Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 17-01846-316

Healthcare Inspection

Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care

July 31, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review opioid prescribing to high-risk veterans receiving VA purchased care.

Overdose deaths involving prescription opioids have quadrupled since 1999. In 2014, more than 14,000 people died from overdoses involving prescription opioids. The opioid epidemic has impacted veterans, and overdose deaths among veterans remain elevated when compared to the civilian population.

Because of the prevalence and complexity of chronic pain in the veteran population, VHA developed and deployed two initiatives in 2014 to improve the safety and management of chronic pain in veterans: the Opioid Safety Initiative (OSI), and enabling VA providers to participate in state prescription drug monitoring programs (PDMP). The OSI includes specific management guidelines, a toolkit for prescribers that focuses on patient education, alternative therapeutic approaches to chronic pain, and an emphasis on a patient/provider collaboration to manage chronic pain. PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled substance[1] prescriptions to patients. Access to PDMPs allows VA providers to query state prescription drug monitoring databases to determine if non-VA providers have prescribed, and a patient has obtained, controlled substances from outside VA.

Over the last several years, VA has implemented several purchased care programs to enable veterans to access medical care in the community when necessary, including the Veterans Choice Program (Choice) which, under the Veterans Access, Choice, and Accountability Act enacted by Congress in 2014, allows eligible veterans to receive care from providers in their communities.

We determined that with the expansion of community partnerships, a significant risk exists for patients who are prescribed opioid prescriptions outside of VA. Patients suffering from chronic pain and mental health illness who receive opioid prescriptions from non-VA clinical settings where opioid prescribing and monitoring guidelines conflict with the guidelines in place within VA may be especially at risk.

Moreover, the risk is exacerbated when information about opioid prescriptions is not shared between VA and non-VA providers. Because of identified challenges related to health information sharing between VA and community providers, we noted that non-VA providers do not *consistently* have access to critical health care information regarding veterans they are treating. For example, access to an up-to-date list of medications and a relevant past medical history is important for any provider when caring for a patient, but particularly with high-risk veterans such as those with chronic pain and mental

[1] 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 whether they have an accepted medical treatment use, abuse potential, and likelihood of causing dependence when abused.

health illness. However, this information is not consistently included in the authorization and consult documentation for VA purchased care.

We also noted that while the ability to query PDMP databases is now available, VA providers would not likely access the PDMP when they are not prescribing controlled substances to a specific patient. Timely notification of veteran patients receiving non-VA opioid prescriptions would allow more immediate VA provider awareness and action, if any action were required. For example, if all routine non-VA opioid prescriptions were submitted directly to VA pharmacies, VA pharmacy staff could alert the VA provider of record that a non-VA opioid prescription was being dispensed. This would also allow the same level of pain management committee oversight by VA of opioid prescriptions prescribed by VA and non-VA providers.

We recommended that the Acting Under Secretary for Health:

- Require that all participating VA purchased care providers receive and review the evidence-based guidelines for prescribing opioids outlined in the Opioid Safety Initiative.
- Implement a process to ensure all purchased care consults for non-VA care include a complete up-to-date list of medications and medical history until a more permanent electronic record sharing solution can be implemented.
- Require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording of the prescriptions in the patient's VA electronic health record.
- Ensure that if facility leaders determine that a non-VA provider's opioid prescribing practices are in conflict with Opioid Safety Initiative guidelines, immediate action is taken to ensure the safety of all veterans receiving care from the non-VA provider.

Comments

The Acting Under Secretary for Health concurred with Recommendations 1, 2, and 4, concurred in principle with Recommendation 3, and provided acceptable action plans. (See Appendix B, pages 12–17 for the Acting Under Secretary's comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review opioid prescribing to high-risk veterans receiving VA purchased care. The purpose of the review was to identify the extent of opioid prescribing by non-VA providers and potential related patient safety issues.

Background

Overdose deaths involving prescription opioids have quadrupled since 1999. In 2014, more than 14,000 people died from overdoses involving prescription opioids.[2] With increasing opioid overdose deaths, the emphasis on opioid prescribing has shifted to opioid dose reduction, increased assessment, and monitoring of patients on chronic opioid therapy.

The opioid epidemic has impacted veterans, and overdose deaths among veterans remain elevated when compared to the civilian population.[3] Considering the unique experience of veterans, it is not surprising that so many veterans suffer from some form of chronic pain. In 2013, the VA Principal Deputy Under Secretary for Health informed Congress that more than 50 percent of veterans receiving care at Veterans Health Administration (VHA) facilities were affected by chronic pain.[4]

Recent data suggest that over 63 percent of veterans receiving chronic opioid treatment[5] from VA for pain also have a mental health diagnosis.[6] Pain management becomes even more complicated when a patient's chronic pain occurs in the setting of comorbidities such as PTSD (post-traumatic stress disorder), depression, traumatic brain injury, and substance use disorder.

Because of the prevalence and complexity of chronic pain in the veteran population, VHA developed and deployed two initiatives in 2014 to improve the safety and management of chronic pain in veterans: the Opioid Safety Initiative (OSI), and the enabling of VA providers to participate in state prescription drug monitoring programs (PDMP). PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled substance[7] prescriptions to patients. Access to PDMPs allows VA providers to query state prescription drug monitoring databases to determine if

[2] Centers for Disease Control and Prevention, http://www.cdc.gov/drugoverdose/data/overdose.html. Accessed August 23, 2016.
[3] Bohnert AS, Ilgen MA, Galea S, McCarthy JF, Blow FC. Accidental poisoning mortality among patients in the Department of Veterans Affairs Health System. Med Care. Apr 2011 49(4) 393 3962011;4):393-396
[4] Witness Testimony of Deputy Under Secretary for Health, VHA, dated October 10, 2013. Page 2.
[5] Chronic opioid treatment is defined as more than 90 days on opioid medications.
[6] OIG pre-publication internal data.
[7] 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 whether they have an accepted medical treatment use, abuse potential, and likelihood of causing dependence when abused.

non-VA providers have prescribed, and a patient has obtained, controlled substances outside the VA.

The OSI includes specific management guidelines, a toolkit for prescribers that focuses on patient education, alternative therapeutic approaches to chronic pain, and an emphasis on a patient/provider collaboration to manage chronic pain. The OSI relies on data within VHA electronic health records (EHR) to identify patients who are prescribed opioids; this also allows identification of concurrent benzodiazepine[8] use. Veterans Integrated Service Network (VISN) and facility oversight committees are then able to make determinations as to which patients would be considered high risk as well as to identify providers whose prescribing practices are not consistent with the evidence-based OSI guidelines.

While VHA has responded aggressively to the opioid epidemic with the OSI, no such initiative is in place for veterans who are prescribed medications outside VA. Over the last several years, VA has implemented several purchased care programs to enable veterans to access medical care in the community, including the Veterans Choice Program (Choice), which, under the Veterans Access, Choice, and Accountability Act enacted by Congress in 2014, allows eligible veterans to receive care from providers in their communities. This Act required VA to implement Choice in 90 days and the ambitious timeline has been blamed for many of the well-publicized challenges with the Choice program.

We determined that with the expansion of community partnerships, a significant risk exists for patients who are prescribed opioid prescriptions outside of VA. Patients suffering from chronic pain and mental health illness who receive opioid prescriptions from non-VA clinical settings where opioid prescribing and monitoring guidelines conflict with the guidelines in place within VA may be especially at risk.

Moreover, the risk is exacerbated when information about opioid prescriptions is not shared between VA and non-VA providers. VA has acknowledged the importance of and the challenges inherent in care coordination with non-VA providers. In its "Plan to Consolidate Programs of Department of Veterans Affairs to Improve Access to Care", submitted to Congress on October 30, 2015, VHA, citing the Agency for Healthcare Research and Quality (AHRQ), stated: "…care coordination involves deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care."[9]

When a patient is referred for care through one of VA's purchased care programs, an authorization for care from VA should include all information related to that patient that is relevant to the care being requested from the non-VA provider. We noted that, with

[8] Benzodiazepines belong to a class of drugs used to treat anxiety and in some cases for insomnia and muscle spasms. Chronic use can lead to physical and psychological dependence. Serious side effects including death can occur when combined with opioids. 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.

[9] Section 3.3, p. 21, citing https://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html. Accessed September 22, 2015.

the challenges related to health information sharing, non-VA providers do not *consistently* have access to critical healthcare information on the veterans they are treating. For example, access to an up-to-date list of medications and a relevant past medical history is important for any provider when caring for a patient, but especially so with high-risk veterans such as those with chronic pain and mental health illness.[10] Similarly, without immediate sharing of information, VA providers may also not be aware of treatment plans or new medications prescribed by non-VA providers. These gaps in care coordination are particularly risky when treatment plans by either or both groups of providers include opioid therapy.

A recent study[11] of the impact of the OSI found overall reductions in the number of patients being prescribed high-dose opioids, and a reduction in the number of patients on concurrent chronic opioid therapy and benzodiazepines. The success of the OSI is in large part attributable to opioid prescription data in the VA EHR which allows for appropriate monitoring of patients, including oversight by facility providers, pharmacists, and VISN and facility Pain Committees. Comparable monitoring does not exist for opioid prescriptions written *and* filled outside of the VA system unless a non-VA provider or the patient makes the effort to notify VA[12] or the VA provider routinely accesses the PDMP.[13] In these instances, the patient's VA EHR can be updated appropriately.

To understand the magnitude of potential risk for patients as it relates to non-VA providers prescribing opioids, we looked at the current volume of opioid prescriptions dispensed by VA pharmacies but written by providers contracted through Choice, VA's newest purchased care program. Under Choice, prescriptions for veterans who are authorized care through Choice are required to be filled at a VA pharmacy; however, a veteran can choose to fill the prescription outside the VA and pay for the prescriptions with his or her own funds.

Scope and Methodology

We initiated our review in December 2016 and completed our work in May 2017.

[10] The contracts in place with third party administrators who engage and manage Choice providers require that medical documentation, including information about prescribed medications, be submitted to VA within 14 days, but this standard is not routinely met. The failure by non-VA providers to provide timely documentation was exacerbated when VA entered into a contract modification with third party administrators which "decoupled" the payment to the providers from their obligation to provide records. We have previously reported on this issue (see appendix A for a list of relevant reports), and continue to recommend that VA enforce provisions in the contracts which require timely submission of complete clinical documentation.

[11] Lin LA, Bohnert ASB, Kerns RD, Clay MA, Ganoczy D, Ilgen MA; Impact of the Opioid Safety Initiative on opioid-related prescribing in veterans. National Center for Biotechnology Information website, https://www.ncbi.nlm.nih.gov/pubmed/28240996. Accessed June 19, 2017.

[12] A VA provider can manually enter non-VA prescribed and/or dispensed prescriptions into the EHR.

[13] The PDMP does not provide a fail-proof way to ensure access to prescription information. There are limitations to accessing the PDMP for patients who receive opioids in neighboring states or for providers who are not licensed by the state in which they care for patients. In addition, a provider would not likely access the PDMP when they are not prescribing controlled substances to the specific patient.

We conducted interviews with knowledgeable VHA leadership and staff. We reviewed *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, as well as VA's Opioid Safety Initiative, current medical literature, and the VA-purchased care Choice contract.

We identified all VA patients who filled at least one oral or transdermal outpatient opioid prescription at a VA pharmacy in FY 2016[14] by using VA administrative pharmacy data, which contained all VA-filled inpatient and outpatient prescription records housed in the VA Corporate Data Warehouse (CDW).[15] We 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. We included all opioid products in the 10 selected opioid types that were categorized as U.S. Drug Enforcement Administration (DEA) schedule II or III controlled substances.

We acquired the Choice provider list files that included all Choice providers as of November 2016. We then searched the VA administrative staff file in CDW to find the VA provider identification number for each of these Choice prescribers. For purposes of this report, we considered the filled prescription as ordered by a Choice provider if the prescription was from a provider on our Choice prescriber list.

Statistical Analyses

We included only filled opioid prescriptions in FY 2016 that were original orders.

For each patient in the study population, we defined the patient's prescriber group as:

- "VA Only" if all opioid prescriptions of the patient were ordered by VA providers.
- "Choice Only" if all opioid prescriptions of the patient were ordered by Choice providers.
- "Both VA and Choice" if some of the patient opioid prescriptions were ordered by VA providers and some were ordered by Choice providers.

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

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

[14] We did not include patients receiving hospice or palliative care during the FY or within 1 year prior to their first outpatient opioid prescription due to the unique needs of this population.
[15] CDW is the VA repository for administrative, clinical, and operational data.

Inspection Results

Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care

During FY 2016, 13,928 patients were prescribed opioid medications by Choice providers or a combination of Choice and VA providers, which were filled in VA pharmacies (see Table below). Of this number, 5,590 patients were prescribed opioid medications exclusively by Choice providers. Because all prescriptions filled at VA pharmacies will appear in the patient's VA EHR, any provider within the system would be able to view the patient's current medications and prescription medication history.

While 13,928 may appear modest when compared with the overall number of veterans prescribed opioids within the system (877,253), it is important to note that the actual number of opioid prescriptions dispensed to these 13,928 patients totaled 85,729.

Table. Outpatient Opioid Prescriptions in FY 2016, by VA or Choice Provider

Prescriber Group	# Rx	Rx Percent	# Patients	Patient Percent
Total	4,874,642	100	877,253	100
VA Only	4,788,913	98.2	863,325	98.4
Choice Only	12,688**	0.3	5,590*	0.6
VA and Choice	73,041**	1.5	8,338*	1.0

Source: VAOIG

**5, 590 + 8, 338 = 13, 928*

***12, 688 + 73, 041 = 85, 729*

A unique sub-set of patients are those not currently using VA services other than the VA pharmacy, such as the "forty milers" who qualify for care through Choice due to the distance from their home to the nearest VA facility. These veterans' VA EHRs would likely contain very little information beyond basic demographic data. It is feasible that VA is filling controlled substances for these patients with limited information beyond this basic data. While communicating with prescribers, conducting medication reconciliation, and educating the patient on the appropriate use and associated risks of each dispensed medication are expected of a pharmacist, this particular population presents obvious challenges to accomplishing these important tasks.

Most importantly, because these results were obtained from VA outpatient pharmacy data, these numbers do not include opioid prescriptions which were written by non-VA providers but filled by non-VA pharmacies and paid for by the veteran. A veteran receiving care from a Choice provider may choose to pay for prescriptions, for example, when traveling to a VA pharmacy is inconvenient. With a low cost prescription, it may be more convenient for a patient to have the prescription filled at a local, non-VA

pharmacy and pay for it directly.[16] A patient may also choose to fill a prescription at a non-VA facility in order to avoid having the information recorded in the EHR, for example, if the patient is attempting to obtain opioids from multiple providers. In these instances where a nexus does not exist between the pharmacy and the VA, the opioid medications will not automatically become part of the patient's VA EHR medication list, and are therefore not subject to timely medication reconciliation or other care coordination or risk oversight by VA. This information becomes part of the patient's VA EHR only if the patient reports the medication to his/her VA provider, or the non-VA provider submits records documenting the prescription, the VA provider reviews the submission, and takes action to update the VA EHR. For optimal clinical decision-making, submission from the non-VA provider and review by the VA provider of new opioid prescriptions must also be timely.

The following are actual patient case examples that demonstrate the risks we have identified.

Case Summaries

Patient 1

At the time of his death, the patient was a male in his forties with a past medical history significant for PTSD, chronic low back pain, obstructive sleep apnea, obesity, and depression. During the 4 years prior to his death, he had been hospitalized twice for suicidal ideation and a reported suicide attempt. He was followed routinely at his local VA Medical Center (VAMC) by both mental health and primary care providers (PCP).

The patient was compliant with his medications and follow-up appointments. His mental health issues were managed with psychotherapy as well as medications including sertraline (SSRI) for his depression and temazepam (a benzodiazepine) prescribed for insomnia. He continued to experience chronic back pain with acute exacerbations and was prescribed gabapentin, a non-narcotic medication, used to treat pain. He was referred outside of VA to a pain management physician who offered him spinal injections to alleviate his pain. Medical records from these visits document that the non-VA physician also prescribed oral opioids to treat the patient's pain.

Our review of the patient's VA prescription profile showed that these prescriptions were not filled at a VAMC pharmacy. The VA EHR does not contain evidence that his VA providers were aware that he was being prescribed opioids by the pain management physician. While the non-VA pain management physician did document the patient's medical history in his non-VA clinic notes, these notes did not contain a list of the patient's prescription medications that were concurrently prescribed by his VA providers, including the benzodiazepine. The authorization forwarded from the VA to the non-VA provider did not include a medication list or any other information related to

[16] According to the Choice contract, veterans can submit a copy of a prescription and a payment receipt to their VA facility for reimbursement if a medication was considered "urgent".

the patient's past medical history beyond the chief complaint listed as "chronic back pain".

A few days prior to his death, the patient presented for a VA mental health appointment. During that appointment he denied being suicidal or homicidal. Hours later, the non-VA pain management provider prescribed a 30-day supply of morphine tablets, 30 milligrams each, to be taken twice daily as needed for pain. This prescription was filled at the VA pharmacy the following day. The patient was found dead several days later. The cause of death listed on the death certificate is suicide caused by toxic levels of sertraline, morphine, and gabapentin. There is no evidence in the medical record that any of his VA providers were aware of the new opioid prescriptions.

Although this patient was appropriately screened for suicidal ideation by his VA mental health provider several days prior to his death, the disconnect between the community and VA providers in this case is concerning. System providers and the non-VA provider were creating health care management plans with incomplete information; for instance, one can question whether the non-VA provider would have prescribed morphine had he/she been aware of the patient's other medications, particularly the benzodiazepine, or of the patient's mental health history, including history of suicide ideation/attempt. Opportunities for educating the patient on the danger of unintentional overdose with benzodiazepines and opioids were missed, as were opportunities to consider alternative medications to avoid such risk in a patient with complex mental health issues and chronic pain. Ideally, each of the patient's providers should have had access to all current information relating to this patient, including all medications prescribed. While providers routinely ask patients to list their current medications, not all patients choose to or are able to provide complete and accurate information.

Patient 2

This patient is a male in his 30s followed at a VAMC since 2007. He has a past medical history of chronic neck and back pain, depression, PTSD, and Attention Deficit Disorder (ADHD). The patient has been seen routinely by his PCP and mental health provider since 2007. In 2009, the patient suffered significant exacerbations of his depression and anxiety. In addition, he reported increased pain from his chronic pain condition. These issues led to multiple medication additions and further dosage adjustments, including escalating doses of benzodiazepines and opioids. Over the next few years, the patient was on various combinations of hydrocodone, Percocet, methadone, and Adderall,[17] along with his admitted daily use of marijuana (through a state issued medical marijuana card). In late 2014, at the request of the patient, a consult to receive mental health care within the community was placed.

After the initial evaluation with a community mental health nurse practitioner (NP), the NP made a recommendation for the patient to see a pain management specialist. In

[17] Adderall is a stimulant medication used to treat ADHD and some sleeping disorders.

addition, she suggested that the VA provider prescribe fentanyl patches,[18] which was documented and forwarded to the patient's VA PCP. The VA PCP, after consulting with the VA Pain Management Service, favored a slow taper of all opioids, initiation of non-opioid pain medication, initiation of medication to manage expected opioid withdrawal symptoms, as well as development of a more comprehensive pain management approach to include physical therapy, acupuncture, chiropractic care, and other complementary care. The patient initially agreed to comply with this approach and a slow taper of opioids and benzodiazepines began, and various referrals for complementary care were placed.

In late 2015, the patient requested and was referred to a non-VA pain management provider. During a VA primary care encounter in May 2016, the patient reported his frustrations with the strict requirements of this non-VA pain management practice, which supported the continued taper of opioid medication, concurrent evaluation and treatment by a physical therapist, and a trial of non-narcotic pain medication. In August 2016, he reported to his VA PCP that the community pain specialty practice had been shut down by the State Medical Commission, and he would need to get his pain management from VA. At this time, the patient was offered a consult to the VA tele-pain clinic, where he could be evaluated by a pain specialist located in the parent facility. Although clinic scheduling staff documented multiple attempts to coordinate this appointment, the patient never responded.

The patient was then evaluated by another community mental health provider through Choice. After a few visits, this provider suggested to the patient that he see a pain management provider within her practice. In that this was a referral made by a non-VA provider, care was not provided through Choice and the VA EHR does not contain evidence that the patient's VA PCP was aware of this referral. During the first appointment, this non-VA pain management provider initiated treatment with 60 milligrams of methadone daily (a marked increase in the morphine equivalents[19] that he was receiving as part of the VA taper), a continuation of the benzodiazepines, and a stimulant to treat his ADHD, as well as testosterone injections.

In the fall of 2016, the patient called in a request to his VA PCP for a refill of his opioid medication, which was being tapered. The VA PCP reviewed the PDMP web site and noted that the patient was also being prescribed opioids from another provider. She then sent a letter to the patient explaining that she would no longer prescribe opioid medications to him, but that he could continue to see her for all other primary care follow-up. The following month, the patient requested a Choice consult for mental health care, and specifically requested care with the provider discussed above who had prescribed the methadone. This consult was placed by a VA staff member. In the consult, the staff member noted, "Non-VA prescribing provider has submitted the requested assessment and treatment plan for continuing care for this veteran with mood

[18] A fentanyl patch is a cutaneous patch that holds a reservoir of fentanyl, a potent synthetic opioid. It is indicated to treat severe chronic pain, and offers the advantage of providing controlled continuous release of the medication.
[19] A morphine equivalent is a measurement which attempts to compare the potency of one opioid against the other, using morphine as a standard value.

disorder and medical issues." The consult was approved for this patient to continue care with the provider through Choice.

As of publication of this report, the patient has not returned to the VA for care.

Conclusions

We determined that 13,928 of the 877,253 veterans who were prescribed opioid medications during FY 2016 received the prescription from Choice providers or a combination of Choice and VA providers and filled it in a VA pharmacy. The 13,928 veterans received a total of 85,729 prescriptions.

VHA has responded aggressively and with some success to the opioid epidemic with the deployment of the OSI. However, no such initiative is in place for veterans who are prescribed medications outside VA. We determined that a significant risk exists for patients who suffer from chronic pain and mental health illness when those patients receive opioid prescriptions from clinical settings where the non-VA opioid prescribing and monitoring practices conflict with the guidelines in place within VA.

Health information sharing between VA and non-VA providers has been a significant problem throughout the history of VHA's purchased care programs. Rapid implementation of Choice, in particular, limited opportunities to proactively design a streamlined and effective process for the coordination of care being provided to patients. As the first patient example illustrates, current gaps in health information exchange between VA and non-VA providers can put certain patients at significant risk for serious medication interaction and unintentional or intentional overdose.

The number of FY 2016 prescriptions cited above does not include opioid prescriptions written by non-VA providers, filled by non-VA pharmacies, and paid for by the veteran. In these instances, where a nexus does not exist between the pharmacy and the VA, the opioid medications will not automatically become part of the patient's VA EHR medication list, and are therefore not subject to timely medication reconciliation or other care coordination or risk oversight by VA. Requiring that all opioid prescriptions be submitted directly to and filled by a VA pharmacy will close that gap and ensure that VA providers have information about all opioids prescribed to a patient by all providers.

We made four recommendations.

Recommendations

1. We recommended that the Acting Under Secretary for Health require that all participating VA purchased care providers receive and review the evidence-based guidelines outlined in the Opioid Safety Initiative.

2. We recommended that the Acting Under Secretary for Health implement a process to ensure all purchased care consults for non-VA care include a complete up-to-date list of

medications and medical history until a more permanent electronic record sharing solution can be implemented.

3. We recommended that the Acting Under Secretary for Health require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording of the prescriptions in the patient's VA electronic health record.

4. We recommended that the Acting Under Secretary for Health ensure that if facility leaders determine that a non-VA provider's opioid prescribing practices are in conflict with Opioid Safety Initiative guidelines, immediate action is taken to ensure the safety of all veterans receiving care from the non-VA provider.

Appendix A

Prior OIG Topic-Related Reports

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

3/30/2017 | *16-00462-192* | *Summary* | *Report*

Audit of Veteran Wait Time Data, Choice Access, and Consult Management in VISN 6

3/2/2017 | *16-02618-424* | *Summary* | *Report*

Review of the Implementation of the Veterans Choice Program

1/30/2017 | *15-04673-333* | *Summary* | *Report*

Healthcare Inspection - Alleged Inappropriate Opioid Prescribing Practices, Rutherford County Community Based Outpatient Clinic, Rutherfordton, North Carolina

9/29/2016 | *15-01982-113* | *Summary* | *Report*

Review of VA's Award of the PC3 Contracts

9/22/2016 | *15-01396-525* | *Summary* | *Report*

Healthcare Inspection – Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System San Diego, California

1/5/2016 | *15-00827-68* | *Summary* | *Report*

Healthcare Inspection – Unexpected Death of a Patient During Treatment with Multiple Medications, Tomah VA Medical Center, Tomah, WI

8/6/2015 | *15-02131-471* | *Summary* | *Report*

Healthcare Inspection – Alleged Inappropriate Opioid Prescribing Practices, Chillicothe VA Medical Center, Chillicothe, OH

12/9/2014 | *14-00351-53* | *Summary* | *Report*

Healthcare Inspection - VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy

5/14/2014 | *14-00895-163* | *Summary* | *Report*

Acting Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: JUN 29 2017

From: Acting Under Secretary for Health (10)

Subj: OIG Draft Report, Healthcare Inspection: Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care (VAIQ 7809144)

To: Director, Office of Congressional Reports and Correspondence (009L)

1. Thank you for the opportunity to review and comment on VA Office of Inspector General (OIG) draft report Healthcare Inspection: Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care. I concur with recommendations 1, 2, and 4, and concur in principle with recommendation 3. The attachment to this memorandum contains action plans in response to the recommendations.

2. The Office for Community Care (OCC) agrees with community provider education on the Opioid Safety Initiative and will distribute guidelines. OCC currently provides community providers with applicable medical history information and an updated list of medications including pain management treatment.

3. OCC concurs with having all opioid prescriptions returned to the VA pharmacy from the community, but does enforce two exceptions – 14-day urgent/emergent prescriptions, and opioid treatment programs that provide office-based medications.

4. Further, OCC concurs that those non-VA providers who prescribe opioids in conflict with the Opioid Safety Initiative should be referred for review through either national contractor or local patient safety infrastructure.

5. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

Poonam Alaigh, M.D.

Comments to OIG's Report

The following Acting Under Secretary's comments are submitted in response to the recommendations in the OIG report:

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report: Healthcare Inspection: Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care

Date of Draft Report: June 8, 2017

Recommendations/ Actions	Status	Target Completion Date

The Veterans Health Administration's (VHA) work related to OIG Draft Report, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care, addresses the following High Risk area: 1 –ambiguous policies and inconsistent processes; 2– inadequate oversight and accountability (Report to Congressional Committees, "GAO High-Risk Series, An Update," GAO 15-290)

Recommendation 1: Require that all participating VA purchased care providers receive and review the evidence-based guidelines for prescribing opioids outlined in the Opioid Safety Initiative.

VHA Comments: Concur. This recommendation relates to High Risk Area 1 (ambiguous policies and inconsistent processes).

The VA Office of Community Care (OCC) will provide evidence-based guidelines for prescribing opioids as outlined in the Opioid Safety Initiative (OSI). The guidelines will be provided to VA's third party administrators (TPAs) and will include a requirement to share these with all participating community care providers and to confirm receipt and review of this requirement with them. For those providers who have contracted directly with a VA Medical Center (e.g., sharing agreements, affiliate agreements, and direct contracts), OCC will develop a distribution and confirmation policy and procedure for VA Medical Center use.

OCC will work with current and future TPAs as appropriate to receive confirmations of the receipt of this provider guideline/education. OCC will also ensure availability of evidence-based guidelines as outlined in the Opioid Safety Initiative through online access.

At completion of these actions, the Office of Community Care will provide documentation of:

- Copy of provider guidelines for Opioid Safety
- Copy of TPA communications with community providers
- Copy of policy and procedures regarding distribution of guidelines.

Status:	Target Completion Date:
In process	September 2017

Recommendation 2: Implement a process to ensure all purchased care consults for non-VA care include a complete up-to-date list of medications and medical history until a more permanent electronic record sharing solution can be implemented.

VHA Comments: Concur. This recommendation relates to High Risk Area 2 (inadequate oversight and accountability).

VA's consult process requirements currently specify that a complete up-to-date list of medications and all applicable medical history information (i.e., prior pain management treatment, controlled substance agreements, applicable behavior health flags) be included with community care consults sent to the TPAs and shared with VA community care providers. The VA Office of Community Care has recently implemented a medical documentation tool that simplifies the process of gathering and organizing all applicable medical history information and a complete up-to-date list of medications into one uniform document. The REFDOC tool compiles a package of documentation including a comprehensive medications list including outpatient and pain management meds dispensed by VA in last 12 months and current medications prescribed by Non-VA sources that are recorded in the VA data warehouse. This complete package is automated and therefore assures complete information is transmitted to the Non-VA provider. This electronic tool will be fully implemented nationwide in late 2017.

At completion of this action, the Office of Community Care will provide documentation of:

- Consult policy and procedure regarding medical documentation to be included with consults.
- Confirmation that REFDOC tool is fully implemented at all VA medical facilities.

Status:	Target Completion Date:
In process	March 2018

Recommendation 3: Require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording of the prescriptions in the patient's VA electronic health record.

VHA Comments: Concur in principle. This recommendation relates to High Risk Area 2 (inadequate oversight and accountability).

Under the current Choice contract, VA is primarily responsible for supplying Veterans with all non-urgent/non-emergent medications prescribed in accordance with the VHA National Formulary Handbook and as part of the health care treatment authorized by the VA. VA agrees that Veterans receiving community care should fill as many prescriptions as possible through VA pharmacies and will work with non-VA providers and Veterans to ensure greater awareness of this objective. VA will develop a communication update and/or prescribing reminder for submitting opioid prescriptions directly to a VA pharmacy when appropriate.

However, it should be noted that there are specific clinical exclusions currently recognized within the contract that are intended to ensure quality of Veteran care. This includes those with explicit medication needs such as urgent/emergent situations and medication needs for Opioid Use Disorders (OUD), i.e. Office Based Buprenorphine and Opioid Treatment Programs (OTP). The inclusion of these exceptions was reviewed and vetted by subject matter experts from VA Pharmacy and National Mental Health Program-Substance Use Disorders. Outside of our national contracts, such exclusions should also be permitted with sharing agreements, affiliate agreements, and direct contracts.

In addition, when it is imperative to begin urgent/emergent medications at the time of prescribing and/or not possible or convenient to obtain the medications from a VA pharmacy within the timeframe needed, VA's third party administrator (TPA) contract allows the prescribing provider to write a prescription for up to a 14-day supply without refills. Any and all subsequent refills must be submitted to a VA pharmacy for processing.

In terms of OUD care, the contract also allows the prescribing of a 30-day medication induction and stabilization period for the Veteran receiving services through the Office Based Buprenorphine setting. Likewise, the TPA contract allows providers ordering buprenorphine-containing drugs or methadone through certified OTPs to be dispensed or administered at the OTP rather than through a VA pharmacy, and there are no patient limits.

These exclusions are otherwise documented within the VA medical record as community providers are expected to return medical documentation to the VA directly or through the TPAs. As included within the process of the Opioid Safety Initiative, VA providers are also able to search the state Prescription Monitoring Programs in order to verify prescriptions filled through community pharmacies.

At completion, the Office of Community Care will provide documentation of:

- Copy of national contract portions outlining pharmacy benefit and OUD care.
- Communication update and/or prescribing reminder for submitting opioid prescriptions directly to a VA pharmacy when appropriate.

Status:	Target Completion Date:
In process	September 2017

Recommendation 4: Ensure that if facility leaders determine that a non-VA provider's opioid prescribing practices are in conflict with Opioid Safety Initiative guidelines, immediate action is taken to ensure the safety of all veterans receiving care from the non-VA provider.

VHA Comments: Concur. This recommendation relates to High Risk Area 1 (ambiguous policies and inconsistent processes). For care purchased both through national contracts or through local agreements, VA's Office of Community Care is establishing a Veteran Integrated Service Network (VISN) level quality and patient safety infrastructure that will improve local oversight of issues. In partnership with the third party administrator (TPA) contractors, concerns noted by VA providers and staff. Opioid prescribing will be reported through. This VISN level oversight is being built on top of the already existing patient safety infrastructure where patient safety are investigated and reviewed by local VA medical center staff. If a non-VA provider is noted to have opioid prescribing practices that are in conflict with the evidence based guidelines outlined in the Opioid Safety Initiative, the patient safety manager will initiate the standard procedures for a root cause analysis of the activity. Confirmed deviations involving jeopardizing Veteran health and/or safety will warrant immediate action that may include cessation of all referrals to that provider and reporting to the appropriate prescribing authority. The establishment and procedures for the VISN quality and patient safety infrastructures is being incorporated in a patient safety manual currently in development.

The new infrastructure will supplement that national contract requirement in the existing and future TPA contracts which establish a joint VHA/contractor quality and safety committees responsible for reviewing potential quality of care and Veteran safety issues reported from a variety of sources, i.e., VA facility leaders, VA providers, staff, Veterans, and community providers. Each contractor, following their respective continuous quality monitoring plan that may involve non-VA peer review, investigates the reported potential quality concern for deviations in the standard of care and/or patient safety. Confirmed deviations involving jeopardizing Veteran health and/or safety, immediate action is taken by the contractor to ensure the safety of all Veterans receiving care in the community.

It should be noted that VA must recognize the possibility that differences in opioid prescribing and monitoring practices disparities can/do exist between the VA and non-VA community providers. Reasoning includes a lack of comprehensive pain treatment modalities in many communities (e.g. acupuncture, pain specialists, etc.). Therefore, while VA agrees that our community providers should be educated on and attempt to adopt the evidence-based guidelines as outlined in the Opioid Safety Initiative, it is not assumed that their lack of adoption reflects poor quality of care without any evidence of egregious activity.

At completion, the Office of Community Care will provide documentation of:

- Copy of Patient Safety Manual outlining OCC quality and patient safety infrastructure.
- Copy of national contract portion outlining current quality and patient safety processes.

Status:	Target Completion Date:
In process	September 2017

Appendix C

OIG Contact and Staff Acknowledgments

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Appendix D

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