Report No. DODIG-2020-048

INSPECTOR GENERAL

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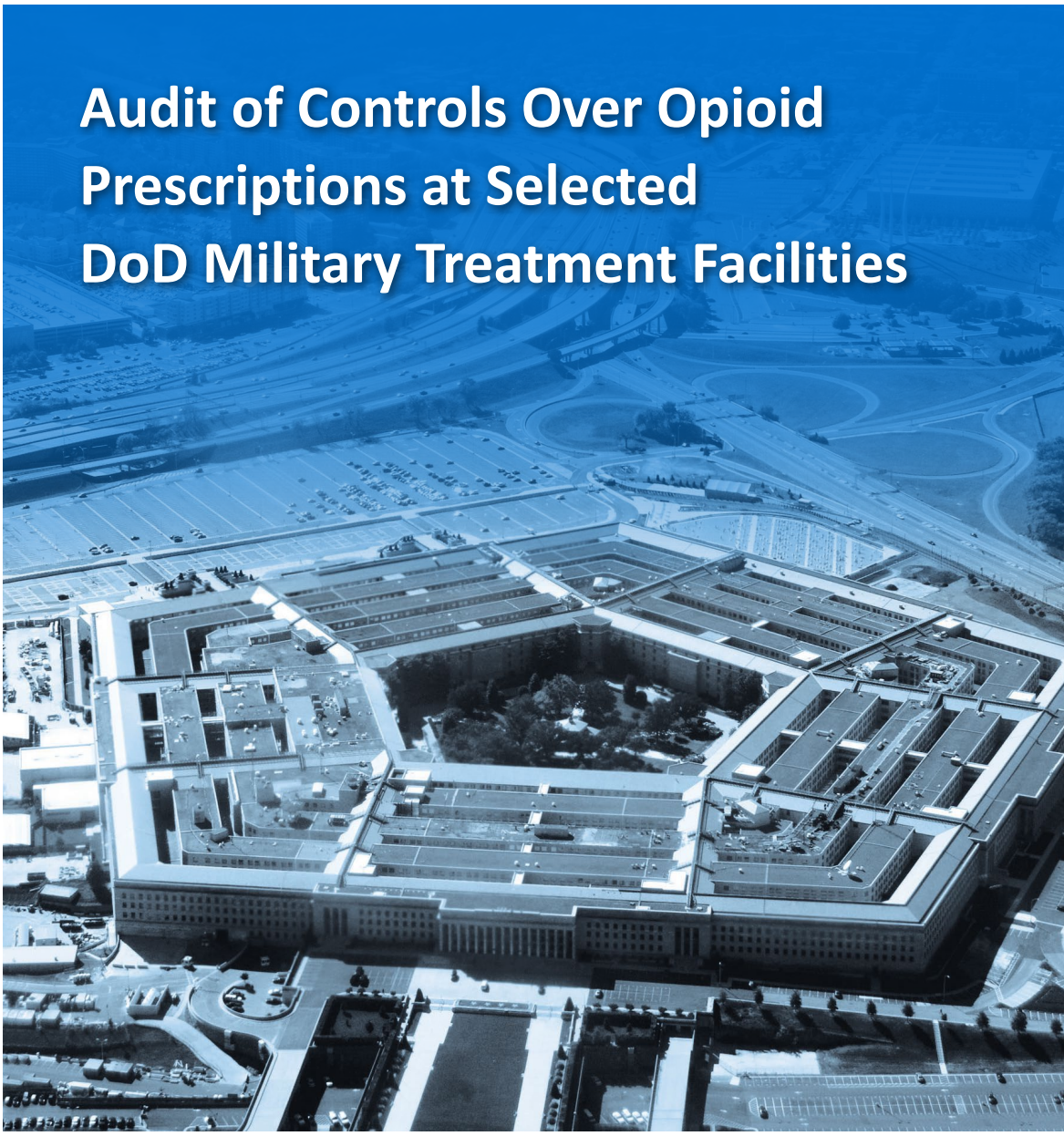
JANUARY 10, 2020

Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities



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INSPECTOR GENERAL
INTEGRITY
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DEPARTMENT OF DEFENSE

Results in Brief

Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities

January 10, 2020

Objective

The objective of this audit was to determine whether selected DoD military treatment facilities (MTFs) overprescribed opioids for DoD beneficiaries. DoD beneficiaries are active duty service members, retirees, and eligible family members who receive health care at MTFs, which the Defense Health Agency (DHA) and the Surgeons General of the Military Departments oversee.

In this audit, we focused on specific examples of beneficiaries who received opioids from 2015 to 2017 at Madigan Army Medical Center (MAMC) in Joint Base Lewis–McChord, Washington; Naval Medical Center Portsmouth (NMCP) in Portsmouth, Virginia; and Joint Base Elmendorf-Richardson (JBER) Hospital in Anchorage, Alaska.

Background

Opioids are a class of drugs that includes the illegal drug heroin; synthetic opioids, such as fentanyl; and legally prescribed pain relievers, such as oxycodone, hydrocodone, and morphine. Opioid pain relievers are generally safe when taken for a short time and as prescribed by a doctor; however, because they produce euphoria in addition to pain relief, they are more likely to be misused (taken in higher doses than prescribed or without a doctor's prescription). Regular use—even as prescribed by a doctor—can lead to dependence and, when misused, opioid pain relievers can lead to addiction, overdose incidents, and death. Prescriptions for

Background (cont'd)

controlled substances, like opioids, must be issued for a legitimate medical purpose by health care providers acting in the usual course of their professional practice.

The Centers for Disease Control and Prevention (CDC) published a guideline for prescribing opioids to beneficiaries with chronic pain. The guideline is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. According to the CDC, opioid use disorder is a "problematic pattern of opioid use that causes significant impairment or distress." The CDC guideline states that to prevent this disorder, providers prescribing opioids should: (1) prescribe the lowest effective dosage; (2) carefully reassess evidence of individual benefits and risks when considering increasing dosage to more than 50 morphine milligram equivalents (MME) per day; and (3) avoid increasing dosage to more than 90 MME per day or carefully justify a decision to adjust the dosage to greater than 90 MME per day.

In addition, the Department of Veterans Affairs (VA)/DoD "Clinical Practice Guideline for Opioid Therapy for Chronic Pain" recommends against prescribing opioid doses over 90 MME per day to treat chronic pain. Beneficiaries who are prescribed higher doses of opioids are at higher risk for opioid overdose and overdose death. The VA/DoD guideline recommends that, for beneficiaries prescribed doses equal to or over 90 MME per day, the provider evaluate the beneficiary for tapering to a reduced dose or to discontinue use of the opioid.

DoD guidance states that 90 days of continuous opioid therapy with no greater than a 30-day break in use is considered long-term opioid therapy. Beneficiaries prescribed long-term opioid therapy are also at a higher risk for opioid-related complications, such as overdose or addiction.

Results in Brief

Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities

Finding

By examining patient records, we identified examples of beneficiaries at the three MTFs we reviewed who may have been overprescribed opioids from 2015 through 2017. For example, a beneficiary received an average of 450 MME per day for 16 months, which is five times the CDC's recommended maximum dose of 90 MME that chronic pain beneficiaries should avoid.

We concluded that MTFs potentially overprescribed opioids from 2015 through 2017 because the DHA and Military Departments did not have policies and processes in place to identify and monitor beneficiaries who were prescribed over 90 MME per day. In December 2017, the DoD began implementing tools that are expected to help the DoD to identify and monitor beneficiaries who receive prescriptions that deviate from VA/DoD and CDC opioid clinical practice guidance, such as beneficiaries who receive opioids for more than 90 days or are prescribed opioids at or above 90 MME per day. In June 2018, the DHA issued a procedural instruction that requires the DoD to monitor the percentage of beneficiaries who are prescribed more than 90 MME per day and the beneficiaries receiving long-term opioid therapy.

However, the staff at the MTFs we visited did not prevent providers from prescribing unusually high doses of opioids. For example, at one MTF we visited, a pharmacist stated that many of the beneficiaries received an unusual amount of opioids, but the pharmacist would not acknowledge that providers overprescribed opioids to their beneficiaries. At another MTF we visited, a pharmacist stated that "there is not a will" to stop some beneficiaries from receiving their opioid medications, and a physician stated that it was a professional courtesy among physicians not to criticize how other physicians provided services and prescriptions to their beneficiaries. Additionally, MTF officials did not intervene to prevent providers from prescribing unusually high doses of opioids.

We attempted to determine how many beneficiaries received an opioid prescription written by MTF providers with a dose greater than the CDC guideline of 90 MME per day for calendar years 2015 through 2018. However, we did not use the analysis in the report because we identified numerous errors and limitations in the DoD Medical Health System Data Repository when we compared the data to the beneficiaries' medical records. As a result, we determined that the data was unreliable for calculating the number of beneficiaries that received opioid prescriptions solely from MTF providers.

The DoD needs to monitor opioid prescriptions and hold providers accountable for not following clinical practice guidance. The DoD should also carefully justify why the provider did not follow the guidance so that beneficiaries identified in this report, and potentially other beneficiaries receiving opioids from MTFs, will not be at increased risk of being overprescribed opioids; developing opioid use disorder; progressing to the use of heroin; and possibly dying of an opioid overdose. Furthermore, overprescribing opioids increases the risk that people other than the prescribed beneficiary will have access to and use the opioids for nonmedical use.

Recommendations

We recommend that the DHA Director continue to monitor MME doses per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids. Also, we recommend that the DHA Director implement controls to ensure that the prescriptions in the Military Health System Data Repository exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid form are accurate and consistent among all systems.

Results in Brief

Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities

Management Comments and Our Response

The DHA Director agreed with the recommendation to continue to monitor MME doses per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids. The DHA stated that it has already implemented solutions to the findings in the report. Additionally, the DHA and Military Departments will continue to strengthen efforts to identify, monitor, and intervene in patients with increased health risks from any appropriate use of opioids while working to develop increased capacity to provide non-pharmacologic pain treatments at MTFs.

Comments from the Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides documentation to support that the DHA is able to identify unusually high opioid prescriptions, and holds providers accountable for those prescriptions, if appropriate.

The DHA Director partially agreed with the recommendation to implement controls to ensure that the prescriptions in the Military Health System Data Repository (MDR) exist and that the dispense date and metric quantity field for opioid prescriptions in liquid form are accurate and consistent among all systems. The Director stated that the DHA has internal controls to ensure that data on prescriptions in the MDR exist and are accurate. The Director also stated that a method exists to identify and separate prescription data from MTF and TRICARE providers, and is not an error in the validity of the MDR system. The future use of the new Military Health System (MHS) GENESIS Electronic Health Record system will significantly improve the data quality for prescriptions and the standardization of the metric quantity field for liquid opioid prescriptions.

Comments from the Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the Director provides documentation to support that the MHS GENESIS system has improved the data quality for prescriptions and the standardization of the metrics quantity field for liquid opioid prescriptions.

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

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Director, DHA	None	1.a, 1.b	None

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

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

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

January 10, 2020

MEMORANDUM FOR DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities (Report No. DODIG-2020-048)

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.

You agreed with one recommendation and partially agreed with another recommendation. We consider both recommendations resolved because the response and actions described by you met the intent of our recommendations. Therefore, the two recommendations that were addressed are considered resolved and open. As described in the Recommendations, Management Comments, and Our Response section of this report, the recommendations may be closed when we receive adequate documentation showing that all agreed-upon actions to implement the recommendations have been completed. Therefore, please provide us your response concerning specific actions in process or completed on the recommendations for these actions in your comments to the draft report. Your response should be sent to followup@dodig.mil.

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

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

Contents

Introduction

Objective

We determined whether selected DoD military treatment facilities (MTFs) overprescribed opioids for DoD beneficiaries. In the report, we focused on specific examples of beneficiaries who received opioids from 2015 to 2017 at Madigan Army Medical Center (MAMC) in Joint Base Lewis-McChord, Washington; Naval Medical Center Portsmouth (NMCP) in Portsmouth, Virginia; and Joint Base Elmendorf-Richardson (JBER) Hospital in Anchorage, Alaska. See the Appendix for the scope and methodology.

Background

Opioids

According to the National Institute on Drug Abuse, opioids are a class of drugs that includes the illegal drug heroin; synthetic opioids, such as fentanyl; and legally prescribed pain relievers, such as oxycodone, hydrocodone, and morphine. Opioid pain relievers are generally safe when taken for a short time and as prescribed by a doctor. However, because they produce euphoria in addition to pain relief, they can be misused (taken in higher doses than prescribed, or taken without a doctor's prescription).

Regular use—even as prescribed by a doctor—can lead to dependence and, when misused, opioid pain relievers can lead to addiction, overdose incidents, and death. The most common use for opioids is to treat acute pain. However, since the 1990s, opioids have been increasingly used to treat chronic pain, despite sparse evidence to support the effectiveness of long-term use. Some beneficiaries experience a worsening of their pain or increased sensitivity to pain as a result of opioid therapy, a phenomenon known as hyperalgesia.

Misuse of prescription drugs is described as taking a medication in a manner or dose other than prescribed, such as self-medicating for pain by using a past opioid prescription received legitimately for a prior injury; using someone else's prescribed medication, even if for a legitimate medical complaint (this would be considered transfer of a controlled substance); 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 a substance use disorder. This disorder develops when continued misuse of the drug changes the 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. The Centers for Disease Control and Prevention (CDC) states that, in 2017, opioids were involved in 47,600 overdose deaths, as of June 2019.[1]

Federal Law and Other Guidance on Prescribing Opioids to DoD Beneficiaries

The Controlled Substances Act

In 1970, the Controlled Substances Act created five drug schedules, or classifications, that group drugs based on risk of abuse or harm.[2] Schedule I drugs are considered unsafe for use, even under medical supervision. Schedule II drugs are defined as drugs with a high potential for abuse, with abuse potentially leading to severe psychological or physical dependence. These drugs are considered dangerous. Opioids classified as Schedule II drugs include hydrocodone, oxycodone, morphine, fentanyl, and many others. Other opioids classified as Schedule III and Schedule IV drugs, such as Tramadol (Schedule IV), are considered to have a lower potential for abuse and a lower risk of dependence than Schedule I and II drugs. Prescriptions for controlled substances, like opioids, must be issued for a legitimate medical purpose by practitioners acting in the usual course of their professional practice.[3]

Federal Guidance for Prescribing Opioids

The CDC published a guideline for prescribing opioids to beneficiaries with chronic pain. The guideline is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. According to the CDC, opioid use disorder is a "problematic pattern of opioid use that causes significant impairment or distress."[4] The guideline is not intended for beneficiaries who are in active cancer treatment, palliative care, or end-of-life care. To prevent this disorder, the CDC provided guidelines over the prescribing of opioids, as shown in Figure 1.

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[1] The CDC is one of the major operating components of the Department of Health and Human Services. The CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States.

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

[3] Title 21, Code of Federal Regulations, section 1306.04, Purpose of issue of prescription, states in part: "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rest with the pharmacist who fills the prescription."

[4] CDC definition of Opioid Use Disorder, "Prevent Opioid Use Disorder," see www.cdc.gov/drugoverdose/prevention/opioid-use-disorder.html.

Figure 1. CDC Recommendations for Opioids

Source: The CDC.

In addition, the CDC guideline states that providers should evaluate the potential benefits and harm of chronic pain opioid therapy with the beneficiary within 1 to 4 weeks of starting opioid treatment or escalating the dose and again at least every 3 months, if not more frequently. If the benefits do not outweigh the potential harm of continued opioid therapy, clinicians should optimize other therapies and work with beneficiaries to taper opioids to lower dosages or to taper and discontinue opioids.

The Department of Veterans Affairs (VA)/ DoD "Clinical Practice Guideline for Opioid Therapy for Chronic Pain" also recommends against prescribing opioid doses over 90 MME per day to treat chronic pain. Beneficiaries prescribed higher doses of opioids are at higher risk for opioid overdose and overdose death. For example, a Veterans Health Administration study of beneficiaries with chronic pain found that those who died of opioid overdoses were prescribed an average of 98 MME per day, while others who did not die from opioid overdose were prescribed an average of 48 MME per day. The VA/DoD guideline recommends that the provider evaluate the beneficiary for tapering to a reduced dose or to discontinue use of the opioid if the beneficiary was prescribed doses equal to or over 90 MME per day.[5]

Veterans Health Administration study of beneficiaries with chronic pain found that those who died of opioid overdoses were prescribed an average of 98 MME per day, while others who did not die from opioid overdose were prescribed an average of 48 MME per day.

[5] VA/DoD "Clinical Practice Guideline for Opioid Therapy for Chronic Pain," Version 3.0 – 2017

DoD guidance states that 90 days of continuous opioid therapy with no greater than a 30-day break in use is considered long-term opioid therapy. Beneficiaries prescribed long-term opioid therapy are also at a higher risk for opioid-related complications, such as overdose or addiction.[6]

Opioids Prescribed by Military Treatment Facilities

DoD beneficiaries—active duty service members, retirees, and eligible family members—can receive health care at military hospitals and clinics, also known as military treatment facilities (MTFs), located on military installations around the world. The Defense Health Agency (DHA) and the Surgeons General of the Military Departments oversee the MTFs. The National Defense Authorization Act for FY 2017 mandated that by October 1, 2018, the DHA would be responsible for the administration of all military medical treatment facilities. In a June 2018 report to Congress, the DoD proposed a phased approach to transition, citing the scope of the changes required by law. The National Defense Authorization Act for FY 2019 amended the original deadline for full transition from October 1, 2018, to September 30, 2021, aligning with the DoD's proposed timeline. Under the phased approach, the Military Departments transferred authority, direction, and control of eight military medical treatment facilities to the DHA on October 1, 2018. The DHA assumed control of all MTFs in the continental United States on October 1, 2019, but will rely on direct support from the Military Medical Departments until the DHA's management structure is fully operational.

Review of Internal Controls

DoD Instruction 5010.40 requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls. We identified internal control weaknesses with the prescription of opioids to DoD beneficiaries at MTFs. Specifically, the DHA and Military Departments did not identify and monitor those beneficiaries prescribed over 90 MME per day from 2015 to 2017. However, in December 2017, the DoD began implementing monitoring tools to help the DoD to identify and monitor for unusual opioid prescriptions. We will provide a copy of the report to the senior official responsible for internal controls in the DHA and Military Departments.

[6] DHA Procedural Instruction 6025.04, "Pain Management and Opioid Safety in the Military Health System," June 8, 2018.

Finding

Selected Military Treatment Facilities Potentially Overprescribed Opioids to Beneficiaries

By examining patient records, we identified examples of beneficiaries at the three MTFs we reviewed, who may have been overprescribed opioids during 2015, 2016, and 2017. For example, one beneficiary received an average of 450 MME per day for 16 months, which is five times the CDC recommended maximum dose of 90 MME that chronic pain beneficiaries should avoid.

MTFs potentially overprescribed opioids from 2015 through 2017 because the DHA and Military Departments did not have policies and processes in place to identify and monitor beneficiaries who were prescribed over 90 MME per day. In December 2017, the DoD began implementing tools that are expected to help the DoD to identify and monitor beneficiaries who receive prescriptions that deviate from VA/DoD and CDC opioid clinical practice guidance, such as beneficiaries who receive opioids for more than 90 days or are prescribed opioids at or above 90 MME per day. In June 2018, the DHA issued a procedural instruction that requires the DoD to monitor the percentage of beneficiaries who are prescribed more than 90 MME per day and the beneficiaries receiving long-term opioid therapy.

However, the staff at the MTFs we visited did not prevent providers from prescribing unusually high doses of opioids. For example, at one MTF we visited, a pharmacist stated that many of the beneficiaries received an unusual amount of opioids, but the pharmacist would not acknowledge that the providers overprescribed opioids to their beneficiaries. At another MTF we visited, a pharmacist stated that "there is not a will" to stop some beneficiaries from receiving their opioid medications, and a physician stated that it was a professional courtesy among physicians not to criticize how other physicians provided services and prescriptions to their beneficiaries. Additionally, MTF officials did not intervene to prevent providers from prescribing unusually high doses of opioids.

We attempted to determine how many beneficiaries received an opioid prescription written by MTF providers with a dose greater than the CDC guideline of 90 MME per day for calendar years 2015 through 2018. However, we did not use the analysis in the report because we identified numerous errors and limitations in the DoD Military Health System Data Repository (MDR) when we compared the data to

the beneficiaries' medical records. As a result, we determined that the data was unreliable for the purpose of calculating the number of beneficiaries that received opioid prescriptions solely from MTF providers.

The DoD needs to monitor opioid prescriptions and hold providers accountable for not following clinical practice guidance. The DoD should also carefully justify why the provider did not follow the guidance so that beneficiaries identified in this report, and potentially other beneficiaries receiving opioids from MTFs, will not be at increased risk of being overprescribed opioids; developing opioid use disorder; progressing to the use of heroin; and possibly dying of an opioid overdose. Furthermore, overprescribing opioids increases the risk that people other than the prescribed beneficiary will have access to and use the opioids for nonmedical use.

Three Military Treatment Facilities May Have Overprescribed Opioids

We identified examples at three MTFs where MTF personnel may have overprescribed opioids to beneficiaries who were routinely prescribed over 90 MME per day. We nonstatistically selected 15 beneficiaries—5 beneficiaries from each of the following locations.

- Madigan Army Medical Center (MAMC), Tacoma, Washington
- Naval Medical Center Portsmouth (NMCP), Portsmouth, Virginia
- Joint Base Elmendorf–Richardson Hospital (JBER), Anchorage, Alaska

We selected these 15 beneficiaries because they received a high number of opioid prescriptions while being treated at MTFs from 2015 to 2017 for the treatment of non-cancer chronic pain, such as back and leg pain, and pain caused from prior surgery. These beneficiaries are examples of a larger population of beneficiaries receiving more than the CDC recommended dose of 90 MME per day and beneficiaries who have been identified as receiving long-term opioid therapy consisting of a 90-day supply without a break in treatment longer than 30-days as stated in the DHA's Procedural Instruction 6025.04. Below are six examples of beneficiaries who received an unusually high amount of opioids.[7] Although beneficiaries may receive opioids for legitimate purposes, these high amounts of MME and the length of time the individual was prescribed opioids raise concern.

[7] We focused our reviews on beneficiaries who received opioids in 2015, 2016, and 2017.

Madigan Army Medical Center

From 2015 through 2017, eight providers at MAMC prescribed opioids to a retired military dependent (Beneficiary 1) suffering from non-cancer chronic pain. From May 2016 through September 2017, the beneficiary's provider prescribed five opioid prescriptions per week with an average of 450 MME per day—peaking at 632 MME per day in August 2016—along with prescription sedatives.

The beneficiary's provider prescribed five opioid prescriptions per week with an average of 450 MME per day—peaking at 632 MME per day.

For example, in 2017, the MAMC provider prescribed the beneficiary a daily dose of 532 MME:

- oxycodone, 5 milligrams, 12 pills per day (90 MME per day), 10-day supply;
- oxycodone-acetaminophen, 5 to 325 milligrams, 12 pills per day (90 MME per day), 10-day supply;
- hydromorphone, 4 milligrams, 12 pills per day (192 MME per day), 10-day supply;
- morphine sulfate, 10 milligrams/5 milliliters, 20 milliliters per day (40 MME per day), 10-day supply;
- fentanyl, 50 micrograms, one patch every 3 days (120 MME per day), 15-day supply; and
- zolpidem tartrate (a central nervous system depressant), which when taken with opioids, increases the risk of an overdose.

In 2018, a provider at a different MTF reduced the beneficiary's MME per day to one opioid prescription of 160 MME per day. However, the medical record did not indicate that the reduction of opioids was a result of decreased pain for the beneficiary. We consider the beneficiary receiving more than five times the dose the CDC recommends that chronic pain beneficiaries avoid and another provider at a different MTF significantly reducing the beneficiary's MME per day as an indication that the MAMC providers could have overprescribed opioids. Table 1 shows the total number of units (patches, tablets, or solution) that MAMC providers prescribed to Beneficiary 1 from 2015 through 2017. For instance, Beneficiary 1

received 10,116 oxycodone tablets from MAMC providers in 2017, the equivalent of 210 MME per day (about 28 pills per day at 5 MG each) for oxycodone alone over the course of one year.

Table 1. Opioids Prescribed to Beneficiary 1 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Fentanyl	12 MCG/HR/patch	7	0	25
Fentanyl	25 MCG/HR/patch	6	0	40
Fentanyl	50 MCG/HR/patch	82	153	46
Hydrocodone-Acetaminophen	5-325 MG/tablet	210	2,360	270
Hydromorphone HCL	2 MG/tablet	0	0	1,320
Hydromorphone HCL	4 MG/tablet	2,344	3,660	3,894
Oxycodone HCL	5 MG/tablet	2,160	3,660	5,154
Oxycodone-Acetaminophen	5-325 MG/tablet	3,815	3,660	4,962
Morphine Sulfate	10 MG/5 ML/solution	8,940	5,050	6,210

Source: Military Health System Data Repository.

In another example, from 2015 to 2017, two providers at MAMC prescribed opioids to a retired military dependent (Beneficiary 2) suffering from non-cancer chronic pain. From 2015 through 2017, the beneficiary's provider routinely prescribed the beneficiary 10-day supply of opioids.

For example, in 2017, the MAMC provider prescribed the beneficiary a daily dose of 90 MME:

- oxycodone, 5 milligrams, 6 pills per day (45 MME per day), 10-day supply; and
- oxycodone-acetaminophen, 5 to 325 milligrams, 6 pills per day (45 MME per day), 10-day supply.

During October 2017, the provider wrote to the beneficiary through electronic message that he could not justify lifelong narcotic use to oversight and regulatory agencies. The provider informed the beneficiary of the side effects of opioids, such as hyperalgesia, which is a condition in which opioids increase pain rather than control it. The provider advised the beneficiary that chronic opioid use was "not a good idea." Despite this, the beneficiary insisted on receiving an opioid prescription and the provider wrote a new prescription. We consider a provider not justifying long-term use and continuing to prescribe opioids, after recommending a reduction as an indication that the MAMC provider could have overprescribed opioids. Table 2 shows the total number of units (tablets) that MAMC providers prescribed to Beneficiary 2 from 2015 through 2017. For instance, Beneficiary 2 received 3,450 oxycodone tablets from MAMC providers in 2017, the equivalent of 68 MME per day (about 9 pills per day at 5 MG each) for oxycodone over the course of one year.

The provider wrote to the beneficiary through electronic message that he could not justify lifelong narcotic use to oversight and regulatory agencies. Despite this, the beneficiary insisted on receiving an opioid prescription and the provider wrote a new prescription.

Table 2. Opioids Prescribed to Beneficiary 2 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Tramadol HCL	50 MG/tablet	180	0	0
Oxycodone HCL	5 MG/tablet	1,410	2,270	1,060
Oxycodone-Acetaminophen	5-325 MG/tablet	1,350	2,280	2,390

Source: Military Health System Data Repository.

Naval Medical Center Portsmouth

From 2015 through 2017, nine providers at NMCP prescribed opioids to a dependent of a military retiree (Beneficiary 3) suffering from non-cancer chronic pain. The beneficiary received as much as 864 MME per day through two opioid prescriptions from the NMCP. In the fall of 2014, the NMCP provider wrote in the beneficiary's medical record that the beneficiary's narcotic dose was too high for a primary care physician to prescribe without appropriate safety measures for follow

up and monitoring. The provider referred the beneficiary to a pain management specialist for the third time so that the beneficiary could be monitored and assisted with the high opioid dose.

In 2016, the provider began significantly tapering the beneficiary's dosage. For example, the NMCP provider prescribed the beneficiary a daily dose of 411 MME:

- hydromorphone, 2 milligrams, 12 pills per day (96 MME per day), 14-day supply; and
- oxycodone, 15 milligrams, 14 pills per day (315 MME per day), 14-day supply.

In January 2017, the NMCP provider further reduced the dosage to 403 MME per day. However, medical records did not indicate that the reduction of opioids was a result of decreased pain for the beneficiary. In February 2017, the beneficiary started treatment with a civilian pain management provider and no longer received opioids from the NMCP. We consider the beneficiary routinely receiving 90 MME per day and another NMCP provider significantly reducing the beneficiaries MME per day as an indication that the NMCP providers could have overprescribed opioids. Table 3 shows the total number of units (tablets) that NMCP providers prescribed to Beneficiary 3 from 2015 through 2017. For instance, Beneficiary 3 received 1,456 oxycodone tablets from NMCP providers in 2015, the equivalent of 480 MME per day (about 4 pills per day at 80 MG each) for oxycodone alone over the course of one year.

Table 3. Opioids Prescribed to Beneficiary 3 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Oxycodone HCL	15 MG/tablet	0	588	392
Oxycodone HCL	80 MG/tablet	1,456	1,071	0
Hydromorphone HCL	2 MG/tablet	0	1,008	308
Hydromorphone HCL	8 MG/tablet	3,608	1,846	0

Source: Military Health System Data Repository.

In another example, from 2015 through 2017, 21 providers at the NMCP prescribed opioids to an active duty member (Beneficiary 4) suffering from non-cancer chronic and acute pain. This beneficiary moved from provider to provider (commonly

referred to as "doctor shopping") and obtained multiple prescriptions for narcotics. From 2015 through 2017, the beneficiary received 43 opioid prescriptions from NMCP providers across five different specialties for numerous medical conditions.

In 2016, the beneficiary had surgery at the NMCP. At discharge, the beneficiary received opioid prescriptions totaling 126 MME per day for 8 days, and a prescription for a benzodiazepine, which when taken with opioids, increases the risk of an overdose. Four days after the surgery, the beneficiary was seen at a civilian hospital for a narcotic overdose—the beneficiary tested positive for opioids and benzodiazepines. Following the overdose, the beneficiary had scheduled follow up visits with pain management providers at the NMCP, and the doses were tapered. The beneficiary continued to receive opioids from 2015 through 2017 from multiple NMCP providers. In 2018, the beneficiary received opioids from NMCP dental providers and a different MTF.

We consider the beneficiary receiving more than 90 MME per day, which resulted in a narcotic overdose and the providers prescribing the beneficiary opioids even though the beneficiary showed a pattern of doctor shopping as an indication that the NMCP providers could have overprescribed opioids. Table 4 shows the total number of units (tablets) that NMCP providers prescribed to Beneficiary 4 from 2015 through 2017.

Table 4. Opioids Prescribed to Beneficiary 4 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Hydromorphone HCL	2 MG/tablet	0	763	10
Oxycodone HCL	5 MG/tablet	30	0	36
Oxycodone HCL	10 MG/tablet	0	36	6
Oxycodone HCL	20 MG/tablet	0	21	0
Oxycodone HCL	40 MG/tablet	0	63	0
Oxycodone-Acetaminophen	5-325 MG/tablet	30	0	0
Hydrocodone-Acetaminophen	5-325 MG/tablet	14	40	22

Source: Military Health System Data Repository.

Joint Base Elmendorf-Richardson Hospital

From 2015 through 2017, seven providers at JBER prescribed opioids to a dependent of a military retiree (Beneficiary 5) suffering from non-cancer chronic pain. The beneficiary routinely received two opioid prescriptions every month, typically one for a 30-day supply and another ranging from a 5 to 30-day supply.

For example, in 2015, one JBER provider prescribed the beneficiary a daily dose of 455 MME:

- oxycodone hydrochloride, 80 milligrams, 3 pills per day, (365 MME per day), 23-day supply; and
- oxycodone-acetaminophen, 5-325 milligrams, 12 pills per day, (90 MME per day), 5-day supply

In 2016, a JBER provider wrote in the beneficiary's medical record that the beneficiary was taking more than the U.S. Food and Drug Administration's recommended daily dose of narcotic medication. The beneficiary resisted the provider's recommendation to lower her opioid dosage, stating that she was unable to tolerate a lower dose of medication because it would affect her quality of life. The provider suggested that the beneficiary consider slowly decreasing her dose of narcotic pain medication over time. Despite this, the beneficiary stated that she was not ready to decrease her dosage. The provider did not decrease the beneficiary's dosage because the provider acknowledged that the beneficiary was not ready to decrease her dosage at that time.

Throughout 2016 and 2017, the beneficiary continued to receive at least 390 MME per day. We consider the beneficiary receiving more than four times the 90 MME dose that the CDC recommends providers avoid prescribing and the doctor's acknowledgement that the beneficiary should decrease dosage as an indication that JBER providers could have overprescribed opioids. Table 5 shows the total number of units (tablets) that JBER providers prescribed to Beneficiary 5 from 2015 through 2017. For instance, Beneficiary 5 received 2,450 oxycodone tablets from JBER providers in 2015, the equivalent of 390 MME per day (about 3 pills per day at 80 MG each and about 4 pills per day at 5 MG each) for oxycodone over the course of one year.

Table 5. Opioids Prescribed to Beneficiary 5 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Oxycodone HCL	80 MG/tablet	1,250	1,080	1,080
Oxycodone-Acetaminophen	5-325 MG/tablet	1,200	1,440	1,380

Source: Military Health System Data Repository.

In another example, from 2015 to 2017, 12 providers prescribed opioids to a dependent of a military retiree (Beneficiary 6) suffering from non-cancer chronic pain. In 2015, the beneficiary was dismissed from a civilian pain clinic because the beneficiary violated the terms of the "pain agreement" by receiving narcotic

pain medications from JBER and failing to provide a urine sample to the civilian pain clinic.[8] From 2015 to late 2016, the beneficiary received two 30-day supply prescriptions of oxycodone on the same day, totaling up to 405 MME per day. From late 2016 to 2017, the same provider prescribed the beneficiary three 30-day supply prescriptions of oxycodone monthly that totaled 525 MME per day.

For example, in 2016, one JBER provider prescribed the beneficiary a daily dose of 525 MME, including:

- oxycodone hydrochloride, 40 milligrams, 2 pills per day (120 MME per day), 30-day supply;
- oxycodone hydrochloride, 15 milligrams, 6 pills per day (135 MME per day), 30-day supply; and
- oxycodone hydrochloride, 30 milligrams, 6 pills per day (270 MME per day), 30-day supply.

We consider the beneficiary receiving more than five times the 90 MME dose that the CDC recommends providers avoid prescribing as an indication that the JBER providers could have overprescribed opioids. Table 6 shows the total number of units (tablets) JBER providers prescribed to Beneficiary 6 from 2015 through 2017. For instance, Beneficiary 6 received 4,150 oxycodone tablets from JBER providers in 2016, the equivalent of 392 MME per day (about 11 pills per day at various strengths each) for oxycodone alone over the course of one year.

Table 6. Opioids Prescribed to Beneficiary 6 From 2015 Through 2017

OPIOID MEDICATION	STRENGTH AND UNIT TYPE	NUMBER OF UNITS PRESCRIBED 2015	NUMBER OF UNITS PRESCRIBED 2016	NUMBER OF UNITS PRESCRIBED 2017
Hydrocodone-Acetaminophen	7.5-325 MG/ tablet	0	30	0
Hydrocodone-Acetaminophen	10-325 MG/ tablet	0	0	60
Hydromorphone HCL	2 MG/tablet	0	60	0
Oxycodone	15 MG/tablet	1,255	2,340	2,340
Oxycodone	20 MG/tablet	28	0	0
Oxycodone	40 MG/tablet	28	628	780
Oxycodone HCL	10 MG/tablet	470	42	0
Oxycodone HCL	30 MG/tablet	780	1,140	2,340

Source: Military Health System Data Repository.

[8] A "pain agreement" outlines the conditions under which opioids will be prescribed for pain management and the responsibilities of the patient and the provider in the beneficiary's pain care.

The DHA and Military Departments Did Not Have Tools to Monitor Daily Doses for Beneficiaries Until 2018

In 2015 to 2017, beneficiaries were allowed to receive unusually high amounts of opioids —for years in some cases—because the DHA and the Military Departments did not identify and monitor beneficiaries who received over 90 MME per day. Specifically, the DoD MDR, which is managed by the DHA, did not store MME per day information to allow analysts to easily examine MME per day for beneficiaries. However, in December 2017, according to the DHA and Military Departments officials, they began implementing monitoring tools that are in various stages of development. These tools are expected to allow the DHA and the Military Departments to identify and monitor beneficiaries for unusual opioid prescriptions. The DHA and the Military Departments are implementing the following tools.

- The Opioid Registry is a collaborative, multi-disciplinary effort to support providers, staff, and decision-makers in improving the safety and quality of care of beneficiaries on opioid prescriptions and allows providers at MTFs to run reports, which includes MME per day for a beneficiary.
- Military Health System (MHS) GENESIS remedy tickets have been submitted to establish automatic notifications to providers when opioids are being prescribed. MHS GENESIS is a new electronic health record system being deployed to all MTFs and provides enhanced, secure technology to manage health information.

In addition, the DHA issued a procedural instruction in June 2018 that requires the DoD to monitor beneficiaries for opioid prescriptions that are not following the guidance provided in VA/DoD "Clinical Practice Guideline for Opioid Therapy for Chronic Pain."[9] The DHA also developed the MHS Stepped Care Model to provide guidance, support, and accountability and to assure that the MHS utilizes VA/DoD and CDC clinical practice guidance while optimizing opioid safety. The MHS Stepped Care Model seeks to enable Clinical Communities to provide evidence-based pain management guidelines to effectively treat acute and chronic pain; promote non-pharmacologic treatment; prevent acute pain from becoming chronic; and minimize use of opioids. According to DHA officials, the Enterprise Solutions Board as the authority, approval, and reporting entity will oversee and synchronize the Clinical Communities and Pain Management Clinical Support Services as procedures are implemented, recommend resource prioritization, and

[9] DHA Procedural Instruction 6025.04, "Pain Management and Opioid Safety in the MHS."

monitor clinical improvement efforts. For instance, the DHA procedural instruction requires on a quarterly basis that the Enterprise Solutions Board examine opioid prescription data to monitor:

- beneficiaries who receive prescriptions of more than 90 MME/day;
- dosages for beneficiaries who are on long-term opioid therapy; and
- co-prescription of benzodiazepines and opioids.

Since the DHA is developing monitoring tools, we did not make recommendations to the DHA for additional monitoring tools.

The DHA and Military Departments Opioid Prescriptions Need More Oversight

The staff at the MTFs we visited did not prevent providers from prescribing unusually high doses of opioids. We interviewed pharmacy staff at MAMC, JBER, and NMCP to obtain feedback on selected beneficiaries at their respective MTFs in 2018. A MAMC pharmacist stated that many of the beneficiaries received an unusual amount of opioids, but the pharmacist was not willing to say that MAMC providers overprescribed opioids to their beneficiaries. The MAMC pharmacist stated that a panel of physicians would have to conduct a medical review and determine whether the providers overprescribed opioids to the beneficiaries. In addition, the MAMC pharmacist stated that MAMC pharmacy staff do not have the time to challenge prescriptions that the pharmacy fills. The JBER pharmacist would not state whether he believed that any of the five JBER beneficiaries were overprescribed opioids. The JBER pharmacist stated that "there is not a will" to stop some beneficiaries from receiving their opioid medications. A JBER physician stated that it was a professional courtesy among physicians not to criticize how physicians provided services and prescriptions to their beneficiaries.

A JBER physician stated that it was a professional courtesy among physicians not to criticize how physicians provided services and prescriptions to their beneficiaries.

NMCP officials stated that the opioid prescriptions for the five NMCP beneficiaries were prescribed within guidelines. As a result, we concluded that the MTF staffs we visited did not prevent providers from prescribing unusually high doses of opioids.

In May 2019, DHA officials stated that they implemented opioid prescription monitoring processes with multi-level oversight that included elements, such as monthly oversight of prescribed opioids, and also enabled leadership to detect long-term trends in MHS-wide oversight. The DHA officials stated that the culture of accountability for opioid prescribing at the DHA is to provide oversight

of providers' patterns on a quarterly basis. Additionally, regional and local commanders and directors provide oversight and accountability for pain and opioid management.

According to DHA officials, each MTF has a monthly peer-review system in place that can identify opioid prescribing by providers. The Sole Provider Committee at each MTF has the responsibility of regularly reviewing opioid use data. The MHS Pain Management Clinical Support Service develops and supports the tools necessary for the MHS, regional, and local MTF leadership to oversee opioid prescribing practices. For example, providers who prescribe opioids are required to take Opioid Prescriber Safety Training. Furthermore, the DHA has implemented training for pain management and opioid prescribing practices using the "Stepped Care model" to all MTF primary care providers. This training pertains to the safety of prescribing opioids, referrals and access to specialists, to include offering non-pharmacy approaches to pain management. The DHA indicated that management of providers' practices relating to opioid prescribing is best handled at the MTFs using the Controlled Substance Provider Profile and Opioid Registry.

The DHA's Procedural Instruction on Pain Management and Opioid Safety in the MHS directs the DHA Pharmacy Operations Divisions to notify MTF Commanders and Directors of opioid prescribers who fall outside of VA, DoD, and CDC prescribing practice guidelines. Additionally, the DHA became a part of the National Association of Boards of Pharmacy's Prescription Monitoring Program Interconnect System used by the states and established the MHS prescription drug monitoring program which permits bi-directional sharing of federal Schedule II-V controlled substance dispensing information between state healthcare providers and MTF providers. The purpose of the drug monitoring program is to ensure that beneficiaries' complete controlled substance medication histories are available to providers and pharmacists.

To ensure that beneficiaries are not being overprescribed opioids, the DHA should continue to monitor MME per day by beneficiary, examine data for unusually high opioid prescriptions, and, if appropriate, hold providers accountable for overprescribing opioids.

MDR Data was Unreliable

We attempted to determine how many beneficiaries received an opioid prescription written by MTF providers with a dose greater than the CDC guideline of 90 MME per day for calendar years 2015 through 2018. However, we did not use the analysis in the report because we identified numerous errors and limitations to our analysis in the MDR data when we compared the data to the beneficiaries' medical

records. As a result, we determined that the data was unreliable for the purpose of calculating the number of beneficiaries that received opioid prescriptions from MTF providers.

Specifically, in January 2019, we retrieved data from the MDR for all opioid prescriptions that were listed as dispensed from MTF pharmacies from 2015 to 2018. To test the reliability of the data, we compared the relevant MDR data fields to the Composite Health Care System (CHCS) supporting documentation for 335 randomly selected opioid prescriptions recorded as dispensed. CHCS serves as the DoD's electronic health record. It also enables DoD providers to document patient health information and history, electronically order laboratory and radiology tests and services, retrieve test results, and order and prescribe medications. Additionally, we examined the 335 prescriptions recorded as to determine whether the prescription came from a TRICARE provider or an MTF provider.

Based on our review of the MDR data, we determined that the data had too many errors or limitations to our analysis to be reliable for our report. For instance, we identified the following types of errors or limitations to our analysis.

1. The CHCS records had no data on the prescriptions for 9 of 335 prescriptions (2.7 percent). For example, the MDR shows a beneficiary was prescribed and dispensed an opioid on April 12, 2018; however, the CHCS record did not have any information about that MDR prescription. Therefore, the beneficiaries may not have received the opioid prescription and the calculations for number of days on opioids and MME per day would be incorrect.
2. The CHCS records did not show dispense dates for 41 of 335 prescriptions (12.1 percent) even though the MDR showed the prescriptions as dispensed. For example, the MDR showed a prescription dispensed on December 18, 2015; however, the CHCS record showed the prescription transmitted through the system but not dispensed. Therefore, the beneficiaries may not have received the opioid and the calculations for number of days on opioids and MME per day would be incorrect.
3. The CHCS records showed different dispense dates for the prescriptions than the MDR for 54 of 335 prescriptions (16.1 percent). For example, the MDR showed the dispense date for one prescription as December 16, 2017, but the dispense date in the CHCS records was 3 days later on December 19, 2017. Therefore, the MME calculations for number of days on opioids and MME per day would be incorrect.
4. The opioid prescription was written by a TRICARE provider (non-MTF provider), but was dispensed by an MTF pharmacy for at least 73 of 335 prescriptions (21.8 percent). For example, the beneficiary was prescribed an opioid from a civilian provider in San Antonio, Texas,

but went to Lackland Air Force Base Satellite Pharmacy to receive the opioid. We did not consider this an error in the MDR data because the MTF pharmacy actually dispensed the prescription. However, it limited our analysis because our audit objective was to determine whether MTF providers overprescribed opioids, and TRICARE providers actually prescribed these opioids. As a result, we could not isolate the opioid prescriptions written by only MTF providers.

5. The amounts of the liquid opioid prescriptions in the MDR were incorrect for 9 of 335 prescriptions (2.7 percent). For example, according to the MDR, one beneficiary received 29,500 metric quantity of liquid hydrocodone for a 6-day supply. According to the beneficiary's medical record and the dispensing pharmacy records, the beneficiary was only prescribed 250 milliliters of hydrocodone. In another example, the MDR showed a "1" in the metric quantity, which is most likely referring to 1 bottle. Therefore, the MME calculation would be incorrect if we relied on the MDR data.

Table 7 shows the summary of errors of the 335 data sample.

Table 7. Data Sample Summary of Errors

	No CHCS Information	Not Dispensed	Dispense Date Error	TRICARE Provider	Wrong Amount of Milliliters	Total Errors	No. of Prescriptions w/ Errors
Overall No. of Errors	9	41	54	73	9	186	152
Overall Error Rate	**2.7%**	**12.2%**	**16.1%**	**21.8%**	**2.7%**	**55.5%**	**45.4%**

Source: The DoD OIG.

As a result of these errors and limitations to our analysis, we determined that the data was unreliable for the purpose of showing (1) the number of opioid prescriptions prescribed by MTF providers to DoD beneficiaries, (2) the number of DoD beneficiaries on long-term opioid therapy, and (3) the number of DoD beneficiaries that were prescribed and dispensed 90 or more MME/day by MTF providers.

The errors we identified in the MDR for opioid prescriptions could negatively affect the DHA's ability to track MME per day for beneficiaries and identify those beneficiaries prescribed and dispensed over 90 MME per day. The errors we identified related to CHCS not containing complete information on prescriptions, incorrect dispense dates, and inaccurate liquid quantities could significantly affect calculations used to determine if patients are potentially overprescribed opioids. The DHA Director should implement controls to ensure the prescriptions

in the MDR exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid form in the MDR are accurate and consistent among all systems.

Conclusion

The DoD needs to monitor opioid prescriptions and hold providers accountable for not following clinical practice guidance. The DoD should also carefully justify why the provider did not follow the guidance so that beneficiaries identified in this report, and potentially other beneficiaries receiving opioids from MTFs, will not be at increased risk of being overprescribed opioids; developing opioid use disorder; progressing to the use of heroin; and possibly dying of an opioid overdose. Furthermore, overprescribing opioids increases the risk that people other than the prescribed beneficiary will have access to and use the opioids for nonmedical use.

Management Comments on the Finding and Our Response

Defense Health Agency Comments

The DHA Director disagreed with some of the findings in the report. The DHA Director was concerned that the concept of overprescribing adopted by the DoD OIG team was based on a misinterpretation of the CDC guidelines and lack of familiarity with the clinical practice of medicine. The Director discussed the '90 MME per day' guidance in the DHA Procedural Instruction on Pain Management and Opioid Safety stating that it is one of many risk factors that prescribers should consider when prescribing opioids and not as a single indicator of overprescribing. The DHA Director stated that the DoD OIG used prescribing data from 2015 through 2017; therefore, it did not reflect DoD actions intended to integrate the recommendations from the CDC Guideline and the VA/DoD "Clinical Practice Guideline for Opioid Therapy for Chronic Pain," issued in 2017, into MHS policies and provider tools.

The Director stated that the data obtained from the MTFs by the DoD OIG was insufficient to determine if the risk of a given dosage exceeded the benefit to individual patients. The Director stated that while the population statistics used by the CDC can identify dosages that increase risk for the entire patient population, they do not identify the risk of a specific dosage of opioids to any individual patient. That individual risk must be an integral part of the patient-provider discussion and active care plan.

The Director stated that tools have been implemented, such as the Opioid Registry, the Prescription Drug Monitoring Program, and the new MHS GENESIS Electronic Health Record. Additionally, providers are required to be trained in opioid prescribing, naloxone has been made widely available across the MHS, and the

use of the sole-prescriber program to limit beneficiaries to a sole provider or sole pharmacy can be used. The Director stated that data indicated that patients prescribed 90 MME or greater per day had continually trended downward since 2016 and as of June 2019, represented a very small percentage of DoD beneficiaries with opioid prescriptions.

The DHA Director stated that the MHS had developed the Opioid Registry in Care Point in 2016 and refined it with a phased rollout in 2017 to improve the safety and quality of care for patients on opioid prescriptions. Also, the Director stated that MHS GENESIS will have automatic notifications to providers to prompt them when opioids are being prescribed.

The Director stated that the DoD OIG team received anecdotal feedback from some staff at the three MTFs visited; however, these individual anecdotes do not represent the safety culture of MHS. The Director stated that the DHA and the Services have taken concrete steps to provide strong oversight on opioid prescriptions, such as the MHS Stepped Care Model, DHA Procedural Instruction 6025.04, and local MTF controls.

The DHA Director also stated that the 'Date Dispensed' field represents the date the label is generated for prescription filling and verification purposes and does not represent the date the patient took physical possession of the medication. These physical dispensing records are only available at the point of service (that is, dispensing pharmacy), and may include additional information such as physical signature logs in which the patients confirms receipt of the medication. Once fully implemented, MHS GENESIS will improve standardization of the dispensing process across the MHS.

Finally, the DHA Director stated that the current methodology exists to identify and separate prescription data from MTF and TRICARE providers, and is not an error, in and of itself, in the validity of the MDR system.

Our Response

We commend the DHA on implementing numerous tools to increase the oversight on prescribing opioids to DoD beneficiaries. However, we disagree that we misinterpreted the CDC guidelines on prescribing opioids. We agree with the Director that the 90 MME calculation is one of many risk factors that prescribers should consider when prescribing opioids. Other factors should be considered to determine the appropriate dosage for the patients. However, we disagree that the MME calculation should not be used as an indicator of providers potentially overprescribing opioids to patients. Most of the beneficiaries we reviewed were prescribed amounts well over 90 MME per day, including one beneficiary at NMCP

that was prescribed as much as 864 MME per day, which was almost 10 times the amount the CDC recommends to avoid. Beneficiaries with high MME doses need to be identified and reviewed for overdose risk and potential tapering.

As stated in the report, we nonstatistically selected 15 beneficiaries—5 beneficiaries from each of the three MTFs we reviewed—who received a high number of opioid prescriptions during 2015, 2016, and 2017. The audit began in March 2018; therefore, we only examined patients from 2015, 2016, and 2017. We discussed the selected beneficiaries with the applicable MTF staff while at the MTF. No officials at MAMC and JBER stated that we were misinterpreting the CDC guidance. NMCP officials stated that the opioid prescriptions for the five NMCP beneficiaries were prescribed within guidelines, even for the beneficiary who overdosed.

In June 2018, we briefed the DHA and Military Department officials on 9 of the 15 beneficiaries we reviewed, which included 5 of the 6 beneficiaries in this report. After the briefing, we provided the DHA with the identifying information of the 9 beneficiaries we reviewed from the MTFs, which would enable the DHA to review the beneficiaries' medical records.

Furthermore, in October 2018, a MAMC official, through the Army Medical Command, provided comments to us stating that MAMC had an opioid epidemic in one of their clinics we reviewed. The MAMC official stated that in the span of a very short period, six providers retired or left. Their patients were re-distributed to other providers and it was quickly noted that some of these patients were routinely prescribed excessive amounts of chronic opioids for conditions in which chronic narcotics were not indicated. The MAMC official stated that in the past there was a commonly accepted practice as noted by a physician from Joint Base Elmendorf-Richardson that "it is a professional courtesy among physicians not to criticize how physicians provide services and prescriptions to their patients."

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Defense Health Agency Director:

a. Continue to monitor morphine milligrams equivalent per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA has already implemented solutions to the findings in the report. The Director stated that the DHA pain management and opioid safety initiatives have resulted in a steady decline in opioid prescribing and increased adoption of risk mitigation strategies. The Director also stated that beyond monitoring patients prescribed high daily doses of opioids, the DHA also monitors patients on long-term opioid therapy with 'Risk Index for Overdose' or 'Serious Opioid-Induced Respiratory Depression' scores greater than 32, and beneficiaries prescribed benzodiazepine who have a higher risk for opioid overdose. The DHA and Military Departments will continue to strengthen efforts to identify, monitor, and intervene in patients with increased health risks from any appropriate use of opioids, while working to develop increased capacity to provide non-pharmacologic pain treatments at MTFs.

Our Response

Comments from the Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides documentation to support that the DHA is able to identify unusually high opioid prescriptions and hold providers accountable for those prescriptions, if appropriate.

b. Implement controls to ensure that prescriptions in the Military Health System Data Repository exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid form in the Military Health System Data Repository are accurate and consistent among all systems.

Defense Health Agency Comments

The DHA Director partially agreed with the recommendation, stating that the DHA has internal controls to ensure that data on prescriptions in the MDR exist and are accurate. The Director stated that current methodology exists to identify and separate prescription data from MTF and TRICARE providers, and is not an error, in and of itself, in the validity of the MDR system. The ability to standardize the definition of 'Date Dispensed' is a limitation experienced in both MTF and civilian pharmacies. The DoD's current system limitations do not allow the capture and transmittal of end-point patient dispensing data into the MDR. Legacy prescription claim fields cannot be adjusted prior to the prescription being completed or expiring. The future use of the MHS GENESIS system will drastically improve the data quality for prescriptions and the standardization of the metric quantity field for liquid opioid prescriptions.

Our Response

Comments from the Director addressed the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides documentation to support that the MHS GENESIS system has improved the data quality for prescriptions and the standardization of the metrics quantity field for liquid opioid prescriptions.

Unsolicited Comments

Department of the Army Comments

Although not required to comment, the Deputy Assistant Secretary of the Army (Military Personnel) agreed with the recommendations. The Army stated that monitoring tools had been developed and were in various implementation stages as of December 2017. The Army's comments provided descriptions of the management tools available to oversee opioid prescriptions to DoD beneficiaries. The Army stated that opioid prescribing guidelines are based on current best evidence. The Army did not comment on the specific Army beneficiaries we identified in this report. For the full text of the Deputy Assistant Secretary's comments, see the Management Comments section of this report.

Our Response

We acknowledge and appreciate the Deputy Assistant Secretary's comments.

Department of the Navy Comments

The Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) partially agreed with the recommendation, stating that the DHA Director should continue to monitor MME per day by beneficiary and make this accessible in all electronic medical record programs to better enable physicians to provide high-quality health care. The Deputy Assistant Secretary also recommended that the DHA Director examine and determine what constitutes unusually high opioid prescriptions before holding providers accountable, determine what is considered "overprescribing," and educate providers. The Deputy Assistant Secretary stated that a numerical cut–off, such as 90 MME, should not be taken in isolation as the only factor in overprescribing. The Deputy Assistant Secretary stated that while the CDC guidelines recommend less than 90 MME for opioid naïve (not previously treated) patients, it is unclear what dosages might be appropriate for non-opioid naïve patients or what might be unusually high for a given disease process. The Deputy Assistant Secretary recommended that the DHA consider using the peer feedback program enacted by the NMCP as a best practice to improve accountability.

The Deputy Assistant Secretary recommended removing the statement, " ... a physician stated that it was a professional courtesy among physicians not to criticize how other physicians provide services and prescriptions to their beneficiaries." The Deputy Assistant Secretary stated that using this sole provider's comment in isolation does not provide a true picture of widespread practices at the time. The Deputy Assistant Secretary stated that there was no clinician or pharmacist subject matter expert on the DoD OIG team, limiting the ability to provide medical interpretation.

The Deputy Assistant Secretary recommended removing the phrase, " ... unusually high doses of opioids." The Deputy Assistant Secretary stated that it is not a medically accepted standard definition and should be removed throughout the report. The Deputy Assistant Secretary stated that the report does not define "unusually high doses of opioids" yet uses this phrase frequently to validate findings.

The Deputy Assistant Secretary recommended that the Beneficiary 3 case be removed as it would be extremely difficult for the DoD OIG team to determine whether care was appropriate without including a physician, clinical pharmacist, nurse or anyone with medical expertise, or to ask for a peer reviewer to review whether or not the care was appropriate. The Deputy Assistant Secretary stated that it is a non-medical assessment of the medical management of a complicated chronic pain patient in which the non-medical assessment in itself is not indicative of medical mismanagement.

The Deputy Assistant Secretary recommended that the Beneficiary 4 case be removed as there was no clinical peer review undertaken. The Deputy Assistant Secretary stated that the following statements from the report are misleading.

> (1) It is unclear that doses of 120 MME would indicate clear over prescribing, as patient was on 90 MME prior to surgery.
>
> (2) Immediately after admission at OSH, patient received even higher doses of MME suggesting he may have been taking medications other than opioids and benzodiazepines prescribed by NMCP.
>
> (3) Doctor shopping might also indicate that the providers were appropriately limiting opioids, and the patient was unhappy.

The Deputy Assistant Secretary recommended that the sentence, "NMCP officials stated that the opioid prescriptions for the five NMCP beneficiaries were prescribed within guidelines" be removed. The Deputy Assistant Secretary stated that before the NMCP staff members made these statements, a peer review of the cases was not conducted nor was an official medical records review performed. The Deputy

Assistant Secretary stated that the pharmacists were asked to make this judgment in isolation of a complete medical or multidisciplinary review of management strategies with these patients.

Our Response

We acknowledge and appreciate the Deputy Assistant Secretary's comments. We did not modify the recommendation to the DHA to add requirements to make the MME-per-day calculation available in all electronic medical records programs because the DHA Director stated that in his comments, various systems and tools will provide the DHA and facility personnel with enhanced abilities to monitor opioid prescribing patterns and MME calculations.

We agree with the Deputy Assistant Secretary that the 90 MME calculation should not be viewed in isolation. Other factors should be considered to determine the appropriate dosage for the patients. However, we used the MME calculation as an indicator of providers potentially overprescribing opioids to patients. Most of the beneficiaries we reviewed were prescribed amounts well over 90 MME per day, including one beneficiary at NMCP that was prescribed as much as 864 MME per day, which was almost 10 times the CDC amount to avoid. While we agree the MME per day should not be taken in isolation, we believe it is an indicator of potential overprescribing.

We did not delete the statements from MTF officials as requested by the Deputy Assistant Secretary. We received several comments, including those statements from pharmacists and other officials at different MTFs, that led us to conclude that MTF personnel did not prevent providers from prescribing unusually high doses of opioids. As such, we included those statements in the report.

We did not delete the phrase "unusually high doses of opioids" in the report. We decided that this phrase provided an appropriate description for the amounts of opioids prescribed to many of the beneficiaries we reviewed. Although beneficiaries may receive opioids for legitimate purposes, these high amounts of MME and the length of time the individual was prescribed opioids raise concern.

We did not delete our discussion of Beneficiary 3 from the report because it is an important example where NMCP providers could have overprescribed opioids to a DoD beneficiary. As stated earlier in the report, the CDC recommends to avoid prescribing over 90 MME per day to patients; however, the NMCP prescribed up to 864 MME per day to the beneficiary, which was almost 10 times that amount. We consider this an unusually high dose of opioids. We conferred with NMCP physicians, pharmacist, and other medical staff to obtain their insight on various

beneficiaries including Beneficiary 3. NMCP personnel and the Deputy Assistant Secretary did not provide evidence to demonstrate that the beneficiary was not overprescribed by NMCP personnel.

We did not delete our discussion of Beneficiary 4 from the report because it is an important example where NMCP providers could have overprescribed opioids to a DoD beneficiary, which may have been a factor in that beneficiary's overdose. Additionally, the patient was prescribed opioids and benzodiazepine, which when taken with opioids, increases the risk of an overdose. The example shows the importance of closely monitoring patient opioid prescription practices as this beneficiary overdosed a few days after receiving the opioid and benzodiazepine prescriptions from NMCP. Finally, we conferred with NMCP physicians, pharmacist, and other medical staff to obtain their insight on various beneficiaries including Beneficiary 4. NMCP personnel and the Deputy Assistant Secretary did not provide evidence to demonstrate that the beneficiary was not overprescribed by NMCP personnel.

Appendix

Scope and Methodology

We conducted this performance audit from March 2018 through November 2019 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.

Review of Documentation, Interviews, and Observations

We obtained MDR data for all Schedule II opioid transactions that were prescribed to beneficiaries at MTFs from January 1, 2015, to December 31, 2017. We nonstatistically selected three MTFs from different Military Departments and examine medical records for beneficiaries who routinely received opioid prescriptions at those MTFs. We selected MAMC, NMCP, and JBER Hospitals because they had a high number of Schedule II opioid prescriptions compared to other MTFs in their respective Military Departments.

We nonstatistically selected 15 beneficiaries—5 beneficiaries from each of the three MTFs we reviewed—who received a high number of opioid prescriptions during 2015, 2016, and 2017. We reviewed the selected beneficiaries' medical records to determine whether the beneficiaries:

- received greater than a 90-day supply of medication or multiple prescriptions on the same fill date that equated to greater than a 90-day supply of pills;
- had office visits corresponding to filled prescriptions; and
- received a prescription for a daily dosage greater than 90 MME which CDC guidelines states to avoid.

We performed site visits to MAMC, NMCP, and JBER Hospital. We interviewed various MTF officials at each site, including MTF commanders and pharmacists, about internal controls for prescribing opioids to beneficiaries. We asked MTF pharmacy officials for feedback regarding five specific beneficiaries who may have been overprescribed opioids by providers at their respective MTFs.

Use of Computer-Processed Data

In January 2019, we used computer processed data from the Military Health System Data Repository (MDR) for all opioid prescriptions that were listed as dispensed from MTF pharmacies from 2015 to 2018. To test the reliability

of the data, we compared the relevant MDR data fields to CHCS supporting documentation to randomly selected 335 opioid transactions. Additionally, we examined the 335 prescriptions to determine whether the prescription came from a TRICARE provider or an MTF provider. Based on our testing, we determined that the data was unreliable for the purpose of showing (1) the number of opioid prescriptions prescribed by MTF providers to DoD beneficiaries, (2) the number of DoD beneficiaries on long-term opioid therapy, and (3) the number of DoD beneficiaries that received 90 or more MME/day by MTF providers. However, the MDR data used for the six beneficiaries in the report was reliable. We tested the MDR data by comparing prescription transactions for the six beneficiaries in the report to their health information.

Use of Technical Assistance

We obtained support from the DoD Office of Inspector General Quantitative Methods Division in developing a random sample of opioid prescriptions to test the reliability of the computer processed data.

Prior Coverage

No prior coverage has been conducted on controls over opioid prescriptions at military treatment facilities during the last 5 years.

Management Comments

Defense Health Agency Director

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Program Director for Audit
Acquisition, Contracting, and Sustainment
U.S. Department of Defense Office of Inspector General
4800 Mark Center Drive
Alexandria, VA 22350-1500

Dear [redacted]:

I am in receipt of the Department of Defense Inspector General's (DoD IG's) Draft Report No. D2018-D000AW-0102.000, "Audit of Controls over Opioid Prescriptions at Selected DoD Military Treatment Facilities (MTFs)." The Defense Health Agency (DHA) concurs with Recommendation (1a): Continue to monitor doses, examine data, hold providers accountable; and partially concurs with Recommendation (1b): Implement controls to ensure accurate Military Health System (MHS) Data Repository (MDR) information.

Please see the attached DHA's response to the audit's findings and recommendations. Specifically, in response to Recommendation (1a), DHA and Military Departments have instituted more rigorous monitoring of opioid prescribing practice since 2018. In response to Recommendation (1b), DHA Pharmacy Operations Division has been standardizing how MTF Pharmacies are entered into MDR and Composite Health Care System. Civilian pharmacies also experience the same data problem due to non-standardized data entry methods. MHS GENESIS, our Electronic Health Records, will help improve prescription data.

Thank you for the opportunity to review and respond to the draft report recommendations. My point of contact for this topic is [redacted]. [redacted] can be reached at [redacted] or via email at [redacted].

FOR RONALD J. PLACE
LTG, MC, USA
Director

Attachment:
DHA Response to DoD OIG Report D2018-D000AW-0102.000

Defense Health Agency Director (cont'd)

Defense Health Agency Response to

Department of Defense Office of Inspector General (DoD OIG) Report: "**Audit of Controls Over Opioid Prescriptions at Selected Military Treatment Facilities**," Project No. D2018-D000AW-0102.000

The Defense Health Agency (DHA) is providing responses to the four overarching findings and the two-part recommendation in the DoD OIG report. The objective of this audit was to determine whether selected DoD military treatment facilities (MTFs) overprescribed opioids for DoD beneficiaries.

The DoD OIG found the following:

Finding #1: Three military medical treatment facilities (MTFs) may have overprescribed opioids.
Finding #2: DHA and Military Departments (MILDEPs) did not have tools to monitor daily doses for beneficiaries until 2018.
Finding #3: DHA's and MILDEPs' opioid prescription processes need more oversight.
Finding #4: Military Health System Data Repository (MDR) data was unreliable.

Specifically, DoD OIG recommends that DHA Director:

a. Continue to monitor morphine milligrams equivalent (MME) per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids.

b. Implement controls to ensure that the prescriptions in the MDR exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid forms in the MDR are accurate and consistent among all systems.

Summary Statement: DHA agrees with Recommendation 1a and partially agrees with Recommendation 1b. The Air Force Surgeon General (SG), Army SG, and Navy SG will provide separate responses to address the specific references in the report to instances of potential "overprescribing" opioids by MTF providers. DHA appreciates the opportunity to provide additional information and context to several of the findings in the report.

Finding #1: Three MTFs may have overprescribed opioids.

DHA Comment:
DHA is concerned that the concept of "overprescribing" adopted by the IG investigators was based on a misinterpretation of the Centers for Disease Control and Prevention (CDC) opioid guidelines and lack of familiarity with the clinical practice of medicine. Although the "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016[1]" recommends avoidance of escalating opioid dosage above 90 MME per day, it does not state that dosages for

[1] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

1

Defense Health Agency Director (cont'd)

patients already taking high dose opioids must be tapered. Indeed, the authors of the CDC opioid guideline[2], the American Academy of Pain Medicine[3] and the U.S. Department of Health and Human Services (HHS)[4] have cautioned against misinterpretation of the guidelines and urged caution with opioid tapering or discontinuation of opioids that is not in the best overall health interests of patients.

While the DHA included the "90 MME per day" guidance in the 2018 Pain Management and Opioid Safety Procedural Instruction, it is one of many risk factors that prescribers are to consider when prescribing opioids and not as a single indicator of "overprescribing." The IG report utilized prescribing data from 2015 to 2017 and therefore did not reflect DoD actions intended to integrate the recommendations from the CDC Guideline and the U.S. Department of Veterans Affairs (VA)-DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain[2] into MHS policies and provider tools.

The data obtained from the MTFs by IG investigators was insufficient to determine if the risk of a given dosage exceeded the benefit to individual patients. While the population statistics used by CDC can identify dosages that increase risk for the entire patient population, it does not identify the risk of a specific dosage of opioids on any individual patient. That individual risk must be an integral part of the patient-provider discussion and active care plan. The IG report identified a particularly complicated patient treated at Madigan Army Medical Center (MAMC) who was already taking high-dose opioids (greater than 90 MME per day) at the time of referral, and was under the specialized care of a physical medicine and rehabilitation specialist with fellowship training in pain medicine. Given the history of opioid treatment and the intense oversight the patient received, it would be incorrect to label this patient as being "overprescribed" opioids.

Current and in development MHS prescriber tools and training arguably exceed the recommendations in the IG report:

1. The Opioid Registry, a patient look-up tool in CarePoint, allows DHA leadership as well as designated facility administrators and providers to view opioid prescribing across the MHS including average MME per prescription. The Prescription Drug Monitoring Program allows the pharmacist to see prescriptions filled by other providers and pharmacies, even in other states. The Army, Navy and Air Force each have comprehensive pain programs that provide oversight and awareness of these tools and provider prescribing practices.

2. MHS GENESIS, DoD's new Electronic Health Record, will be able to alert prescribers when criteria for long-term opioid therapy are met, when there is a current active benzodiazepine

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[2]Dowell D, Haegerich T, Chou R, No short cuts to safer opioid prescribing, NEJM, June 13, 2019.
[3]Kroenke K, Alford DP, Argoff C, et al. Challenges with implementing the Centers for Disease Control and Prevention opioid guideline: a Consensus Panel report. Pain Med 2019; 20:724-735.
[4]HHS Guide for clinicians for the appropriate dosage reduction or discontinuation of long-term opioid analgesics. October 2019.
[5] Department of Veterans Affairs (VA) and Department of Defense (DoD) 2017, VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, accessed 25 November 2019, https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf

2

Defense Health Agency Director (cont'd)

prescription, and the status of "Informed Consent" contract and "Urine Drug Screening" test of patient.

3. Providers are required to be trained in opioid prescribing in compliance with federal, state, and local laws along with Medication –Assisted Treatment (MAT) of Opioids training for the applicable providers. In addition to these opioid safety measures, the MHS has made naloxone, an opioid antagonist to counter the effects of opioid overdose, widely available, the sole prescriber program can be used to limit beneficiaries to a sole provider or a sole pharmacy to avoid multiple prescribers of opioids, and patient informed consent occurs prior to opioids being prescribed.

Lastly, available data indicate that DoD patients who are prescribed opioids at 90 MME per day or greater have been on a continued downward trend since at least 2016 and as of June 2019 represent a very small percentage of DoD beneficiaries with opioid prescriptions: 0.1% for active duty (AD), 0.4% non-AD under 65, and 0.8% for non-AD over 65.

Finding #2: DHA and MILDEPs did not have tools to monitor daily doses for beneficiaries until 2018.

DHA Comment:
Beginning in 2016 and refined with a phased rollout in 2017, MHS developed the Opioid Registry in Care Point to improve the safety and quality of care for patients on opioid prescriptions. The Registry offers stakeholders access to near-real time demographic, clinical, and pharmaceutical data of patients related to opioids such as morphine equivalent daily dosages. High-risk opioids and other medications such as antidepressants, benzodiazepines, and sleep medications, concurrently prescribed with opioids, can be flagged to alert staff of potential fatal overdoses.

Provider utilization of the Opioid Registry is a key component of the MHS Stepped Care Model implementation training program that is preparing Primary Care Pain Champions for all MTFs. In conjunction with the planned deployment of the new electronic health record (MHS GENESIS), detailed remedy tickets have been submitted to establish automatic notifications to providers to prompt them when opioids are being prescribed, for a review of safety issues and other factors to promote most appropriate use.

There are ongoing efforts to improve the coordination and quality of pain-management services. DHA Pharmacy Operations Division (POD) generates aggregated beneficiary data to include, the percentage of beneficiaries who receive prescriptions of more than 90 MME/day, the average MME for beneficiaries who are on long-term opioid therapy, and the percentage of beneficiaries receiving a co-prescription of benzodiazepines. These reports are provided to the DHA Enterprise Solutions Board (ESB) and the Pain Management Clinical Support Service, which have oversight of MHS pain management, for action.

Defense Health Agency Director (cont'd)

Finding #3: DHA's and MILDEPs' opioid prescriptions need more oversight.

DHA Comment:
The DoD OIG evaluation team received anecdotal critical feedback from some staff at the three visited MTFs. However, these individual anecdotes do not represent the safety culture of MHS.

The DHA and Services have taken concrete steps in providing strong oversight on opioid prescriptions. In 2018, DHA started to implement the MHS Stepped Care Model, a standardized and enterprise model of pain management and opioid safety that aligns with High Reliability Organization Operating Model creating conditions for high reliability at the point of care. The Stepped Care Model was considered by the Joint Commission as a potential best practice, it utilizes an interdisciplinary approach to pain management and opioid safety. It also requires the presence of leadership regarding pain management and safe opioid prescribing, provision of non-pharmacologic pain treatments, and monitoring of opioid use to maximize patient safety.

The DHA Procedural Instruction (PI) 6025.04 Pain Management and Opioid Safety in the MHS, published in June 2018, provides guidance on implementation of effective pain management and opioid safety consistent with CDC and VA-DoD guidelines. It provides guidance on opioid prescription limits and requires referral to pain specialists of patients on long-term opioid therapy. It requires all opioid prescribers to be trained on opioid prescribing every 3 years.

Providers are held accountable through peer review and monitoring of opioid prescribing practice by the local MTF leadership. The POD provides on a quarterly the MHS Controlled Substance Provider Profile reports, which are posted on CarePoint, to identify for MTF commanders providers whose opioid prescribing practices may be inconsistent with CDC guideline and VA-DoD CPG on opioid prescribing. The MTF leaders can intervene as necessary with these providers to ensure appropriate opioid prescribing practice. The MTF commanders and directors can determine whether any further training, review, or action regarding these providers is necessary. The POD also provides quarterly aggregate reports to the DHA ESB through the Pain Management Clinical Support Service on the overall opioid prescribing pattern of providers, the percentage of patients on long-term opioid therapy (LOT), and the median MME for LOT population.

Finding #4: MDR data was unreliable.

DHA Comment:
Per the MDR data dictionary, the "Date Dispensed" field represents the date the label was generated for prescription filling and verification purposes and does not represent the date the patient took physical possession of the medication. These physical dispensing records are only available at the point of service (i.e. dispensing pharmacy), and may include additional information such as physical signature logs in which the patients confirms receipt of the medication. Once fully implemented, MHS GENESIS will improve standardization of the dispensing process across the MHS. However, current system limitations prohibit the transmittal of this final end-point dispensing information into the MDR.

Defense Health Agency Director (cont'd)

Current methodology exists to identify and separate prescription data from MTF and TRICARE providers, and is not an error in and of itself in the validity of the MDR system. This was noted by the investigators, but still considered an "error" in evaluating data validity.

An analysis between legacy and MHS GENESIS sites has shown a significant improvement in the validity of dispensing quantities for liquid opioids. Additionally, abnormal quantities are screened for by the pharmacy benefits manager, Express Scripts, Inc. for possible evaluation and referral to the MTF to possible correct invalid prescription claims.

Recommendation 1a:

We recommend that the Defense Health Agency Director: Continue to monitor morphine milligrams equivalent per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids.

DoD Position: Concur

Comment:
DHA has already implemented solutions to the findings in the DoD OIG report as part of the DHA's pain management and opioid safety initiatives. DoD's ongoing efforts to improve pain management and opioid safety have resulted in steadily declining opioid prescribing and increased adoption of risk mitigation strategies. Beyond monitoring patients prescribed high daily doses of opioids, DHA is also monitoring patients on long term opioid therapy, those with Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD) scores greater than 32 and those who are co-prescribed benzodiazepines who have a higher risk for opioid overdose. DHA and MILDEPs will continue to strengthen our efforts to identify, monitor, and intervene in patients with increased health risks from any appropriate use of opioids while working to develop increased capacity to provide non-pharmacologic pain treatments at MTFs.

Recommendation 1b:

We recommend that the Defense Health Agency Director: Implement controls to ensure that the prescriptions in the Military Health System Data Repository exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid forms in the Military Health System Data Repository are accurate and consistent among all systems.

DoD Position: Partially Concur

Comment:

DHA has internal controls to ensure that data on prescriptions in the MDR exist and are accurate. Current methodology exists to identify and separate prescription data from MTF and TRICARE providers, and is not an error in and of itself in the validity of the MDR system as cited by the IG evaluation team.

The ability to standardize the definition of "Date Dispensed" is a limitation experienced both in MTF pharmacies and civilian pharmacies. DoD's current system limitations do not allow the

5

Defense Health Agency Director (cont'd)

capture and transmittal of end-point patient dispensing data into the MDR. Legacy prescription claim fields cannot be adjusted prior to the prescription being completed or expiring.

However, the future enterprise use of MHS GENESIS system will drastically improve the data quality for prescriptions and the standardization of metric quantity field for liquid opioid prescriptions.

6

Deputy Assistant Secretary of the Army (Military Personnel)

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT SECRETARY OF THE ARMY
MANPOWER AND RESERVE AFFAIRS
111 ARMY PENTAGON
WASHINGTON, DC 20310-0111

SAMR-MP

MEMORANDUM FOR U.S. Army Audit Agency, Office of Deputy Auditor General, Forces and Infrastructure Audits, 6000 6th Street, Building 1464, Fort Belvoir, VA 22060-5609

SUBJECT: Draft Report on Controls over Opioid Prescriptions at Selected DOD Military Treatment Facilities (Project Number D2018-000AW-0102.000)

1. Thank you for the opportunity to review and provide a response to the Department of Defense Office of Inspector General (DODIG) Draft Report on Controls over Opioid Prescriptions at Selected DOD Military Treatment Facilities. The Army concurs with DODIG draft report recommendations 1.a. and 1.b.

2. Army comments for the DODIG draft report recommendations, provided by the Army Office of the Surgeon General, are enclosed.

3. The Secretariat point of contact for this response is [redacted].

ANGERS.JEFFREY [redacted] Digitally signed by ANGERS.JEFFREY [redacted] Date: 2019.11.26 15:31:32 -05'00'

Encl

JEFFREY P. ANGERS
Deputy Assistant Secretary of the Army
(Military Personnel)

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042-5140

DASG-CS

25 NOV 2019

MEMORANDUM FOR Assistant Secretary of the Army (Manpower and Reserve Affairs), ATTN: Assistant Deputy for Medical Affairs [redacted] 111 Army Pentagon, Washington, DC 20310-0111

SUBJECT: Reply to DODIG Draft Report, Controls over Opioid Prescriptions at Selected DOD Military Treatment Facilities (Project Number D2018-000AW-0102.000)

1. Thank you for the opportunity to review this draft report. Our comments are enclosed for your consideration in the Army response.

2. Our point of contact is [redacted], Internal Review and Audit Compliance Office, [redacted], or email: [redacted].

FOR THE SURGEON GENERAL:

Encl

RICHARD R. BEAUCHEMIN
Chief of Staff

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

U.S. Army Medical Command (MEDCOM) and
Office of the Surgeon General (OTSG)

Comments on DODIG Draft Report
Controls over Opioid Prescriptions at Selected DOD Military Treatment Facilities
(Project No. D2018-D000AW-0102.000)

RECOMMENDATION 1: Defense Health Agency Director:

a. Continue to monitor morphine milligrams equivalent per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids.

b. Implement controls to ensure that the prescriptions in the Military Health System Data Repository exist and that the dispense date and the metric quantity field for opioid prescriptions in liquid forms in the Military Health System Data Repository are accurate and consistent among all systems.

RESPONSE: Concur. Monitoring tools have been developed and are in various implementation stages since December 2017, as outlined below. These tools allow the Defense Health Agency (DHA) and military medical treatment facilities (MTFs) to fully implement these recommendations.

1. The Opioid Registry/Patient Look-up Tool in CarePoint—specifically, the Opioid Risk and Recommended Clinical Actions (ORRCA) was made available at point of care in December 2017. Training on how to use the ORRCA is being provided during the Military Health System (MHS) Stepped Care Model Implementation Training which began in all MTF locations in January 2019. The Opioid Registry allows facilities and physicians to run a report which includes morphine milligram equivalents (MME) per day. Training on how to use the Opioid Registry for these purposes is being provided during the MHS Stepped Care Model Implementation Training. Interim overview and awareness is being provided by the Army's Comprehensive Pain Program Office. The Army also included the ORRCA in OPORD 19-09 for Pain Management (attached), as well as including Opioid Prescribing Guidelines, Training and Clinical Tools describing the Opioid Registry

2. The MHS Controlled Substance Provider Profile (CSPP) in CarePoint currently allows visibility of the average MME per prescription.

3. MHS GENESIS remedy tickets were submitted by the Comprehensive Pain Program Office to establish automatic notifications to providers when opioids are being prescribed and:

Encl

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

a. The patient meets criteria for long-term opioid therapy (LOT) and prompts the provider to assess the status of Informed Consent and Urine Drug Screen and implement if these items are not completed.

b. The opioid prescription(s) exceed(s) 90 MME per day. The notification then informs the provider to initiate a gradual taper as clinically appropriate or reconsider the current dose.

c. There is a current active benzodiazepine prescription.

MHS GENESIS remedy tickets have also been submitted to notify the provider of the current MHS Opioid Prescribing guidelines for Opioid-Naïve patients.

It is important to note that in the instance of electronic health record (EHR) notifications, clinicians are responsible for evaluating the appropriate application of guidelines to the individual patient clinical situation and documenting the clinical decision making in the EHR. For the legacy EHR, use of the ORRCA at point-of-care is critical to meeting this recommendation.

DHA-PI 6025.04 Pain Management and Opioid Safety requires the Pharmacy Operations Division to inform MTF Commanders and Directors of prescribers who may fall outside the VA-DOD and Centers for Disease Control opioid prescribing clinical practice guidelines. Army OPORD 19-09 includes this reporting requirement.

4. The tools outlined above will allow for full implementation of DODIG's recommendations. The prescribing reports identify variance and drive intervention at the provider level. These interventions may include further education, review, or other actions as deemed necessary.

DHA has been assessing opioid prescribing variance among specific Clinical Communities to identify opportunities for change. The Pain Management Clinical Support Service works with the Clinical Communities to achieve these goals.

Express Script and Managed Care Support contractors work together to monitor opioid prescriptions by identifying patients that may need more oversight of prescription use and reaching out to those patients. In these cases the beneficiary will be offered an evaluation and if indicated, treatment and case management. In addition, the beneficiary may be placed on the Sole Provider Program that limits opioid prescriptions to one provider and/or one pharmacy, limiting the risk of multiple prescriptions. In addition, as part of their contract to provide the purchased care pharmacy benefit, Express-Scripts identifies potential trends in overprescribing of controlled substances. This information is available through DHA Pharmacy Operations Division and to MTFs with affected patients.

Among the initiatives currently available, Medication-Assisted Treatment training is given to designated providers in compliance with Federal, State, and Local laws. Two other initiatives near completion are: (i) standardized informed consent forms for

2

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

patients being initiated on opioid therapy; and (ii) enhancements to clinical urine drug testing for screening and confirmation of controlled or illicit substances for those on long-term opioid therapy.

Opioid prescribing guidelines are based on current best evidence. It is important to stress that clinicians still maintain the responsibility to determine what is best for the individual patient and clinical situation. Opioid safety measures include the above tools, availability of naloxone, sole prescriber program, informed consent, and patient and provider education.

3

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

GENERAL: Opioid safety is a key initiative in providing safe and quality comprehensive pain management. As such, opioid safety is a key priority of the Army Comprehensive Pain Management strategy. Opioids should be prescribed only when necessary, in the lowest effective dose, and for the shortest duration needed. Research shows taking opioids for acute pain is associated with a greater likelihood of long-term opioid use. Further, a greater amount of initial opioid exposure (i.e., higher total dose, longer duration prescription) is associated with greater risks of long-term use, misuse and overdose.

Prescribing providers, known as clinicians throughout the remainder of this document, must review and be familiar with the Department of Veterans Affairs-Department of Defense (VA/DOD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain, February 2017 and the Center for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain, 28 March 2016.

In addition to the VA/DOD and CDC guidelines, clinicians will review and be familiar with the MHS Opioid Prescribing Guidelines as discussed in this annex.

MHS OPIOID PRESCRIBING GUIDELINES for ACUTE PAIN:

1. Definition of Opioid-Naïve Patients: For the purposes of this annex, opioid naïve patients are those who have not received opioids in the 30 days prior to the acute event or surgery.

2. Application of Guidelines: Appropriate variations in practice may occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Clinicians are responsible for evaluating the appropriateness of applying these guidelines in the setting of any particular clinical situation and documenting the clinical decision making in the patient encounter via the electronic health record (EHR).

3. Acute Pain in Uncomplicated, Opioid Naïve Patients:

   a. This category includes post-operative pain from minor outpatient procedures and acute pain episodes from injury not requiring major surgical procedures.

   b. Recommend limiting opioid prescriptions to no more than a 5-day supply of short-acting opioids.

   c. Rarely are renewal prescriptions clinically necessary in these patients. Patients must first be clinically re-evaluated with documentation in the EHR. If a renewal is given, recommend limiting to a 3-day supply of short acting opioids.

C-1

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

4. Post-Operative Pain from Major Procedures:

a. This category includes major procedures expected to produce moderate to severe postoperative pain.

b. Recommend limiting opioid prescriptions to no more than a 10-day supply of short-acting opioids.

c. Renewal prescriptions may be clinically necessary in these patients. Patients must first have a surgical re-evaluation with documentation in the EHR. If a renewal is given, recommend limiting to a 7-day supply.

5. Required Consultations with the Tertiary Level of the Stepped Care Model: Patients who meet the following criteria require consultation with the Interdisciplinary Pain Management Center (IPMC) or with a Pain Management Specialist. Consultation does not imply automatic transfer of care. Consultation may be completed through formal referral to the IPMC; through telephone consultation between the PCM and the the pain sub-specialist; or through guidance gained from the case presentation at the Telementoring for Pain clinics. Consultation guidance should be documented in the electronic health record.

a. Complex post-operative or post-injury patients who are either unable to taper opioid or are increasing opioid use after surgery / procedure / injury.

b. All patients taking over 90 morphine milligram equivalents (MMEs) of opioids daily.

c. All patients meeting the definition of long-term opioid therapy (LOT) which is defined as greater than 90 days of continuous use of opioids in the last six (6) months.

d. Patients who have had greater than six (6) months of pain in one or multiple regions of the body in which improvement in patient function has not been achieved through previous treatment plans.

6. Patients who are not Opioid Naïve: Clinicians should use their best clinical judgment for all patients including those patients who are not opioid-naïve or have other medical or surgical complications (e.g., cancer; terminal conditions).

DOD OPIOID PRESCRIBER SAFETY TRAINING

1. Clinicians who are privileged providers performing clinical duties for at least 0.1 clinical full-time equivalent (FTE) and who prescribe controlled substances, must complete DOD Opioid Prescriber Safety Training (OPST).

C-2

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

2. Training is available online at: http://dhaj7.adobeconnect.com/opioidtraining18/event/registration.html

3. Initial training must be completed by at least 90% of prescribers meeting the above criteria within six (6) months of publication of this order.

4. Refresher training will be completed every three years thereafter.

5. Record of completed training will be documented in the Digital Training Management System (DTMS) at https://dtms.army.mil per local policy. Regional Health Commands will provide quarterly updates by fiscal year (FY) to the CPMP program office on the overall percent of assigned providers who have completed required initial and refresher training as of the current quarter.

STANDARDIZED PATIENT EDUCATION AND INFORMED CONSENT

1. Clinicians should educate patients receiving an opioid prescription on the risks and benefits of the medication.

2. Clinicians must use a written informed consent for patients who:

a. Meet the definition of long-term opioid therapy (LOT) which is defined as greater than 90 days of continuous use of opioids in the last six (6) months.

b. Are at risk for opioid use disorder.

c. Have had opioid-related adverse events.

d. Are receiving renewals of opioid prescriptions.

** Patients meeting any of the above criteria, need to have an updated informed consent on file annually or on annual basis.

3. Clinicians should continue to use current facility informed consent and education products for opioid therapy until DHA publishes the standardized informed consent and patient education for opioid therapy form(s).

4. The MHS Standardized Informed Consent and Patient Education for Opioid Therapy forms will be adopted into clinical workflows within 120 days of publication of the standardized forms. As of the publication of this order, the standardized form is not available.

C-3

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

OPIOID REGISTRY AND OPIOID PATIENT LOOK UP TOOL – CAREPOINT

1. To assist clinicians and clinical staff with familiarization of the CarePoint Opioid Registry and Patient Look Up Tool, online webinars are available at:

a. The opioid registry is accessed at: https://carepoint.health.mil/

b. Registry training webinar https://dha-cei.adobeconnect.com/p30ij5f2coq/

c. Opioid and pharmacy training: https://dha-cei.adobeconnect.com/mhsphp/

d. Providers must first verify the account with the assigned Composite Health Care System CHCS username and password in order to process patient level data in the Military Health System Population Health Portal (MHSPHP).

(1) Verification takes places in the profile settings.

(2) Verify the profile name and contact information.

(3) Clinic verify next to the PHI Verification.

(4) Enter the assigned MTF, then clinic Validate, then **Save**.

(5) Close the browser window and reopen a new one to refresh the system.

(6) This step only needs to be completed the first time a provider accesses MHSPHP.

2. CarePoint Opioid Registry: This Opioid Registry provides information pertaining to a specified population of patients and can be used at the clinic or MTF level to assess population opioid safety data.

a. Steps for accessing the opioid registry in CarePoint information portal:

(1) Select Apps on the blue menu at the top of the monitor screen.

(2) Scroll and select the icon for MHSPHP (Military Health System Population Health Portlets) – suggest clinicians select "Favorite" at this point to add in finding app easier in the future.

(3) Expand the Clinical Registries at the left of the screen.

(4) Scroll down and select on **Opioid Management.**

C-4

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

b. Information available in the opioid registry includes:

(1) Morphine equivalent daily dose (MEDD) data for current month, previous month, max in last 12 months and latest month with MEDD. This only includes tablets (no liquid, injectable or inhaled opioids).

(2) Opioid risks: active benzodiazepine, active opioid, high-risk opioid, concurrent opioid-benzo, current methadone Rx, current long-acting Rx, current fentanyl patch Rx.

(3) Information on opioid or benzo dispensed (e.g., date and prescription)

(4) Co-morbidities

(5) Appointments and ER visits

(6) Date of Urine Drug Screening

(7) Prescription management program status (formerly known as "sole provider" program). Levels of restriction:

(a) Type I - Restrict all medication to specific pharmacy and/or prescriber (may be more than one pharmacy, prescriber).

(b) Type II - Restrict controlled medication to specific pharmacy and/or prescriber (may be more than one pharmacy, prescriber).

(c) Type III - Exclude controlled medication or specific non-controlled medication at mail order or retail pharmacy.

c. The registry information can be filtered by Defense Medical Information System DMIS by choosing the filter option from the tool bar and then further filtered within that filter option by Clinic (Provider Group Selection) or by provider (PCM Name Selection).

d. Summary reports for all the conditions set in the filters listed in c. above can be accessed from Opioid Management screen by selecting the green puzzle icon from the tool bar and scrolling down and selecting from the following:

(1) Opioid Patient Summary.

(2) Opioid Risk and Recommended Clinical Actions (ORRCA) – see figure 1.

(3) Opioids Appointment Summary Report.

C-5

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM

3. CarePoint Patient Look-Up Tool for Opioid Safety: This tool is useful at the point of care to access individual patient summary information related to opioid safety. The Opioid Risk and Recommended Clinical Action (ORRCA) is a report that displays opioid safety metrics consistent with the VA/DOD and CDC CPGs cited as references (i) and (j) cited in the corresponding OPORD for this ANNEX. Clinicians should use this report when managing patients on long-term opioid therapy.

a. The Patient Look-Up tool is accessed from the MHSPHP app by selecting Patient Look-up on the left side of the screen.

b. Enter the barcode / EDIPN / SPONSSN / Name to access the individual patient record.

c. Summary information provided on the initial screen includes: Current MEDD; RIOSORD Index Score; Probability of Opioid Induced Respiratory Depression; Last Naloxone; Sole Prescriber; Opioid Dispensing History; and RIOSORD Criteria.

d. From this summary screen, providers can print any or all of the following for the individual patient:

(1) Opioid Summary Report.

(2) Patient Summary Report.

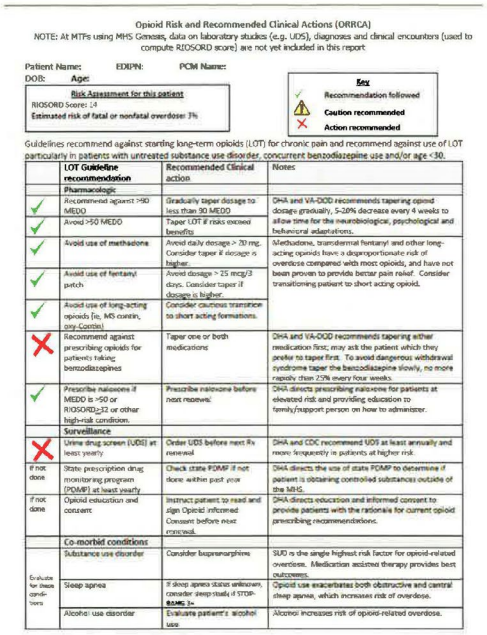
(3) ORRCA – see figure 1.

(4) RIOSORD Naloxone Screening.

C-6

Deputy Assistant Secretary of the Army (Military Personnel) (cont'd)

ANNEX C (Opioid Prescribing Guidelines, Training and Clinical Tools) to OPORD 19-09 (Army Comprehensive Pain Management Program) - USAMEDCOM



Opioid Risk and Recommended Clinical Actions (ORRCA)

NOTE: At MTFs using MHS Genesis, data on laboratory studies (e.g. UDS), diagnoses and clinical encounters (used to compute RIOSORD score) are not yet included in this report

Patient Name: EDIPN: PCM Name:
DOB: Age:

Risk Assessment for this patient
RIOSORD Score: 14
Estimated risk of fatal or nonfatal overdose: 3%

Key
✓ Recommendation followed
⚠ Caution recommended
✗ Action recommended

Guidelines recommend against starting long-term opioids (LOT) for chronic pain and recommend against use of LOT particularly in patients with untreated substance use disorder, concurrent benzodiazepine use and/or age <30.

	LOT Guideline recommendation	Recommended Clinical action	Notes
	Pharmacologic		
✓	Recommend against >90 MEDD	Gradually taper dosage to less than 90 MEDD	DHA and VA-DOD recommends tapering opioid dosage gradually, 5-20% decrease every 4 weeks to allow time for the neurobiological, psychological and behavioral adaptations.
✓	Avoid >50 MEDD	Taper LOT if risks exceed benefits	
✓	Avoid use of methadone	Avoid daily dosage > 20 mg. Consider taper if dosage is higher.	Methadone, transdermal fentanyl and other long-acting opioids have a disproportionate risk of overdose compared with most opioids, and have not been proven to provide better pain relief. Consider transitioning patient to short acting opioid.
✓	Avoid use of fentanyl patch	Avoid dosage > 25 mcg/3 days. Consider taper if dosage is higher.	
✓	Avoid use of long-acting opioids (ie, MS contin, oxy-Contin)	Consider courteous transition to short acting formations.	
✗	Recommend against prescribing opioids for patients taking benzodiazepines	Taper one or both medications	DHA and VA-DOD recommends tapering either medication first; may ask the patient which they prefer to taper first. To avoid dangerous withdrawal syndrome taper the benzodiazepine slowly, no more rapidly than 25% every four weeks.
✓	Prescribe naloxone if MEDD is >50 or RIOSORD≥12 or other high-risk condition.	Prescribe naloxone before next renewal	DHA directs prescribing naloxone for patients at elevated risk and providing education to family/support person on how to administer.
	Surveillance		
✗	Urine drug screen (UDS) at least yearly	Order UDS before next Rx renewal	DHA and CDC recommend UDS at least annually and more frequently in patients at higher risk.
If not done	State prescription drug monitoring program (PDMP) at least yearly	Check state PDMP if not done within past year	DHA directs the use of state PDMP to determine if patient is obtaining controlled substances outside of the MHS.
If not done	Opioid education and consent	Instruct patient to read and sign Opioid Informed Consent before next renewal.	DHA directs education and informed consent to provide patients with the rationale for current opioid prescribing recommendations.
	Co-morbid conditions		
Evaluate for these conditions	Substance use disorder	Consider buprenorphine	SUD is the single highest risk factor for opioid-related overdose. Medication assisted therapy provides best outcomes.
	Sleep apnea	If sleep apnea status unknown, consider sleep study if STOP-BANG ≥	Opioid use exacerbates both obstructive and central sleep apnea, which increases risk of overdose.
	Alcohol use disorder	Evaluate patient's alcohol use	Alcohol increases risk of opioid-related overdose.

Figure 1: Opioid Risk and Recommended Clinical Action (ORRCA)

C-7

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel)

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DoD ISSUANCE COORDINATION RESPONSE

COMPONENT COORDINATOR RESPONSE

December 3, 2019

SUBJECT: Proposed Administrative Instruction Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000

On behalf of my Component, my formal response to this issuance is: Concur with comment. Below are comments for your consideration.

My point of contact for this action is [redacted] at [redacted] or [redacted]

X [signature]

Double-click the 'X' to insert a digital signat...
or print and sign a hard copy.

Coordinating Official's Name: Dr. Russ Beland
Coordinating Official's Position Title: Deputy Assistant Secretary of the Navy (MMP)
Coordinating Official's Component: Assistant Secretary of the Navy (M&RA)

DD FORM 818, AUG 2016 **UNCLASSIFIED**

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000

CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
1	20	1		☐	**Coordinator Comment and Justification:** Regarding recommendation 1.a., "Continue to monitor morphine milligrams equivalent per day by beneficiary, examine data for unusually high opioid prescriptions, and if appropriate, hold providers accountable for overprescribing opioids." Partially concur. It is recommended that the Defense Health Agency (DHA) director continue to monitor morphine milligrams equivalents per day by beneficiary, and readily make this accessible in all Electronic Medical Record (EMR) programs so as to better enable physicians to provide high quality health care. It is recommended that the DHA director examine and determine what constitutes unusually high opioid prescriptions prior to holding those accountable. Whilst the Centers for Disease Control and Prevention guidelines do recommend morphine milligram equivalents (MME) less than 90MME for opioid naïve patients, it is unclear what dosages might be appropriate for non-opioid naïve patients, or what might be unusually high for a given disease process. It is recommended that the DHA determine what is considered "overprescribing," and provide education to providers. A numerical cut off such as 90MME should not be taken in isolation as the only factor in "overprescribing." It is recommended that the peer feedback program enacted by the Naval Medical Center Portsmouth (NMCP) Long-term Opioid Therapy and Safety (LOTS) committee be considered as a best practice in order to improve accountability. Complex patients who are non-opioid naïve may have >90MME as part of the escalating resources required for multidisciplinary management. Noting high risk patients with >90MME should be an objective measure to indicate a need for systematic multidisciplinary evaluation and management, and by itself should not be regarded as an indication of poor or criminal practice in the care of these high risk patients. **Coordinator Recommended Change:** Change wording to, "Continue to monitor MMEs per day by beneficiary, and readily make this accessible in all EMR programs so as to better enable physicians to provide high quality health care."	[redacted]

DD FORM 818, AUG 2016 REPLACES SD FORM 818, WHICH IS OBSOLETE

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2

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000						
CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
					Originator Response: Choose an item. **Originator Reasoning:**	
2	ii	3		☐	**Coordinator Comment and Justification:** Regarding the sentence, "a physician stated that it was a professional courtesy among physicians not to criticize how other physicians provided services and prescriptions to their beneficiaries." Using this sole provider's comment in isolation does not provide a true picture of widespread practices at the time. NMCP has had a long-standing and active LOTS Committee that provides regular feedback to physicians regarding their opioid prescribing habits. The opportunity to visit and get updates in these areas (re-interview staff, provide access to prescribing provider, conduct medical review of these cases) is needed in order to provide a more accurate and complete assessment. There was no clinician or pharmacist subject matter expert on the Department of Defense (DoD) Office of Inspector General (OIG) team, limiting the ability to provide medical interpretation. We recommend having one or both as part of any further assessments. **Coordinator Recommended Change:** This statement should be removed. **Originator Response:** Choose an item. **Originator Reasoning:**	[redacted]
3	Mult.			☐	**Coordinator Comment and Justification:** The phrase "unusually high doses of opioids" is not a medically accepted standard definition. Data collection as performed does not adequately assess what is considered a usual dose or unusual doses, nor does it compare prescribing practices in the DoD to any outside institutions in the community to determine what is usual. This report fails to	[redacted]

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3

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000

CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
					define "unusually high doses of opioids," yet uses this phrase frequently in order to validate findings. **Coordinator Recommended Change**: This statement should be removed throughout the report. **Originator Response**: Choose an item. **Originator Reasoning**:	[redacted]
4	9-10			☐	**Coordinator Comment and Justification**: It would be extremely difficult for the DoD OIG team to determine whether care was appropriate for "Beneficiary 3" without including a physician, clinical pharmacist, nurse and/or anyone with medical expertise, or to ask for a peer reviewer to review whether or not the care was appropriate. MME alone should not be used to assess whether or not clinical standards are being met. For this case in particular, an NMCP pharmacist was able to discern that when the patient was referred out to a civilian pain management provider, the MME's of opioids were actually increased. **Coordinator Recommended Change**: This case should be removed, as it is a non-medical assessment of the medical management of a complicated chronic pain patient, in which the non-medical assessment in itself is not indicative of medical mismanagement. **Originator Response**: Choose an item. **Originator Reasoning**:	[redacted]
5	10-11			☐	**Coordinator Comment and Justification**: For Beneficiary 4, there was also no clinical peer review undertaken. The following misleading statements are noted: (1) it is unclear that doses of 120MME would indicate clear over prescribing, as patient was on 90MME prior to surgery. This would be a small dose increase in	[redacted]

DD FORM 818, AUG 2016 **REPLACES SD FORM 818, WHICH IS OBSOLETE** **UNCLASSIFIED**

4

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000

CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
					a non-opioid naïve patient; (2) immediately after admission at OSH, patient received even higher doses of MME suggesting he may have been taking medications other than opioids and benzodiapines prescribed by NMCP; (3) doctor shopping might also indicate that the providers were appropriately limiting opioids, and the patient was unhappy.	[redacted]
					Coordinator Recommended Change: This case should be removed, as it is a non-medical assessment of the medical management of a complicated chronic pain patient, in which the non-medical assessment in itself is not indicative of medical mismanagement.	
					Originator Response: Choose an item.	
					Originator Reasoning:	
	6	16	1		**Coordinator Comment and Justification**: Regarding the sentence, "NMCP officials stated that the opioid prescriptions for the five NMCP beneficiaries were prescribed within guidelines." Prior to the NMCP staff members making these statements, a peer review of the cases was not conducted, nor was an official medical records review performed. These pharmacists were asked to make this judgement in isolation of a complete medical or multidisciplinary review of management strategies to date on with these patients.	[redacted]
				☐	**Coordinator Recommended Change**: This sentence should be removed.	
					Originator Response: Choose an item.	
					Originator Reasoning:	

DD FORM 818, AUG 2016 REPLACES SD FORM 818, WHICH IS OBSOLETE UNCLASSIFIED 5

Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000

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HOW TO FILL OUT THE DD 818 MATRIX

GENERAL GUIDANCE:

- **To sort table** by page/paragraph number, hover your mouse over the top of the first cell in the "page" column until a downward arrow appears; click and drag to the right to select both page and para columns. Under Paragraph on the Home ribbon, select A-Z button, set to sort by Column 3 and then Column 4, and select "OK." **To add new rows**, copy and paste a blank row to keep consistent formatting. **To add automatic numbering to column 2**, select entire column and click on the Numbering button under Paragraph on the Home ribbon.

COORDINATING OSD AND DOD COMPONENTS:

- Do not use the DD Form 818-1.
- Fill in the memo indicating your Component's position on the issuance. Fill in the authorized coordinator's name, position, and Component. The authorized coordinator (digitally) signs the response after the comment matrix has been completed. **Making additional changes after filling in a digital signature invalidates and removes the signature.**
- Use the comment matrix to provide comments to the OSD Component that created the issuance. Complete the header and footer and Columns 1-7:

COLUMN 1 Enter the classification of the comment. If any material is **classified**, follow DoDM 5200.01 guidance for marking the document. If all comments are unclassified, mark the header and footer and ignore the column.

COLUMN 2 Order comments by the pages/paragraphs that they apply to in Columns 3 and 4.

COLUMNS 3&4 As stated.

COLUMNS 5 Only mark this box if you non-concur with the issuance and the comment in the applicable row is part of the basis for that non-concur. A nonconcur is typically used only when an issuance contains: (a) a violation of the law or contradiction of Executive Branch policy or of existing policy in a DoDD, DoDI, or other instrument approved by the Secretary or Deputy Secretary of Defense; or (b) an unnecessary risk to safety, life, limb, or DoD materiel; waste or abuse of DoD appropriations; or unreasonable burden on a DoD Component's resources.

COLUMN 6 Place only one comment per row. Enter your comment, justification, and recommended changes in the first two areas provided. If any material is **classified**, follow DoDM 5200.01 guidance for marking the document.

COLUMN 7 As stated.

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Deputy Assistant Secretary of the Navy (Military Manpower and Personnel) (cont'd)

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DoD ISSUANCE COORDINATION RESPONSE: Department of Defense Office of Inspector General Draft Report, "Audit of Controls Over Opioid Prescriptions at Selected DoD Military Treatment Facilities," Project No. D2018-D000AW-0102.000						
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- **Review** the comments, **resolve** any conflicting views, and **confirm** that the completed matrix accurately represents your Component's position. Upload the form to the DoD Directives Program Portal in **Microsoft Word format (.docx)**, with the signed memo representing your Component's position.

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7

Acronyms and Abbreviations

CDC	Centers for Disease Control and Prevention
CHCS	Composite Health Care System
DHA	Defense Health Agency
JBER	Joint Base Elmendorf-Richardson
MAMC	Madigan Army Medical Center
MDR	Military Health System Data Repository
MHS	Military Health System
MME	Milligrams of Morphine Equivalent
MTF	Military Treatment Facility
NMCP	Naval Medical Center Portsmouth


INSPECTOR GENERAL
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