

DEPARTMENT OF THE ARMY HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND 2748 WORTH ROAD JBSA FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO ATTENTION OF

OTSG/MEDCOM Policy Memo 15-039

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MEMORANDUM FOR COMMANDERS, MEDCOM REGIONAL MEDICAL COMMANDS

SUBJECT: Guidance for Managing Polypharmacy and Preventing Medication Overdose in Patients Prescribed Psychotropic Medications and Central Nervous System Depressants

1. References:

a. Public Law 104-191 Health Insurance Portability and Accountability Act of 1996, 21 August 96.

b. Army Regulation 40-68, Clinical Quality Management, 22 May 09.

c. MEDCOM Regulation 40-51, Medical Review Officers and Review of Positive Urinalysis Drug Testing Results, 13 May 11.

d. OTSG/MEDCOM Policy 13-051, Soldiers in Transition High-Risk Medication Review and Sole Provider Program, 9 Sep 13.

e. OTSG/MEDCOM Policy 14-080, Release of Protected Health Information (PHI) to Unit Command Officials, 24 Sep 14.

f. OTSG/MEDCOM Policy 15-028, Sole Provider Program, 8 May 15.

g. Army Patient-Centered Medical Home (PCMH) Operations Manual, Leaders Guide to Army PCMH, US Army Medical Command, Version 2, Apr 14.

h. Army Soldier Centered Medical Home (SCMH) Manual, Leaders Guide to Army SCMH Transformation, Version 1, Apr 14

j. Army PCMH Implementation Manual, Leaders Guide to Army Patient Centered Medical Home Transformation, US Army Medical Command, Version 2, Apr 14.

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k. Army PCMH Operations Manual Clinical Pharmacy Services Annex, US Army Medical Command, Version 1, Apr 14.

I. Hyman J, et al. Suicide Incidence and Risk Factors in an Active Duty US Military Population. American Journal of Public Health. Supplement 1, 2012, Vol. 102, No. S1.

m. Britton PC, et al. Differences Between Veteran Suicides With and Without Psychiatric Symptoms. American Journal of Public Health. Supplement 1, 2012, Vol. 102, No. S1.

n. Seal KH, et al. Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan. Journal of the American Medical Association, 7 Mar 12, Vol. 307, No.9, Corrected on 13 Mar 12.

o. Logan J, et al. Characteristics of Suicides Among US Army Active Duty Personnel in 17 US States From 2005 to 2007. American Journal of Public Health. Supplement 1, 2012, Vol. 102, No. S1.

p. Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model 2.0, American Pharmacists Association and the National Association of Chain Drug Stores Foundation, Mar 08.

2. Purpose: To provide guidance on the management of polypharmacy involving psychotropic medications and central nervous system depressants (CNSDs) in order to reduce adverse events and optimize the health of the Soldier and other Beneficiaries (Family Members and Retirees) receiving care in the Military Health System.

3. Proponent: The proponent for this policy is the Chief, Allied Clinical Services, Patient Care Integration Directorate, MEDCOM G-3/5/7.

4. Background:

a. The increased use of prescription drugs, specifically psychotropic medications and CNSDs (particularly opioids), is a public health concern and one of the many factors that may contribute to medication overdose. Risks associated with some of these medications include drug interactions and additive adverse effects, misuse and abuse, physical and psychological dependence, potential for withdrawal, and cognitive impairment. Members of the healthcare team must carefully consider the risks associated with prescribing medications from one or more of these classes of drugs.

b. It is not known to what extent prescription medications contribute to suicides or suicidal behavior. A high percentage of individuals who attempt suicide or who exhibit suicidal behavior have underlying mental disorders, which are often co-morbid with

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physical health problems. Such individuals are thus expected to be in a group with a high likelihood of being prescribed psychotropic and CNSD medications.

c. Alcohol and drug overdose is a common method involved in suicide and suicide attempts, and a high percentage of military suicides and suicide attempters have been found to have filled a prescription for at least one of seven medication groups (opiate agonists, antidepressants, antipsychotics, anticonvulsants, anxiolytics, sleep medications, or stimulants) within one year prior to the event. Opioid agonists have become of particular concern due to the potential for respiratory depression with overdoses or in association with other medications, and there has been growing recognition of the national problem with opioid overprescribing and epidemic overdose deaths in the US.

5. Definitions:

a. Polypharmacy:

(1) Prescriptions for four or more of any type of medication, including one or more opioid, within the previous 30 days.

(2) Prescriptions for four or more medications from the seven categories of psychotropics and CNSDs (opioid, stimulant, anxiolytic, antidepressant, antipsychotic, anticonvulsant, or sleep medication) within the previous 30 days.

(3) Three or more emergency room visits in the last 12 months where each visit is linked with a new opioid prescription and at least one of these visits occurred in the last 30 days.

b. CNSDs: Medications such as opioid analgesics, benzodiazepines, and sedativehypnotics that either as a single agent or in combination can result in suppression of respiratory drive. These medications may be used as musculoskeletal relaxants, or to treat conditions such as pain, insomnia, acute stress reactions, panic attacks, and seizure disorders.

c. Psychotropic Medications: Medications that act on the brain to affect mood, cognition, or perception. These medications are commonly prescribed to treat psychiatric conditions, such as clinically significant anxiety, depression, sleep disturbance, and psychosis. Psychotropic medications include selective serotonin reuptake inhibitors, benzodiazepines, antipsychotics, stimulants, and other classes of medications used to treat a variety of behavioral health conditions.

d. Medication Reconciliation: A process of documenting a complete, accurate, and current list of all medications including prescription, over-the-counter, and herbal

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medications taken by a patient. This process includes discontinuing medications that are no longer clinically indicated, and communicating the patient's reconciled medication profile to other healthcare providers when the patient transitions from one level of care to another or at each outpatient encounter.

e. Sole Provider Programs (SPPs): Also known as patient review and restriction programs or "lock-in" programs (Reference 1f). SPPs enable Military Treatment Facilities (MTFs) to monitor, identify and prevent overuse, and possible abuse of physician services and controlled prescription drugs without having to terminate pharmacy benefits altogether. These programs do this by allowing MTFs to restrict beneficiaries suspected of unsafe behavior, or those patients with a complicated medication profile for whom a single provider is necessary for safe care, to a single designated provider, pharmacy, or both.

f. MTF Prescription Restriction Program/MTF Lock-In Program: Program available for use by all DoD Services, and used by all Army MTF SPPs as the method to indicate that a beneficiary is enrolled in the SPP. After enrolling and registering the beneficiary in the MTF Prescription Restriction Program as an SPP beneficiary, the sole provider may place certain limits on the beneficiary's access to the pharmacy benefit.

g. Comprehensive Medication Therapy Review (MTR): A process of collecting and evaluating patient-specific medication information and therapies to identify and prioritize medication-related issues. The clinical pharmacist works collaboratively with concerns the patient, Primary Care Manager (PCM), and other healthcare professionals have to develop a medication action plan, provide education and information, and improve the patient's self-management of his/her medications.

h. Clinical Pharmacy Referral: A patient is automatically identified for a clinical pharmacy referral according to the polypharmacy definition. Pharmacy staff will perform an initial medication review for these patients to determine if further intervention is indicated. If deemed necessary, a clinical pharmacist appointment will be requested for a comprehensive medication therapy review (MTR) and to educate the patient on the appropriate use of all medications, indications for medication usage, and monitoring for adverse effects. Healthcare providers may also order a clinical pharmacy referral for a specific patient at any time. The clinical pharmacist communicates recommendations regarding medication-related concerns or nonadherence to the patient's PCM by documenting the medication-related action plan in AHLTA.

i. Informed Consent: The process wherein the provider discusses with the patient his or her diagnosis, the nature and purpose of the proposed treatment, and discloses to the patient the risks and possible outcomes of the proposed treatment along with the available alternatives. The patient then decides whether the potential benefits outweigh the risks and whether to proceed with the provider's proposed treatment or one of the

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alternatives. This process and the patient's decision are documented in the patient's medical record.

6. Responsibilities:

a. US Army Medical Command (MEDCOM): The Chief, Allied Clinical Services, Patient Care Integration Directorate, MEDCOM G-3/5/7 serves as the proponent for this policy and prepares a quarterly roll up and analysis of MEDCOM-wide performance and effectiveness measures for the MEDCOM Commander. Proponent will assess effectiveness of policy annually in report to the MEDCOM Commander.

b. Regional Medical Commands (RMCs)/Regional Health Commands (RHCs): RMC/RHC Pharmacy Consultants ensure that MTF Pharmacies report performance and effectiveness measures to the MEDCOM Pharmacy Program Manager/OTSG Pharmacy Consultant using metrics, reporting frequency and method as directed below in paragraph 7.c. of this policy.

c. MTF Commander: Ensure all aspects of this policy are implemented and followed. Coordinate with Unit Commanders supported by the MTF for polypharmacy screening and referral. Ensure providers and healthcare professionals complete required polypharmacy and medication therapy management training when applicable.

d. PCM: Actively coordinate care for the patient through communication with the patient, clinical pharmacists, other healthcare providers, and Commanders (when required to communicate impact on Soldier readiness).

e. Healthcare Provider: All privileged providers exercising prescriptive authority must ensure that medication reconciliation is completed on patients during transitions in the level of care provided (e.g., discharge from inpatient to ambulatory settings) and at each outpatient encounter.

f. Soldier/Patient: Take an active responsibility for his/her care through open communication with their PCM, other healthcare providers, and Commanders (when required to communicate impact on Soldier readiness). The patient will work with his/her PCM to establish treatment and health goals.

g. Soldier's Commander: Actively communicate with Soldier's PCM on issues of medical concern and consider limitations on performance of duties and/or deployment status placed on Soldiers by their PCMs due to medication-related profiles.

h. Clinic Support Staff: Responsible for performing duties in accordance with the Army PCMH Operations Manual.

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i. Nursing Personnel: Responsible for performing duties in accordance with Army PCMH Operations Manual.

j. Clinical Pharmacist: Functions as a privileged provider in accordance with AR 40-68. The clinical pharmacist will have an AHLTA schedule template to meet the demand and scope of services of the practice setting.

k. MTF Chief, Pharmacy: Ensures general supervision, clinical assessment, and on-going professional practice evaluations of clinical pharmacists engaged in polypharmacy consultation and referrals are done.

I. MTF Education and Credentialing Departments: Ensure that providers and healthcare professionals complete any required polypharmacy and medication therapy management training when applicable, and that such training is documented in training records and competency assessment folders.

7. Policy: This policy provides guidance for implementing the process, deploying organizational resources, making decisions pertaining to competing priorities and delivery of care, measuring performance and effectiveness, and establishing a culture of patient-centered care to address polypharmacy-related issues through education, communication and collaboration.

a. Process:

(1) Training and Education: Healthcare providers and professionals must complete required polypharmacy and medication therapy management training when applicable. Training may include evidence-based pharmacotherapy, risks of polypharmacy and its management, documentation of medication-related impact on readiness in medical profiles, and documenting informed consent pertaining to medication use. At least 90% of newly hired ambulatory healthcare providers (includes primary care physicians, physician assistants, pharmacists and nurse practitioners) must complete the White House Office of National Drug Control Policy (ONDCP) recommended training on the proper prescribing and disposal of prescription drugs, with a focus on opiate pain relievers and benzodiazepines, within 90-days of initial employment. Ambulatory healthcare providers fulfill this one time training requirement by completing "Do No Harm" training and recording completion in the Defense Training Management System (DTMS).

(2) Polypharmacy-Medication Analysis and Reporting Tool (Poly-MART) Report:

(a) On the 15th day of every month, each MTF will download the Poly-MART report from the Defense Health Agency (DHA), Pharmacy Operations Division (POD) Pharmacy Analytics Support Section (PASS). This report will identify Active Duty

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Service Members (ADSM) and Beneficiaries (Family Members and Retirees) enrolled to the MTF who met polypharmacy criteria during the previous calendar month. The MTF Pharmacy Department will coordinate and manage monthly report retrieval and perform the initial medication review described in paragraph 5.h of this policy. All patients recommended for a clinical pharmacist appointment will be referred to the pharmacy staff supporting the medical home team for scheduling the appointment with a comprehensive MTR. Clinical pharmacists will complete the MTR within 30 days from the date of receiving the Poly-MART report. The percentage of patients with a completed MTR will be reported as directed below in paragraph 7.c. of this policy.

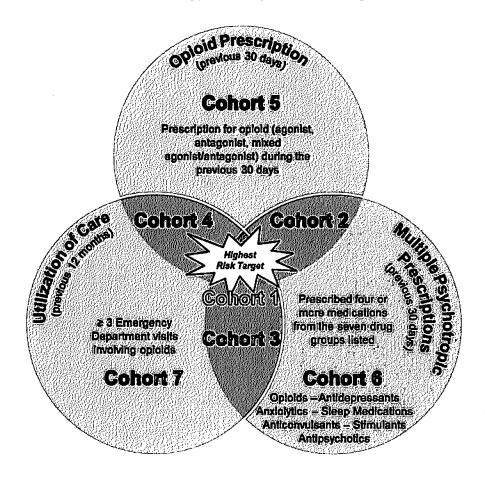
(b) The polypharmacy definition is used as the basis for generating the Poly-MART and determining who will meet criteria for referral to a clinical pharmacist on the medical home team. Figure 1 depicts graphically the components of this case definition (clinical pharmacist polypharmacy referral target). If clinical pharmacist staffing is insufficient to complete all referrals, then those patients who fall into the intersection of the three circles will receive highest priority, following those who fall into the intersection of two of the circles.

(3) Comprehensive MTR: Clinical pharmacists complete a comprehensive MTR during appointments with referred patients. The MTR includes, but is not limited to, a complete and accurate list of current medications, including over-the-counter medications and nutritional/herbal supplements, assessment of overuse or underuse, medication adherence, and drug-drug interactions. The clinical pharmacist will use the AHLTA Tri-Service Workflow Team (TSWF) Clinical Pharmacy Alternate Input Method (AIM) Form to document and communicate the clinical observations and medication therapy management plan to the patient's PCM.

(4) Treatment Plan: Based on the findings of the comprehensive MTR and medication action plan provided by the clinical pharmacist, the PCM and the patient will formulate a treatment plan and follow-up care. Providers concerned with a patient's behavior of nonadherence with medications, including the risk of unsafe medication use, should limit the quantity of medication prescribed. In such cases, providers should initiate frequent, brief clinical visits to closely monitor the patient's condition and adherence to medication. Clinical observations and resultant changes in the treatment plan should be clearly documented in the clinical record and discussed with the patient. Healthcare providers should consider clinically appropriate non-medication therapies to replace or augment medication therapy to achieve specific treatment goals. Primary care providers should have a low threshold for referring patients to behavioral health resources to augment medication therapy with other modalities of treatment, such as psychotherapy for behavioral health concems.

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Figure 1: Clinical Pharmacist Polypharmacy Referral Target



(5) Prescription Quantity Limits: Providers initiating new prescriptions for psychotropic medications or CNSDs, or changing currently prescribed psychotropic medications or CNSDs for an existing condition, will limit quantities to no more than a 30-day supply, and monitor for effectiveness, adverse effects, and compliance with medication therapy. Once the optimum dose has been reached, and the medication is not a Schedule II-IV medication, providers may prescribe for up to a 90-day supply with up to three refills.

(6) Prescriptions for Controlled Substances: Medical providers will prescribe only the minimum quantity of controlled substances necessary to treat an acute illness or injury. Quantities of controlled substances used to treat acute conditions will not exceed a 30-day supply. Providers prescribing controlled substance medications (Schedule III-IV) to treat chronic conditions may prescribe a 30-day supply of medication, with up to five refills. Prescriptions for Schedule II controlled substances are limited to a 30-day supply with no refills.

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(7) Pharmacy Referrals: Any healthcare provider with patient specific medication or polypharmacy concerns should submit a Clinical Pharmacy consult for a comprehensive MTR.

(8) Informed Consent for Polypharmacy: Knowledge about the associated risks of polypharmacy is essential to improving medication safety. The provider must review identified risks and potential interactions with the patient, providing education on prevention and management of adverse events. The provider must document in an AHLTA note that the patient provided informed consent orally. The note should include a brief description of the key risks that were discussed and whether or not the indication for which the medication is being used is a Food and Drug Administration-approved indication or the medication is being used off-label. This conversation with the patient should be supplemented with patient medication handouts with more detailed information on appropriate use and risks of the medication.

(9) SPP: Patients at increased risk of unsafe medication use should be enrolled in the MTF's SPP to optimize care. Healthcare providers are expected to adhere to guidance contained in Reference 1f.

(10) Special populations: For specific populations who are identified to be at risk for polypharmacy, such as Warriors in Transition, healthcare providers are expected to adhere to additional published guidance contained in Reference 1d.

(11) Collaboration between clinicians and Commanders: The Health Insurance Portability and Accountability Act Privacy Rule recognizes the unique context of the military mission and allows appropriate disclosure of select protected health information to Commanders to ensure the safety and promote the well-being of their Soldiers. Soldiers who meet criteria for a comprehensive MTR may experience medicationrelated effects, impacting the Soldier's readiness or ability to perform duties. Healthcare providers will seek collaborative communication with Commanders (or their designated representatives) as needed (Reference 1e).

b. Organization: Clinical pharmacist staffing includes one FTE clinical pharmacist for every 6,500 beneficiaries enrolled to the medical home to meet the anticipated demand for polypharmacy referrals.

c. Metrics: Compliance with this policy requires MTFs to report monthly and annual measures of performance through their RMC/RHC Pharmacy Consultant to the MEDCOM Pharmacy Program Manager/OTSG Pharmacy Consultant.

(1) Measure of Performance: Percentage (goal > 90%) of newly hired ambulatory healthcare providers (primary care physicians, physician assistants, pharmacists, and nurse practitioners) completing "Do No Harm" training within 90 days

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of initial employment. This is a one-time training requirement for newly privileged ambulatory care providers. MTF Education and Training Departments will document and track "Do No Harm" completion in DTMS.

(2) Measure of Effectiveness: Percentage (goal > 95%) of newly identified patients with a completed clinical pharmacist MTR documented in AHLTA within 30 days of receiving the referral report. MTF Pharmacy Chiefs report monthly using the method directed by MEDCOM Pharmacy Program Manager/OTSG Pharmacy Consultant.

FOR THE COMMANDER:

FIØRE, JR.

Chief of Staff