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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Pain Management
Services in Veterans Health
Administration Facilities



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess Veterans Health Administration (VHA) medical facilities' pain management services at the request of Senators Edward J. Markey and Richard Blumenthal and Representatives Ralph Abraham, Dan Benishek, Gus Bilirakis, Ryan Costello, Seth Moulton, Beto O'Rourke, Kathleen Rice, Dina Titus, and Jackie Walorski. Specifically, the OIG looked at pain management practices including opioid prescribing and the treatment of substance abuse.

This report presents OIG's review of VHA's pain management services in two distinct sections. Each section describes the background, scope, and methodology specific to the issue(s) reviewed. The first section details issues related to pain management more broadly, and the second section details aspects of opioid prescribing. The OIG studied different populations and data for each section, and presents the sections separately.

Section One

Pain is a complex phenomenon that is an individual, subjective experience, which is often characterized by its duration. Chronic pain lasts longer than 90 days. Because of its persistent nature, chronic pain is particularly problematic to treat. Pain management is a medical specialty that has evolved in conjunction with advances in pharmacology and interventional procedures. A comprehensive and integrated approach to pain management may require the involvement of several medical specialties.

The OIG conducted an electronic survey of 141 VHA medical facilities from April 27, 2016, through May 11, 2016 and had a 100 percent response rate. A broad range of outpatient pain management services were reviewed excluding hospice, palliative, and end-of-life care. The survey was used to determine staffing within pain clinics, the breadth of Substance Use Treatment programs, pain management education for providers, access to Prescription Drug Monitoring Programs (PDMPs),¹ and facility leaders' level of satisfaction with the current methods of monitoring opioid prescribing and pain management care.

The *Drug Addiction Treatment Act of 2000* limits the number of patients that a physician may treat for opioid dependency with approved buprenorphine products. To determine whether the Suboxone® prescribing limit restricted veteran access, the OIG reviewed all prescriptions for Suboxone® in FY 2015 and calculated the number of prescriptions written by each provider. Due to the significant variation in the number of Suboxone® prescriptions written by providers, the OIG also reviewed the number of Suboxone® prescriptions written at each facility. The

¹ PDMPs are statewide databases of electronically transmitted prescribing and dispensing data of controlled substances.

distribution of the number of Suboxone® prescriptions was compared between facilities that reported having enough providers to meet demand and those that did not. The OIG calculated the minimum, 25th percentile, 50th percentile (median), 75th percentile, and maximum number of prescriptions for both groups.

In general, the OIG found that pain management services were offered at most VA medical facilities. Almost all VA medical facilities had at least one pain management specialist, and slightly over half had a Board-Certified Pain Medicine specialist, the specialty requiring the most extensive training. The OIG also asked about substance use clinics with addiction-focused pharmacotherapy such as methadone or Suboxone®. Overall, 96 percent (135/141) of the facilities offered substance abuse treatment using either methadone or Suboxone®.

The OIG also identified facilities that provided specialized services for substance abuse treatment. Eighty-two percent of facilities (116/141) reported having an Intensive Outpatient Program. Fifty-nine percent of facilities (83/141) reported having residential treatment programs. Ninety-five percent of facilities (134/141) reported offering at least one specialized substance abuse treatment program. Ninety-seven percent of facilities (137/141) reported offering at least one specialized outpatient clinic for substance use treatment or substance use clinic with addiction-focused pharmacotherapy.

While the OIG was able to characterize the distribution of pain specialists and pain clinics in VHA, a staffing standard was not identified that would allow determination as to whether this pattern of staffing sufficed to meet demand for pain services. The bulk of chronic pain management care comes from primary care providers. The delivery of pain management care consistent with guidelines can be time-consuming and when patients receiving such care are prescribed chronic opioids as well, the demands on the provider may be considerably increased compared to the delivery of routine care.

The OIG found that the Suboxone® prescribing limit was not the primary reason that facilities were unable to meet the demand for Suboxone®. While there was considerable variation in the prescribing patterns of individual providers, the level of prescribing for the vast majority of providers was well below the threshold where the Suboxone® prescribing limit would take effect.

VHA was utilizing facility-specific lectures and computer training for pain education at 84 and 76 percent of VA Medical Centers (VAMCs) respectively. Specialty Care Access Network-Extension for Community Health Outcomes² was used in over half of all VA facilities. Each facility's needs for pain education is different because the configuration of VA facilities is affected by many variables, including the type of hospital, clinical staff level of pain specific

² Specialty Care Access Network Extension for Community Healthcare Outcomes is an approach, using case-based training, to provide specialty care consultation and education to rural primary care providers through the use of video teleconferencing equipment.

training and experience, academic affiliations, geographic location, and access to specialists willing to provide pain instruction. Individual facilities should ascertain their own educational needs.

VA providers are required to review and reconcile, with the patient, the list of medications in the current electronic health record (EHR) with the medications the patient is actually taking. This safety check cannot effectively occur if access to PDMP information is either nonexistent or inefficient. The OIG found that 41 percent (58/141) of the facilities reported that out-of-state licensed providers had no access to PDMPs. Of the 58 facilities that employed staff who were unable to access PDMPs, 71 percent (41/58) reported having alternative processes allowing a review of PDMP data, such as having a licensed state pharmacist or other appropriate providers review the PDMP and document the findings in the EHR.

Forty percent of facilities reported being “dissatisfied,” “somewhat dissatisfied,” or “neutral” about their ability to monitor pain management practices at their facility. Reasons for this dissatisfaction included the need for better pain assessment tools, an inability to provide specialized pain care or assess purchased pain care at facilities without pain management specialists, and the lack of a clear standard on how to provide pain management, all of which present challenges in measuring and evaluating pain management practices and patient outcomes of provided services.

Section Two

Medication reconciliation provides an important safety net to preventing medication errors for both the patient and provider. The medication list in the provider’s EHR should match what the patient states he/she is taking. The OIG found that 36.0 percent of the patients in the study population received medication management or pharmacy reconciliation during FY 2015, similar to the 38.8 percent found in the OIG’s 2014 report on the topic.³

Complementary and Integrative Health (CIH), previously referred to as complementary and alternative medicine or CAM, is increasingly seen as an adjunct to traditional plans of care for pain management. The OIG determined that 22.8 percent of opioid patients received at least one care episode from any CIH services in FY 2015 and 16.7 percent received this care after their first opioid prescription in FY 2015.

³ VAOIG, *Healthcare Inspection—VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*, Report No.14-00895-163, May 14, 2014. OIG’s data did not take into account medication reconciliation performed by primary care providers during clinic visits if it was not recorded as a Current Procedural Terminology (CPT) code.

The OIG found that 42.4 percent of active substance use patients received substance use disorder treatment in FY 2015, an increase from 31.2 percent in FY 2012.⁴ However, the OIG determined that 4.6 percent received both treatment for substance use and a UDT within 90 days of each filled opioid prescription, a decrease from 10.5 percent in FY 2012.⁵

The concurrent use of benzodiazepines and opioids can be dangerous. Benzodiazepines have been strongly associated with death from opioid overdose and with an increased risk of death due to methadone toxicity. The OIG found that outpatient benzodiazepines were dispensed to 15.1 percent of the study population, with the percentage of chronic opioid users being 1.6 times that of non-chronic users. The OIG determined that 78.1 percent of the opioid patients who received outpatient benzodiazepines in FY 2015 were dispensed benzodiazepines concurrently with opioids. The percentage of chronic opioid users with concurrent benzodiazepines was 96.4, and the percentage of non-chronic users was 57.2.

Additionally, the OIG analyzed VA patterns of dispensing outpatient opioids and monitoring patients on opioid therapy.

The OIG recommended that the Under Secretary for Health:⁶

1. Ensures that VA facilities have formal processes in place for providers to access state PDMPs to reconcile medications dispensed by private providers and those dispensed by VA, and that this process is in compliance with the providers' state licensing requirements.
2. Evaluates the use of facility-specific panel readjustments or other means of increasing resources for primary care providers who manage chronic pain conditions for a significant proportion of his/her panel and takes action as appropriate.
3. Evaluates and determines the adequacy of the number of pain specialists at each facility through formalized assessments and takes action as appropriate.
4. Ensures that VA facilities without pain specialists have formalized designated resources of pain care provided by providers.
5. Evaluates the use of pain assessment tools across VHA to ensure that those tools used by facilities provide information that improves oversight to patients who are treated for chronic pain conditions.

⁴ VAOIG Report No. 14-00895-163, May 14, 2014, p. 32.

⁵ For this report, the OIG used the terms urine drug test(ing) and urine drug screen (ing) interchangeably. Both terms appear in VA/VHA pain management documents and education materials. The OIG attempted to use these terms consistently with the cited reference.

⁶ Recommendations directed to the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

6. Develops a formal evaluation of the provision of pain management services within VA to complement the Opioid Safety Initiative.
7. Ensures that VA's practice of routine and random urine drug tests both prior to initiating and during take-home opioid therapy to confirm the use of opioids is in alignment with guidelines.
8. Ensures that opioid patients with active (not in remission) substance use disorder undergo urine drug testing and receive treatment for the substance use disorder.
9. Evaluates and determines that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with guidelines.
10. Ensures that medication reconciliation is performed to prevent adverse drug interactions.

Comments

The Executive in Charge, Office of the Under Secretary for Health, concurred with recommendations 1–6, 9, and 10; concurred in principle with recommendations 7 and 8; and provided acceptable action plans. (See Appendix F, pages 66–76 for the comments of the Executive in Charge.) The OIG will follow up on the planned actions until they are completed.



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Abbreviations

CIH	Complementary and Integrative Health
COT	chronic opioid therapy
EHR	electronic health record
FY	fiscal year
OIG	Office of Inspector General
OSI	Opioid Safety Initiative
PCP	primary care provider
PDMP	Prescription Drug Monitoring Programs
SCAN-ECHO	Specialty Care Access Network-Extension for Community Health Outcomes
SUD	substance use disorder
UDT	urine drug testing or tests
VAMC	VA Medical Center
VHA	Veterans Health Administration



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess Veterans Health Administration (VHA) facilities' pain management services at the request of Senators Edward J. Markey and Richard Blumenthal and Representatives Ralph Abraham, Dan Benishek, Gus Bilirakis, Ryan Costello, Seth Moulton, Beto O'Rourke, Kathleen Rice, Dina Titus, and Jackie Walorski. Specifically, the OIG looked at pain management practices including opioid prescribing and the treatment of substance abuse.

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Section 1

In this section, the broad background issues related to pain management and the survey results of 141 VHA medical facilities on pain management services are discussed.

Background

Definition of Pain

Pain is a complex phenomenon that is an individual, subjective experience. Because psychological and social factors can affect the pain experience, patients with similar injuries may experience pain differently. Pain is often identified as a biopsychosocial phenomenon and can produce emotional and cognitive effects in addition to affecting an individual's ability to fulfill societal roles, such as work.

Pain may be characterized by its duration. Pain lasting less than three months is defined as acute pain. For patients with acute pain, attention is primarily devoted to the treatment of identifiable physical causes such as inflammation, soft tissue damage, broken bones, and nerve damage. Chronic pain lasts longer than three months and can develop in the absence of an acute injury or persist beyond the resolution of identifiable physical causes of pain. The focus of this section and report is on chronic pain.

Because of its persistent nature, chronic pain is particularly problematic to treat and has often been refractory to conventional treatments. Propagation of chronic pain separate from physiological causations can make the treatment plan more complex. Comprehensive pain

management, particularly for chronic pain, extends beyond the use of opioids, injections, and surgeries and looks to incorporate prevention, counseling, and the facilitation of self-care, which are features of successful treatments. Often, pain management for veterans becomes even more complicated because chronic pain problems may include multiple issues:

- Homelessness
- Posttraumatic stress disorder (PTSD)
- Cognitive impairment from traumatic brain injury and other conditions
- Depression
- Combat injuries
- Polytrauma
- Substance abuse and other complex psychosocial issues⁷

Pain Management and Treatment Options

The options available to manage and treat pain are broad. Expert groups such as the Institute of Medicine (IOM⁸) recognize that “interdisciplinary, biopsychosocial approaches are the most promising for treating patients with persistent (chronic) pain.”⁹ According to the IOM, pain management “...treatments can include medications, surgery, behavioral interventions, psychological counseling, rehabilitative and physical therapy, and complementary and alternative therapies.”¹⁰ Healthcare providers should tailor pain care to each patient’s experience, and self-management of pain should be promoted.

Because of its complexity, treatment options, and refractory nature, chronic pain management represents a significant challenge to healthcare professionals in all clinical settings. Within VHA, various clinicians provide pain relief to veterans including primary care providers (PCPs) and pain specialists. Because the number of patients with chronic pain significantly outnumbers pain specialists, the bulk of pain care is provided by PCPs with referrals to specialists as deemed

⁷ VHA Directive 2009-053, *Pain Management*, October 28, 2009. This VHA Directive expired October 31, 2014 and has not been updated.

⁸ In 2015, members of the Institute of Medicine changed the name of the organization to the National Academy of Medicine.

⁹ Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, Report Brief, June 2011. <http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research/Report-Brief.aspx>. (The website was accessed on May 30, 2016.)

¹⁰ Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, Report Brief, June 2011.

necessary. Provision of comprehensive pain care should include access to an array of specialists because of the breadth of conditions that can cause or worsen pain symptoms. Additionally, Complementary and Integrative Health (CIH) therapies are recommended as one of the earliest steps in the treatment of chronic pain.

Roles of PCPs and Pain Specialists in VHA Pain Management

PCPs

In all clinical settings, both outside and within VHA, most patients with acute and chronic pain will initially see their PCP. Over half of PCPs treat chronic pain¹¹ and one out of five outpatient visits is for primary symptoms or diagnoses of pain.¹²

A patient with pain symptoms may be cared for by a single provider with individualized therapy or by an interdisciplinary team. Even in cases where an interdisciplinary team is not utilized, the importance of an interdisciplinary approach to the diagnosis and management of pain is important. The management of chronic pain is often complicated by its refractory nature. The initial approach taken to treat pain may be unsuccessful or the pain may progress, necessitating the provider to trial different medications, order various blood tests and studies, and initiate referrals to specialists or interdisciplinary teams. Limitations to accessing referral sources may prevent such evaluations.

PCPs in VHA manage patients with chronic pain who are on chronic opioid therapy (COT) and deemed low to moderate risk for opioid misuse. PCPs may refer patients deemed higher risk for opioid misuse to behavioral health, structured pain clinics, or substance use disorder (SUD) facilities. The number of patients on COT in a PCP's panel¹³ may depend on various factors, including the provider's level of comfort with chronic pain management with opioids, the type of pain conditions diagnosed, and concurrent mental health diagnoses (that is, SUD, PTSD, major depression). PCPs new to VHA often "inherit" panels with patients already on COT for years. The complexities of pain management become apparent if the new PCP has a lower level of comfort to continue or monitor those chronic pain patients on COT. Further, if access to pain specialty services is limited, the ability to formulate a treatment plan that is acceptable to both the patient and provider is compromised.

¹¹ Breuer B, Cruciani R, Portenoy RK. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: a national survey. *South Med J.* 2010 Aug;103(8):738-47.

¹² Daubresse M., Chang H., Yu Y., et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010. *Med Care.* 2013; 51:870–878.

¹³ A panel is a group of patients who obtain their primary medical care from the same VA primary care team.

Pain Management Specialists

In cases where treatment is inadequate or pain persists, and chronic pain management is beyond the expertise of a single provider, PCPs and patients benefit from access to and collaboration with pain management specialists. According to VHA Directive 2009-053, *Pain Management*,¹⁴ PCPs must have access to pain consultative and treatment sources to effectively evaluate and manage the multifaceted conditions and complex psychosocial issues of chronic pain.¹⁵ This directive also states that integrating behavioral health in the primary care of chronic pain is essential to optimize clinical outcomes and provide essential support to the medical care of patients.¹⁶ Providing access to pain specialty care will enhance the PCP's ability to provide the patient with good pain care.

As the understanding of the complexities of pain has grown, it has become more important to have providers with specialized knowledge and skills to treat these conditions. A specialist who provides pain management services often has

- An in-depth knowledge of the physiology of pain,
- The ability to evaluate patients with complicated pain problems,
- An understanding of specialized tests for diagnosing painful conditions,
- The knowledge to prescribe medications for varying pain problems, and
- Skills to perform procedures and interventional techniques, such as nerve blocks and spinal injections.¹⁷

In addition, pain management specialists play an important role in coordinating additional care such as physical therapy, psychological therapy, and rehabilitation programs in order to offer patients a comprehensive treatment plan with a multidisciplinary approach to the treatment of pain.¹⁸

VHA utilizes a variety of pain management specialists:

¹⁴ VHA Directive 2009-053.

¹⁵ VHA Directive 2009-053.

¹⁶ VHA Directive 2009-053.

¹⁷ VHA Directive 2009-053.

¹⁸ VHA Directive 2009-053.

- **Anesthesiologists**—specialists who have in-depth knowledge of the prescription of pain medication as well as pain procedures.¹⁹
- **Certified Registered Nurse Anesthetists**—advanced practice nurses who may provide pain medications to patients in different practice settings and may provide pain procedures when allowed by state law.²⁰
- **Neurologists**—specialists who treat diseases of the nervous system.²¹ Illnesses, disorders, and injuries that involve the nervous system can result in pain and often benefit from a neurologist’s management and treatment.
- **Orthopedic Surgeons**—surgeons who manage pain arising from disorders of the musculoskeletal system and utilize a variety of procedures including therapy, pain procedures such as joint and soft tissue injections, and various types of surgery to relieve pain.
- **Pain Medicine Subspecialists**—physicians who have completed a one-year accredited fellowship in Pain Medicine in addition to their primary specialty certification.²² Pain Medicine subspecialists often serve as consultants to other physicians for the evaluation, treatment, and rehabilitation of persons in pain.
- **Physical Medicine and Rehabilitation Physicians**—specialists who diagnose, evaluate, and manage patients with physical and/or cognitive impairment and disability, specializing in maximal restoration or development of physical, psychological, social, occupational, and vocational functions in persons whose abilities have been limited by disease, trauma, congenital disorders, or pain.²³

¹⁹American Society of Anesthesiologists. <https://www.asahq.org/whensecondscount/patients%20home/pain%20management>. (The website was accessed on August 13, 2016.)

²⁰ American Association of Nurse Anesthetists. <http://www.aana.com/ceandeducation/becomeacrna/Pages/default.aspx>. (The website was accessed on September 26, 2016.)

²¹ American Academy of Neurology. <http://patients.aan.com/go/workingwithyourdoctor>. (The website was accessed on November 13, 2017.)

²² The American Board of Medical Specialties recognizes subspecialty certificates in Pain Medicine for those physicians who are board certified in Anesthesiology, Family Medicine, Physical Medicine and Rehabilitation, Neurology, and Psychiatry. Physicians with board certification in Emergency Medicine and Radiology have also been approved for the subspecialty but certificates have not yet been issued.

²³American Board of Physical Medicine and Rehabilitation. <https://www.abpmr.org/>. (The website was accessed on August 13, 2016.)

- **Psychiatrists**—physicians who deal with emotional, mental, or behavioral disorders²⁴ and employ their expertise to treat pain as well as manage comorbid conditions such as depression or addiction that may complicate the treatment of pain.
- **Psychologists**—experts who help people cope with the thoughts, feelings, and behaviors that accompany chronic pain. In addition, psychologists may collaborate with other health care professionals to address both the physical and emotional aspects of a patient’s pain.
- **Rheumatologists**—physicians who received further training in the diagnosis and treatment of musculoskeletal disease and systemic autoimmune conditions that can affect the joints, muscles, and bones that cause pain, swelling, stiffness, and deformity.²⁵

Pain Management Education for PCPs

The objective of pain management education for PCPs is to increase providers’ comfort level to manage pain. To achieve these goals, the educational components should ultimately teach providers to recognize, manage, and safely treat acute and chronic pain.

A 2011 IOM report recognized education deficiencies in training physicians for pain management beginning in medical school.²⁶ In a 2008 report that described the survey responses of 279 VHA PCPs, 74 percent reported that they were expected to manage chronic pain conditions that they felt were beyond their scope of practice, training, or experience at least some of the time.²⁷ Approximately one third of VHA PCPs who responded did not feel confident about using opioids²⁸ to treat chronic non-cancer pain.²⁹

Several studies have noted concerns about the prevalence of opioid prescribing and the education and training of physicians in this aspect of pain management. For patients with primary

²⁴ American Psychiatric Association. <https://www.psychiatry.org/patients-families/what-is-psychiatry>. (The website was accessed on November 13, 2017.)

²⁵ American College of Rheumatology, <http://www.rheumatology.org/I-Am-A/Patient-Caregiver/Health-Care-Team/What-is-a-Rheumatologist>. (The website was accessed on September 26, 2016.)

²⁶ Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, Report Brief, June 2011.

²⁷ Allison R. Mitchinson, MPH; Eve A. Kerr, MD, MPH; and Sarah L. Krein, PhD, RN. Management of Chronic Noncancer Pain by VA Primary Care Providers: When Is Pain Control a Priority? *Am J Manag Care*. 2008;14:77-84.

²⁸ Opioids are a class of drugs prescribed by providers to relieve pain, but which have a potential for misuse. SAMHSA – Opioids. <https://www.samhsa.gov/atod/opioids>. (The website was accessed on February 12, 2017.)

²⁹Allison R. Mitchinson, MPH et al, 2008.

symptoms or a diagnosis of pain, opioids are prescribed approximately 20 percent of the time.³⁰ In 2013, a study reported that VHA providers described inadequacy of training, in particular, training in the management of opioids in complex patients with co-occurring addiction and behavioral health problems. Additional areas of concern by those surveyed included their physical exam skills, when to order imaging, when to refer to a specialist, how to choose between various treatments, and which tools to use to best monitor therapy response.³¹ A review published in 2017 found significant discrepancies between the prevalence of chronic pain in society and the low priority assigned to educating future physicians about the complexities of pain and the social context of those afflicted.³²

A paradox exists where pain management education is recognized to be lacking by those who assess and treat pain. Providing PCPs with comprehensive pain management education will allow for enhanced and efficient patient care. With this education, PCPs can be equipped to better manage pain, either in the initial management of the patient or when a pain specialist completes a referral and sends the patient back to the referring provider.

Specific Pain Management Education Programs in VHA

VHA has utilized two newer programs to deliver and increase pain education in addition to traditional education through lectures. The first program, Specialty Care Access Network-Extension for Community Health Outcomes (SCAN-ECHO), uses case-based training for PCPs and their teams and is often located at smaller VHA facilities or in rural areas. The training is designed to increase provider knowledge, competencies, and professional training hours in a specific specialty area.³³ The second program is Specialty Care Mini-Residency programs. The Mini-Residency program uses a VHA approved standardized national curriculum with a three-day face-to-face component to educate and train PCPs, with a particular emphasis on training PCPs assigned to community based outpatient clinics.

³⁰ Daubresse M., Chang H., Yu Y., et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010. *Med Care*. 2013; 51:870–878.

³¹ Lincoln et al. Barriers and Facilitators to Chronic Non-Cancer Pain Management in Primary Care: A Qualitative Analysis of Primary Care Providers' Experiences and Attitudes. *J Palliative Care Med* 2013, S3.

³² Webster F et al. From Opiophobia to Overprescribing: A Critical Scoping Review of Medical Education Training for Chronic Pain. *Pain Medicine* 2017; 18: 1467–1475.

³³ Department of Veterans Affairs – Fact Sheet - Specialty Care Access Network-Extension for Community (SCAN-ECHO). <https://www.va.gov/HEALTH/docs/Specialty-Care-Access-Network.pdf>. (The website was accessed on March 2, 2017.)

VHA Stepped Model of Care Applied to Pain Management

The 2009 VHA *Pain Management* Directive outlined a new treatment strategy for pain, the Stepped Care Model.³⁴ The Stepped Care Model is a method of providing effective treatment for patients experiencing acute and chronic pain and provides guidance for the management of most pain conditions in primary care. The model supports easy access in primary care to consultations with specialists, particularly an interdisciplinary pain specialty team. This results in an interdisciplinary teamwork approach to providing biopsychosocial and patient-centered pain management in the primary care setting.

The Stepped Care model incorporates an increased emphasis on teaching patient self-management and increased system support for primary care. Pharmacists assist with medication and opioid management and behavioral health technicians screen for mental health comorbidities. The model also incorporates guidelines and clinical algorithms.

Opioid Use Guidelines in Pain Management

VHA, in collaboration with the Department of Defense (DoD), has published several versions of clinical practice guidelines for the management of opioid therapy for chronic pain since 2003.³⁵ The latest guidelines were published in February 2017 (after the study period for this report) and updated recommendations for the evaluation, treatment, and management of patients with chronic pain. The guidelines are intended to guide the treatment of patients with chronic pain by providing evidence-based information but are not intended to define a standard of care. Successful implementation of the guidelines would improve a provider's ability to

- Assess the patient's condition, provide education, and determine the best treatment methods in collaboration with the patient and a multidisciplinary care team;
- Optimize the patient's health outcomes and function, and improve quality of life;
- Minimize preventable complications and morbidity; and
- Emphasize the use of patient-centered care.

³⁴ VHA Directive 2009-053; VA Under Secretary for Health Memorandum, *Validity of VHA Policy Document*, June 29, 2016.

³⁵ VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, March 2003; VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010; VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2017.

Methods of Monitoring Opioid Prescribing

COT poses patient safety risks that can change over time. The treatment plan for a patient on COT includes clinical assessments and reassessments, urine drug testing/tests (UDT),³⁶ and Prescription Drug Monitoring Program (PDMP) data checks. When ongoing, this plan allows a provider to analyze the risk and benefits of COT. VHA also tracks data and produces reports on opioid prescribing that provide detail for leadership at facility, VISN, and national levels.

Clinical Assessments and Reassessments

The 2010 VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain (2010 CPG) recommends that clinicians assess patients regarding their compliance with taking opioid medications appropriately as well as for evidence of misuse, abuse, or addiction.³⁷ The 2010 CPG further recommends that patients be assessed for compliance with other components of the treatment plan such as follow-up visits and other tests. Even when a patient is on a stable dose of medication, the 2010 CPG recommends regular reassessments at a frequency of every one to six months depending on the patient's individual circumstances.³⁸

UDTs

UDTs provide critical information that assists the provider in the analysis of proper opioid compliance and use by the patient. They can provide indicators if a patient is not taking opioids as prescribed, or if there is evidence of diversion, or illegal, unprescribed drug use, such as selling or trading. With a UDT, a drug that is prescribed and taken as directed should show in the patient's urine. Additionally, the UDT can screen for drugs that are not on the patient's medication list and that should not be detectable in the urine. UDTs provide substantial information that supports the safety of the patient.

Providers must be able to interpret UDTs effectively. Evaluating UDT results requires knowledge on how to interpret the results and the clinical context of taking opioids (for example, as needed, around the clock). UDTs may fail to show that the patient is taking the prescribed opioid. Providers must understand how the patient is taking the medicine, and that the absence of an opioid in the UDT results does not necessarily indicate diversion. UDTs may be falsified, and the clinician must be aware of urine testing inconsistencies. Providers must also be ready to

³⁶ In this report, the terms urine drug screen(ing) and urine drug test(ing) are used interchangeably. These terms appear in VA/VHA pain management documents and education materials. The OIG attempted to use these terms consistently with the cited reference.

³⁷ VA/DoD Clinical Practice Guideline, 2010.

³⁸ VA/DoD Clinical Practice Guideline, 2010.

discuss treatment plans with the patient when illegal substances are detected or if diversion is suspected.

PDMPs

PDMPs are statewide databases of electronically transmitted prescribing and dispensing data of controlled substances.³⁹ States developed PDMPs to support the legitimate use of controlled substances by monitoring opioid prescribing and prescription drug diversion, abuse, and addiction. PDMPs support states' efforts in abuse prevention, education, research, and law enforcement. By accessing a PDMP database, VHA providers can determine if a patient is receiving controlled substances from non-VHA providers in the state. This information is important for VHA providers since many veterans are managed by both VHA and non-VHA providers.

States vary widely as to which health care providers are authorized to request and receive prescription data. Most states allow practitioners and pharmacists licensed in the state to obtain PDMP reports.⁴⁰ PDMPs also vary from state-to-state on which controlled substances are monitored.⁴¹ The VHA Pain Management Opioid Safety Educational Guide recommends obtaining data from the PDMP before initiating COT and annually at a minimum.⁴²

Depending on individual state requirements, VHA providers and pharmacists can register with the state and query state PDMP databases. However, VHA providers and pharmacists may be licensed in a state other than the state where their practicing facility is located. Out-of-state licensed providers may not be allowed to access that state's PDMP database because of the state-based nature of PDMPs.⁴³

³⁹ A controlled substance is a drug whose manufacturing, dispensing, and possession are regulated by the government. Drugs considered to be controlled substances are divided into and regulated according to five schedules: I, II, III, IV, and V. Substances are placed in schedules based on the presence of an accepted medical treatment use, abuse potential, and the likelihood of causing dependence when abused.

⁴⁰ United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, State Prescription Drug Monitoring Programs, http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm. (The website was accessed on August 23, 2016.)

⁴¹ Prescription Drug Monitoring Program Training and Technical Assistance Center, <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>. (The website was accessed on August 8, 2016.)

⁴² United States Department of Veterans Affairs, *Pain Management Opioid Safety*, Educational Guide 2014. Pages 7, 8. http://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Toolkit_Provider_AD_Educational_Guide_7_17.pdf.

⁴³ Prescription Drug Monitoring Program Training and Technical Assistance Center. <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>. (The website was accessed on August 8, 2016.)

Evolving Role of Opioids in Pain Management

Since the publication of the 2010 CPG, the role of opioids in the treatment of chronic pain has evolved from: (a) consider opioids after other options failed to (b) use only in a rare subset of patients. A recent systematic review looking at the effectiveness and risks of long-term opioid therapy for chronic pain found insufficient evidence on improved pain and function while finding evidence for dose-dependent risk of serious harm.⁴⁴

A study in the New England Journal of Medicine suggests that increased intensity of physician opioid prescribing was positively associated with the probability that a patient would become a long-term opioid user in the next 12 months.⁴⁵

Prominent medical organizations such as the Centers for Disease Control and Prevention and the American College of Physicians have issued guidelines within the past year recommending a limited use of opioids for chronic pain and a preference for non-opioid treatments. Centers for Disease Control guidelines also included many recommendations included in the 2010 CPG, such as limiting the co-prescription of benzodiazepines and opioids, regular follow-up with patients, and UDT at initiation and at least annually.

The 2017 VA/DoD guideline for the management of opioid therapy for chronic pain (2017 CPG) recommends against the use of long-term opioids in the treatment of chronic pain, unlike the previous version that counseled weighing the risks and benefits and considering opioids after other options had failed.⁴⁶ The 2017 CPG recommends that opioids be initiated in a “rare subset of individuals.”

Regulatory Initiatives Affecting Opioid Prescribing in VHA

The Drug Enforcement Agency (DEA) has made changes to its classification of two commonly prescribed opioids, hydrocodone and tramadol, that have restricted such prescribing. The DEA classifies controlled substances from Schedule I through V. Schedule I and II drugs have high abuse potential compared to other scheduled drugs. In October 6, 2014, the DEA changed hydrocodone combination products from schedule III to schedule II. This change resulted in stricter limitations to the distribution of hydrocodone by requiring a new prescription each time this medication is requested. On August 18, 2014, the DEA placed tramadol into a schedule IV

⁴⁴ Chou, R, Turner, J, Devine, B, et al. The Effectiveness and Risks of Long-term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop. *Annals of Internal Medicine*. 2005. 162(4): 276-286.

⁴⁵ Barnett, ML et al. Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use. *N Engl J Med* 2017;376:663-73.

⁴⁶ VA/DoD Clinical Practice Guideline 2003; VA/DoD Clinical Practice Guideline 2010; VA/DoD Clinical Practice Guideline 2017.

category. Previously, tramadol was not a scheduled drug. The DEA recognized the abuse potential for tramadol and changed its classification.

State Medical Licensing

In response to the opioid crisis, state medical boards have updated providers' prescribing guidelines with increased regulations. Some state medical boards have established opioid dispensing regulations as licensure requirements for providers. In March 2016, Massachusetts became the first state to pass legislation restricting providers to a seven-day supply limit for first time adult opioid prescriptions and to a seven-day supply prescription limit overall for minors.⁴⁷ Connecticut and New York enacted similar legislation in July 2016, limiting a provider to no more than a seven-day supply for an initial acute pain prescription.^{48, 49} Before prescribing certain controlled substances, providers in 29 states must check PDMP databases. The North Carolina medical board started "The Safe Opioid Prescribing Initiative" program to assist the state in identifying providers who may be prescribing opioids recklessly and improperly.⁵⁰ Regulations are being designed to ensure providers use caution in prescribing opioids and regularly monitor patients receiving opioids.⁵¹

While non-VHA providers are licensed in the states that they practice, VHA providers may practice in any VA facility regardless of their licensing state. However, the VHA provider must adhere to his/her state's licensure requirements even though they may be practicing in a different state. For example, a provider with a license from New York but practicing in Oklahoma must adhere to the New York dispensing regulations. The fact that some VHA providers work in one state but are licensed in another can complicate pain management practices if the state in which they work is one that does not allow out-of-state licensees to access the PDMP.

⁴⁷ American Bar Association Health Law Section, Prudent Prescribing: An Overview of Recent Federal and State Guidelines for Opioid Prescriptions, http://www.americanbar.org/publications/aba_health_esource/2016-2017/opioids/prescriptions.html. (The website was accessed on February 6, 2017.)

⁴⁸ Health Systems Connecticut Passes 7 Day Opioid Prescription Limit, <http://www.healthsystems.com/news/connecticut-passes-7-day-opioid-prescription-limit>. (The website was accessed on February 6, 2017.)

⁴⁹ New York State Department of Health, https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/. (The website was accessed on February 6, 2017.)

⁵⁰ American Bar Association Health Law Section, Prudent Prescribing: An Overview of Recent Federal and State Guidelines for Opioid Prescriptions, http://www.americanbar.org/publications/aba_health_esource/2016-2017/opioids/prescriptions.html. (The website was accessed on February 6, 2017.)

⁵¹ American Bar Association Health Law Section, Prudent Prescribing: An Overview of Recent Federal and State Guidelines for Opioid Prescriptions, https://www.americanbar.org/publications/aba_health_esource/2016-2017/opioids/prescriptions.html. (The website was accessed on February 6, 2017.)

Opioid Safety Initiative

The VHA Opioid Safety Initiative (OSI) was chartered in August 2012 and implemented nationwide in August 2013. On December 10, 2014, the OSI Update established goals for safe, evidence-based, veteran-centric pain care. VHA has other programs that complement OSI such as Opioid Overdose and Naloxone Distribution, Stratification Tool for Opioid Risk Mitigation, and the Opioid Therapy Risk Report.

Created in July 2014, the Pain Management Opioid Safety VA Educational Guide (Educational Guide) outlines chronic pain treatment strategies, including the consideration of non-opioid treatment options, opioid treatment with an assessment of the patient at every visit, re-evaluations of the treatment plan, and consultation with a specialist based on selected clinical factors. The Educational Guide also outlines screening for risk factors of addiction and misuse. The Opioid Risk Tool, a screening tool mentioned in the Educational Guide, may be useful for predicting risk of future aberrant drug-related behavior. On October 1, 2014, VHA's "National Pain Management Program office convened a national task force comprised of multidisciplinary pain experts to create an OSI Toolkit..."⁵² The OSI Toolkit is located on the VHA Pain Management internet site and contains documents and presentations to guide providers in their clinical decisions about starting, continuing, or tapering opioid therapy, and other challenges related to safe opioid prescribing.

Treatment Drugs for Addiction and Overdose

Methadone, naltrexone, and Suboxone®, a combination medication that contains buprenorphine/naloxone, are the three medications used to treat opioid addiction. Naloxone is used to treat opioid overdose.⁵³ Providers can prescribe naltrexone, naloxone, and Suboxone® in a variety of clinical settings. However, providers can only prescribe methadone for the purpose of treating opioid addiction within special programs and clinical settings.⁵⁴

⁵² VHA Opioid Safety Initiative Toolkit, October 1, 2014, http://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp. (The website was accessed on July 15, 2016.)

⁵³ Naloxone Kits and Naloxone Autoinjectors, Recommendations for Issuing Naloxone Kits and Naloxone Autoinjectors for the VA Overdose Education and Naloxone Distribution Program, https://vaww.portal.oig.va.gov/directorates/54/NationalReviews/2016-00538-HI-0640/Background/Naloxone_Kits_and_Autoinjector_Recommendations_for_Use_June_2015.pdf. (The website was accessed on June 2015.)

⁵⁴ U.S. Department of Veterans Affairs, Mental Health Treatment Programs for Substance Use Problems, <http://www.mentalhealth.va.gov/res-vatreatmentprograms.asp>. (The website was accessed on January 17, 2017.)

Methadone

Although initially used for pain management, providers have used methadone for decades to treat patients addicted to heroin and narcotic pain medications. Methadone blocks painful opiate withdrawal symptoms while also blocking the euphoric effects of opioids. Patients receive methadone for opioid addiction only under the supervision of a physician within a certified opioid treatment program. Providers may allow patients to take methadone at home between program visits only after patients have established a period of stability. Methadone is highly restricted and when used to treat opioid addiction, it can only be dispensed in specialized clinical settings.⁵⁵

Naltrexone

Naltrexone is a medication used to treat alcohol and opioid use disorders. It is available in both oral and injectable forms. The oral form is used for alcohol use disorder and the injectable form is used for the treatment of opioid use disorder. Naltrexone injection reduces opioid cravings with no abuse or diversion potential. However, with naltrexone, patients may develop a reduced tolerance to opioids and experience a greater sensitivity to the same previously used dose of opioid. A patient relapse with the same opioid could result in possible life-threatening consequences, including circulatory collapse and respiratory arrest.⁵⁶ Providers do not typically choose naltrexone as the first line agent in the treatment of opioid use disorders.⁵⁷

Buprenorphine and Suboxone®

Buprenorphine is an opioid medication used for the treatment of opioid dependence. Like opioids, it causes euphoria and respiratory depression but with weaker effects. It has a lower potential for misuse, increased safety in cases of overdose, and diminished effects from physical dependency on opioids, such as withdrawal symptoms and cravings.⁵⁸ Although buprenorphine can reduce pain, the 2010 CPG recommends against using buprenorphine for pain management only.

Physicians most often prescribe buprenorphine as Suboxone®, a combination medication that contains both buprenorphine and naloxone. Suboxone® can treat opioid addiction and guard

⁵⁵ SAMHSA- Methadone, <https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>. (The website was accessed on January 17, 2017.)

⁵⁶ SAMHSA- Naltrexone. <http://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone>. (The website was accessed on October 18, 2016.)

⁵⁷ Progress in Neuro-psychopharmacology and Biological Psychiatry. <https://www.ncbi.nlm.nih.gov/pubmed/26577297>. (The website was accessed on December 1, 2016.)

⁵⁸ SAMHSA-Buprenorphine. <http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>. (The website was accessed on October 18, 2016.)

against intravenous abuse of medication. Unlike methadone treatment for opioid addiction, physicians can administer Suboxone® treatment in an office setting rather than a highly structured clinic. However, the DEA regulates Suboxone® prescribing more than other opioids. Physicians must meet qualifications for a waiver to prescribe Suboxone® before the DEA will assign them a special identification prescribing number.⁵⁹ The number of patients that a physician may treat with Suboxone® is initially limited to 30. A year after receiving the initial waiver to prescribe Suboxone®, physicians can apply to have that limit increased to 100 patients. Since August 8, 2016, physicians who have had a waiver to treat 100 patients for at least one year can become eligible to increase their patient limit to 275.⁶⁰ In OIG's discussion with congressional staffers, they expressed concern that the Suboxone® prescriber limit may be limiting veteran access to Suboxone® treatment. The OIG addressed this concern in its analysis.

Naloxone

Naloxone is a medication used to block or reverse the effects of opioid medications including respiratory depression and hypotension. If administered promptly, naloxone can reverse opioid overdoses and is a potentially life-saving treatment for patients. With the increasing number of fatalities related to opioid overdose deaths, interest in ensuring access to naloxone by friends and family of patients with an overdose history as well as first responders has increased. To address opioid overdose deaths among VA patients, VA initiated the Overdose Education and Naloxone Distribution program. Components of the program include issuing naloxone kits to veterans who are either prescribed opioids and/or at increased risk for opioid overdose as well as educating veterans, friends, and family of high-risk veterans on the use of naloxone kits or autoinjectors.⁶¹ The 2017 CPG recommends prescribing Naloxone and accompanying education on its use as a risk mitigation strategy for those patients on long-term opioids.

⁵⁹ SAMHSA - *How to Qualify for a Physician Waiver*. <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver>. (The website was accessed on March 29, 2016.)

⁶⁰ Physicians are also required to have additional certification in addiction medicine or addiction psychiatry and practice in a qualified practice setting. For details, see: http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/understanding-patient-limit275.pdf.

⁶¹ Naloxone Kits and Naloxone Autoinjectors, Recommendations for Issuing Naloxone Kits and Naloxone Autoinjectors for the VA Overdose Education and Naloxone Distribution Program, https://vaww.portal.oig.va.gov/directorates/54/NationalReviews/2016-00538-HI-0640/Background/Naloxone_Kits_and_Autoinjector_Recommendations_for_Use_June_2015.pdf. (The website was accessed on June 2015.)

Risk of Overdose

A study of risk factors for opioid overdose in VHA patients published in 2014⁶² concluded that “the risk of life-threatening toxicity, including overdose, in medical users of prescription opioids is an alarming, escalating public health problem.” Substantial risk exists when even a relatively low daily dose of opioids is used in patients who are vulnerable due to sociodemographic factors, concomitant medical and psychiatric conditions, and simultaneous use of other medications or substances.⁶³ At higher doses, the risk of opioid overdose increases several fold.

VHA Substance Abuse Treatment Programs

While most care for veterans with SUD is provided outside of SUD Specialty Care settings in general mental health clinics, specialty SUD services are required to be available at least by consultation in person or using tele-mental health. Patients who have been treated in specialized SUD programs may be stabilized sufficiently to be followed over the long-term in general mental health settings. According to VHA,⁶⁴ at least one tertiary, interdisciplinary pain rehabilitation program must be available in each Veteran Integrated Service Network to manage more complex cases.

Opioid Treatment Program

An opioid treatment program provides first line outpatient treatment for patients with chronic opioid dependence. These programs must meet the requirements outlined in 42 C.F.R. § 8, Certification of Opioid Treatment Programs.⁶⁵

Intensive Outpatient Program

An intensive outpatient program provides a specialized form of care that falls between residential/inpatient care and the more traditional models of ambulatory care. Intensive outpatient treatment is intended to help patients with SUD establish a period of initial abstinence, initiate care for co-occurring medical and mental health conditions, and promote engagement in continuing care for relapse prevention. The program may serve as an initial level of care or as a step-down program from inpatient or residential care or as an additional support for patients who are not progressing well in standard ambulatory care.

⁶² Zedler, B., Xie, L., et al. (2014). Risk Factors for Serious Prescription Opioid-Related Toxicity or Overdose among Veterans Health Administration Patients. *Pain Medicine* **15**: 1911-1929.

⁶³ Zedler et al, 2014.

⁶⁴ VHA Directive 2009-053.

⁶⁵ These requirements are more detailed than required for the treatment of pain or the prescription of Suboxone® in the outpatient setting.

Domiciliary Substance Abuse Program or Substance Abuse Residential Rehabilitation Treatment Program

Substance abuse programs provide residential/inpatient rehabilitation and treatment services for SUD patients with multiple and severe medical conditions, co-occurring mental illnesses, or psychosocial deficits. The programs aim to provide a 24-hour, seven-day per week structured and supportive residential environment as part of a SUD rehabilitative treatment before full community re-entry.

Relevant OIG Work

In 2014, the Senate Committee on Veterans' Affairs requested that OIG conduct a national review⁶⁶ to assess the provision of VA outpatient (that is, take-home) opioids and monitoring of patients on opioid therapy. The OIG published a report with six recommendations directed to the Under Secretary for Health:

1. Ensure that the practice of prescribing acetaminophen is in compliance with acceptable standards.
2. Ensure that VA's practice of routine and random UDTs prior to initiating and during take-home opioid therapy to confirm the appropriate use of opioids is in alignment with acceptable standards.
3. Ensure that follow-up evaluations of patients on take-home opioids are performed timely.
4. Ensure that opioid patients with active (not in remission) substance use receive treatment for substance use concurrently with urine drug tests.
5. Ensure that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with acceptable standards.
6. Ensure that medication reconciliation is performed to prevent adverse drug interactions.

Eleven VA OIG hotline reports concerning opioid issues were published in 2017. See Appendix A for a list of recent OIG reports relevant to this topic.

Scope and Methodology

From April 27 to May 18, 2016, the OIG conducted an electronic survey of 141 VHA medical facilities and had a 100 percent response rate. For the purposes of the OIG's survey, pain management services were reviewed for outpatient care of veterans that included a broader range of services than the Pain Clinic, but excluded hospice, palliative care, and end-of-life care. Sections of the survey were directed to the Chiefs of Staff, Primary Care, Mental Health, and

⁶⁶ VAOIG Report No. 14-00895-163, May 14, 2014.

Pharmacy to determine staffing within pain clinics, substance use treatment programs, pain management education for providers, access to PDMP, and the level of satisfaction with the current methods of monitoring opioid prescribing. The OIG team evaluated the survey responses and interviewed the individuals who completed the surveys at select facilities to clarify and/or expand on their responses.

The OIG developed descriptive statistics of the survey data to assess the types of pain and SUD specialists available at VA medical facilities. The OIG team looked at types of substance use treatment programs available at VA facilities and examined the content and delivery methods of pain education. VA medical center leaders were also asked to provide their assessment of their medical facilities' ability to monitor opioid prescribing and pain management services. The responses were summarized and analyzed using frequency analysis.

To determine whether the Suboxone® prescribing limit restricted veteran access, the OIG team reviewed all the prescriptions for Suboxone® written at the relevant facilities in FY 2015 and calculated the number of prescriptions written by each provider. The OIG team also calculated descriptive statistics to understand the distribution of provider prescribing activity. The OIG team calculated the 50th, 95th, and 99th percentiles in this population. The OIG team estimated the minimum number of annual prescriptions⁶⁷ that a provider at the Suboxone® prescribing limit would write and compared this estimate to the distribution of the provider prescribing activities to estimate the percentage of providers who were prescribing at the Suboxone® prescriber limit.

The OIG reviewed the number of Suboxone® prescriptions written at each facility because of the significant variation in the number of Suboxone® prescriptions written by providers. The OIG team also compared the distribution of the number of Suboxone® prescriptions between facilities that reported having enough providers to meet demand and those that did not. The OIG team calculated the minimum, 25th percentile, 50th percentile (median), 75th percentile, and maximum number of prescriptions for both groups.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency

⁶⁷ The OIG team made several assumptions in determining criteria for this minimum: (1) The provider had 100 patients throughout FY 2015 (this was the Suboxone® prescriber limit during the time period); (2) The patient received Suboxone® continuously during this time period; (3) Prescriptions for Suboxone® were written for one month; (4) Providers applied to have their patient limit increased after one year. These criteria were designed to be sensitive but not specific, for example, to detect all prescribers who are prescribing at the Suboxone® prescriber limit but also will capture a number of prescribers that are prescribing below this limit.

Inspection Results

Issue 1: Description of VHA Pain Management Staffing and Clinics Staffing

Six percent (8/141) of the facilities reported not having any pain management specialists. Fifty-four percent (76/141) of the facilities reported having a Board-Certified Pain Medicine physician, the specialist with the most advanced pain training. The OIG found that 53 percent (75/141) of the facilities reported having at least one of the following non-physician providers specializing in pain management: (1) Certified Registered Nurse Anesthetist, (2) Nurse Practitioner, and (3) Physician Assistant.

Because of the importance of psychosocial factors in the manifestation of pain, the OIG included questions in the survey about psychiatrist and psychologist staffing. Twenty-one percent (29/141) and 76 percent (107/141) of the facilities reported that they had a psychiatrist and psychologist who provided pain management respectively. Because psychiatrists were often located in facilities with psychologists, 23 percent (32/141) of the facilities had neither specialist who provided pain management.

Pain Clinics

Eighty-six percent (121/141) of the facilities reported having a pain clinic, and 41 percent (58/141) reported having a polytrauma clinic specializing in pain management. In addition, 71 percent (110/141) of the facilities reported one or all of the following clinics specializing in pain management: (1) chiropractic, (2) acupuncture, and (3) Complementary and Integrative Health.

Pain rehabilitation programs are another type of pain clinic that focus on teaching patients how to manage pain. These programs have an interdisciplinary staff of psychologists, physicians, physical therapists, nurses, occupational therapists, and vocational rehabilitation counselors.⁶⁸ Fourteen percent (20/141) of the facilities reported that they had a Commission on Accreditation of Rehabilitation Facilities (CARF)⁶⁹ accredited interdisciplinary pain rehabilitation program. Interdisciplinary pain rehabilitation programs provide rehabilitation that is individualized for the

⁶⁸ Institute for Chronic Pain (ICP), *Treating Chronic Pain (Pain Centers)*, <http://www.instituteforchronicpain.org/treating-common-pain/pain-centers>. (The website was accessed on August 23, 2016.)

⁶⁹ CARF is an accrediting body that evaluates health and human service programs across the continuum of care, serving children to seniors. The services include many types of living and care options, including addiction and substance abuse treatment, rehabilitation after an injury or disease, employment for persons with a disability, home and community services, and retirement living. CARF International, <http://www.carf.org/Programs/>. (The website was accessed on September 28, 2017.)

needs of patients with persistent pain and are designed to maximize patient participation and quality of life.⁷⁰

While it was possible to characterize the distribution of pain specialists and pain clinics in VHA, the OIG was unable to determine whether this pattern of staffing sufficed to address the demand for pain services.

Issue 2: Description of VHA Substance Use Treatment

The OIG asked facilities to describe services that were offered for substance use treatment because SUD is a significant comorbidity in chronic pain patients. While recognizing that most SUD care was delivered at general mental health clinics, the OIG team focused on those clinics that offer specialized care to veterans.

The OIG asked about substance use clinics with addiction-focused pharmacotherapy such as methadone or Suboxone®. Overall, 96 percent (135/141) of facilities offered substance abuse treatment using either methadone or Suboxone®. Twenty-three percent of facilities (32/141) reported having an outpatient methadone clinic. Eighty-one percent of facilities (114/141) reported having an outpatient Suboxone® clinic. Of the facilities without an outpatient Suboxone® clinic, 78 percent (21/27) had at least one provider waived to prescribe Suboxone®. The six medical facilities that had no Suboxone® provider also did not have a methadone clinic.

The OIG asked facilities about specialized services for substance abuse treatment. Eighty-two percent of facilities (116/141) reported having an Intensive Outpatient Program. Fifty-nine percent of facilities (83/141) reported having residential treatment programs. Ninety-five percent of facilities (134/141) reported offering at least one specialized substance abuse treatment program.⁷¹ Ninety-seven percent of facilities (137/141) reported offering at least one specialized outpatient clinic for substance use treatment or substance use clinic with addiction-focused pharmacotherapy.

Suboxone® Prescribers

Although the OIG found 1,089 Suboxone® prescribers throughout VHA in FY 2015, 50 percent of the facilities (71/141) reported that they did not have enough Suboxone® prescribers to meet the demand at their facility. For those 1,089 Suboxone® prescribers in FY 2015, half wrote 31 prescriptions or less; only 5 percent wrote 701 prescriptions or more, and only 1 percent (eleven providers) each wrote more than 1,413 prescriptions. The OIG team estimated that a prescriber with a panel at the Suboxone® prescribing limit would write a minimum of 1,200 prescriptions

⁷⁰ CARF International, <http://www.carf.org/Programs/>. (The website was accessed on August 19, 2016.)

⁷¹ A substance abuse treatment program was defined as a program such as an Intensive Outpatient Program, a residential treatment program, or other outpatient clinics for substance abuse disorders.

per year and concluded that the number of providers prescribing at the limit represents a small percentage of prescribers at most. Because the criterion was designed to be sensitive but not specific, the OIG team recognizes that the analysis above represents an overestimate of the number of providers at the Suboxone® prescribing limit.

The number of reported Suboxone® prescribers at each facility ranged from 0 to 32; the OIG did not see a pattern that indicated that facilities with a higher number of prescribers were more likely to meet Suboxone® demand. Because of the wide variation in the number of prescriptions by provider, the OIG team also looked for a similar pattern with regard to the number of Suboxone® prescriptions written at each facility. The distribution of the number of facility Suboxone® prescriptions was similar between those facilities meeting Suboxone® demand and those that did not. For those facilities that reported being unable to meet demand, the most common reason given was that not enough providers chose to manage patients with opioid addiction (49/71). None of the facilities reported that the ability to meet the demand for Suboxone® was restricted by the current Suboxone® patient prescribing limit.

Recent administrative changes made it less likely that the prescribing limit would restrict Suboxone® prescribing in VHA. This survey and analysis was completed prior to the Substance Abuse Mental Health Services Administration increase in the patient limit from 100 to 275.⁷²

In FY 2015, the Suboxone® patient prescribing limit was not the reason that facilities were unable to meet demand for Suboxone® prescribing. Two possible solutions for increasing Suboxone® prescribing to meet demand would be to increase the number of prescriptions being written by each provider or to increase the number of providers that are waived to prescribe Suboxone®.

The OIG noted that many of VHA's Suboxone® prescribing physicians were writing a relatively small number of prescriptions. The OIG team inferred that such prescribers were not specialists treating opioid addiction but instead either provided coverage for the patients of such specialists⁷³ or prescribed to a small number of patients in their panel. Such physicians may not have been in a position to significantly expand the number of patients with opioid addiction that they managed. Furthermore, such prescribers were likely to be psychiatrists or PCPs who were already in short supply, so trying to increase Suboxone® prescribing by asking such providers to increase their prescribing may have resulted in shortages in those critical need areas.

⁷² Physicians are also required to have additional certification in addiction medicine or addiction psychiatry and practice in a qualified practice setting. For details, see: http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/understanding-patient-limit275.pdf.

⁷³ Based on other OIG work, most of the Suboxone® prescribing at a facility was performed by three individuals while the rest of the prescribers (approximately 20) provided coverage when one of three were on leave or out sick.

The OIG team reasoned that VHA’s difficulty with meeting demand for Suboxone® was primarily related to an insufficient number of providers who manage patients with opioid addictions.

Issue 3: Description of VHA Provider Pain Management Educational Efforts

According to VHA Directive 2009-053, VHA provider pain management education includes evaluation of pain, stepped care in treating pain, and reviewing the use of opioids as part of the treatment plan for chronic pain. In addition, ordering UDT and interpretation of UDT results are an integral part of caring for the patient on COT, and the results directly influence future care plans for the patient.

Facility clinical leaders assess pain care rendered by providers through continuous clinical review. In turn, facility leadership has the responsibility of ensuring that education efforts are supported through allocation of time and resources so that providers receive that education.

Facility Leadership Role in Pain Education

An objective in the VHA Pain Management Strategy⁷⁴ is to assure that clinicians practicing in the VA healthcare system are adequately prepared to assess and manage pain effectively. VHA Directive 2009-053 stated that “all clinical staff (for example physicians, psychologists, nurses, pharmacists, therapists, and chaplains), should have orientation related to the principles of pain assessment and management upon being hired, as well as ongoing education and training.”

Chronic pain management encompasses assessment, diagnosis, treatment, and follow-up of patients. Because the demographics of staff vary by facility, training requirements set forth by leadership are ideally designed to adjust for those differences. The approach may be different based on the treating provider’s training and available resources, to include pain management specialists and support staff.

All surveyed VA facility respondents answered that they provided pain education to providers. The survey included specific questions about modalities and a write-in section. The number of modalities used ranged from one to six. Table 1 codifies the complexity⁷⁵ of the facility to the number of modalities utilized. A Level 1 facility is more complex than a Level 3. Similar rates

⁷⁴ VHA Pain Management Strategy is outlined at https://www.va.gov/PAINMANAGEMENT/VHA_Pain_Management_Strategy.asp. (The website was accessed on August 16, 2017.)

⁷⁵ The Facility Complexity Model classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex. The model is reviewed and updated with current data every three years. The most recent model is the FY 2014 model, which was approved and signed by the Under Secretary for Health on March 25, 2015.

were noted for Levels 1, 2, and 3 facilities for providing at least six or more modalities, at 8 percent (7/84), 8 percent (2/25), and 6 percent (2/31), respectively.

Table 1. Facility Complexity Levels and Number of Modalities Used

Facility Complexity Level	Total Number of Facilities	Number (%) of Facilities Using One Modality	Number (%) of Facilities Using Two to Five Modalities	Number (%) of Facilities Using Six Modalities
1 a, b, and c	84	9 (11)	68 (81)	7 (8)
2	25	5 (20)	18 (72)	2 (8)
3	31	2 (6)	27 (87)	2 (6)
Unassigned	1		1 (100)	

Source: OIG analysis of VHA survey data

Based on the education section of the survey, the OIG found that provider pain management education is mandatory in approximately half (74/141) of the facilities, but voluntary education is provided for in most (136/141). This indicates that although facilities recognize the importance of education, the individual aspects of the amount and type of pain management training is at the discretion of the providers.

For all 74 facilities that required mandatory provider education, the components (Table 2) were consistent with those in the OSI. The OIG listed the most commonly utilized education programs in VHA, according to the survey results (Table 3). While facility lectures and Training Management System⁷⁶ are traditional methods of delivering education in VA, the OIG found that over half (81/141) of the facilities utilized SCAN-ECHO, a case based training for PCPs and their teams, for pain education.

⁷⁶ The Talent Management System offers computerized training for VA employees and staff.

Table 2. Percent of the 74 Facilities Requiring Mandatory Opioid Education, by OSI Components

Components	Number of Facilities	Percentage
Urine Drug Screening and Monitoring	66	89.2
Alternatives to Opiates	63	85.1
Clinical Indications for Use	62	83.8
Pharmacology and Safety	61	82.4
Other	30	40.5

Source: *OIG Pain Management Survey Results*

Table 3. Facilities (141) Answers to Modalities Available for Training Primary Care Providers

Programs	Number of Facilities	Percentage
Facility In-service or Lecture	118	83.7
Talent Management System, Excluding the Mini Residency	107	75.9
Specialty Care Access Network - Extension for Community Healthcare Outcomes (SCAN-ECHO)	81	57.4
Cyberseminar/Webinar	74	52.5
Mini Residency (TMS and face-to-face components)	23	16.3
Preceptorship with Pain Specialist (face-to-face)	22	15.6

Source: *OIG Pain Management Survey Results*

PCPs must be better educated on the benefits, limitations, and dangers of prescribing opioids. However, pain education should include elements beyond opioid prescribing as part of a comprehensive plan to provide appropriate pain clinic services. An expected end result of this education is more scrutiny by the clinician regarding initiating opioids, and safer, increased surveillance for patients already on opioids.

Issue 4: Access to State PDMPs

The OIG found that 41.4 percent (58/141) of the facilities reported that out-of-state licensed providers working at the facility could not access PDMPs. Among the 58 facilities with providers who did not have access to the state's PDMP, 71 percent (41/58) of these facilities had alternative processes allowing a review of PDMP data, such as having a licensed state

pharmacist or other appropriate providers review the PDMP and document the findings in the medical record.

Seventeen (of the 58) facilities did not report having alternative processes to describe how out-of-state licensed providers accessed the PDMP. Because six of the responses indicated that the facility had an alternative process or was developing one, the OIG team considered 11 facilities as having no alternative processes for out-of-state licensed providers to access PDMP information. Forty-seven percent (8/17) provided additional details about PDMP access. Among the eight facilities, the OIG found that

- Licensed state pharmacists queried the PDMP, 37.5 percent (3/8),
- State PDMPs were developing plans to allow out-of-state providers access to the state PDMP, 37.5 percent (3/8), and
- State PDMPs did not allow and had no plans to allow out-of-state providers access, 25 percent (2/8).

For the 83 (out of 141) facilities who reported that out-of-state providers had access to the PDMP, the OIG asked whether all opioid prescribers had access to the PDMP. Thirty-four percent (28/83) of the facilities were unaware of whether all opioid prescribers had access.

Issue 5: Oversight of Pain Management Patients

Monitoring VA Providers' Opioid Prescribing Practices

The OIG asked whether facility leaders were satisfied with the current methods of monitoring providers' opioid prescribing practices. The OIG found (Table 4) that 81 percent (114/141) of the facilities responded as being "satisfied" or "somewhat satisfied" with the current methods of monitoring opioid prescribing at the facility. The remaining 19 percent reported responses of neutral or lower, and 4 percent (6/141) of the facilities responded as being "dissatisfied" or "somewhat dissatisfied" with the current methods of monitoring opioid prescribing.

Table 4. Percent of 141 Facilities’ Reported Satisfaction with the Monitoring of Provider Opioid Prescribing

Response	Number of Facilities	Percentage
Very Satisfied	46	32.6
Somewhat Satisfied	68	48.2
Neutral	21	14.9
Somewhat Dissatisfied	4	2.8
Not Satisfied	2	1.4

Source: OIG Pain Management Survey Results

The OIG asked for the reasons why the six facilities expressed dissatisfaction. The reasons included

- A perception that opioid initiative requirements interfered with the clinician’s autonomy to practice medicine,
- The National OSI Dashboard compares VA facilities by relative ranking and small changes in opioid prescribing practices can result in large changes in ranking,
- The existing opioid prescribing standards lack assurance of appropriate clinical follow-up, and
- The lack of compliance by providers in following the guidelines.

Monitoring Pain Management Consistent with the Stepped Model of Care

The VA Stepped Model of Care is a strategy designed to provide effective treatment to patients with chronic pain.⁷⁷ The OIG noted that 60 percent of facility leaders reported being “very satisfied” or “somewhat satisfied” that current methods of monitoring pain management allow leadership to determine whether patients receive pain management consistent with the Stepped Model of Care. The remaining 40 percent of facilities reported views of neutral or lower, with 12 percent (17/141) (Table 5) responding that they were “somewhat dissatisfied” to “dissatisfied,” that current methods of monitoring pain management allow facility leaders to determine whether patients receive pain management consistent with the Stepped Model of Care.

⁷⁷ VHA Directive 2009-053.

Table 5. Percent of 141 Facilities' Reported Satisfaction with the Monitoring of Provider Pain Management.

Response	Number of Facilities	Percentage
Very Satisfied	25	17.7
Somewhat Satisfied	60	42.6
Neutral	39	27.7
Somewhat Dissatisfied	10	7.1
Not Satisfied	7	5.0

Source: OIG Pain Management Survey Results

These facilities expressed multiple reasons for dissatisfaction in response to an open-ended query. Dissatisfaction that was expressed tended to follow five themes:

- Lack of reliable data; difficulty aggregating subjective pain assessments; and inadequate assessment tools
- Lack of pain management resources and expertise to provide care or adequate pain management training for other pain treating staff
- Inability to evaluate purchased pain care or provide specialized pain care at facilities without pain management specialists
- Lack of a clear standard on how to provide pain management presents challenges in assessing pain, pain management practice, and measuring and evaluating patient outcomes of the services they provided
- Frustration with comparisons to other facilities using incomplete or limited data

Twice as many facilities reported that they were not satisfied with their ability to monitor pain management compared to opioid prescribing. The comments from those facilities expressing dissatisfaction with their methods of monitoring pain management reflected the difficulty of assessing pain and the impact of pain care on patients as well as the complexity of measuring the quality of pain management care.

Section 2

In this section, VA patterns of dispensing outpatient opioids and monitoring patients on opioid therapy are analyzed.

Background

More than 50 percent of all veterans enrolled and receiving care at VHA are affected by chronic pain, which is a much higher rate than in the general adult population.⁷⁸ Veterans who suffer from chronic pain also experience much higher rates of other co-morbidities (PTSD, depression, traumatic brain injury) and socioeconomic dynamics (disability, joblessness) that may contribute to the challenges of pain management when treated with opioids.

In 1998, the VHA National Pain Management Strategy was initiated, which established pain management as a national priority. The overall objective of the strategy was to develop a comprehensive, integrated system-wide approach to pain management that reduces pain and suffering and improves quality of life for veterans experiencing acute and chronic pain. In 2009, VHA issued a directive⁷⁹ for the improvement of pain management consistent with the VHA National Pain Management Strategy.

In 2003, VA and DoD published the first Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (2003 CPG) to improve pain management, quality of life, and quality of care for veterans. The 2003 CPG was revised in 2010 and 2017 to update the evidence base of the original 2003 CPG.⁸⁰ Additionally, the scope was widened to include patients with cancer who have chronic pain because of the disease itself or the treatment they are receiving.

Opioid therapy is intended for patients who suffer from moderate to severe chronic pain and who have had limited success with non-opioid or non-pharmacological therapy and who may benefit from opioid therapy for pain control. Opioids are powerful medications that can help manage pain when prescribed for the right condition and when used properly. However, if prescribed inappropriately or if used improperly, they can cause serious harm, including overdose and death. Patient adherence with the proper use of opioids is crucial in the delivery of appropriate opioid therapy. Patient assessments, follow-up evaluations, and UDTs are recommended monitoring tools for safe and effective use of opioids.

⁷⁸ Statement of Dr. Robert L. Jesse, M.D., Principal Deputy Under Secretary for Health, Veterans Health Administration, Before the Subcommittee on Health, U.S. House of Representatives, October 10, 2013.

⁷⁹ VHA Directive 2009-053.

⁸⁰ VA/DoD Clinical Practice Guideline 2003; VA/DoD Clinical Practice Guideline 2010; VA/DoD Clinical Practice Guideline 2017.

Adverse Effects of Opioid Therapy

While opioids are useful for managing chronic pain, adverse effects are potential limitations to their use.⁸¹ Therefore, providers need to weigh the risks against the benefits of opioid use either alone or in combination with other medications that could cause adverse effects, such as benzodiazepines, and against expected effects such as constipation.

Even a single large dose of opioids can cause severe respiratory depression or death. Long-term use or abuse of opioids can lead to physical dependence (a normal adaptation to chronic exposure) and addiction. In cases of long-term use or abuse, withdrawal symptoms may occur if opioids are too rapidly reduced or stopped without tapering. These symptoms can include restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, and involuntary leg movements. In general, extreme caution must be used when prescribing opioids with other substances that depress the central nervous system (CNS), such as benzodiazepines, because in combination, there is an increased risk of life-threatening respiratory depression.⁸²

Selected Recommendations for UDTs from the 2010 CPG⁸³

The 2010 CPG provided education and guidance on chronic (more than 1 month) opioid therapy to providers. However, 2010 CPG recommendations for UDTs are applicable to all patients on opioid therapy, regardless of the length of time.

Specifically, the 2010 CPG recommends routine and random UDTs prior to initiation of and during opioid therapy. The frequency of UDTs should be increased based on risk level for aberrant drug-related behaviors and following each dose increase. The risk of opioid misuse in patients on opioid therapy is reported to be as high as 30 percent and patients with a history of SUD are at higher risk of developing problematic drug use, addiction, or relapse. UDTs can identify patients using illicit substances and can assist in the diagnosis of SUD. They can also help identify patient adherence to opioid therapy and drug diversion.

Medication Reconciliation

Medication reconciliation ensures the maintenance of accurate, safe, effective, and above all, patient-centered medication information.⁸⁴ One of The Joint Commission's national patient

⁸¹ Swegle, J. M. and C. Logemann (2006). Management of common opioid-induced adverse effects. *Am Fam Physician* 74(8): 1347–1354.

⁸² Jones, J. D., S. Mogali, et al. (2012). Polydrug abuse: a review of opioid and benzodiazepine combination use. *Drug Alcohol Depend* 125(1–2): 8–18.

⁸³ VA/DoD Clinical Practice Guideline, May 2010.

⁸⁴ VHA Directive 2011-012, *Medication Reconciliation*, March 9, 2011. This VHA Directive expired March 31, 2016 and has not been updated.

safety goals is medication safety by maintaining and communicating accurate patient medication information.⁸⁵ VHA requires that medication reconciliation be performed across the continuum of care, including outpatient encounters, to prevent adverse drug interactions. VHA also requires that patients be educated about their medications prior to or at the time of dispensing according to the patient's individualized drug regimen.⁸⁶ Clinicians are required to discuss necessary drug information, potential drug interactions, and necessary laboratory tests for monitoring medication therapy outcomes and to evaluate the medication order to ensure appropriate dosing, taking into account the renal and liver function of the patient. Prior to initiating opioid therapy, the 2010 CPG recommends that providers carefully evaluate potential drug interactions (such as methadone with benzodiazepines and fentanyl with alcohol and other CNS depressants).

Benzodiazepines

Benzodiazepines are a type of psychoactive (mind-altering) medication known as anxiolytics and/or anticonvulsants that are most often prescribed to treat anxiety, acute stress reactions, panic attacks, seizures, and sleep disorders. They are one of the most widely prescribed medications in the U.S., particularly among elderly patients. Familiar names include Valium® (diazepam) and Xanax® (alprazolam). Benzodiazepines act on the CNS to slow its function and promote relaxation, thereby reducing muscle tension and other physical symptoms of anxiety. Benzodiazepines may cause respiratory depression in susceptible patients. Therefore, they generally should not be used with opioids because the combination increases the risk of life-threatening respiratory depression.

Benzodiazepines have the potential for abuse. They can be chronically abused, or intentionally or accidentally taken in overdose. While death and serious illness rarely result from benzodiazepine abuse alone, the concurrent use of benzodiazepines and opioids can be dangerous because both depress the CNS.⁸⁷ Benzodiazepines have been strongly associated with death from opioid overdose.⁸⁸

Scope and Methodology

The study population contains all VA patients who filled at least one oral or transdermal outpatient opioid prescription from VA in FY 2015 and who did not receive any hospice or

⁸⁵ The Joint Commission Sentinel Event Alert, Issue 35, January 25, 2006.

⁸⁶ VHA Handbook 1108.05, *Outpatient Pharmacy Services*, May 30, 2006. This Handbook was in effect during the time frame of the events discussed in this report; it was rescinded and replaced by VHA Handbook 1108.05, *Outpatient Pharmacy Services*, June 16, 2016.

⁸⁷ Jones, J. D., S. Mogali, et al. (2012). Polydrug abuse: a review of opioid and benzodiazepine combination use. *Drug Alcohol Depend* **125**(1–2): 8–18.

⁸⁸ Toblin, R. L., L. J. Paulozzi, et al. (2010). Mental illness and psychotropic drug use among prescription drug overdose deaths: a medical examiner chart review. *J Clin Psychiatry* **71**(4): 491–496.

palliative care during the FY or within one year prior to their first outpatient opioid prescription. In addition to following the patients retrospectively through the end of FY 2015, the OIG also looked back to evaluate whether they filled any opioid prescriptions for outpatient use and whether they experienced certain medical conditions during FY 2014.

The study period includes background shifts in opioid provision in VA because VA's effort of monitoring adherence to its interim guidance⁸⁹ through the routine review of data from the OSI Dashboard, and providing feedback on outliers where needed, after the publishing of OIG's report *Healthcare Inspection—VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*, (Report Number 14-00895-163, May 14, 2014).

The study population encompasses some Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn (OIF/OEF/OND) veterans as well as veterans from other service eras, such as Operations Desert Shield and Desert Storm. As a result, the outcomes that the OIG observed in this population may be different from those of OEF/OIF veterans only.⁹⁰

Study Population

The OIG included all VA patients who filled any oral or transdermal outpatient opioid prescriptions from a VA outpatient pharmacy or consolidated mail outpatient pharmacy in FY 2015 and who did not receive any hospice or palliative care in the FY or within one year prior to their first filled prescription.

The OIG identified the study population using the VA administrative Pharmacy data housed in the VA Corporate Data Warehouse, which contained all VA filled inpatient and outpatient prescription records. The OIG first identified opioid products using the following 10 types of opioids: (1) codeine, (2) fentanyl, (3) hydrocodone, (4) hydromorphone, (5) meperidine, (6) methadone, (7) morphine, (8) oxycodone, (9) oxymorphone, and (10) tapentadol. The OIG included all opioid products in the 10 selected opioids that were categorized as U.S. Drug Enforcement Administration (DEA) schedule II or III controlled substances (as indicated in the dimension tables associated with the administrative Pharmacy data). Drugs and other substances that are considered controlled substances under the *Controlled Substances Act* are divided into five schedules, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. Schedule II controlled substances have a high potential for abuse that may lead to severe psychological or physical dependence. Schedule III controlled substances have less potential for abuse than substances in Schedules I or II, and abuse of Schedule III drugs may

⁸⁹ This problem is discussed in the OIG report *Healthcare Inspection – VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*, Report No. 14-00895-163, May 14, 2014, p. 55.

⁹⁰ Seal, K. H., Y. Shi, et al. (2012). "Association of mental health disorders with prescription opioids and high-risk opioid use in US veterans of Iraq and Afghanistan." *JAMA* **307**(9): 940–947.

lead to moderate or low physical dependence or high psychological dependence. All opioids selected for this study were oral medications only except for fentanyl, which also comes in transdermal form.

The OIG then searched the VA Pharmacy data file to identify VA patients for the study by including all those patients who filled at least one prescription of the opioids on OIG's list in FY 2015 for outpatient use.⁹¹ The OIG then linked all these patients with VA administrative inpatient and outpatient (including non-VA care under VA auspices) treatment files to identify and then exclude those patients who received hospice or palliative care (Appendix C) anytime in FY 2015 or within one year of their first outpatient opioid prescription in FY 2015.

Chronic Users and Non-Chronic Users of Opioids

As in the 2014 report, the OIG classified the study population into two subpopulations, chronic users and non-chronic users of opioids, based on the number of days they were on opioids. The OIG counted overlapping supply days from different prescriptions once only for the number of days on opioids as in the OIG's 2014 report. For example, if a patient filled one prescription that supplied opioids from March 3, 2015, through March 10, 2015, then filled another prescription that supplied opioids from March 8, 2015, through March 14, 2015, the OIG counted the number of days on opioids as 12 instead of 15 after taking into account the overlapping supply days from March 8, 2015, to March 10, 2015. Figure 3 in Appendix B shows the OIG's calculation of days on opioids for a patient with five filled prescriptions.

Although the computation is much more complex, the OIG's definition of days on opioids better reflects the physical days a patient should be on opioids through taking into account both partially and totally overlapping prescriptions. Totally overlapping prescriptions may result from either intentional combination use of different opioid drugs (for example, morphine and hydrocodone) or unintentional combination use of the same opioids to attain dosages that are not readily available by manufacturers (for example, to reach a daily dose of 85 mg methadone, a patient may be given both a filled prescription of three tablets of METHADONE HCL 5MG TAB and a filled prescription of seven tablets of METHADONE HCL 10MG TAB simultaneously). Because days on opioids are less than or equal to the simple sum of the supply days, the OIG's calculated daily doses using days on opioids (as the denominator) are greater than or equal to those calculated based on just a simple sum of the supply days. Similarly, the OIG's numbers of chronic users (more than 90 days on opioids) are less than or equal to those calculated based on just a simple sum of the supply days.

The OIG defined patients as *chronic users* of opioids if they were on opioids for more than 90 days in FY 2015 and as *non-chronic users* if they were on opioids 90 days or less. Rather than a

⁹¹ The OIG used the Dispense Date field to identify oral or transdermal outpatient opioid prescription that were filled.

simple sum of the number of supply days from all filled prescriptions, the OIG defined days on opioids by counting overlapping supply days from different prescriptions once only rather than just taking a simple sum of the number of supply days from all filled prescriptions as in the literature.⁹²

The OIG's definition of chronic users of opioids (more than 90 days) is relevant only to the given time period because of the nature of cross-sectional data. For example, the non-chronic users in FY 2015 would be considered chronic users if they were initiated on opioid therapy during the 4th quarter of FY 2015 (that is, new patients in FY 2015) and continued the therapy through FY 2016. This would also apply to the non-chronic users in FY 2015 if they were initiated on and continued with therapy through FY 2014 (that is, existing patients in FY 2015) but ended prior to the 2nd quarter of FY 2015. Similarly, chronic users in FY 2015 would not be chronic users in FY 2016 if they were on outpatient opioids for 30 days or less in FY 2016. (See Figure 4 in Appendix B for examples.) The OIG results by chronic and non-chronic users should be viewed within the context of this limitation that is common to cross-sectional studies. For this reason, this study included all patients, whether on chronic (more than one month as defined by the 2010 CPG) or non-chronic outpatient opioid therapy. Note that the OIG defined patients as *chronic users* of opioids if they were on opioids for more than 90 days in FY 2015, while 2010 CPGs defined *chronic therapy* as more than one month.

Data and Study Variables

After identifying the study population, the OIG linked the population to FY 2014 and FY 2015 VA administrative treatment data to find

- Information on VA clinical visits and associated clinical diagnoses,
- Laboratory data to obtain detailed urine drug test records, and
- FY 2014 pharmacy prescription data to check for any filled opioid prescriptions for outpatient use during that FY.

The OIG determined patients' vital status as of the end of FY 2015 using the SPatient data table in the Corporate Data Warehouse. If a patient had more than one death date listed, the OIG (arbitrarily) used the later date as the death date. For example, if both 6/8/2015 and 8/6/2015 were listed as the death date for a patient, the OIG would use 8/6/2015 as the patient death date.

⁹² Seal, K. H., Y. Shi, et al. (2012). "Association of mental health disorders with prescription opioids and high-risk opioid use in US veterans of Iraq and Afghanistan." *JAMA* 307(9): 940–947.

Prevalence of Patients Dispensed Outpatient Opioids in FY 2015

The OIG defined the prevalence as the percent of patients who filled any outpatient opioids at VA during FY 2015 among those VA patients who had at least one clinical (that is, with at least one valid ICD-9 diagnostic code) outpatient encounter in FY 2015.

Baseline Characteristics

The OIG defined a medical condition as a *baseline* condition if it was diagnosed within one year prior to (or at the time of) the patient's first filled opioid prescription in FY 2015. The OIG considered a patient to have a *mental health diagnosis* if the patient was diagnosed with any specific codes within the category of Mental Disorders (290–319) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). The category of Mental Disorders of ICD-9-CM corresponds to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Revised (DSM-IV-R). Except for the category of *psychological pain*, the OIG used Hoge's definitions⁹³ to create the following specific categories of mental health diagnoses based on ICD-9-CM diagnostic codes:

- Adjustment disorders: 309.0, 309.24, 309.28, 309.3, 309.4, 309.9
- Posttraumatic stress disorder (PTSD): 309.81
- Anxiety disorders excluding PTSD: 300.00, 300.01, 300.02, 300.21, 300.22, 300.23, 300.29, 300.3, 308.3
- Mood disorders: 296.0, 296.2–296.7, 296.80, 296.89, 296.90, 300.4, 301.13, 311
- Major depression: 296.2, 296.3
- Personality disorders: 301.0, 301.2, 301.4, 301.50, 301.6, 301.7, 301.81–301.84, 301.89, 301.9
- Psychotic disorders: 295.1–295.4, 295.6, 295.7, 295.9, 297.1, 297.3, 298.8, 298.9
- Substance use: 291, 292 (except 292.2), 303–305 (except 305.1 and 305.8)
- Alcohol-related disorders: 291, 303, 305.0
- Drug-related disorders: 292 (except 292.2), 304, 305.2–305.7
- Psychological pain: 307.80 and 307.89. 305.9

⁹³ Hoge, C. W., S. E. Lesikar, et al. (2002). Mental disorders among U.S. military personnel in the 1990s: association with high levels of health care utilization and early military attrition. *Am J Psychiatry* **159**(9): 1576-1583.

The OIG adapted Seal's definitions⁹⁴ to determine whether a patient was diagnosed with any *primary pain* (Appendix D). These *primary pain site* diagnoses included ICD-9-CM non-cancer diagnostic codes that could result in pain serious enough to warrant an opioid medication.

The OIG determined that a patient was diagnosed with *pain of the nervous system and sense organs* if one of the following ICD-9-CM diagnostic codes in the category of *pain of the nervous system and sense organs* was found

- Acute pain: 338.1,
- Chronic pain: 338.2,
- Neoplasm-related pain: 338.3, or
- Chronic pain syndrome: 338.4.

The OIG deemed a patient was diagnosed with *pain* if he or she had a diagnosis of *primary pain site* and/or *pain of the nervous system and sense organs*.

Dispensing Patterns

The 2010 CPG recommends more careful monitoring of opioid patients treated with benzodiazepines as co-administration of these products may result in adverse drug interactions. Benzodiazepines have been strongly associated with death from opioid overdose⁹⁵ and with an increased risk of death due to methadone toxicity.⁹⁶ The OIG determined whether the patients were receiving benzodiazepines concurrently with opioids. The OIG defined a patient as having received *concurrent benzodiazepine and opioid prescriptions* in FY 2015 if the patient had at least one filled outpatient opioid prescription with supply days that overlapped with the supply days of at least one filled outpatient benzodiazepine prescription. For the study, the OIG included the benzodiazepine prescriptions from the VA Pharmacy file identified as one the following 14 types of benzodiazepines: (1) alprazolam, (2) chlordiazepoxide, (3) clorazepate, (4) diazepam, (5) estazolam, (6) flurazepam, (7) halazepam, (8) lorazepam, (9) midazolam, (10) oxazepam, (11) prazepam, (12) quazepam, (13) temazepam, and (14) triazolam. For each patient in the study population, the FY 2015 Pharmacy data was searched to look for any filled benzodiazepine prescription records based on the above list.

The OIG calculated *morphine equivalent* dose for each filled opioid prescription using the formula (Quantity * Strength * Potency factor) to standardize opioid doses across different types

⁹⁴ Seal, K. H., Y. Shi, et al., 2012.

⁹⁵ Toblin, R. L., L. J. Paulozzi, et al. (2010). Mental illness and psychotropic drug use among prescription drug overdose deaths: a medical examiner chart review. *J Clin Psychiatry* **71**(4): 491–496.

⁹⁶ Caplehorn, J. R. and O. H. Drummer (2002). Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines. *Aust N Z J Public Health* **26**(4): 358–362; discussion 362–353.

of opioids.⁹⁷ The *daily morphine equivalent* was calculated as the sum of the morphine equivalents for each filled opioid prescription in FY 2015 divided by the number of days on opioids during the FY.

Screening and Monitoring Patients on Outpatient Opioids

The 2010 CPG guidance includes the screening and monitoring of opioid patients by UDTs and patient follow-up contacts.⁹⁸ It strongly recommends use of UDTs to assess illicit drug use and adherence to prescribed medications. A UDT should be obtained prior to opioid initiation and randomly at follow-up visits to confirm the appropriate use of opioids. The OIG searched UDT records in the Laboratory data for each patient in the study population to determine whether a patient received any UDTs. A urine sample may be used to test for one substance or multiple substances. The OIG categorized a UDT by test substance into one or all of three specific types (see Appendix E for urine drug testing Logical Observation Identifiers Names and Codes by type):

- (1) Heroin or morphine
- (2) Non-morphine opioid compounds
- (3) Non-opioid abusable substances

To take into account specific 2010 CPG recommendations for initiation and duration of opioid therapy, the OIG assessed the extent to which VA screened and monitored opioid patients in alignment with 2010 CPG recommendations separately by new and existing patients on outpatient opioids. The OIG considered a patient as a *new patient* for FY 2015 if he or she was initiated on outpatient opioids in FY 2015 and did not fill any outpatient opioid prescriptions at VA in FY 2014 (that is, at least one year without any outpatient opioids prior to initiation in FY 2015). The OIG designated a patient as an *existing patient* if he or she had filled at least one outpatient opioid prescription at VA in FY 2014.

For new patients who were initiated on outpatient opioids in FY 2015, the OIG determined whether they had received a UDT within 30 days prior to opioid initiation in FY 2015.

For existing patients, the OIG determined whether they had received an annual UDT. Patients were counted as having an annual UDT if a UDT record was found in the FY 2015 VA Laboratory data. For patients who died in FY 2015 and for whom a UDT was not found in the FY, the OIG also checked for a UDT by looking back in FY 2014 for a period that was sufficient to satisfy the one-year timeframe from the date of death. For example, for a patient who died on August 31, 2015, and for whom a UDT was not located in FY 2015, the OIG looked back to the

⁹⁷ Korff, M. V., K. Saunders, et al. (2008). De facto long-term opioid therapy for noncancer pain. *Clin J Pain* **24**(6): 521–527.

⁹⁸ VA/DoD Clinical Practice Guideline, May 2010.

period of September 1–30, 2014, for a UDT to make up for the missing month of September in order to satisfy the one-year timeframe (that is, September 1, 2014–August 31, 2015, specifically for this patient).

For informational purposes, for existing patients who had received an annual UDT, the OIG further investigated whether any of their UDTs were conducted while they were on opioids. If any UDT was conducted within seven days of the end of the supply days of any filled opioids, the OIG considered that the UDT was conducted while they were on opioids. The OIG used seven days to take into account the presence of opioids in the urine for up to seven days without any opioid in-take.

The 2010 CPG specifies that *chronic* (for more than one month⁹⁹) opioid therapy is absolutely contraindicated in patients with active (not in remission) substance use disorders (SUDs) who are not in treatment¹⁰⁰ and should be initiated with caution in patients receiving treatment for SUDs¹⁰¹. Active, regular monitoring of illicit substance use and adherence to the prescribed opioid regimen is strongly recommended for all patients but is crucial in this high-risk subpopulation.¹⁰²

The OIG designated a patient as with active SUD if any of the following ICD-9-CM diagnostic codes were found for the patient in FY 2015: 291, 292, 303.00–303.02, 303.90–303.92, 304.00–304.02, 304.10–304.12, 304.20–304.22, 304.30–304.32, 304.40–304.42, 304.50–304.52, 304.60–304.62, 304.70–304.72, 304.80–304.82, 304.90–304.92, 305.00–305.02, 305.20–305.22, 305.30–305.32, 305.40–305.42, 305.50–305.52, 305.60–305.62, 305.70–305.72, 305.80–305.82, 305.90–305.92.

The OIG considered that an active substance use patient had received treatment for substance use if any of the following VA codes were found for the patient in FY 2015:

- Treating specialty codes: 25–27, 37, 39, 85, 88, 1K, 1L, 1M
- Clinic stop codes: 513, 514, 519, 523, 534, 539, 545, 547, 548, 560

For all patients with active SUD in FY 2015, the OIG determined whether they had received both

- Treatment for SUD, and
- A UDT within 90 days of each filled opioid prescription.

⁹⁹ VA/DoD Clinical Practice Guideline, May 2010, p. 3.

¹⁰⁰ VA/DoD Clinical Practice Guideline, May 2010, p. 25.

¹⁰¹ VA/DoD Clinical Practice Guideline, May 2010, p. 24.

¹⁰² VA/DoD Clinical Practice Guideline, May 2010, p. 56.

For UDT analysis, the OIG excluded active substance use patients who did not have any filled opioid prescriptions that were at least 90 days prior to the end of the follow-up period (September 30, 2015, or the patient's date of death if the patient died in FY 2015).

Prevalence of Serious Adverse Effects

Increasing use of opioids has been associated with increasing rates of opioid-related serious adverse effects.^{103, 104, 105, 106} The OIG determined percentages of opioid patients with evidence of a serious adverse effect that may be reasonably expected to be related to opioid therapy.¹⁰⁷

The OIG classified a patient with *opioid overdose* if the patient was diagnosed with an opioid or heroin overdose (ICD-9-CM codes: E850.1, E850.2, E935.1, E935.2, E980.0, 965.0, E850.0, and E935.0) or had filled any naloxone prescriptions.

The OIG considered that a patient experienced *sedative overdose* if the patient was diagnosed with any of these ICD-9-CM codes:¹⁰⁸ E851, E852, E853.0–E853.2, E853.8, E853.9, E937.0, E937.8, E938.0, E939.1, E939.2, E939.4, E939.5, E980.1–E980.3, 967.0, 967.8, 968.0, and 969.1–969.5.

The OIG designated a patient as having been involved with *possible and confirmed suicide attempts* if the patient was diagnosed with any of these ICD-9-CM codes:¹⁰⁹ E950–E959, E980.6, E980.8, E981–E984, E988, and V62.84.

The OIG defined a patient as having experienced *drug delirium* if the patient was diagnosed with any of these ICD-9-CM codes:¹¹⁰ 292.1, 292.2, 292.8, and 292.9.

¹⁰³ Kuehn, B. M. (2010). Alarming nonfatal overdose rates found for opioids, sedatives, and tranquilizers. *JAMA* 303(20): 2020–2021.

¹⁰⁴ Clegg, A. and J. B. Young (2011). Which medications to avoid in people at risk of delirium: a systematic review. *Age Ageing* 40(1): 23–29.

¹⁰⁵ VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD)*, March 7, 2012. This handbook expired March 31, 2017, and has not been updated.

¹⁰⁶ VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*. <https://securereports3.vssc.med.va.gov/Reports/Pages/Report.aspx?ItemPath=%2fMentalHealth%2fMHOpioid%2fOpioidMatrixReport>. (This website is an internal VA site that is not accessible to the public. It was accessed on December 30, 2013.)

¹⁰⁷ https://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html. (The website was last accessed on September 4, 2018.)

¹⁰⁸ VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*.

¹⁰⁹ VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*.

¹¹⁰ VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*.

The OIG identified a patient as having received *drug detoxification* if the ICD-9-CM procedure codes 94.65 or 94.66 were found for the patient.

***Psychosocial Treatment for Pain, Pain Clinic Service,
Complementary and Integrative Health Service, and Medication
Management/Pharmacy Reconciliation***

The OIG determined whether the population of opioid patients received psychosocial treatment for pain or Pain Clinic service or had prescription management encounters anytime in FY 2015 or after the patient’s first opioid prescription.

Psychotherapy, including cognitive behavioral therapy, is recommended to reduce pain and improve function in chronic pain patients.¹¹¹ The OIG designated a patient as having received *psychosocial treatment for pain* if any of the following procedure codes¹¹² were found for the patient, which would indicate mental health treatment, behavioral medicine or behavioral health treatment, psychotherapy, and stress management:

- Current Procedural Terminology (CPT)¹¹³ codes: 90801, 90802, 90804–90829, 90845–90857, 96150–96155, 97532, 98960–98962, 99401–99404, 99411, 99412, 99510, 4306F, 90785, 90791, 90792, 90832–90834, 90836–90840
- ICD-9-CM procedure codes: 94.31, 94.33, 94.37, 94.38, 94.44, 94.49
- Healthcare Common Procedure Coding System (HCPCS)¹¹⁴ codes: H0002, H0004, H0017–H0019, H0023–H0025, H0030, H0031, H0032, H0035, H0046, H2001, H2012, H2014, H2017–H2020, H2027, G0177, S9454, T2048

Thus, OIG data did not take into account patients who were offered psychosocial treatment for pain but declined.

Treatment of chronic pain requires care to recover or maintain physical, social, and occupational function and may include Pain Clinic service. The OIG identified a patient as *receiving care from a Pain Clinic* if any encounters for the patient were found with the VA Clinic Stop Code of 420. Complementary and Integrative Health (CIH – previously referred to as complementary and alternative medicine or CAM) is increasingly seen as an adjunct to traditional plans of care. The

¹¹¹ Roditi, D. and M. E. Robinson (2011). The role of psychological interventions in the management of patients with chronic pain. *Psychol Res Behav Manag* 4: 41–49.

¹¹² VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*.

¹¹³ CPT is a code set that is used to report medical procedures and services.

¹¹⁴ HCPCS codes are billing codes used by Medicare and are numbers assigned to every task and service a medical practitioner may provide to a Medicare patient.

OIG considered a patient as *receiving* CIH modalities using the following CPT codes and groupings:

- CIH: 90875, 90876, 90880, 90901, 90911, 97014, 97032, 97110, 97112, 97124, 97140, 97150
- Acupuncture: 97810, 97811, 97813, 97814
- Osteopathic Care: 98925, 98926, 98927, 98928, 98929
- Chiropractic Care: 98940, 98941, 98942, 98943

Opioid patients frequently have complex co-morbid conditions, making them more likely to be given multiple medications that can interact dangerously with opioid medications. A review of medications by a pharmacist or other health care professional can prevent harmful interactions between these medications. The OIG classified a patient as *receiving medication management/pharmacy reconciliation* if any¹¹⁵ of these CPT codes were found for the patient: 99605, 99606, 99607, 90862, and 1160F or the Clinic Stop Codes 160 or 176. OIG's data did not take into account medication reconciliation performed by PCPs during clinic visits if it was not recorded as a CPT code.

Statistical Analyses

The OIG performed descriptive data analyses using SAS statistical software (SAS Institute, Inc., Cary, NC), version 9.4 (TS1M3).

The study was performed in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

¹¹⁵ VHA National Center for Patient Safety and Office of Mental Health Operations. *Opioid Therapy Guideline Adherence Report*.

Inspection Results

VA dispensed outpatient opioids to 996,667 patients during FY 2015 (Table 6). The OIG excluded a total of 43,148 patients from its analyses. This accounted for 4.3 percent of the entire FY 2015 patients dispensed with outpatient opioids. Most (33,962/43,148 = 78.7 percent) of the excluded patients were those who had received hospice or palliative care in FY 2015 or within one year prior to their first outpatient opioid prescription in FY 2015. In addition, the OIG excluded 2,715 (6.2 percent) patients who did not receive any outpatient clinical care in FY 2015 and 6,471 (15.0 percent) patients who were identified as either non-veteran patients or test patients. Thus, the OIG's study population consists of 953,519 (non-hospice/palliative care) patients.

Table 6. Exclusions of VA Patients Dispensed Outpatient Opioids in FY 2015

All Patients with Outpatient Opioids in FY 2015	996,667
Exclusions (Total)	43,148
Patients with Hospice or Palliative Care ¹	33,962
No Outpatient Clinical Visit in FY 2015	2,715
Non-Veteran or Test Patient	6,471
Study Population	953,519

¹ One year prior to first opioid prescription or in FY 2015

Source: VA OIG analysis of administrative data

Issue 1: Prevalence of VA Patients Dispensed Outpatient Opioids

The 953,519 opioid patients accounted for 16.7 (953,519/5,719,464) percent of all VA (non-hospice/palliative care) patients who had at least one outpatient encounter at VA in FY 2015. Figure 1 shows age-specific prevalence of opioid prescriptions in FY 2015. Nearly one out of four patients in the age group of 55–64, the highest prevalence, received at least one outpatient opioid prescription at VA in FY 2015.

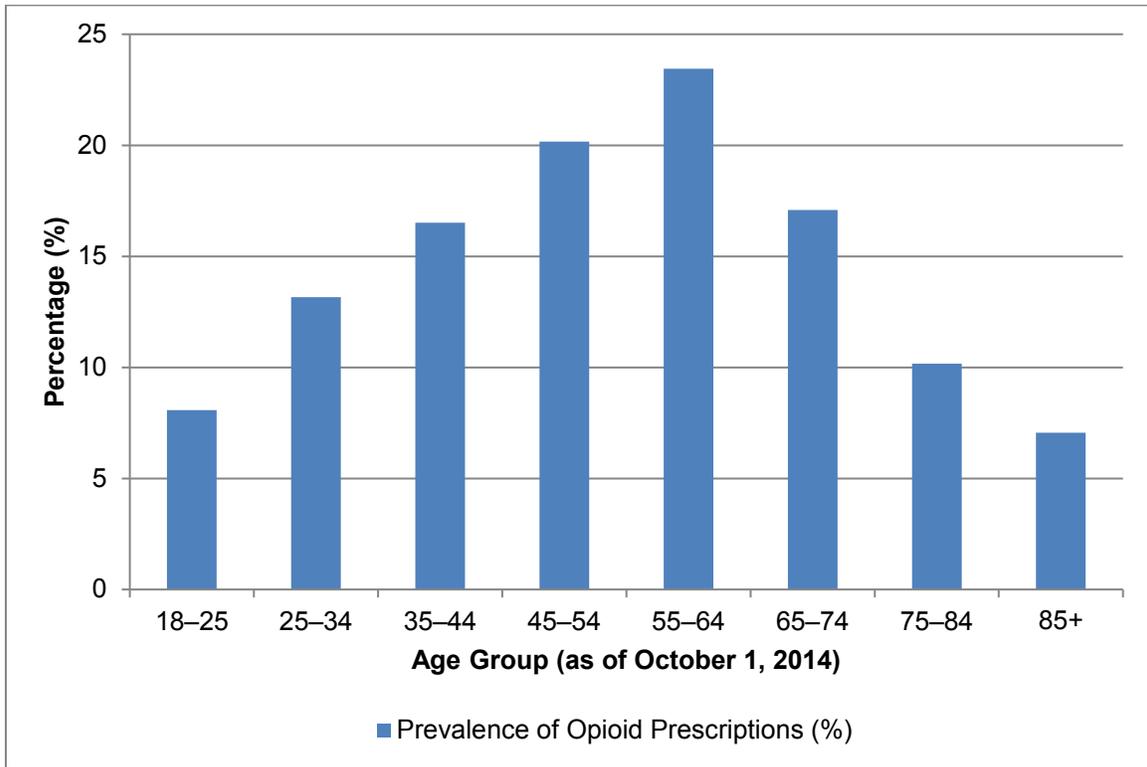


Figure 1. Prevalence of Opioid Prescriptions from October 1, 2014, to September 30, 2015, by Age Group

Source: VA OIG analysis of administrative data (FY15Prevalence)

Issue 2: Baseline Characteristics of VA Outpatient Opioid Patients

Table 7 shows the baseline (at the first outpatient opioid prescription in FY 2015) characteristics of the study population combined and separately, by whether days on outpatient opioids in FY 2015 were 90 or less (non-chronic users) or more than 90 (chronic users). About four out of ten (41.4 percent) of the patients were chronic users.

Table 7. Baseline Characteristics of VA Outpatient Opioid Patients in FY 2015¹¹⁶

	All patients with outpatient opioids		90 days or less on opioids (non-chronic users)		More than 90 days on opioids (chronic users)	
	953,519 #	%	559,175 #	58.6% %	394,344 #	41.4% %
Male	872,248	91.5	505,438	90.4	366,810	93.0
Age at first opioid prescription in FY 2015						
Mean (standard deviation)	59.8	(0.01)	58.9	(0.02)	61.0	(0.02)
Median	62		62		63	
Pain diagnosis within 1 year prior to first opioid prescription	841,227	88.2	476,415	85.2	364,812	92.5
Primary pain site (of non-cancer origin)	837,102	87.8	474,860	84.9	362,242	91.9
Pain of the nervous system and sense organs	92,250	9.7	36,587	6.5	55,663	14.1
Mental health diagnosis within 1 year prior to first opioid prescription	595,122	62.4	330,009	59.0	265,113	67.2
PTSD	203,572	21.3	114,743	20.5	88,829	22.5
Substance use	138,720	14.5	81,495	14.6	57,225	14.5
Pain or mental health diagnoses within 1 year prior to first opioid prescription	895,353	93.9	515,803	92.2	379,550	96.2
Pain and mental health diagnoses within 1 year prior to first opioid prescription	540,996	56.7	290,621	52.0	250,375	63.5
Pain and PTSD	188,586	19.8	103,797	18.6	84,789	21.5
Pain and substance use	126,295	13.2	72,156	12.9	54,139	13.7
Primary pain site and mental health diagnoses within 1 year prior to first opioid prescription	538,409	56.5	289,693	51.8	248,716	63.1
Primary pain site and PTSD	187,835	19.7	103,540	18.5	84,295	21.4
Primary pain site and substance use	125,727	13.2	71,907	12.9	53,820	13.6
Pain of the nervous system and sense organs and mental health diagnoses within 1 year prior to first opioid prescription	68,563	7.2	26,115	4.7	42,448	10.8
Pain of the nervous system and sense organs and PTSD	26,189	2.7	10,347	1.9	15,842	4.0
Pain of the nervous system and sense organs and substance use	18,492	1.9	7,790	1.4	10,702	2.7
Died in FY 2015	16,773	1.8	10,690	1.9	6,083	1.5

Source: VA OIG analysis of administrative data (FY15OpBaseline, FY15BenzoFreq, FY15OpMH, FY15OpPain)

¹¹⁶ See Appendix D, Primary Pain Site Diagnoses with Codes.

A majority (91.5 percent) of the patients were male, which mirrored the gender composition of VA patients. The average and the median patient age at first opioid prescription in FY 2015 was 59.8 and 62, respectively. See Appendix B, Figure 2 for more details on age distributions.

The OIG observed that 88.2 percent of the patients were diagnosed with pain within one year prior to or on their first day dispensed with outpatient opioids in FY 2015. The OIG noted that 87.8 percent of the opioid patients were diagnosed with primary pain site of non-cancer origin that could result in pain serious enough to warrant an opioid medication. Nearly 96 percent (88,125/92,250) of patients diagnosed with pain of the nervous system and sense organs were also diagnosed with primary pain site. As expected, both primary pain site and pain of the nervous system and sense organs were more prevalent among chronic users.

Table 8 gives detailed information on pain diagnoses for the study population. It shows that a higher percentage of chronic users were diagnosed with chronic pain (7.9 percent versus 3.7 percent) and chronic pain syndrome (6.1 percent versus 1.5 percent)—a complex syndrome that involves multiple factors.

Table 8. Percent of Patients Diagnosed with Pain Within One Year Prior to First Outpatient Opioid Prescription in FY 2015¹¹⁷

	All patients with outpatient opioids 953,519	90 days or less on opioids (non-chronic users) 559,175	More than 90 days on opioids (chronic users) 394,344
Pain	88.2	85.2	92.5
Primary pain site	87.8	84.9	91.9
Arthritis	51.2	48.6	55.0
Back pain	53.8	45.6	65.4
Fractures	6.3	7.1	5.2
Generalized pain	4.3	2.7	6.6
Headaches	10.9	11.0	10.7
Musculoskeletal pain	32.5	33.6	31.0
Neuropathy	16.2	15.0	17.9
Other pain	2.7	2.4	3.1
Reproductive pain	0.5	0.7	0.3
Visceral pain	15.2	17.1	12.5
Wound injury	5.4	5.7	5.1
Pain of the nervous system and sense organs	9.7	6.5	14.1
Acute pain	1.5	1.7	1.2
Neoplasm-related pain	0.1	0.1	0.1
Chronic pain	5.5	3.7	7.9
Chronic pain syndrome	3.4	1.5	6.1

Source: VA OIG analysis of administrative data (FY15OpPain)

¹¹⁷ See Appendix D - Primary Pain Site Diagnoses with Codes.

Table 9 gives detailed information on mental health diagnoses. It indicates that more than half (62.4 percent) of the opioid patients had been diagnosed with mental health issues within one year prior to first outpatient opioid prescription. Approximately one third (33.5 percent) of the patients had been diagnosed with mood disorders, one in five (21.3 percent) with PTSD, and one in seven (14.5 percent) with substance use. The OIG noted that higher percentages of chronic users were consistently diagnosed with each category of the mental health issues except for adjustment disorders (5.4 percent for non-chronic users vs. 5.1 percent for chronic users), psychotic disorders (2.8 percent for non-chronic users vs. 2.7 percent for chronic users), and alcohol-related disorders (10.8 percent for non-chronic users vs. 9.8 percent for chronic users). While 14.5 percent of the entire study population had been diagnosed with substance use, 3.8 percent of the population had been diagnosed with both alcohol and drug related disorders.

Table 9. Percent of Patients Diagnosed with Mental Health Issues Within One Year Prior to First Outpatient Opioid Prescription in FY 2015

	All patients with outpatient opioids 953,519	90 days or less on opioids (non-chronic users) 559,175	More than 90 days on opioids (chronic users) 394,344
Mental health	62.4	59.0	67.2
Adjustment disorders	5.3	5.4	5.1
Anxiety disorders excluding PTSD	15.7	14.5	17.4
PTSD	21.3	20.5	22.5
Mood disorders	33.5	30.6	37.6
Excluding major depression	27.6	25.5	30.6
Major depression	12.2	11.1	13.7
Personality disorders	1.9	1.8	1.9
Psychotic disorders	2.8	2.8	2.7
Psychological pain	0.7	0.4	1.2
Substance use	14.5	14.6	14.5
Alcohol-related disorders	10.1	10.8	9.1
Drug-related disorders	8.2	7.9	8.6

Source: VA OIG analysis of administrative data (FY15OpMH)

The OIG observed that 93.9 percent of the study population had been diagnosed with pain or mental health issues and 56.7 percent of patients with both (see Table 7: Baseline Characteristics of VA Outpatient Opioid Patients in FY 2015). The percentages of patients being diagnosed with both pain and mental health issues were 11.5 points higher for chronic users than non-chronic users.

Issue 3: VA Dispensing Patterns of Outpatient Opioids

Approximately four out of 10 (38.4 percent) patients in the study population were new patients in the sense that they were initiated on outpatient opioid therapy in FY 2015 after not being on outpatient opioids for at least more than one year (Table 10). Six out of 10 (61.0 percent) non-chronic users were new patients in contrast to less than one in 10 (6.4 percent) of chronic users.

Table 10. Dispensing Patterns of Outpatient Opioids in FY 2015

	All patients with outpatient opioids 953,519		90 days or less on opioids (non-chronic users) 559,175 58.6%		More than 90 days on opioids (chronic users) 394,344 41.4%	
	#	%	#	%	#	%
New outpatient opioids in FY 2015 (new patients)	366,459	38.4	341,055	61.0	25,404	6.4
Morphine equivalent 200 mg/day or more	12,896	1.4	1,220	0.2	11,676	3.0
Outpatient benzodiazepine prescription	143,535	15.1	67,066	12.0	76,469	19.4
Concurrent benzodiazepine and opioid prescriptions ¹	112,131	78.1	38,388	57.2	73,743	96.4

¹ Percentages based on patients with outpatient benzodiazepine prescriptions.

Source: VA OIG analysis of administrative data (FY15OpBaseline, FY15BenzoFreq)

Opioid dosages with a morphine equivalent at least 200 mg/day were dispensed to 1.4 percent of the study population, which accounted for 3.0 percent of chronic users and 0.2 percent of non-chronic users. Because the goal of pain management is to decrease pain to a level that allows the patient to continue routine activities and there is no maximum dose of opioids, the appropriate dose of opioids is the dose that controls pain so that the patient is functional. An opioid dosage of at least 200 mg/day morphine equivalent alone is not indicative of inappropriate prescribing.

The concurrent use of benzodiazepines and opioids can be dangerous because opioids and benzodiazepines can depress the central nervous system and thereby affect heart rhythm, slow respiration, and even lead to death. Benzodiazepines have been strongly associated with death from opioid overdose¹¹⁸ and with an increased risk of death due to methadone toxicity.¹¹⁹ The OIG found that outpatient benzodiazepines were dispensed to 15.1 percent of the study population, with the percentage of chronic opioid users being 1.6 times that of non-chronic users. The OIG determined that 78.1 percent (112,131/143,535) of the opioid patients who received outpatient benzodiazepines were dispensed benzodiazepines concurrently with opioids. The percentage of chronic opioid users with concurrent benzodiazepines was 96.4, and the percentage of non-chronic users was 57.2.

Issue 4: VA Patterns of Screening and Monitoring Opioid Patients

Patients sometimes do not take opioids as prescribed or use non-prescribed opioids. A UDT is useful for assessing adherence to therapy and detecting illicit drug use. The 2010 CPG calls for a

¹¹⁸ Toblin, R. L., L. J. Paulozzi, et al. (2010). Mental illness and psychotropic drug use among prescription drug overdose deaths: a medical examiner chart review. *J Clin Psychiatry* 71(4): 491–496.

¹¹⁹ Caplehorn, J. R. and O. H. Drummer (2002). Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines. *Aust N Z J Public Health* 26(4): 358–362; discussion 362–353.

UDT prior to initiating opioid therapy and a UDT randomly at follow-up visits to confirm the appropriate use of opioids.

For new opioid patients—who were initiated on outpatient opioids in FY 2015 after not having been on outpatient opioids for at least more than one year—the OIG identified whether they received a UDT within 30 days prior to initiating their opioid therapy in FY 2015.

For existing opioid patients—who were on outpatient opioids at least from FY 2014—the OIG identified whether they received an annual UDT.

The 2010 CPG specifies that chronic (for more than one month) opioid therapy is absolutely contraindicated in patients with active (not in remission) SUDs who are not in treatment. It recommends that active substance use patients receive SUD treatment concurrently with UDT as an adjunctive tool at regular intervals. For the subpopulation of active substance use patients who had at least 90 days available for follow-up in FY 2015, the OIG identified whether they received both a treatment for substance use and a UDT within 90 days of each filled opioid prescription.

New Patients on Outpatient Opioids

Table 11 shows UDT rates for new patients (that is, patients who were not given any outpatient opioids in FY 2014, which was at least one year before initiating their outpatient opioid therapy) prior to initiating opioid therapy, by month (days) on opioids. The rates increased from 6.4 percent for those who were on non-chronic opioid therapy one month (30 days) or less, to 11.5 percent for those who were on opioid therapy two–three months (31–90 days), to 23.1 percent for chronic users (more than three months (91 or more days) on opioids).

Table 11. Conducting a Urine Drug Test on Patients Within 30 Days Prior to Initial Prescription in FY 2015, New Outpatient Opioid Patients, by Days on Opioids

	Number of New Patients	Number of New Patients with UDT 30 Days Prior to Initial Prescription in FY 2015	Percentage ¹
Total	366,459	30,406	8.3
1 month (30 days) or less on opioids	286,482	18,284	6.4
2–3 months (31–90 days) on opioids	54,573	6,253	11.5
More than 3 months (91 or more days) on opioids	25,404	5,869	23.1

¹ Even if half of the patients had been initiated with the opioid therapy by the Choice Program, the percentages would have increased to 12.8, 22.9, and 46.2, respectively.

Source: VA OIG analysis of administrative data. (FY15UDSBef30_60_90)

Veterans who are authorized care through the Choice Program are required to have prescriptions filled at VA pharmacies. Veterans have to pay for Choice prescriptions themselves if they do not use the VA pharmacy, unless previously approved by VA or if it is an urgent/emergent need medication (for up to a 14-day supply, without refills). As a result, Choice prescriptions are also

included in the VA outpatient administrative Pharmacy data. At the time this report was written, the VA administrative data in the Corporate Data Warehouse did not permit the OIG to identify Choice prescriptions.¹²⁰

Because of the inclusion of VA outpatient opioid prescriptions from the Choice Program, some of the new patients who received Choice Program opioid prescriptions would have their opioid therapy initiated by Choice providers, rather than by VA providers. Consequently, the true UDT percentages prior to initiating opioid therapy by VA providers would be higher than those shown in Table 11.

Table 12 shows what the UDT percentages would be if 10, 20, 30, 40, and 50 percent of the new patients’ opioid therapies were initiated by Choice providers. Even in the unlikely situation that half of new patients whose opioid therapy was initiated by Choice providers, the VA UDT percentages prior to initiating opioid therapy would have increased to 12.8, 22.9, and 46.2, respectively, which was still less than one out of two new patients who received UDT prior to their opioid therapy initiation by VA providers.

Table 12. Conducting Urine Drug Tests on Patients within 30 Days Prior to Initial Prescription in FY 2015 for the Assumed Percentages of the Patients Whose Outpatient Opioid Therapies were Initiated by the Choice Program, New Outpatient Opioid Patients, by Days on Opioids

	Total (%)	1 month (30 days) or less on opioids (%)	2–3 months (31–90 days) on opioids (%)	More than 3 months (91 or more days) on opioids (%)
VHA Data	8.3	6.4	11.5	23.1
10% Choice	9.2	7.1	12.7	25.7
20% Choice	10.4	8.0	14.3	28.9
30% Choice	11.9	9.1	16.4	33.0
40% Choice	13.8	10.6	19.1	38.5
50% Choice	16.6	12.8	22.9	46.2

Source: VA OIG analysis of administrative data (FY15UDSBef30_60_90)

Existing Patients on Outpatient Opioids

The 2010 CPG recommends a UDT randomly at follow-up visits to confirm the appropriate use of opioids.¹²¹ The OIG found that VA conducted an annual UDT for 61.3 percent (Table 13) of existing opioid patients in FY 2015, increased significantly from 37.9 percent as was determined in FY 2012.¹²² The OIG noted that the increase was mainly from the chronic users: 77.0 percent

¹²⁰ The OIG has developed the methodology for identifying Choice prescriptions from VA administrative data. For a description of the methodology, see VAOIG Healthcare Inspection *Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care* (Report No. 17-01846-316, July 31, 2017).

¹²¹ VA/DoD Clinical Practice Guideline, May 2010, p. 37.

¹²² VAOIG Report No. 14-00895-163, May 14, 2014, p. 28.

of the chronic opioid users received the annual UDT in FY 2015, increased from 40.9 percent in FY 2012, while 34.7 percent of their non-chronic user counterparts received the annual UDT in FY 2015, similar to the 33.7 percent in FY 2012.

The OIG found that the majority of annual UDT increases in FY 2015 were tests for other non-opioid abusable substances (69.8 percent in FY 2015 vs. 37.7 percent in FY 2012). The OIG noted that this increase pattern was consistent across chronic (70.3 percent in FY 2015 versus 40.7 percent in FY 2012) and non-chronic users (68.2 percent in FY 2015 versus 33.6 percent in FY 2012). Approximately one of three annual UDTs in FY 2015 tested for substance types of morphine or heroin (37.0 percent) and of non-morphine opioid compound (31.6 percent). The test for non-morphine opioid compound was least performed.

Table 13. Conducting an Annual Urine Drug Test, FY 2015 Existing Patients on Outpatient Opioids, by Test Substance Type and Days on Opioids

	Number of Existing Patients	Percentage
All patients (587,060)		
Any urine drug tests	359,791	61.3
Test for morphine or heroin	133,208	37.0
Test for non-morphine opioid compound	113,797	31.6
Test for other non-opioid abusable substance	251,189	69.8
Patients on opioids more than 3 months (91 days or more) (368,940)		
Any urine drug tests	284,125	77.0
Test for morphine or heroin	108,124	38.1
Test for non-morphine opioid compound	91,924	32.4
Test for other non-opioid abusable substance	199,607	70.3
Patients on opioids less than 3 months (90 days or less) (218,120)		
Any urine drug tests	75,666	34.7
Test for morphine or heroin	25,084	33.2
Test for non-morphine opioid compound	21,873	28.9
Test for other non-opioid abusable substance	51,582	68.2

Source: VA OIG analysis of administrative data (FY15UDSAnnual)

The OIG found that regardless of test substance type (Table 14), approximately 76–77 percent of the UDTs were conducted while patients were on opioids, an increase from 60–62 percent in FY 2012.¹²³

¹²³ VAOIG Report No. 14-00895-163, May 14, 2014, p. 29.

Table 14. Conducting an Annual Urine Drug Test, FY 2015 Existing Outpatient Opioid Patients Who Received an Annual Urine Drug Test While on Opioids, by Test Substance Type

	Number of Existing Patients with Annual UDT	Existing Patients with UDT while on Opioids	Percentage
Any urine drug tests	357,957	285,255	79.7
Test for morphine or heroin	130,429	100,374	77.0
Test for non-morphine opioid compound	113,769	86,036	75.6
Test for other non-opioid abusable substance	251,158	193,882	77.2

Source: VA OIG analysis of administrative data (FY15UDSAnnualOnOpioids)

Active (Not in Remission) Substance Use Patients

The 2010 CPG recommends that active (not in remission) substance use patients receive SUD treatment concurrently with UDT as an adjunctive tool at regular intervals.¹²⁴ Among the study population, 13.6 (129,852/953,519) percent were diagnosed with active substance use in FY 2015 (Table 15).

The OIG found that 42.4 percent of the active substance use patients received an SUD treatment in FY 2015, increased from 31.2 percent in FY 2012. However, 6.6 percent of the patients received at least 1 UDT within 90 days of every (filled) outpatient prescription of opioids, decreased from 19.2 percent in FY 2012.¹²⁵ This decrease might be explained, in part, by the fact that the VA administrative Pharmacy data included opioid prescriptions from the Choice Program, but the VA providers did not manage these Choice Program patients. For the active substance use patients who filled one or more outpatient opioid prescriptions at least 90 days prior to the end of follow-up, the OIG determined that 4.6 percent received both treatment for substance use and a UDT within 90 days of each filled opioid prescription, decreased from 10.5 percent in FY 2012.¹²⁶

¹²⁴ VA/DoD Clinical Practice Guideline, May 2010, p. 90.

¹²⁵ VAOIG Report No. 14-00895-163, May 14, 2014, p. 32.

¹²⁶ VAOIG Report No. 14-00895-163, May 14, 2014, p. 32.

Table 15. Treating Patients for Substance Use and Conducting at Least One Urine Drug Test Within 90 Days of Each Filled Opioid Prescription in FY 2014, Active Substance Use Patients

	Number of VA Eligible Patients	Treatment/Urine Drug Test	Percentage
Treating active substance use patients and conducting a urine drug test within 90 days of each filled opioid prescription	113,561	5,267	4.6
Treating active substance use patients	129,852	55,000	42.4
Conducting a urine drug test within 90 days of each filled opioid prescription	113,561	7,501	6.6

Source: VA OIG analysis of administrative data (FY15OpOtherDX, FY15TrtActiveSUDPat, FY15SUDUDTAnalysis_Tr90Day2, FY15SUDUDTAnalysis_90Day)

Issue 5: VA Patterns of Providing Psychosocial Treatment for Pain, Pain Clinic Service, CIH Services, and Medication Management/Pharmacy Reconciliation for Outpatient Opioid Patients

Psychotherapy, including cognitive behavioral therapy, is recommended to reduce pain and improve function in chronic pain patients. The OIG found that 47.1 (45.2 in 2014 report) percent (Table 16) of the opioid patients received at least one psychosocial treatment for pain in FY 2015 and 39.7 (35.1 in 2014 report) percent received this treatment after their first opioid prescription.

Table 16. Psychosocial Treatment for Pain, Pain Clinic Service, CIH Services, and Medication Management/Pharmacy Reconciliation for Outpatient Opioid Patients in FY 2015

	All patients with outpatient opioids		90 days or less on opioids (non-chronic users)		More than 90 days on opioids (chronic users)	
	#	%	#	%	#	%
	953,519		559,175	58.6%	394,344	41.4%
Anytime in FY 2015						
Psychosocial Treatment for Pain	449,553	47.1	259,954	46.5	189,599	48.1
Pain Clinic	97,278	10.2	37,785	6.8	59,493	15.1
Any of the following CIH	217,005	22.8	133,333	23.8	83,672	21.2
Acupuncture	15,668	1.6	7,286	1.3	8,382	2.1
Complementary and Integrative Health	203,514	21.3	126,970	22.7	76,544	19.4
Chiropractic Care	18,674	2.0	10,288	1.8	8,386	2.1
Osteopathic Care	1,594	0.2	754	0.1	840	0.2
Medication Management/Pharmacy Reconciliation	342,831	36.0	189,191	33.8	153,640	39.0
After first opioid prescription in FY 2015						
Psychosocial Treatment for Pain	378,373	39.7	195,205	34.9	183,168	46.4
Pain Clinic	86,170	9.0	28,678	5.1	57,492	14.6
Any of the following CIH	177,560	18.6	98,476	17.6	79,084	20.1
Acupuncture	13,381	1.4	5,373	1.0	8,008	2.0
Complementary and Integrative Health	165,141	17.3	93,103	16.7	72,038	18.3
Chiropractic Care	15,249	1.6	7,296	1.3	7,953	2.0
Osteopathic Care	1,321	0.1	525	0.1	796	0.2
Medication Management/Pharmacy Reconciliation	293,057	30.7	145,059	25.9	147,998	37.5

Source: VA OIG analysis of administrative data (FY15OpOtherDX, FY15NoPsychoSclDX_Data, OpioidPsychoScl2)

Treatment of chronic pain involves a stepped care approach oriented toward recovering or maintaining physical, social, and occupational function. This approach requires increasing levels of expertise dependent upon the complexity of the pain concerns of the individual veteran. In the most complex cases, such care will involve a broad array of specialty rehabilitation, pain medicine, surgical, and CIH services. Referral to a Pain Clinic may be another approach to care. The OIG determined that 10.2 percent of the VA patients who were prescribed opioids had received care from a VA Pain Clinic in FY 2015, with 9.0 percent receiving this care after their first filled opioid prescription. This represents an increase over FY 2012 figures, which were 8.7 and 6.8 percent, respectively. The data did not capture all information about the broad array of specialty pain management services, including consultative input from a Pain Clinic, if they were not coded as Pain Clinic service.

CIH is increasingly seen as an adjunct to traditional plans of care for pain management. The OIG determined that 22.8 percent of opioid patients received at least one care episode from any CIH

services in FY 2015 and 16.7 percent received this care after their first opioid prescription in FY 2015. In Table 16, the OIG used the category “Complementary and [Integrative Health]” to represent CIH care episodes that were not chiropractic, osteopathic, or acupuncture.¹²⁷ This category was the most common modality of the CIH services: one out of five (21.3 percent in FY 2015 and 17.3 percent after their first opioid prescription) patients received CIH, while one out of 50 (2.0 percent in FY 2015 and 1.6 percent after their first opioid prescription) patients received chiropractic care, and one or less out of 500 (0.2 percent in FY 2015 and 0.1 percent after their first opioid prescription) patients received osteopathic care.

Opioid patients frequently have complex co-morbid conditions, making them more likely to be given multiple medications that can interact dangerously with opioid medications. A review of medications by a pharmacist or other health care professional can prevent harmful interactions between these medications. The OIG found 36.0 percent of the patients received medication management or pharmacy reconciliation during FY 2015, similar to the 38.8 percent found in OIG’s 2014 report on the topic.

Issue 6: Prevalence of Serious Adverse Effects among Outpatient Opioid Patients

Increasing use of opioids has been associated with increasing rates of opioid-related serious adverse effects. The OIG determined percentages of opioid patients with evidence of a serious adverse effect that may be reasonably expected to be related to opioid therapy for the following five serious adverse effects: (1) opioid overdose, (2) sedative overdose, (3) drug delirium, (4) drug detoxification, and (5) possible and confirmed suicide attempts. The OIG found (Table 17) that 3.3 percent of the population experienced any of these five serious adverse effects, and less than 1 percent of the population experienced each of these adverse effects during FY 2015, except for the adverse effect of possible and confirmed suicide attempts, which was evident in 2.1 percent of the opioid patients. The OIG found that the frequency of opioid overdoses was several folds higher for chronic opioid users versus non-chronic users.

¹²⁷ Examples of such care are massage, biofeedback, and movement therapy.

Table 17. Serious Adverse Effects in Patients Dispensed With Outpatient Opioids in FY 2015

	All patients with outpatient opioids 953,519		90 days or less on opioids (non-chronic users) 559,175 58.6%		More than 90 days on opioids (chronic users) 394,344 41.4%	
	#	%	#	%	#	%
Anytime in FY 2015						
Any of the following adverse effects	31,243	3.3	17,379	3.1	13,864	3.5
Opioid Overdose	7,331	0.8	1,730	0.3	5,601	1.4
Sedative Overdose	981	0.1	536	0.1	445	0.1
Drug Delirium	7,376	0.8	4,840	0.9	2,536	0.6
Drug Detoxification	1,535	0.2	948	0.2	587	0.1
Possible or Confirmed Suicide Attempts	19,612	2.1	12,880	2.3	6,732	1.7
After first opioid prescription in FY 2015						
Any of the following adverse effects	24,979	2.6	11,827	2.1	13,152	3.3
Opioid Overdose	6,822	0.7	1,365	0.2	5,457	1.4
Sedative Overdose	756	0.1	351	0.1	405	0.1
Drug Delirium	5,596	0.6	3,241	0.6	2,355	0.6
Drug Detoxification	1,148	0.1	636	0.1	512	0.1
Possible or Confirmed Suicide Attempts	14,692	1.5	8,493	1.5	6,199	1.6

Source: VA OIG analysis of administrative data (FY15OpOtherDX)

Conclusion

In general, the OIG found that pain management services were offered at most VA medical facilities. In May 2016, almost all VA medical facilities had at least one pain management specialist and slightly over half had a Board-Certified Pain Medicine specialist; the most extensive training was required for the specialist. Overall, 96 percent (135/141) of the facilities offered substance abuse treatment using either methadone or Suboxone®.

The OIG looked at facilities that provided specialized services for substance abuse treatment. Eighty-two percent of facilities (116/141) reported having an Intensive Outpatient Program. Fifty-nine percent of facilities (83/141) reported having residential treatment programs. Ninety-five percent of facilities (134/141) reported offering at least one specialized substance abuse treatment program. Ninety-seven percent of facilities (137/141) reported offering at least one specialized outpatient clinic for substance use treatment or substance use clinic with addiction-focused pharmacotherapy.

The OIG characterized the distribution of pain specialists and pain clinics in VHA but did not identify a staffing standard that would allow determination as to whether this pattern of staffing sufficed to meet demand for pain services. The bulk of chronic pain management care comes from primary care providers. The delivery of pain management care consistent with guidelines can be time-consuming and when patients receiving such care are prescribed chronic opioids as well, the demands on the provider may be considerably increased compared to the delivery of routine care.

The OIG found that the Suboxone® prescribing limit was not the primary reason that facilities were unable to meet the demand for Suboxone®. While there was considerable variation in the prescribing patterns of individual providers, the level of prescribing for the vast majority of providers is well below the threshold where the Suboxone® prescribing limit would take effect.

VHA was utilizing facility-specific lectures and computer training for pain education at 84 percent and 76 percent of VAMCs, respectively. SCAN-ECHO is used in over half of all facilities. Because the configuration of VA facilities is affected by many variables including the type of hospital, clinical staff level of pain specific training and experience, academic affiliations, geographic location, and access to specialists willing to provide pain instruction; each facility's needs for pain education is different. Individual facilities should ascertain their own educational needs.

The OIG found that 41.4 percent (58/141) of the facilities reported that their out-of-state licensed providers had no access to PDMPs. Among the 58 facilities where out-of-state providers did not have access to PDMPs, 71 percent (41/58) of these facilities had alternative processes allowing a data check for patients, such as having a licensed state pharmacist or other appropriate providers query the PDMP and document the findings in the EHR.

Based on analyzing VA administrative data, the OIG found that 16.7 percent of VA patients with at least one clinical encounter were dispensed opioids in FY 2015. The OIG observed that 93.9 percent of the study population had been diagnosed with pain or mental health issues and 56.7 percent of patients with both. The percentages of patients being diagnosed with both pain and mental health issues were 11.5 points higher for chronic users than their counterparts of non-chronic users. Approximately four out of 10 (38.4 percent) patients in the study population were new patients in the sense that they were initiated on outpatient opioid therapy in FY 2015 after not being on outpatient opioids for at least more than one year. Six out of 10 (61.0 percent) non-chronic users were new patients in contrast to less than one in 10 (6.4 percent) of chronic users.

Opioid dosages with a morphine equivalent at least 200 mg/day were dispensed to 1.4 percent of the study population, which accounted for 3.0 percent of chronic users and 0.2 percent of non-chronic users. Because the goal of pain management is to decrease pain to a level that allows the patient to continue routine activities and there is no maximum dose of opioids, the appropriate dose of opioids is the dose that controls pain so that the patient is functional. An opioid dosage of at least 200 mg/day morphine equivalent alone is not indicative of inappropriate prescribing.

The concurrent use of benzodiazepines and opioids can be dangerous because opioids and benzodiazepines can depress the central nervous system and thereby affect heart rhythm, slow respiration, and even lead to death. Benzodiazepines have been strongly associated with death from opioid overdose and with an increased risk of death due to methadone toxicity. The OIG found that outpatient benzodiazepines were dispensed to 15.1 percent of the study population, with the percentage of chronic opioid users being 1.6 times that of non-chronic users. The OIG determined that 78.1 of the opioid patients who received outpatient benzodiazepines were dispensed benzodiazepines concurrently with opioids. The percentage of chronic opioid users with concurrent benzodiazepines was 96.4, and the percentage of non-chronic users was 57.2.

Patients sometimes do not take opioids as prescribed or use non-prescribed opioids. A urine drug test (UDT) is useful for assessing adherence to therapy and detecting illicit drug use. The 2010 CPG calls for a UDT prior to initiating opioid therapy and a UDT randomly at follow-up visits to confirm the appropriate use of opioids.

For new opioid patients—who were initiated on outpatient opioids in FY 2015 after not having been on outpatient opioids for at least more than one year—the OIG identified whether they received a UDT within 30 days prior to initiating their opioid therapy in FY 2015. The OIG determined that 23.1 percent of chronic users (more than three months on opioids) received a UDT within in 30 days prior to initiating their opioid therapy. Because veterans who were authorized care through the Choice Program were required to have prescriptions filled at VA pharmacies, some of the new patients who received Choice Program opioid prescriptions would have their opioid therapy initiated by the Choice providers, rather than by VA providers.

Consequently, the true UDT percentage prior to initiating opioid therapy by VA providers would be higher than 23.1 percent. However, even in the unlikely situation of half of new patients whose opioid therapy were initiated by Choice providers, the VA UDT percentage prior to initiating opioid therapy would have increased to 46.2, or less than one out of two new patients who received UDT prior to their opioid therapy initiation by VA providers.

The 2010 CPG recommends a UDT randomly at follow-up visits to confirm the appropriate use of opioids. For existing opioid patients—who were on outpatient opioids at least from FY 2014—the OIG identified whether they received an annual UDT. The OIG determined that VA conducted an annual UDT for 61.3 percent of existing opioid patients in FY 2015, increased significantly from 37.9 percent as was found in FY 2012. The OIG noted that the increase was mainly from the chronic users: 77.0 percent of the chronic opioid users received the annual UDT in FY 2015, increased from 40.9 percent in FY 2012.

The 2010 CPG specifies that chronic (for more than one month) opioid therapy is absolutely contraindicated in patients with active (not in remission) substance use disorders (SUD) who are not in treatment. It recommends that active substance use patients receive SUD treatment concurrently with urine drug testing as an adjunctive tool at regular intervals. For the subpopulation of active substance use patients who had at least 90 days available for follow-up in FY 2015, the OIG identified whether they received both a treatment for substance use and a UDT within 90 days of each filled opioid prescription. Among the study population, 13.6 percent were diagnosed with active substance use in FY 2015. The OIG determined that 42.4 percent of the active substance use patients received an SUD treatment in FY 2015, increased from 31.2 percent in FY 2012. However, 6.6 percent of the patients received at least one UDT within 90 days of every (filled) outpatient prescription of opioids, decreased from 19.2 percent in FY 2012. For the active substance use patients who filled one or more outpatient opioid prescriptions at least 90 days prior to the end of follow-up, the OIG determined that 4.6 percent, received both treatment for substance use and a UDT within 90 days of each filled opioid prescription, decreased from 10.5 percent in FY 2012. The decrease in SUD treatment and a UDT test might be explained, in part, by the fact that the VA administrative Pharmacy data included opioid prescriptions from the Choice Program, but the VA providers did not manage these Choice Program patients.

Opioid patients frequently have complex co-morbid conditions, making them more likely to be given multiple medications that can interact dangerously with opioid medications. A review of medications by a pharmacist or other health care professional can prevent harmful interactions between these medications. Based on the analysis of VHA administrative data, the OIG found that 36.0 percent of the patients received medication management or pharmacy reconciliation during FY 2015, similar to the 38.8 percent found in OIG's 2014 report on the topic.

The OIG made 10 recommendations to the Under Secretary for Health.¹²⁸

Recommendations 1–10

1. The Under Secretary for Health ensures that VA facilities have formal processes in place for providers to access state prescription drug monitoring programs to reconcile medications dispensed by private providers and those dispensed by VA, and that this process is in compliance with the providers' state licensing requirements.
2. The Under Secretary for Health evaluates the use of facility-specific panel readjustments or other means of increasing resources for primary care providers who manage chronic pain conditions for a significant proportion of his/her panel and takes action as appropriate.
3. The Under Secretary for Health evaluates and determines the adequacy of the number of pain specialists at each facility through formalized assessments and takes action as appropriate.
4. The Under Secretary for Health ensures that VA facilities without pain specialists have formalized designated resources of pain care provided by providers.
5. The Under Secretary for Health evaluates the use of pain assessment tools across the Veterans Health Administration to ensure that those tools used by facilities provide information that improves oversight to patients who are treated for chronic pain conditions.
6. The Under Secretary for Health develops a formal evaluation of the provision of pain management services within VA to complement the Opioid Safety Initiative.
7. The Under Secretary for Health ensures that VA's practice of routine and random urine drug tests both prior to initiating and during take-home opioid therapy to confirm the use of opioids is in alignment with guidelines.
8. The Under Secretary for Health ensures that opioid patients with active (not in remission) substance use disorder undergo urine drug testing and receive treatment for the substance use disorder.
9. The Under Secretary for Health evaluates and determines that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with guidelines.
10. The Under Secretary for Health ensures that medication reconciliation is performed to prevent adverse drug interactions.

¹²⁸ Recommendations directed to the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

Appendix A: Prior OIG Reports

[Healthcare Inspection – Unexpected Death of a Patient: Alleged Methadone Overdose, Grand Junction VA Health Care System, Grand Junction, CO](#)

11/30/2017 | 16-04208-30

[Healthcare Inspection – Opioid Agonist Treatment Program Concerns VA Maryland Health Care System Baltimore, Maryland](#)

10/19/2017 | 16-01091-06

[Healthcare Inspection – Review of Opioid Prescribing Practices, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin](#)

8/22/2017 | 15-02156-346

[Healthcare Inspection – Administrative Summary – Opioid Purchases, VA Northern Indiana Health Care System, Marion, Indiana](#)

8/17/2017 | 16-02160-344

[Healthcare Inspection - Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care](#)

8/1/2017 | 17-01846-316

[Healthcare Inspection - Management of Mental Health Care Concerns, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin](#)

7/27/2017 | 16-00748-319

[Opioid Management Practice Concerns, John J. Pershing VA Medical Center Poplar Bluff, Missouri](#)

6/1/2017 | 16-01077-255

[Healthcare Inspection—Patient Deaths, Opioid Prescribing Practices, and Consult Management, VA Greater Los Angeles Healthcare System,](#)

5/23/2017 | 15-01669-246

[Healthcare Inspection – Alleged Patient Deaths and Management Deficiencies in Home Based Primary Care, Beckley VA Medical Center, Beckley, West Virginia](#)

5/8/2017 | 15-00408-204

Healthcare Inspection – Community Nursing Home Program Safety Concerns, VA Northern California Healthcare System, Mather, California

5/2/2017 | 15-01325-205

Healthcare Inspection – Opioid Prescribing Practice Concerns, VA Illiana Health Care System, Danville, Illinois

3/30/2017 | 16-00462-192

Appendix B: Figures 2–4

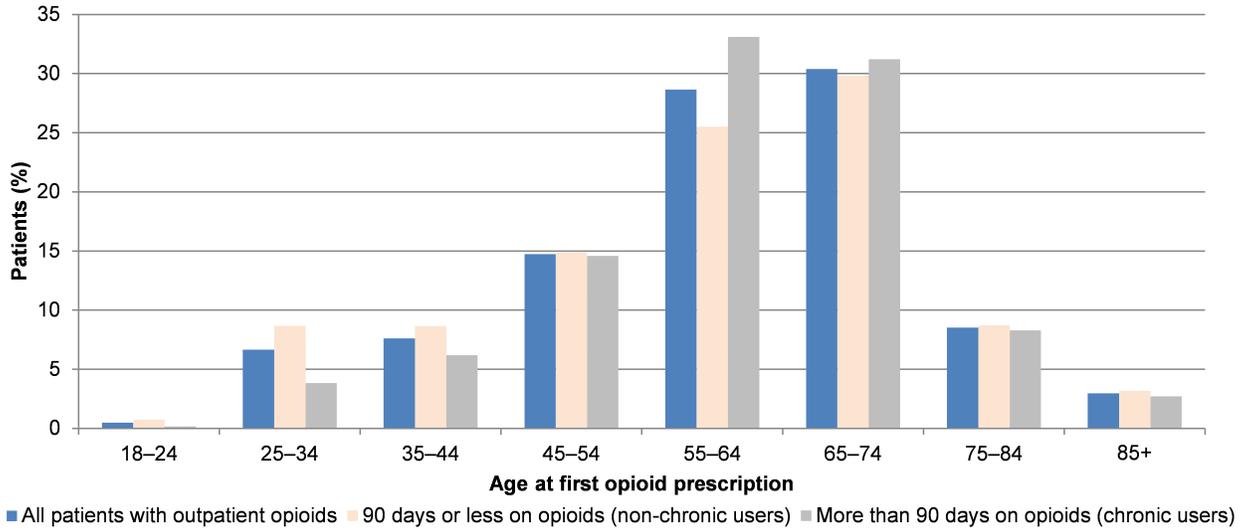


Figure 2. Age (At First Opioid Prescription) Distribution of VA Outpatient Opioid Patients in FY 2015
 Source: VA OIG analysis of administrative data

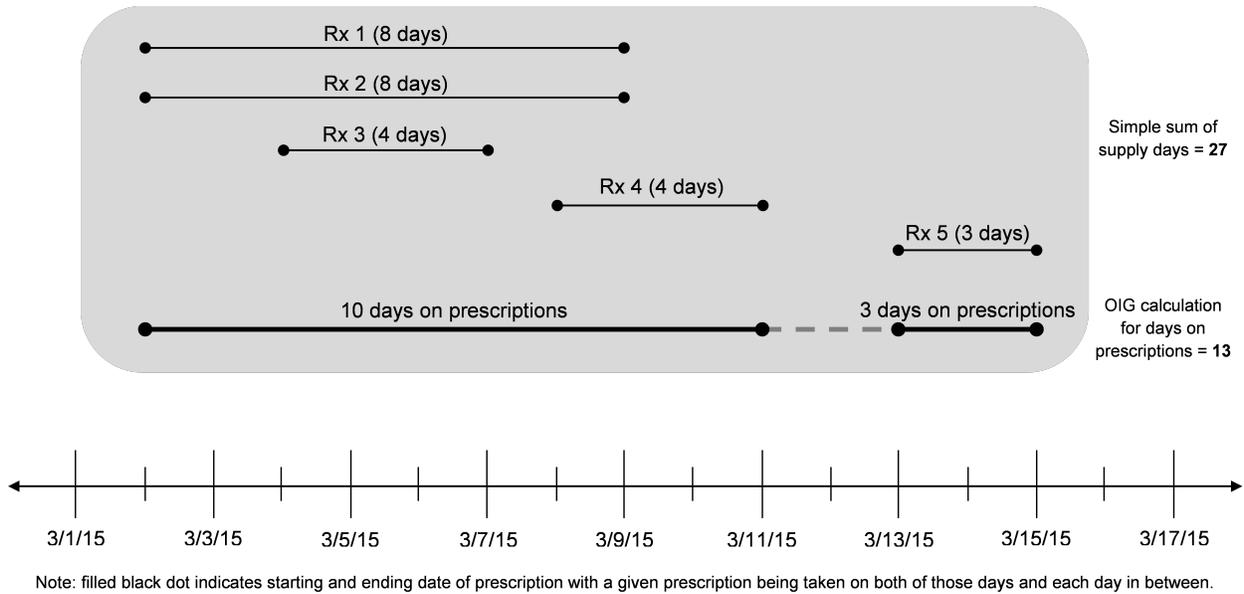


Figure 3. Calculation of Days on (Opioid) Prescriptions
 Source: OIG illustration of calculating days on prescriptions

The OIG classified the study population into two subpopulations, chronic users and non-chronic users of opioids, based on the number of days they were on opioid prescriptions. Rather than simply adding each prescription supply days, the OIG counted overlapping supply days from different prescriptions once only for the number of days on prescriptions. In this illustration, a

patient filled one prescription that supplied opioids from March 3, 2015, through March 10, 2015, then filled another prescription that supplied opioids from March 8, 2015, through March 14, 2015; the OIG counted the number of days on opioids as 12 instead of 15 after taking into account the overlapping supply days from March 8, 2015, to March 10, 2015.

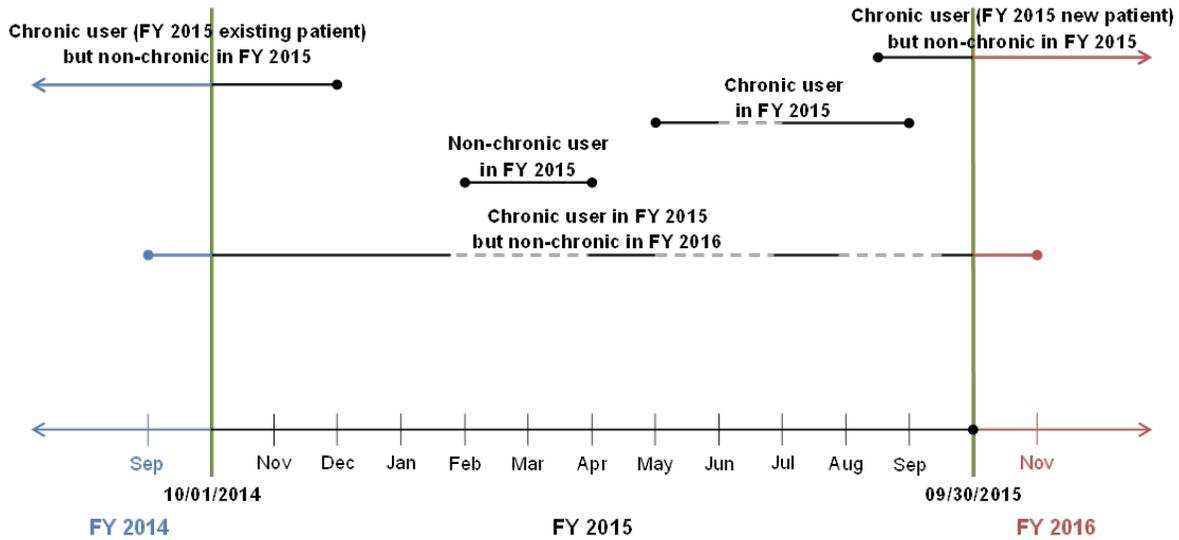


Figure 4. Chronic (> 90 days) Users in Cross-Sectional Study
 Source: OIG illustration that chronic users are defined relevant only to the given time period because of the nature of cross-sectional data

The OIG defined patients as *chronic users* of opioids if they were on opioids for more than 90 days in FY 2015 and as *non-chronic users* if they were on opioids 90 days or less. The OIG’s definition of chronic users of opioids (more than 90 days) is relevant only to the given FY 2015 time period because of the nature of cross-sectional data. As illustrated here, the non-chronic (90 days or less) users in FY 2015 would really be chronic users if they were initiated on opioid therapy during the 4th quarter of FY 2015 (that is, new patients in FY 2015) and continued the therapy through FY 2016. This would also apply to the non-chronic users in FY 2015 if they were initiated on and continued with therapy through FY 2014 (that is, existing patients in FY 2015) but ended prior to the 2nd quarter of FY 2015. Similarly, chronic users in FY 2015 would not be chronic users in FY 2016 if they were on outpatient opioids for 30 days or less in FY 2016. OIG’s results by chronic and non-chronic users should be viewed within the context of this limitation that is common to all cross-sectional studies. For this reason, this study included all patients, whether on chronic or non-chronic outpatient opioid therapy.

Appendix C: Codes for Identifying Hospice and Palliative Care

ICD-9-CM diagnostic code: V66.7

Treating specialty codes: 96, 1F.

CPT/HCPS codes: G9054, G0182, G0337, Q5001–Q5010, S0255, S0271, S9126, T2042, T2043, T2045, T2046.

Clinic stop codes: 351, 353.

Appendix D: Primary Pain Site Diagnoses with Codes

The OIG adapted Seal’s definitions¹²⁹ to determine whether a patient was diagnosed with any *primary pain*. These *primary pain site* diagnoses included ICD-9-CM non-cancer diagnostic codes that could result in pain serious enough to warrant an opioid medication:

- Arthritis: 710 (except 710.5), 711, 713, 714, 715, 716, 717, 718, 719.70, 719.75–719.79, 720.0, V13.4
- Back pain: 720–724 (except 720.0, 723.4, 723.8), 756.1
- Fractures: 733.1, 733.93–733.98, 800–829, 905.0–905.5, V13.51, V13.52, V54.0–V54.2, V66.4, V67.4
- Generalized pain: 780.96
- Headaches: 307.81, 339, 346 (except 346.6), 784.0
- Musculoskeletal pain: 725, 726 (except 726.70, 726.73, 726.79, 726.91), 728.11, 728.12, 728.81, 728.83, 728.86, 728.89, 728.9, 729 (except 729.2, 729.3, 729.6, 729.81, 729.82), 781.99, 830–848, 905.6, 905.7, V43.6, V43.7, V48.3, V49.6, V49.7
- Neuropathy: 053.13, 072.72, 337.0, 337.1, 353–357, 377.33, 377.34, 377.41
- Other pain: 730, 733.0, 780.96
- Reproductive pain: 614, 615, 616.11, 616.2–616.9, 617, 625.1–625.3, 625.5, 625.7, 625.8 626.3, 626.5
- Visceral pain: 550 (except 550.9), 551.0–551.2, 552.0–552.2, 560.81, 562.01, 562.03, 562.11, 562.13, 567.2, 567.8, 569.5, 574, 575.0, 575.1, 577.0, 577.1, 592, 594, 596, 788.0, 789.0, 789.6
- Wound injury: 860–887 (except 873.63), 890–897, 900–904, 905.8, 905.9, 906, 907.2, 908.0–908.4, 925–929, 940–949, 952

¹²⁹ Seal, K. H., Y. Shi, et al. (2012). “Association of mental health disorders with prescription opioids and high-risk opioid use in US veterans of Iraq and Afghanistan.” JAMA 307(9): 940–947.

Appendix E: UDT Logical Observation Identifiers Names and Codes by Type

Type 1 – Heroin or Morphine

10975-1, 10976-9, 10998-3, 11246-6, 11247-4, 12308-3, 13576-4, 16196-8, 16198-4, 16249-5, 16251-1, 16252-9, 16755-1, 16998-7, 17384-9, 17395-5, 18325-1, 18390-5, 18473-9, 19138-7, 19295-5, 19296-3, 19298-9, 19299-7, 19300-3, 19301-1, 19302-9, 19321-9, 19322-7, 19324-3, 19439-9, 19482-9, 19483-7, 19484-5, 19485-2, 19486-0, 19487-8, 19488-6, 19592-5, 19593-3, 19594-1, 19597-4, 19599-0, 19600-6, 19642-8, 19643-6, 19644-4, 19645-1, 19646-9, 19648-5, 19649-3, 19650-1, 20550-0, 21431-2, 27073-6, 3546-9, 3681-4, 3829-9, 3830-7, 3831-5, 3832-3, 3851-3, 3879-4, 5706-7, 8220-6, 9834-3, 9835-0

Type 2 - Non-Morphine Opioid Compounds

11075-9, 11235-9, 12395-0, 14066-5, 16197-6, 16199-2, 16200-8, 16207-3, 16208-1, 16211-5, 16213-1, 16242-0, 16246-1, 16250-3, 16253-7, 16334-5, 16496-2, 17377-3, 17718-8, 17719-6, 18282-4, 18338-4, 19073-6, 19141-1, 19287-2, 19288-0, 19289-8, 19290-6, 19291-4, 19292-2, 19293-0, 19294-8, 19411-8, 19413-4, 19414-2, 19429-0, 19431-6, 19432-4, 19433-2, 19446-4, 19448-0, 19449-8, 19450-6, 19451-4, 19516-4, 19532-1, 19535-4, 19550-3, 19552-9, 19553-7, 19635-2, 19636-0, 19637-8, 19710-3, 19712-9, 19713-7, 20413-1, 20561-7, 26747-6, 26760-9, 26867-2, 27076-9, 27920-8, 29532-9, 33527-3, 3414-0, 3415-7, 3427-2, 3507-1, 3508-9, 3545-1, 3637-6, 3744-0, 3746-5, 3747-3, 3773-9, 3774-7, 3775-4, 38373-7, 3840-6, 3869-5, 3871-1, 3874-5, 3875-2, 3917-2, 3918-0, 9396-3

Type 3 - Non-opioid Abusable Substances

10979-3, 11004-9, 11071-8, 11230-0, 11238-3, 12311-7, 12314-1, 12327-3, 12361-2, 12363-8, 12382-8, 12386-9, 12432-1, 12477-6, 12602-9, 13478-3, 13497-3, 13740-6, 14192-9, 14267-9, 14308-1, 14310-7, 14312-3, 14313-1, 14314-9, 14315-6, 14316-4, 15366-8, 15372-6, 16181-0, 16190-1, 16191-9, 16192-7, 16193-5, 16194-3, 16195-0, 16201-6, 16202-4, 16203-2, 16204-0, 16205-7, 16206-5, 16224-8, 16226-3, 16227-1, 16228-9, 16229-7, 16230-5, 16231-3, 16232-1, 16233-9, 16234-7, 16235-4, 16236-2, 16237-0, 16238-8, 16239-6, 16240-4, 16241-2, 16244-6, 16254-5, 16348-5, 16367-5, 16369-1, 16429-3, 16448-3, 16548-0, 16632-2, 17088-6, 18187-5, 18355-8, 18358-2, 18385-5, 18389-7, 18392-1, 18470-5, 19055-3, 19059-5, 19064-5, 19065-2, 19245-0, 19261-7, 19265-8, 19266-6, 19267-4, 19268-2, 19269-0, 19270-8, 19275-7, 19276-5, 19277-3, 19278-1, 19282-3, 19283-1, 19284-9, 19285-6, 19286-4, 19312-8, 19315-1, 19317-7, 19325-0, 19326-8, 19328-4, 19329-2, 19330-0, 19339-1, 19341-7, 19342-5, 19343-3, 19344-1, 19346-6, 19347-4, 19348-2, 19355-7, 19357-3, 19358-1, 19359-9, 19360-7, 19362-3, 19363-1, 19370-6, 19373-0, 19375-5, 19376-3, 19382-1, 19383-9, 19384-7, 19386-2, 19388-8, 19399-5, 19402-7, 19403-5, 19404-3, 19408-4, 19415-9, 19416-7, 19417-5, 19418-3, 19419-1, 19445-6,

19466-2, 19474-6, 19475-3, 19477-9, 19489-4, 19490-2, 19492-8, 19493-6, 19494-4, 19496-9, 19500-8, 19501-6, 19520-6, 19522-2, 19523-0, 19528-9, 19554-5, 19555-2, 19556-0, 19557-8, 19558-6, 19565-1, 19566-9, 19567-7, 19568-5, 19569-3, 19570-1, 19571-9, 19572-7, 19577-6, 19578-4, 19579-2, 19580-0, 19585-9, 19586-7, 19588-3, 19589-1, 19590-9, 19614-7, 19617-0, 19624-6, 19626-1, 19627-9, 19638-6, 19639-4, 19640-2, 19641-0, 19655-0, 19657-6, 19658-4, 19659-2, 19660-0, 19661-8, 19666-7, 19668-3, 19669-1, 19692-3, 19695-6, 19696-4, 19697-2, 19698-0, 19700-4, 19701-2, 19702-0, 19703-8, 19704-6, 19714-5, 19717-8, 20410-7, 20411-5, 20412-3, 20500-5, 20501-3, 20519-5, 20521-1, 20522-9, 20524-5, 20532-8, 20535-1, 20545-0, 20546-8, 20548-4, 20559-1, 20663-1, 20664-9, 22745-4, 24349-3, 25122-3, 26611-4, 27036-3, 27083-5, 27084-3, 27085-0, 28044-6, 28073-5, 33041-5, 3313-4, 33280-9, 33301-3, 33339-3, 3339-9, 3349-8, 3377-9, 3390-2, 3393-6, 3394-4, 3397-7, 3398-5, 34180-0, 34181-8, 3419-9, 3421-5, 3426-4, 34300-4, 3435-5, 3436-3, 3458-7, 3459-5, 3492-6, 3530-3, 3550-1, 3551-9, 35664-2, 3581-6, 3641-8, 3654-1, 3655-8, 3725-9, 3726-7, 3732-5, 3754-9, 3755-6, 3779-6, 3780-4, 3786-1, 3787-9, 3808-3, 3809-1, 3861-2, 3887-7, 3925-5, 3926-3, 3936-2, 3937-0, 3949-5, 3950-3, 4029-5, 4070-9, 5644-0, 5645-7, 5679-6, 5694-5, 5695-2, 6799-1, 8150-5, 8152-1, 8173-7, 8175-2, 9351-8, 9426-8, 9428-4

Source: OIG review of UDT Logical Observation Identifiers Names and Codes

Appendix F: Executive in Charge, Office of the Under Secretary for Health Comments

Department of Veterans Affairs Memorandum

Date: June 15, 2018.

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Review of Pain Management Services in Veterans Health Administration Facilities (VIEWS 00065180)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Review of Pain Management Services in Veterans Health Administration (VHA) Facilities. VHA concurs with recommendations 1-6 and 9-10, concurs in principle with recommendations 7-8, and provides the attached action plan. VHA also provides technical comments for your consideration.
2. Thank you for your recognition of our innovation and progress in Pain Management Services in VHA. As of March 2018, there are 88,462 fewer patients receiving opioids and benzodiazepines together; a 72 percent reduction from July 2012.
3. VHA has significant concerns about the timing of the data that OIG reviewed, the analysis of the data, and the citations that were referenced in the draft report. VHA is strongly committed to developing long-term solutions that mitigate risks to patients on opioid therapy, as well as address pain care and substance use disorder.
4. We are concerned that the data in the draft report are outdated, especially in the context of opioid prescribing, pain management, and treatment of substance use disorders. For example, OIG conducted an electronic site survey from April 27, 2016 through May 11, 2016, which is now over two years ago. Additionally, the metrics appear to be based on fiscal year (FY) 2015 patient data. FY 2017 data, the latest full year of data, is available for review and would more accurately represent the current status of pain management services in VHA. The Department of Veterans Affairs (VA) publishes opioid prescribing data quarterly on VA's Open Data Portal and this data is current through second quarter FY 2018. Additionally, in May 2017 a summary of VA Efforts Addressing the Opioid Epidemic authored by Walid F. Gellad, MD, MPH, Chester B. Good, MD, MPH and David J. Shulkin, MD was published in the Journal of the American Medical Association (JAMA) Internal Medicine with a robust review of the VA efforts and additional data regarding progress made to that date.
5. There have been extensive developments in best practices, guidelines, training, and research since the initial data collection for this OIG review. Among these developments, include declaration of the Opioid Epidemic as a National Health Emergency, the 2016 publication of Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain, national deployment of VA Mandatory Pain Management training (also updated based on the Comprehensive Addiction Recovery Act), and the January 2017 publication of the VA/DoD Clinical Practice Guidelines (CPG) for Opioid Therapy for Chronic Pain. In reference to the VA/DoD CPG, it appears OIG conducted much of their review based on the 2010 version of the VA/DoD CPG, which are acknowledged as outdated. Our understanding of opioid best practices, pain management, and opioid use disorder, as

well as the evidence supporting CPG have evolved greatly in those seven years and it is important to compare current practice to current recommendations. The CPG is based on a systematic review of both clinical and epidemiological evidence and developed by a panel of multidisciplinary experts. VHA's action plan corresponds to the 2017 guidelines, rather than the 2010 CPG referenced in the draft report. Additionally, in 2012, the Under Secretary for Health chartered the Opioid Safety Initiative (OSI), which was then implemented nationwide in 2013 and is producing the desired results of improving key metrics. The OSI aims to reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated. Metrics are tracked utilizing the OSI Dashboard and are continuing to denote progress in improving care. The dated or absence of reference to these important developments contributes to an inaccurate portrayal of Pain Management Services in VHA.

6. We also disagree with the framing of the CPG in the draft report. OIG presents the CPG as an absolute policy or regulation for patient care, which is an incorrect interpretation. CPGs are not mandatory requirements; rather, they are a general rule, principle, or piece of advice and are provided as recommendations for clinicians to provide individualized case based on the provided clinical content.
7. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

Carolyn M. Clancy, M.D.

Attachments

Comments to OIG's Report

The following Executive in Charge comments are submitted in response to the recommendations in the OIG report.

Recommendation 1

The Under Secretary for Health ensures that VA facilities have formal processes in place for providers to access state prescription drug monitoring programs to reconcile medications dispensed by private providers and those dispensed by VA, and that this process is in compliance with the providers' state licensing requirements.

Concur.

Executive in Charge Comments

The Veterans Health Administration (VHA) agrees with increasing access and utilization of state prescription drug monitoring programs (PDMP). Over the past two years, VHA has put into place numerous activities to increase and ensure the safety of Veterans when prescribing and dispensing medications. Specifically, VHA has set up a variety of formal processes to ensure VHA medical center providers utilize and comply with the state prescription drug monitoring programs. Such activities include:

- The October 2016 issuance of VHA Directive 1306, Querying State Prescription Drug Monitoring Programs, which outlines the requirements for PDMP checks. This directive outlines policies and procedures to ensure the VA is in compliant with the Comprehensive Addiction and Recovery Act (CARA) requirements related to PDMPs and includes:
 - Guidance on who is expected to query state PDMP's and how often
 - Requirements for documenting the query in the patient record
 - Circumstances in which a PDMP query is not required
 - Clarity regarding when State laws for VA Directive takes precedence with regards to PDMP queries
- The April 2018 issuance of USH Notice 2018-08, Conduct of Data-Based Case Reviews of Patients with Opioid Related Risk Factors, included additional guidance on opioid safety practices. This Notice outlined the processes and steps to be taken by the facilities and Veterans Integrated Service Networks (VISN) to continue to decrease patient risk. It includes requirements for conducting point of care-based reviews of risk, including universal precautions, of which prescription drug monitoring program checks is one.
- PDMP checks are performed individually by VHA staff using the differing state interfaces, manually recorded in the patient's electronic record.

- Monitoring occurs through the Opioid Safety Initiative (OSI) Dashboard and Academic Detailing Dashboard.
- From Fiscal Year (FY) 2013 (Quarter 3, ending in June 2013) to FY 2017 (Quarter 4), VHA providers have documented over 2.3 million queries to State PDMPs to help guide treatment decisions.

To demonstrate that VHA's actions are complete, we will provide documentation of the components described in this action plan.

Status: Complete
Completion Date: October 2016

Recommendation 2

The Under Secretary for Health evaluates the use of facility-specific panel readjustments or other means of increasing resources for primary care providers who manage chronic pain conditions for a significant proportion of his/her panel and takes action as appropriate.

Concur.

Executive in Charge Comments

Panel capacities are calculated in the web-based program, Patient Centered Management Module (PCMM). This program automatically calculates the expected panel size modeled on capacity for Primary Care providers each month based on staffing ratios, number of rooms, and complexity of the panel population (via intensity scores). The cohort of chronic pain patients and patients with complex comorbidities are factored into the intensity score. Facility leaders are able to manually override panel capacities in PCMM Web if the cohort of patients with chronic pain is not adequately reflected in the modeled capacity.

The Office of Primary Care Operations (OPCO) will assess the use of facility specific panel readjustments and complexity via PCMM. OPCO will continue to provide national webinars, conference calls, and monthly communities of practice as well as e-consultations, and utilize Specialty Care Access Network-Extension for Community Healthcare Outcomes with support and assistance from subject matter experts from the Office of the Deputy Under Secretary for Health for Policy and Services. Lastly, OPCO will provide recommendations to VHA leadership concerning additional needed pain resources for primary care providers and pain management teams.

VHA will provide the following documentation at completion of this action:

- National webinar presentation
- A copy of the associated documents from an e-consultation

- A copy of the recommendations provided to VHA leadership

Status: In process.

Target Completion Date: May 2019

Recommendation 3

The Under Secretary for Health evaluates and determines the adequacy of the number of pain specialists at each facility through formalized assessments and takes action as appropriate.

Concur.

Executive in Charge Comments

VHA agrees that completing an assessment related to the pain specialists needs within the VISNs and VA medical centers (VAMC) will provide a structure to address deficiencies. The Office of the Deputy Under Secretary for Health for Policy and Services, Office of Specialty Care and the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will establish a team of subject matter experts to evaluate and determine the number of pain specialists recommended at each VAMC. At the conclusion of this evaluation, a report will be provided to the DUSHOM.

VHA will provide a copy of the completed evaluation report provided to the Office of the DUSHOM at completion of this action:

Status: In process.

Target Completion Date: May 2019

Recommendation 4

The Under Secretary for Health ensures that VA facilities without pain specialists have formalized designated resources of pain care provided by providers.

Concur.

Executive in Charge Comments

VHA agrees that for facilities that do not have specific pain specialists on site that provisions should be made to ensure appropriate resources of pain care that is provided by providers.

The Office of the Deputy Under Secretary for Health for Policy and Services (DUSHPS), Office of Specialty Care and the Office of the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will establish a team of subject matter experts to evaluate what resources for pain care treatment within the VAMCs are needed and develop recommendations to the DUSHOM.

VHA will provide the following documentation at completion of this action:

- A copy of the completed evaluation report provided to the Office of the DUSHPS and the Office of the DUSHOM.

Status: In process.

Target Completion Date: May 2019

Recommendation 5

The Under Secretary for Health evaluates the use of pain assessment tools across VHA to ensure that those tools used by facilities provide information that improves oversight to patients who are treated for chronic pain conditions.

Concur.

Executive in Charge Comments

Pain manifests itself in numerous ways (e.g., functional limitations, emotional symptoms, physical sensations, and behavioral changes), and clinicians should be careful to choose the pain assessment tool that most closely corresponds to a patient’s symptoms and conditions. This variation in functionality can cause confusion because pain scales are not interchangeable—a “10” on one scale may not be equivalent to the same score on another. Additionally, pain scales may measure not only pain intensity but also changes over time, functional limitations, emotional aspects, and behavior. Therefore, VHA makes a number of tools available including but not limited to:

- Pain Score,
- Visual Analog scale, and
- The pain, enjoyment of life and general activity (PEG) scale.

The Office of Pain Management routinely evaluates the efficacy of pain management tools and models of care and provides information that is soundly based on best practices and clinical recommendations in the pain community, nationally.

To demonstrate that VHA’s actions are complete, we will provide documentation of the components described in this action plan.

Status: Complete

Completion Date: January 2017

Recommendation 6

The Under Secretary for Health develops a formal evaluation of the provision of pain management services within VA to complement the Opioid Safety Initiative.

Concur.

Executive in Charge Comments

VHA is of strong belief that ensuring overall pain management care in VHA complements the Opioid Safety Initiative (OSI). The Healthcare Analysis and Information Group (HAIG) conducted a Pain Management Survey and published their findings in the 2014 Pain Management in VHA Survey Report. This Report provides a comparative report assessing changes in pain management policy, practice, and resource allocation since 2010. The information gleaned from the survey data has been used to assist in national policy decisions and strategic planning.

VHA is committed to ongoing evaluation of pain resources. The next HAIG Pain Management Survey is in the development stages.

To demonstrate that VHA's actions are complete, we will provide documentation of the components described in this action plan.

Status:	Complete
Completion Date:	November 2014

Recommendation 7

The Under Secretary for Health ensures that VA's practice of routine and random urine drug tests both prior to initiating and during take-home opioid therapy to confirm the use of opioids is in alignment with guidelines.

Concur in principle.

Executive in Charge Comments

The Opioid Safety Initiative (OSI) that was chartered by the Under Secretary for Health in August 2012, was implemented nationwide in August 2013. OSI is producing the desired results of increasing the percentage of patients on long-term opioid therapy with a Urine Drug Screen completed in the last year. The OSI aims to reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated.

VHA issued updated Department of Veterans Affairs and Department of Defense (VA/DOD) Clinical Practice Guidelines (CPG) for Opioid Therapy for Chronic Pain in 2017. These guidelines were issued after the OIG conducted their review and gathered data. Therefore,

references in the report to the prior version of the CPG's are no longer relevant or the recommended clinical best practices. The CPG is based on a systematic review of both clinical and epidemiological evidence and developed by a panel of multidisciplinary experts and the response to this OIG recommendation is based on these current guidelines.

The 2017 CPG recommends, but does not require, urine drug test (UDT) concurrently with therapy as a risk mitigation strategy however, this guideline is limited to opioid therapy for Chronic Pain and does not cover every situation in which opioids would be provided for take home opioid therapy. The CPG does not recommend a UDT prior to initiating long term therapy, however, prior to initiating long term opioid therapy the following risk mitigation strategies are recommended through an informed consent discussion: reviewing the patient's history, checking state PDMPs, or instructing patients about using drug take back programs to dispose of unused medication. VHA does not agree with the specific recommendation to utilize a UDT prior to each and every possible initiation of opioid treatment but it does agree with the intent of the part of the recommendation to perform risk mitigation through activities available in that setting and at that time. During long term opioid therapy, VHA does agree with the recommendation and has been conducting UDT under the auspices of the OSI, however, these tests require consent and the practice of withholding opioid therapy based on consent alone, should not uniformly be used in clinical decisions for care.

As measured by the OSI Dashboard from Quarter 4, FY 2012 (beginning in July 2012) to Quarter 2, FY 2018 (ending in March 2018) there are 214,788 fewer patients on long-term opioid therapy (438,329 to 223,541, a 49 percent reduction). The percentage of patients on long-term opioid therapy with a Urine Drug Screen completed in the last year to help guide treatment decision has increased from 37 percent to 89 percent (52 percent increase).

To demonstrate that VHA's actions are complete, we will provide documentation of the components described in this action plan.

Status:	Complete
Completion Date:	January 2017

Recommendation 8

The Under Secretary for Health ensures that opioid patients with active (not in remission) substance use disorder undergo urine drug testing and receive treatment for the substance use disorder.

Concur in principle.

Executive in Charge Comments

VHA concurs with the general principle of encouraging patients with active substance use disorder to receive urine drug testing and substance use disorder treatment while receiving

opioids. VHA has an existing metric which monitors the rate at which patients with a substance use disorder and an opioid prescription also receive specialty treatment for substance use disorders, as well as a metric which assesses rates of urine drug screening every 90 days in all patients on opioid therapy with a substance use disorder diagnosis. VHA has nationally implemented population management tools to identify patients with active opioid prescriptions but no recent urine drug testing and/or specialty substance use disorder treatment and encourage them to receive those services as part of the Stratification Tool for Opioid Risk Mitigation (STORM).

Although urine drug testing and substance use disorder treatment is clinically optimal for the safety of patients with substance use disorders receiving opioid therapy, VHA emphasizes that risk/benefit decisions must be a shared decision-making process between patient and provider, and the preferences and beliefs of the patient should appropriately be considered in developing a treatment plan and deciding whether to prescribe opioid medication. Moreover, this practice may not be practical due to patient compliance with prescribed treatment plans, attendance of scheduled treatment, or the completion of ordered labs. Additionally, in some instances, it may not be ethical or safe to discontinue or withhold an opioid prescription if a patient refuses a urine drug screen or substance use disorder treatment. Patients with substance use disorders and pain are complex and clinically challenging to manage, as both unmanaged substance use disorders and unmanaged pain can increase risk of overdose, suicide, and other adverse events. Patients are likely to be at risk whether or not an opioid is prescribed, and both starting or stopping a prescription could conceivably contribute to an adverse outcome. Thus, VHA cannot ensure that all patients with substance use disorders and an opioid prescription receive these interventions.

The Office of Mental Health and Suicide Prevention (OMHSP) will initiate efforts to implement a stepped care model of substance use disorder treatment in which substance use disorder services will be provided across the spectrum of care and intensified as needed. Additionally, during summer 2018, OMHSP will convene a train-the-trainer conference to facilitate implementation of this approach across VA medical facilities. Likewise, to aid in the development of stepped care model implementation plans, OMHSP will assess the location and services provided to patients with substance use disorders and opioid prescriptions.

VHA will provide the following documentation at completion of this action:

- A briefing report to VHA leadership highlighting the data described in paragraph 1
- Training materials from the summer 2018 train-the-trainer conference
- A briefing report to VHA leadership highlighting the assessment of location and services provided to patients with substance use disorders and opioid prescriptions.

Status: In process.

Target Completion Date: June 2019

Recommendation 9

The Under Secretary for Health evaluates and determines that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with guidelines.

Concur.

Executive in Charge Comments

VHA continues to review co-prescribing under the auspicious of the OSI and clinical practice guidelines. Clinical guidelines, by definition, are a general rule, principle, or piece of advice and are provided as recommendations for clinicians to provide potential pathways for care. There is no absolute situation regarding concurrent prescribing of opioids and benzodiazepines as there are circumstances where co-prescribing is medically indicated.

The OSI which was chartered by the Under Secretary for Health in August 2012, was implemented nation-wide in August 2013, and is producing the desired results of reducing concurrent prescribing of benzodiazepines and opioids. The OSI aims to reduce over-reliance on opioid analgesics for pain management and to promote safe and effective use of opioid therapy when clinically indicated. VHA issued updated VA/DOD Clinical Practice Guidelines CPG for Opioid Therapy for Chronic Pain in 2017.

As measured by the OSI Dashboard from Quarter 4, FY 2012 (beginning in July 2012) to Quarter 2, FY 2018 (ending in March 2018) there are 88,462 fewer patients receiving opioids and benzodiazepines together (122,633 patients to 34,171 patients, a 72 percent reduction).

To demonstrate that VHA's actions are complete, we will provide documentation of the components described in this action plan.

Status:	Complete
Completion Date:	January 2017

Recommendation 10

The Under Secretary for Health ensures that medication reconciliation is performed to prevent adverse drug interactions.

Concur.

Executive in Charge Comments

VHA published VHA Directive 2011-012, Medication Reconciliation, which addresses this recommendation. This Directive delineates a system-wide approach to managing patient medication information by reconciling medications across the continuum of care. Additionally, VHA published VHA Directive 1161, Essential Medication Information Standards. This

directive establishes policy that outlines the essential medication information elements necessary for review, management, and communication of medication information with Veterans and their health care teams

The Office Reporting, Analytics, Performance, Improvement and Deployment (RAPID) reports a variety of measures through the External Peer Review Program (EPRP) process with results available to the facilities on a monthly basis. Each time EPRP reviews are conducted at any given facility, an exit conference is conducted with that facility leadership to include the facility Director. To ensure that medication reconciliation is performed, RAPID will submit a data pull quarterly, for two quarters, for existing medication reconciliation measures.

VHA will provide two quarters of data for existing medication reconciliation measures at completion of this action.

Status:	In process.
Target Completion Date:	February 2019

OIG Contact and Staff Acknowledgments

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