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DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
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Good morning, Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee. Thank you for the opportunity to discuss oversight of controlled substances and Drug Free Workplace programs at Department of Veterans Affairs (VA) facilities. I am accompanied today by Michael A. Valentino, Chief Consultant for the Veterans Health Administration's (VHA) Pharmacy Benefits Management Service (PBM).

Introduction

VHA is the Nation's largest integrated health care system, and pharmacy services are a vital part of delivering the high-quality health care our Veterans deserve. Our pharmacy program is widely regarded as the professional benchmark for clinical pharmacy practice, drug formulary management, prescription fulfillment services, and medication safety.^{1,2,3}

VHA's PBM is responsible for providing a broad range of pharmacy services via 260 VA medical center and community-based outpatient clinic pharmacies and 7 Consolidated Mail Outpatient Pharmacies (CMOP). In fiscal year (FY) 2016, VHA dispensed more than 147 million prescriptions to over 5 million unique Veterans. Of these, 30 million were provided by medical facility pharmacies, and 117 million by CMOPs.

Oversight of controlled substances is multi-faceted and involves: 1) ensuring VA lists controlled substances on its National Formulary that have evidence of safety and effectiveness; 2) providing evidence-based prescribing criteria for controlled substances; 3) developing internal controls for physical drug security; 4) using electronic

¹ Gellad, W.F., Good, C.B., & Shulkin D.: Addressing the opioid epidemic: Lessons from the Veterans Affairs. *JAMA Int. Med.* (in press).

² Aspinall, S.L., Sales, M.M., Good, C.B., Canzolino, J.J., Calabrese, V., Glassman, P.A., Burk, M., Moore, V., Neuhauser, M.M., Golterman, L., Ourth, H., Morreale, A., Valentino, M., & Cunningham, F.E. Pharmacy benefits management in the Veterans Health Administration revisited: 2004-2014- A decade of advancements. *J. Manag. Care. Pharm.* 2016; 22(9):1058-1063.

³ United States Senate Committee on Veterans' Affairs, Hearing on Overmedication: Problems and Solutions. Apr. 30, 2014. 113th Cong. 2nd sess. Washington: GPO, 2015 (statement of Mark Edlund, Health Services Researcher, RTI International).

prescribing to prevent forgery; 5) monitoring suspected cases of theft or diversion and taking appropriate follow-up action; 6) addressing any controlled substances prescribing that does not align with evidence-based criteria; 7) implementing patient-focused initiatives such as medication take-back programs; 8) overdose education and naloxone distribution; and 9) ensuring the availability of complementary and integrative medicine therapies in place of controlled substances.

As part of its long-standing focus on medication safety, VHA implemented robust controlled substance security measures in the early 1980s. In many cases, these security measures far exceed the requirements of the Controlled Substances Act (CSA). For example, CSA requires that an actual count of scheduled II controlled substances and an estimated count of most of Schedule III through V controlled substances be performed every two years. However, VA performs an actual count of all Schedules of controlled substances every 72 hours. In addition CSA allows Schedule III through V controlled substances to be dispersed among non-controlled substances in the pharmacy. However, VA requires all Schedules of controlled substances to be stored under lock and key, with electronic access controls requiring two-factor authentication.

Individuals who are determined to divert controlled substances may find a way to do so despite the existence of robust controls. This is true within and outside of VA. Data from January 2, 2014, through March 11, 2016, show that VA had 2,405 reports of internal and external losses, some of which were due to diversion. The data also show that approximately 92 percent of controlled substances losses occur in the mailing system during shipping to the Veteran, 1.5 percent of losses are due to diversion by VA staff, 1.2 percent are due to external theft outside of the mailing system, 0.3 percent are due to dispensing errors and 5.6 percent are unknown but likely due to manufacturer shortages in stock bottles, miscounts, or similar issues.

During this same time period, VA dispensed approximately 29 million prescriptions for controlled substances, as well as a very large number of individual doses of controlled substances for hospitalized patients. Using only the number of controlled substance prescriptions, which overestimates reports of loss by not including inpatient doses, the 2,405 reports filed indicate a controlled substance loss rate of 0.008 percent.

Opioid Safety Initiative (OSI)

The OSI was chartered by the Under Secretary for Health in August 2012 and piloted in several Veterans Integrated Service Networks (VISN). Based on the results of these pilot programs, OSI was implemented nationwide in August 2013. The OSI objective is to make the totality of opioid use visible at all levels in the organization. This includes key clinical indicators such as the number of unique pharmacy patients dispensed an opioid, unique patients on long-term opioids who receive a urine drug screen, patients receiving an opioid and a benzodiazepine (which puts them at a higher risk of adverse events), as well as the average morphine equivalent daily dose (MEDD) of opioids.

OSI has demonstrated achievement by multiple metrics, including by: a reduction in the number of patients receiving opiate analgesics; 2) a reduction in the number of patients receiving them for longer than 90 days; 3) a reduction in the concurrent prescription of opiate analgesics with other controlled substances that have potential for drug interactions; 4) a reduction in their average daily dose; and 5) an increase in the number of patients who are receiving opiate analgesics with completed drug screens.

Results of key clinical metrics for the OSI from the fourth quarter 4 of FY 2012 (beginning in July 2012) to the first quarter of FY 2017 (ending in December 2016) are:

- 208,036 fewer patients receiving opioids (679,376 patients to 471,340 patients, a 31 percent reduction);
- 69,148 fewer patients receiving opioids and benzodiazepines together (122,633 to 53,485 patients, a 56 percent reduction);
- 157,300 fewer patients on long-term opioid therapy (438,329 to 281,029, a 36 percent reduction).
- The percentage of patients on long-term opioid therapy who have had a urine drug screen to help guide treatment decisions has increased from 37 percent to 86 percent (a 49 percent increase)
- The overall dosage of opioids is decreasing in the VA system as 26,350 fewer patients (59,499 to 33,149, a 44 percent reduction) are receiving greater than or equal to a 100 MEDD.

Additionally, the desired results of OSI have been achieved despite an overall growth of 119,766 patients who are receiving prescriptions from VA at the same time. While these changes may appear to be modest, given the size of the VA patient population, they signal an important trend in VA's use of opioids. VA expects this trend to continue as it renews its efforts to promote safe and effective pharmacologic and non-pharmacologic pain management therapies.

GAO Report

The Government Accountability Office (GAO) provided VHA a draft report on December 16, 2016, titled *VA HEALTH CARE: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements*. In the report, GAO found that diversion of opioid pain relievers and other controlled substances by health care providers has occurred at several VA medical facilities. VA concurred with GAO's six recommendations from this report:

1. The Under Secretary for Health should ensure that VA medical facilities have established an additional control procedure, such as an alternate controlled substance coordinator or a pool of extra inspectors, to help coordinators meet their responsibilities and prevent missed inspections.

2. The Under Secretary for Health should ensure that VA medical facilities have established a process where coordinators, in conjunction with appropriate stakeholders (e.g., pharmacy officials), periodically compare facility inspection procedures to VHA's policy requirements and modify facility inspection procedures as appropriate.
3. The Under Secretary for Health should improve the training of VA medical facility controlled substance coordinators by ensuring the training includes the inspection procedures that VHA requires.
4. The Under Secretary for Health should ensure that medical facility directors have designed and implemented a process to address nonadherence with program requirements, including documenting the nonadherence and the corrective actions taken to remediate nonadherence or the actions that demonstrate why no remediation is necessary.
5. The Under Secretary for Health should ensure that networks review their facilities' quarterly trend reports and assure facilities take corrective actions when nonadherence is identified.
6. The Under Secretary for Health should ensure that networks monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements.

The final GAO report was published on February 15, 2017, and VA is in the process of implementing the recommendations:

1. VHA's Directive 1108.02, Inspection of Controlled Substances, provides guidance to Facility Directors to ensure the Controlled Substances Programs develop and remain compliant with the requirements. The PBM will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements to: 1) have mandatory training; 2) appoint an alternate Controlled Substance Coordinator; and if one is not already appointed, to provide back-up support; and 3) adding inspectors to the program to ensure inspections are not missed. Each Facility Director will then be provided this memorandum, and Facility Quality Managers (QM) will report compliance to the VISN QM Officer.
2. Each Medical Facility Director will be required to compare the current inspection program policy and procedures with VHA Directive 1108.02 using the Self-Assessment guide. The self-assessment will be completed by a multidisciplinary group including the Controlled Substance Coordinator, Chief of Pharmacy or designee, Nurse Executive or designee, and Facility QM or designee. The results of the self-assessment will be reviewed by the facility QM Committee. An action plan must be developed for identified deficiencies and progress tracked until completion through the QM committee.
3. The Deputy Under Secretary for Health for Operations and Management (DUSHOM) will provide the memorandum developed in response to Recommendation 1 that outlines the requirements that all current and future Controlled Substance Coordinators complete the Talent Management System web-based Controlled Substance Inspector Certification training program in addition to the Controlled Substance Coordinator Orientation Training Course.

The certification course contains detailed information on conducting inspections. VHA Directive 1108.02, Inspection of Controlled Substances, will be updated with this requirement.

4. PBM will develop guidance to be distributed by the DUSHOM directing Medical Facility Directors to assess adherence with program requirements at least quarterly. The facility QM Committee will review and evaluate monthly and quarterly reports for adherence with requirements and corrective actions taken or required to ensure compliance with program requirements in VHA Directive 1108.02. All corrective actions will be documented and followed through to completion by the QM Committee and reported to the Medical Facility Director.
5. PBM will develop a memorandum that outlines the expectations of Directive 1108.02 and specifically the requirements that Networks will: 1) review their facilities' quarterly trend reports and ensure facilities take corrective actions when nonadherence is identified, and 2) monitor their medical facilities' efforts to establish and implement a review process to periodically compare facility inspection procedures to VHA's policy requirements. The DUSHOM will provide this memorandum to each Network Director, who will disseminate it to the Facility Directors, thereby ensuring appropriate actions have been taken to ensure the actions listed in the memorandum are completed.

At completion of each of these actions, the VISN QM Officer will monitor compliance and provide an action plan for any non-compliant facilities within that VISN to PBM and the DUSHOM. The two offices will meet and decide whether any further actions are needed. The status of each response is in process, and the target completion date is October 2017.

VA's Drug Free Workplace Program

VA, as an employer, understands that well-being of its employees is essential to the successful accomplishment of the agency's mission, and is dedicated to maintaining high employee productivity. As such we are committed to implementing Executive Order (EO) 12564, signed by President Ronald Reagan on September 15, 1986, requiring all Federal agencies to develop a plan to combat drugs in the workplace.

VA takes very seriously our mission to provide top quality care and services to our Veterans. In doing so, our human resources offices play a very vital role in implementing our Drug Free Workplace Program (DFWP). As the second largest employer in the Federal Government, VA can and should continue to show the way towards achieving drug-free workplaces through programs designed to offer drug users a helping hand and, at the same time demonstrating that drugs will not be tolerated in the workplace. The use of illegal drugs by VA employees is inconsistent with the special trust placed in such employees who care for Veterans. VA has recently made great strides towards improving the Drug Free Workplace Program.

Beginning in October 2015, Drug Program Coordinators began certifying on a monthly basis that employees selected for random drug testing were tested, when they were tested, or why they were not tested. In November 2015, the Office of Human Resource Management began reviewing the data entered in the notification site for compliance and has continued in the ensuing months to conduct this review. Those Coordinators not in compliance with the certification process are reported to their chain of command until compliance is achieved.

VA is developing procedures to ensure the drug testing coding of employees in Testing Designated Positions (TDP) is accurate and complete. We are working with our HR Smart (VA's recently implemented human resources information system) business partner to implement a monthly process ensuring that all employees occupying Testing Designated Positions identified in VA Directive 5383 are included in the pool of random selectees each month. The update process will run prior to the random selection of employees to be tested that month. In addition, queries are now available to human resource (HR) offices to assist them in ensuring all testing designated positions are appropriately coded.

VA is committed to 100 percent testing of all final selectees for Testing Designated Positions prior to appointment. On March 1, 2016, the Assistant Secretary for Human Resources and Administration published a memorandum stating that 100 percent of all applicants tentatively selected for appointment to a TDP be drug tested prior to appointment.

VA has implemented a process to monitor local compliance with VA's DFWP requirements. Beginning in March 2016, the DFWP website was modified to reflect that Coordinators were to certify that all applicants selected for all TDPs were tested in accordance with VA Handbook 5383. Those Coordinators not in compliance with the certification process are reported to their chain of command until compliance is achieved.

OIG Review of Drug Testing at Atlanta VA Medical Center

In April 2015, the VA Office of Inspector General (OIG) opened an investigation at the Atlanta VA Medical Center (VAMC) to review allegations of a backlog of over 300 unadjudicated background investigations and that mandatory drug testing of new hires did not occur over a 6-month period. It is important to note that this inspection happened before many of the institutional changes described above were implemented.

The investigation substantiated both allegations and found that, as of July 2015, the Atlanta VAMC had a backlog of about 200 unadjudicated background investigations; Atlanta VAMC human resources personnel acknowledged a backlog dating as far back

as 2012. It was also found that the DFWP was not administered from November 2014 to May 2015.

VA appreciates OIG's work in making recommendations to improve our hiring processes. Atlanta VAMC leadership implemented a number of changes in 2016 including:

- realigning the human resources department under the direct supervision of the Medical Center Director;
- hiring a new human resources officer;
- dedicating a senior staff member to the personnel security section to oversee personnel assigned to that function; and
- developing a secondary database to work in tandem with the current system for staffing and tracking all background investigations, expiration, status, open and closed dates.

Atlanta VAMC identified 220 employees who require drug testing, and began notifications to these employees in December 2016. A phased approach is necessary to take into account workload, the number of people tested, and staffing levels. The Atlanta VAMC expects to complete testing by March 2017.

Conclusion

Mr. Chairman, I am proud of the health care our facilities provide to our Veterans, including prescription drug services. With support from Congress, we look forward to continuing to improve our oversight of controlled substances and drug free workplace programs, which will further improve the care our Veterans deserve. Thank you for the opportunity to testify before this subcommittee. I look forward to your questions.