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BUREAU OF MEDICINE AND SURGERY
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IN REPLY REFER TO
BUMEDINST 6320.101
BUMED-M3/M5
14 Mar 2018

BUMED INSTRUCTION 6320.101

From: Chief, Bureau of Medicine and Surgery

Subj: LONG-TERM OPIOID THERAPY SAFETY PROGRAM

Ref: (a) BUMEDINST 6040.71C
(b) ASD(HA) memo of 1 Feb 17 (Department of Defense Opioid Prescriber Safety Training Program)

1. Purpose. This instruction establishes policy and training requirements concerning the Long-Term Opioid Therapy Safety Program, including initial screening standards, required actions related to the safe prescription of opioids, and the continued monitoring of patients on long-term opioid therapy.

2. Scope. This instruction applies to ships and stations having credentialed and privileged Navy Medicine (NAVMED) personnel in direct patient care roles.

3. Background

a. Although the efficacy of opioids in acute pain (injuries, post-operative) and palliative care populations is well founded in research, the evidence basis for long-term opioid therapy in chronic pain populations is suboptimal. Over reliance on opioids can be harmful to patients with chronic pain; patients especially at risk are teenagers or young adults, patients with a personal or family history of alcohol or other substance abuse disorder, and patients with psychiatric co-morbidities. These concerns are reflected in alarming national trends that indicate an increase in opioid usage and secondary complications, including abuse, misuse, dependence, higher care costs and utilization, and adverse outcomes (including death). Therefore, clinician efforts to maximize the benefit and minimize the risk of long-term opioid therapy are imperative to ensure the safety of the patients, their families, and society.

b. A clinical practice guideline for the management of opioid therapy for chronic pain was developed under the auspices of the Department of Veterans Affairs (VA) and the Department of Defense (DoD) as outlined in the 2017 DoD and VA Clinical Practice Guidelines for Management of Opioid Therapy for Chronic Pain, which is available at https://www.healthquality.va.gov/guidelines/Pain/cot. The clinical practice guideline aims to improve pain management, quality of life, and quality of care for patients, as well as provide education and guidance to clinicians, researchers, and other health professionals as they encounter patients with persistent pain and its complications. When treatment of complex and

chronic pain indicates the use of long-term opioid therapy, adherence with published clinical practice guidlines helps safeguard patients from the unintended risks of therapy, enhances the quality of pain management care, and reduces prescription substance abuse.

c. Compliance with these elements of care optimize the safe and effective use of opioid therapy for non-cancer pain, minimize opioid misuse and abuse, and ensure care is provided in a manner consistent with DoD and VA guidelines.

4. Definitions

a. Diagnosis, Intractability, Risk, and Efficacy (DIRE) Tool. The DIRE tool is specifically designed to assess the risk of opioid abuse and suitability of adults for long-term opioid therapy. This tool is available in the Tri-Service Workflow (TSWF) Chronic Opioid Therapy (COT) Alternative Input Method (AIM) form within the Armed Forces Health Longitudinal Technology Application (AHLTA). The DIRE tool will also be available for the Military Health System (MHS) GENESIS.

b. Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The DSM-5 offers common language and standard criteria for the classification of mental health disorders.

c. Medical Executive Committee. Per reference (a), the Medical Executive Committee has the primary authority for activities related to goverance of the organized medical staff and performance improvement of professional services provided by licensed independent practitioners.

d. Healthcare Provider. The healthcare provider is a military or civilian healthcare professional who is granted clinical practice privileges to provide healthcare services in a military medical or dental treatment facility.

e. Long-Term Opioid Therapy Patients. Long-term opioid therapy patients are individuals who are prescribed a consecutive 90-day supply or greater of opioids, allowing for no more than 30-days between the end of one prescription supply and the fill of another prescription.

f. Long-Term Opioid Therapy Safety Committee. The Long-Term Opioid Therapy Safety Committee is a subcommittee under the Medical Executive Committee established to monitor, audit, and make recommendations to improve care and safety of patients receiving long-term opioid treatment.

g. Navy Comprehensive Pain Management Program (NCPMP). The NCPMP is the Bureau of Medicine and Surgery (BUMED) initiative to aid in the restoration of function and relief of pain by broadening access to evidence-based, standardized, multimodal, and interdisciplinary pain care across NAVMED, ensuring treatment efficacy through practice guidelines, education, and analysis of treatment outcomes.

h. Informed Consent and Opioid Care Agreement. NAVMED 6320/40 Consent for Long-Term Opioid Therapy for Pain, is an agreement providing information regarding the risks and benefits of therapy, in addition to complying with all state and federal regulations concerning the prescribing of controlled substances. It outlines the conditions under which opioids will be prescribed for pain management and the responsibilities of the patient and the prescriber in the patient's pain care.

i. Prescription Monitoring Program. The Prescription Monitoring Program was created to identify and monitor beneficiaries who exhibit possible unsafe behavior with regards to controlled medications. It may be used to prevent and decrease the risk of substance misuse and abuse and can be used to limit patients to specific prescriber(s) and pharmacy(s). The program may be used to generate and disseminate information regarding prescription trends.

j. State Prescription Drug Monitoring Programs. The State Prescription Drug Monitoring Programs are state-run programs that collect and distribute data regarding the prescription and dispensing of federally controlled substances and, as individual States deem appropriate, other addictive or abused prescription drugs. Prescription Drug Monitoring Programs are intended to assist clinicians and to support the legitimate medical use of controlled substances while limiting the abuse and diversion of these agents.

k. Electronic Medical Record (EMR). The EMR allows clinicians to document their clinical encounters with patients on long-term opioid therapy. Documentation templates and forms within the EMR may vary, but are available in AHLTA and MHS GENESIS. Existing examples include the TSWF COT AIM Form and the TSWF CORE AIM form. User guides, training slides, interactive videos, and hardcopy forms are available at: http://www.tswf-mhs.com/core-forms.

l. Urine Drug Test. Urine drug test is the evaluation of a urine sample to enhance patient safety, assist in determining if a patient is using illicit substances, assist in the diagnosis of substance use disorder, and monitor medication adherence.

5. Policy. The responsibility for safe opioid prescribing practices and oversight of the Long-Term Opioid Therapy System Program will reside at the command level with support and guidance provided by Chief, BUMED. The four primary tenets of the Long-Term Opioid Therapy Safety Program are training, screening, informed consent and opioid care agreements, and safety surveillance.

a. Training. The Office of the Assistant Secretary of Defense for Health Affairs and the DoD Addictive Substance Misuse Advisory Committee (ASMAC) require privileged providers to complete all DoD mandated opioid misuse prevention trainings. For the purpose of this instruction Independent Duty Corpsmen are required to complete all DoD mandated opioid misuse prevention trainings. Training compliance will be monitored by BUMED Healthcare Operations (BUMED-M3) with assistance from BUMED Education and Training (BUMED-M7) as needed.

b. Screening. Patients must be screened for past psychiatric history to include depression, anxiety, other emotional disorders, risk of suicide (including family history of previous suicide attempts) and substance use history (personal, family, and peer group). The DIRE is an example of a screening tool that may be used to fulfill this requirement prior to beginning long-term opioid therapy. The DIRE tool is available in the TSWF COT AIM form and is available via MHS GENESIS. Patients suffering from acute psychiatric instability, uncontrolled suicide risk, or diagnosed non-nicotine substance use disorder, as defined in the DSM-5, should not be started on opioid therapy. Consider weaning patients off of opioid therapy should any of these conditions develop. Additionally, DoD and VA guidelines recommend against the concurrent use of benzodiazepines and opioid therapy.

c. Informed Consent and Opioid Care Agreements. While on long-term opioid therapy, patients must be educated and informed on the risks associated with prescription opioids. Subsequently, patients must establish an informed consent and opioid care agreement with their provider. NAVMED 6320/40 should be used to meet this requirement and State requirements for prescribing opioids.

d. Safety Surveillance. While on long-term opioid therapy, patients must be assessed regularly for degree of analgesia, opioid-related adverse effects, functional status and activities of daily living and aberrant behavior. A self-reported pain rating scale is an example of a validated pain and functional assessment tool that may be used. Regular urine drug testing is also an important component of surveillance.

6. Responsibilities and Actions

a. Assistant Deputy Chief, BUMED-M3. Develop and update policy oversight for NAVMED, consistent with the 2012 United States Drug Control Strategy and reference (b), the Office of Assistant Secretary of Defense for Health Affairs memorandum on DoD Opiod Prescriber Safety Training Program.

b. Director, Primary Care and Mental Health (BUMED-M33). Serve as the program manager for the NAVMED Long-Term Opioid Therapy Safety program as outlined in reference (b) and the 2012 United States Drug Control Strategy:

(1) Provide subject matter expertise, oversight, policy guidance, and ensure training compliance for all appointed physicians, dentists, nurse practitioners, and physicians assistants.

(2) Perform an annual review of Long-Term Opioid Therapy Safety Program guidance and update training material as necessary.

(3) Establish metrics to measure training compliance of prescribers.

(4) Collaborate with the Office of the Chief Medical Officer (BUMED-M5) and appropriate subject matter experts to establish benchmarks to monitor compliance with Long-Term Opioid Therapy Safety Program guidance and ensure quality.

(5) Ensure NCPMP distributes a confidential and encrypted list of patients meeting the long-term opioid therapy criteria as well as a random sample of patients for chart reviews (as described in paragraph 6e(5)) and the standard chart review template quarterly to the Long-Term Opioid Therapy Safety Program Committee Chair or designated recipient quarterly.

c. NAVMED East and NAVMED West Commanders must:

(1) Ensure command compliance with long-term opioid therapy safety program and policies.

(2) Provide assistance to subordinate commands with the long-term opioid therapy safety policy and compliance.

d. Medical Treatment Facility (MTF) Commanding Officers, Officers in Charge, and U.S. Fleet Forces Surgeon must:

(1) Ensure command compliance with long-term opioid therapy safety program, policies, and requirements.

(2) Ensure all credentialed and privileged providers with prescribing privileges attend and comply with all DoD ASMAC mandated opioid misuse prevention trainings.

(3) Ensure the Medical Executive Committee Chair establishes and maintains a Long-Term Opioid Therapy Safety Committee to oversee and manage the program and ensure compliance with the program requirements.

(4) Ensure command compliance in utilization of an Informed Consent and Opioid Care Agreement through use of NAVMED 6320/40 with all patients on long-term opioid therapy.

e. Long-Term Opioid Therapy Safety Committees must:

(1) Be structured as a committee under the Medical Executive Committee.

(2) Be led by a clinician with experience managing chronic pain patients and prescribing opioids. The committee should also include clinical pharmacist representation.

(3) Designate a member to receive from the program manager of the NCPMP the confidential and encrypted list of patients meeting the long-term opioid therapy criteria as defined in paragraph 4 of this instruction.

(4) Report the number of patients qualifying as long-term opioid therapy patients quarterly to the Medical Executive Committee Chair.

(5) Audit a random sample of five percent of patients' charts quarterly in which patients are prescribed a 90 milligram (mg) morphine equivalent daily dose (MEDD) or higher at any point during the measurement period, in addition to a random sample of five percent of all other long-term opioid therapy patients' charts. Audits will be conducted using the standard chart review template provided quarterly to commands by NCPMP. This standard chart review template was developed and continues to be updated with input from the long-term opioid safety working group in order to measure compliance to the DoD and VA clinical practice guideline for opioid therapy for chronic pain. Patients who undergo chart review and have findings in full compliance with the metrics outlined in the standard chart review template are exempt from further long-term opioid chart reviews for 1 year.

(6) Report all results from chart audits to the Medical Executive Committee Chair.

f. Healthcare Providers Managing Long-Term Opioid Therapy Patients must:

(1) Complete mandated opioid misuse prevention trainings.

(2) Prior to initiating opioid therapy and every year thereafter, conduct a psychiatric and substance abuse history screening that incorporates a tool to assess risk for opioid misuse. Additionally, conduct a face-to-face evaluation of all long-term opioid therapy patients, assess for degree of analgesia, opioid-related adverse effects, and functional status and activities of daily living and aberrant behavior, at every opioid-related visit or at least once every 90-days.

(3) Initiate an Informed Consent and Opioid Care Agreement using NAVMED 6320/40 in the medical record and renew this document annually. If an electronic template is not used, the Consent for Long-Term Opioid Therapy for Pain should be scanned, uploaded, and titled "Opioid Care Agreement" in the EMR. This form is compliant with the Privacy Act of 1974 provided it is filed in the medical record. Health Insurance Portability and Accountability Act of 1966 applies.

(4) Conduct a baseline urine drug test at initiation of long-term opioid therapy and at least every year thereafter while the patient remains on long-term opioid therapy. Use of periodic urine drug test screenings are indicated at the provider's discretion to assess compliance. Frequency may be based on risk factors which include: substance abuse history or prior prescription drug misuse; unsanctioned dose escalations on several occasions; non-adherence to clinician recommendations; unwillingness or inability to comply with treatment plan; and social instability.

(5) Taper or discontinue long-term opioid therapy in patients with frequent 'unexpected' results on urine drug test (e.g., absence of prescribed medication, presence of other prescription opioids, or presence of illegal drugs) or non-adherence with the Informed Consent and Opioid Care Agreement.

(6) Use, when applicable, the EMR for long-term opioid therapy management documentation.

(7) Refer to a addiction medicine specialist when indicated in the 2017 DoD and VA Clinical Practice Guidelines for Management of Opioid Therapy for Chronic Pain (available at https://www.healthquality.va.gov/guidelines/Pain/cot), the DSM-5, and the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality 2016 Report: Guideline for Prescribing Opioids for Chronic Pain, available at http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?s_cid=rr6501e1_w.

(8) Use, when applicable, the Prescription Monitoring Program (PMP), as outlined by the Health.mil MTF Prescription Monitoring Program (available at http://www.health.mil/MTFRxMonitoring) and the Express Scripts TRICARE Prescription Monitoring Program (available at https://www.express-scripts.com/TRICARE/tools/rxMonitoring.shtml), which triggers pharmacy warnings in the electronic health record. The purpose of the PMP is not to evaluate provider compliance, but rather to assist providers in maintaining awareness of a patient's behavior. This program restricts enrolled beneficiaries' access to medications in one of the following ways:

(a) Access to all medications is restricted to a set of authorized clinicians and pharmacies.

(b) Access to controlled medications is restricted to a set of authorized clinicians and pharmacies.

(c) Access to controlled medications or specific non-controlled medications is excluded through mail orders and retail pharmacies.

(9) Monitor long-term opioid therapy patients using the State's PDMP when accessible. In accessing a PDMP, a provider must comply with their license and local requirements. This requirement may not be applicable to Outside Continental United States providers.

7. Records Management. Records created as a result of this instruction, regardless of media and format, must be managed per MANMED Chapter 16, Secretary of the Navy (SECNAV) Manual 5210.1 of January 2012, and the Health Insurance Portability and Accountability Act Privacy and Security Rules, as applicable.

8. Review and Effective Date. Per OPNAVINST 5215.17A, BUMED-M3 will review this instruction annually on the anniversary of its effective date to ensure applicability, currency, and consistency with Federal, DoD, SECNAV, and statutory authority using OPNAV 5215/40 Review of Instruction.

9. Forms. The NAVMED 6320/40 Consent for Long-Term Opioid Therapy for Pain, is available at http://www.med.navy.mil/directives/Pages/NAVMEDForms.aspx.

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Acting

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site: http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx.