but they had not confirmed that a formal request was sent.
10/11/2022 and 10/13/2022	We contacted the DHA Audit Liaison Officer to determine the status of our documentation request for the MTF beneficiaries. The DHA Audit Liaison Officer could not provide an update and was still seeking the appropriate personnel to accommodate our request.

Coordination Efforts to Obtain Medical Documentation for Sample Beneficiaries (cont'd)

Date	Coordination Efforts
10/26/2022	We sent detailed information on the documentation required for each selected beneficiary to the DHA Audit Liaison for the DHA to coordinate the request down to the Markets and MTFs. The DHA Audit Liaison submitted the tasker to the Markets and MTFs on October 27, 2022.
Between 11/2/2022 and 11/30/2022	We coordinated with several Market and MTF POCs to answer questions about the tasker and accepted several requests for extension. Many Market and MTF POCs questioned why the DHA could not obtain the documentation for us. We received documentation for 5 of the 19 sample beneficiaries during this timeframe - beneficiaries B, D, G, Q, and R. We also received limited 5-page documentation for sample beneficiary O. The documentation provided for this beneficiary was not sufficient to perform our review.
12/1/2022	We requested a meeting with DHA officials to provide an update on the status of the audit and documentation request.
Between 12/1/2022 and 12/11/2022	We received documentation for 4 of the 19 sample beneficiaries during this timeframe – beneficiaries A, J, N, and S.
12/12/2022	We held a meeting with the DHA Audit Liaison Officer and DHA POD personnel to provide an update on the audit and status of our documentation request. We discussed the impact of not receiving documentation to support our reviews and the DHA's lack of processes to request the documentation. DHA officials acknowledged the impact of not receiving documentation and lack of processes in place.
1/5/2023	We sent a final request for documentation to the DHA Audit Liaison for the 10 sample beneficiaries who still required medical documentation – beneficiaries C, E, F, H, I, K, L, M, O, and P. We requested a final suspense date of 1/17/2023 and explained that if we did not receive documentation for these 10 beneficiaries, we would conclude that documentation was not available to demonstrate whether providers met Federal and DoD opioid safety recommendations and requirements for these at-risk beneficiaries.
1/17/2023	We did not receive any additional documentation in response to our final request. Therefore, we continued our reviews of beneficiaries with medical documentation and concluded that documentation was not available for the remaining 10 beneficiaries to determine whether providers met Federal and DoD opioid safety recommendations and requirements.

Source: The DoD OIG.

Management Comments

Defense Health Agency



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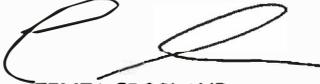
OCT 13 2023

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: Response to Draft Report "Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards," September 5, 2023, DODIG (Project No. D2022-D000AX-0134.000)

This is in response to Department of Defense Office of Inspector General Project (Audit/Research No. D2022-D000AX-0134.000): Audit of Defense Health Agency Controls to Monitor Opioid Prescription Compliance with Federal and DoD Opioid Safety Standards, dated September 5, 2023. The attached responses for recommendations 1, 2, and 3 are provided.

My points of contact on this issue are [REDACTED], who can be reached at [REDACTED] or [REDACTED], or [REDACTED] (Audit Liaison) at [REDACTED] or [REDACTED].


TELITA CROSLAND
LTG, USA
Director

Attachments:
As stated

Defense Health Agency (cont'd)

**DOD IG DRAFT REPORT DATED SEPTEMBER 5, 2023
D2022-D000AX-0134.000**

**“AUDIT OF DEFENSE HEALTH AGENCY CONTROLS TO MONITOR OPIOID
PRESCRIPTION COMPLIANCE WITH FEDERAL AND DOD OPIOID SAFETY
STANDARDS”**

**DEFENSE HEALTH AGENCY RESPONSE
TO THE DOD IG RECOMMENDATIONS**

RECOMMENDATION 1.a: (U) The Department of Defense (DoD) OIG recommended the Defense Health Agency Director reviews the nine at-risk beneficiaries to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers' beneficiaries to identify additional instances where they did not follow recommendations or meet requirements.

DHA RESPONSE: The Defense Health Agency (DHA) concurs and will conduct a review of the nine beneficiaries' medical documentation, provide feedback to the prescribing providers on opioid health practices as clinically indicated, and, if applicable, perform an additional review of three medical charts per provider to determine trends in practice.

RECOMMENDATION 1.b: The DoD OIG recommended the DHA Director implement procedures to review whether DoD medical treatment facility and Managed Care Support Contractor personnel are following and meeting Federal and DoD opioid safety recommendations and requirements. Specifically, the DHA should ensure providers:

1. Complete informed consent covering the risks and benefits of opioid therapy and ensure DoD medical treatment facilities are distributing Defense Health Agency standardized informed consent forms to beneficiaries receiving opioid prescriptions.
2. Perform Prescription Drug Monitoring Program checks at least every 3 months.
3. Provide or refer beneficiaries for care in the tertiary level of the Military Health System Stepped Care Model.
4. Follow up with beneficiaries to evaluate the benefits and potential harms of continued opioid use at least every 3 months and within 1 to 4 weeks of dose escalation.
5. Monitor beneficiaries' opioid use through urine drug testing at least annually.
6. Pursue tapering opioid use to a reduced dose or to discontinuation, where appropriate.

DHA RESPONSE: DHA partially concurs with this recommendation. It concurs to implement procedures for items 1, 2, 3, 4, and 6 to review DoD military medical treatment facility providers' medically appropriate adherence to DoD and Federal opioid safety recommendations. DHA non-concurs with item 5 to monitor urine drug testing at least annually. The DoD/Department of Veterans Affairs (VA) Clinical Practice Guidelines that were current during the study period had a strong recommendation for urine drug testing; however, by 2022 a revised

Defense Health Agency (cont'd)

DoD/VA Clinical Practice Guidelines downgraded urine drug testing to a weak recommendation with no specification of testing frequency (see Fig 1). Closely aligned with the DoD/VA guidelines, the Centers for Disease Control and Prevention (CDC) Opioid Prescribing Guidelines current during the study period included a recommendation for clinicians to “use urine drug testing before starting opioid therapy and consider urine drug testing at least annually.” As with the DoD/VA Guidelines, the updated 2022 CDC guidelines only recommends that clinicians consider the benefits and risks of toxicology testing to assess prescribed medications as well as other substances. DHA does agree that urine drug testing should be included as a risk mitigation intervention when based on clinical and shared decision making with the patient without an associated time frame.

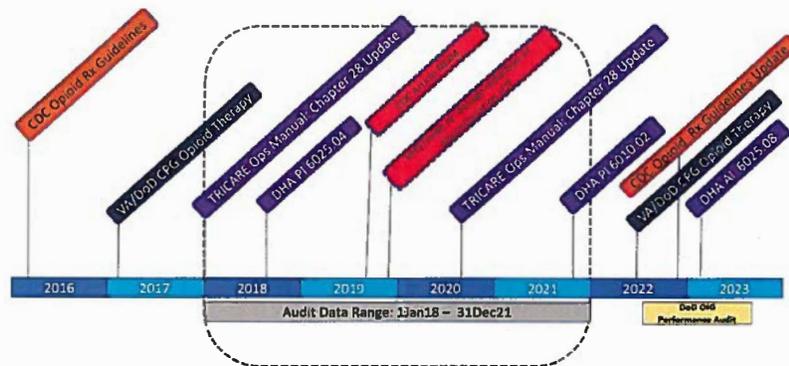
DHA non-concurs for the Managed Care Support Contractor (MCSC) personnel to meet Federal and DoD opioid safety recommendations and requirements. The MCSC will not be able to uniformly comply with this recommendation as MCSC network providers are not “owned” by the MCSCs nor DHA; as such, they are not held to DoD Opioid Safety Recommendations or Requirements. Rather, network providers are held to the standard of care that is widely held across the provider’s specialty and state medical board requirements. There are few Federal requirements as related to opioid safety. For example, all 50 states and the District of Columbia have some form of a naloxone access law; however, the laws vary by state, including co-prescribing requirements (<https://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139>). The DHA provides these additional responses:

1. Complete informed consent covering the risks and benefits of opioid therapy and ensure DoD military medical treatment facilities are distributing DHA standardized informed consent forms to beneficiaries receiving opioid prescriptions. Network providers are held to the standard of care that is widely held across the provider’s specialty and state medical board requirements. The following states do not have a law requiring informed consent before prescribing opioids to adults: CA*, NY, NC, SC*, AL, WI, IL, KS, CO, WY, MT, ID (CA and SC require informed consent for minors).
2. Perform Prescription Drug Monitoring Program (PDMP) checks at least every three months.
 - a. Per the CDC, “State requirements vary, but CDC recommends checking at least once every 3 months and consider checking prior to every opioid prescription.” https://www.cdc.gov/drugoverdose/pdf/pdmp_factsheet-a.pdf
 - b. Some states vary the frequency and morphine milligram equivalents (MME) for which providers must check PDMP. For example, in Alabama, providers “must check the PDMP twice a year if the MME is greater than 30. If MME is greater than 90, the PDMP must be checked with every prescription except for nursing home patients, hospice patients, when pain associated with “malignant pain” and intra-operatively.
3. Provide or refer beneficiaries for care in the tertiary level of the Military Health System (MHS) Stepped Care Model. While a MCSC network provider would generally not refer to the tertiary level of the MHS, they would have the option to refer to a pain specialist.
4. Follow up with beneficiaries to evaluate the benefits and potential harms of continued opioid use at least every three months and within one to four weeks of dose escalation. Though widely accepted, the applicable CDC’s CPG are not law. The CPGs are recommendations; therefore, they are not enforceable for the MCSC networks.

Defense Health Agency (cont'd)

5. Monitor beneficiaries' opioid use through urine drug testing at least annually. A federal requirement to monitor opioid use through urine drug testing annually does not exist. Therefore, this is not enforceable for the MCSC networks.
6. Pursue tapering opioid use to a reduced dose or to discontinuation, where appropriate. While recommended, there is not a Federal requirement for tapering or discontinuing opioid use when appropriate; this is not enforceable for the MCSC networks.

Figure 1. Outline of guidelines and recommendations



RECOMMENDATION 2. A: The DoD OIG recommended that the Director of the Defense Health Agency determine whether the five sample beneficiaries who were not listed on PMP reports should have been identified as candidates through the PMP and based on the results, coordinate with the TRICARE Pharmacy contractor to determine whether the algorithms used to identify candidates on the Prescription Monitoring Program are adequate to identify all at-risk beneficiaries on long-term opioid therapy and receiving high morphine milligram equivalents. If DHA determines the algorithms are not adequate, DHA should coordinate with the TRICARE Pharmacy contractor to adjust the algorithms to ensure they identify all at-risk beneficiaries on long-term opioid therapy and receiving high morphine milligram equivalents.

DHA RESPONSE: DHA concurs with the recommendation. DHA is working to implement this recommendation. DHA plans to work with the TRICARE Pharmacy contractor to refine the identification methodology in alignment with industry standards, state prescription monitoring boards, and Centers for Medicaid and Medicare Services guidelines. This will allow the identification of additional at-risk beneficiaries on long-term opioid therapy and receiving high MME. Once the contract modification is executed, it will take an additional 90 days to 120 days to update the methodology.

The TRICARE Pharmacy contractor updated the MME review process as follows:

1. From January 2018 to April 2018 to flag if 120 MME/day average for recent three months of reporting period; and

Defense Health Agency (cont'd)

2. From April 2018 to present to flag if ≥ 90 MME/day average for the six months' reporting period AND ≥ 200 MME/day anytime during first and last 90 days of period. Further review was conducted on the five sample beneficiaries. The identified candidates were found to be either under the 120 MME threshold or under the 200 MME threshold or under both the 120 MME and 90 MME threshold.

RECOMMENDATION 2.b: The DoD OIG recommended the Defense Health Agency Director increase the number of required Prescription Monitoring Program candidate reviews for the Managed Care Support Contractors, while also implementing standard Prescription Monitoring Program processes and review requirements for all DoD medical treatment facilities to include the number of candidates to review.

DHA RESPONSE: DHA concurs and is working to implement the recommendation to increase the number of required Prescription Monitoring Program candidate reviews sent by the TRICARE pharmacy contractor for the MCSC from 100 to 300.

After the contract modification is executed, it will take an additional 90 to 120 days to increase the number of candidate reviews for MCSC to 300.

In addition, the TRICARE Manuals will be updated to incorporate each MCSC to review 20 candidates of the 300 sent each quarter for enrollment into the PMP. The target completion date for the update is six to nine months following the execution of the contract modification with the TRICARE pharmacy contractor.

In addition, DHA Healthcare Delivery Compliance Inspection program will incorporate updated DHA Pharmacy Operations Division compliance guidance to Military Health System Prescription Monitoring Program Defense Health Agency Administrative Instruction Number 6010.02 dated October 15, 2021, which includes standard Prescription Monitoring Program process and review requirements which will apply to all DoD military medical treatment facilities. The target completion date is September 30, 2026, in accordance with the proposed incremental implementation plan of the overarching DHA Healthcare Delivery Compliance Program.

RECOMMENDATION 2.c: The DoD OIG recommended the Defense Health Agency Director to implement procedures to review DoD medical treatment facility and Managed Care Support Contractor compliance with the Prescription Monitoring Program requirements in Defense Health Agency Instructions and the TRICARE Operations Manual.

DHA RESPONSE: DHA non-concurs with this recommendation. The MCSCs have an existing process in place based upon the requirements of the TRICARE Operations Manual (TOM) to perform a medical review of approximately 100 provider charts per quarter and evaluate those charts against industry standards of care. If the provider is felt to be outside of the standard of care, education and training is provided to the provider and then a follow-up review of additional charts is done to ensure that corrections are implemented. In addition to education/training, appropriate referrals to the contractors' Quality and/or Program Integrity departments will be made if there are concerns of a clinical variance warranting further

Defense Health Agency (cont'd)

review and investigation. These medical reviews of provider prescribing practices include cross referencing the beneficiary PMP program managed by the pharmacy contractor (Express Scripts, Inc.), which identifies and manages the benefits of at-risk beneficiaries.

TRICARE Health Plan (THP) subject matter experts (SMEs) provide ongoing oversight and monitoring of the MCSCs PMP Program(s) including:

1. Quarterly MCSC presentations
2. Review of Quarterly Provider PMP/Q180 report which describes:
 - a. Medical review
 - b. Determination & action:
 - (1) No action (meaning that the case meets standard of care)
 - (2) Intervention
 - (a) Intervention plan with education only
 - (b) Intervention plan with escalation
 - i. Potential Quality Issue
 - ii. Potential Fraud or Abuse
 - (3) Further monitoring needed
 - (4) Not reviewed
 - c. Samples of education materials
3. During instances where the THP SMEs are concerned about the MCSC's findings, THP will connect with the MCSC on the finding in question.

RECOMMENDATION 3.a: The DoD OIG recommended the Defense Health Agency Director review the 10 beneficiaries with insufficient medical documentation to determine whether providers followed or met Federal and DoD opioid safety recommendations and requirements and justified a medical need to provide the high level of opioid dosages and determine whether the beneficiaries need additional medical assistance. In instances where providers cannot justify a medical need to not follow or meet recommendations and requirements, hold the providers accountable for non-compliance with requirements and review instances where they did not follow recommendations, while also reviewing a broader sample of those providers' beneficiaries to identify additional non-compliance.

DHA RESPONSE: DHA concurs and will conduct a review of the 10 beneficiaries' medical documentation, provide feedback to the prescribing providers on opioid health practices, and if applicable, perform an additional review of three medical charts per provider to determine trends in practice.

As previously noted in responses to recommendations 1.a and 1.b, DHA providers are not required to implement 100 percent of all clinical recommendations and best practices contained in the various policies and guidelines. They are allowed and expected to utilize their clinical judgement to align provided care with the patient's treatment goals.

RECOMMENDATION 3.b: The DoD OIG recommended the Defense Health Agency review the Managed Care Support Contractor contracts to determine whether 45 to 60 days is reasonable to provide documentation for at-risk beneficiaries and develop and implement standard operating procedures that outline how personnel should request documentation for at-risk beneficiaries to

Defense Health Agency (cont'd)

ensure compliance with monitoring these beneficiaries.

DHA RESPONSE: DHA non-concurs with this recommendation. The TOM requires the MCSC to “provide responses within 60 days after receiving the TRICARE Pharmacy Program (TPharm) report identifying at-risk beneficiaries.”

The MCSC contracts are performance-based contracts. As such, the government is not able to dictate “how” the MCSCs conduct their business, to include how the MCSC will request documentation nor how they will monitor beneficiaries in one of the above plan/restriction categories as that would be considered a proprietary MCSC best business practice. While this information of “how” MCSCs will fulfill the requirement to request documentation and monitor individual cases is a best business practice, the information may (or may not) be found in the MCSC’s Provider Agreements, which detail the contractual relationship between the MCSC and their Network Providers.

Per TOM chapter 28, section 2, paragraph 2.6 the MCSCs “shall provide responses within 60 days after receiving the TPharm report identifying at-risk beneficiaries.” This means that the contractor must get the medical records, review them, and provide a response listed below within 60 days. Tightening this timeline would be difficult to accomplish without a significant contract modification, with little to no gain. While this Contract Data Requirement List (CDRL) is evaluated by the TPharm program, the MCSCs routinely meet the 60-day requirement to conduct medical reviews and provide documentation for at risk beneficiaries. Per TOM chapter 28, section 2, paragraphs 2.4 and 2.5, the MCSC provides the following items based on the 20 cases they prioritize and review:

1. No action (diagnosis supports utilization)
2. Support plan with restrictions
3. Support plan without restrictions
4. Restrictions only
5. Further monitoring needed
6. Not reviewed

RECOMMENDATION 3.c: The DoD OIG recommended the Defense Health Agency develop and implement a process to obtain medical documentation for DoD beneficiaries from DoD medical treatment facilities and other agencies or health insurance providers to support routine monitoring and medical reviews of at-risk beneficiaries.

DHA RESPONSE: DHA partially concurs with this recommendation. DHA has policies in place for release of information containing Protected Health Information that complies with DoD Instructions related to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and other applicable laws and regulations. Specifically, responsibilities and procedures for obtaining release of medical record information are addressed in Defense Health Agency Procedures Manual 6025.02, “DoD Health Record Lifecycle Management, Volume 1: General Principles, Custody and Control, and Inpatient Records,” (please add date of issuance here) and (what type of issuance is this – please add that here), “DoD Health Record Lifecycle Management, Volume 2: Outpatient Record Components and Dental Records,” (please add date of issuance here).

Defense Health Agency (cont'd)

This OIG recommendation has multiple legal and privacy implications given that DHA has no authority over records generated from outside of the TRICARE program. In addition, DHA designated records set outlines that are part of the government's health records and that are not part of the government's health records. DHA will engage the relevant stakeholders and experts regarding medical records, HIPAA, and the Office of General Counsel to determine to what extent DHA can implement the DoD OIG's recommendation to develop and implement a process to obtain medical documentation for purposes of "routine monitoring and medical reviews of at-risk beneficiaries."

Acronyms and Abbreviations

CDC	Centers for Disease Control and Prevention
DAT	Data Analytics Team
DHA	Defense Health Agency
HHS	Health and Human Services
LOT	Long-Term Opioid Therapy
MDR	Military Health System Data Repository
MHS	Military Health System
MME	Morphine Milligram Equivalent
MSCS	Managed Care Support Contractor
MTF	Medical Treatment Facility
PDMP	Prescription Drug Monitoring Program
PDW	Pharmacy Data Warehouse
PI	Procedural Instruction
PMP	Prescription Monitoring Program
POD	Pharmacy Operations Division
Tpharm	TRICARE Pharmacy
VA	Department of Veterans Affairs



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