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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Virtual Pharmacy Services in the Care of a Patient

HEALTHCARE INSPECTION | REPORT #19-07827-182 | JUNE 18, 2020

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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to evaluate concerns related to a Virtual Pharmacy Services (VPS) pharmacist's discontinuation of an antidepressant medication for a patient of the Minneapolis VA Health Care System (facility), which resulted in no medication prescribed for depression for approximately six weeks prior to the patient's death by suicide while a facility inpatient.[1] The circumstances of the patient's death are discussed in a companion OIG report.[2]

The Veterans Health Administration (VHA) Meds by Mail program employs VPS pharmacists directly and via a contract with a third-party corporation, DLH Solutions, Inc. In processing the patient's prescriptions, a VPS-contracted DLH pharmacist (DLH pharmacist) was prompted with an order check that indicated the patient was taking two antidepressant medications, bupropion and trazodone, that could be considered duplicate therapies.[3] The DLH pharmacist discontinued the bupropion prescription but continued the trazodone. The patient's dose of trazodone was consistent with dosing guidelines for the treatment of insomnia, not depression.[4]

Each VHA medical center is responsible for providing VPS pharmacists with access, privileges, and training to its outpatient pharmacy software to process pending prescriptions remotely.[5] A VHA Pharmacy Benefits Management leader informed the OIG that VPS pharmacists' access to

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[1] VPS is a Meds by Mail program overseen by VHA Pharmacy Benefits Management that provides remote prescription verification processing to VHA medical centers through specific interagency cross-servicing agreements.

[2] VA Office of Inspector General, *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System, Minnesota*, Report No. 19-00468-67, January 7, 2020.

[3] Embedded within the software package is a second program, Medication Order Check Healthcare Application, an order check program that creates alerts for drug interactions, drug dose exceeding maximum daily limitations, and duplicate drug therapy. Mayo Clinic, *Atypical Antidepressants*, June 25, 2016. Although bupropion and trazodone are both atypical antidepressants, the patient was prescribed bupropion for depression and trazodone for insomnia. https://www.mayoclinic.org/diseases-conditions/depression/in-depth/atypical-antidepressants/art-20048208. (The website was accessed on September 20, 2019.)

[4] PDR.net, *Trazodone*. Trazodone is prescribed for depression and insomnia. For depression, dosing starts at 150 milligrams and can be increased up to 400 milligrams daily for outpatients and 600 milligrams daily for inpatients. Dosing for insomnia ranges from 25–150 milligrams. https://www.pdr.net/drug-summary/Trazodone-Hydrochloride-trazodone-hydrochloride-3033.1692?mode=preview. (The website was accessed on December 16, 2019.)

[5] Following initial review of this report, VHA Pharmacy Benefits Management leaders informed the OIG team that the templated Interagency Cross-Servicing Support Agreement (VA Form 2269) has an administrative error stating it is the facility's responsibility to train VPS pharmacists on how to use the outpatient pharmacy software. The Pharmacy Benefits Management leader clarified with the OIG team that Meds by Mail was responsible for the training. Pharmacy Benefits Management leaders said that they had plans to update the Interagency Agreement to accurately reflect Meds by Mail training responsibilities.

patient electronic health record information differed per facility and acknowledged that VPS pharmacists did not receive training on how to navigate VHA's outpatient pharmacy software.

The OIG found that the DLH pharmacist did not access the patient's electronic health record or notify the psychiatrist of the discontinuation. The OIG found that although the facility granted the DLH pharmacist access to the patient's electronic health record, the pharmacist was not aware of this capability. The DLH pharmacist should have reviewed the patient's electronic health record or consulted with the psychiatrist before discontinuing the bupropion. The OIG determined that the discontinuation of the patient's bupropion may have contributed to increased depressive symptoms, including suicidal ideation, in the six weeks following the patient's scheduled depletion of the medication. The OIG was unable to determine that the discontinuation of the medication contributed directly to the patient's death because other potential causal factors existed, such as cognitive impairment and withdrawal symptoms.

The Veterans Health Administration (VHA) delineates the role of the clinical pharmacist in a functional statement or scope of practice, which is used to provide management and oversight of professional activities.[6] The OIG identified discrepancies between the Meds by Mail VPS pharmacist functional statement and the duties the VPS pharmacist could fully perform.[7] VPS pharmacists' inability to fully execute functions may contribute to decisions that are not fully informed and may result in changes to a patient's medication regimen, such as in the case of the patient discussed above.

The OIG found that the VPS productivity measure of 95 prescriptions processed per hour might be an unreasonable target and may contribute to an increased risk for pharmacist error. Further, Pharmacy Benefits Management leaders told the OIG that they did not ensure monitoring of VPS prescription processing accuracy.

Pharmacy Benefits Management leaders failed to clearly outline program management and quality assurance monitoring objectives and processes in both the interagency agreement and staffing contract. Deficiencies in program management and quality assurance monitoring may contribute to adverse patient outcomes.

The OIG made five recommendations to the Under Secretary for Health related to the establishment of a standardized outpatient pharmacy software menu for VPS clinical pharmacists; consistency of clinical pharmacists' functional statements, performance metrics, and the productivity benchmark; and quality assurance objectives.[8]

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[6] VHA Handbook 1108.05, *Outpatient Pharmacy Services,* June 16, 2016, amended August 20, 2019.

[7] The scope of practice is not applicable for the Meds by Mail VPS pharmacists. The Meds by Mail VPS pharmacist at issue for the patient under discussion was contracted by DLH Solutions, Inc.

[8] While the patient at issue received care at the Minneapolis VA Health Care System, the recommendations were directed to the Under Secretary for Health who oversees VHA Pharmacy Benefits Management. The recommendations were submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

OIG Comments to Concerns Raised by the Executive in Charge

The Executive in Charge

- Concurred with recommendations 2 and 4, and provided action plans,
- Concurred in principle with recommendation 1 and provided an action plan,
- Non-concurred with recommendation 3 but provided an action plan, and
- Non-concurred with recommendation 5.

The OIG considers recommendations 1–4 open and will follow up on the planned actions until they are completed. VHA did not concur with or provide an action plan for recommendation 5. This recommendation will be considered not implemented.

Despite submitting action plans for four of the five OIG recommendations, the Executive in Charge expressed concerns about the OIG's inspection (see appendix B for the full comments).

At the outset, it should be noted that, as embedded in VHA policy and practice, the delivery of quality mental health care requires integrated and seamless coordination of a variety of trained professionals functioning as a team. Within VHA, psychiatrists, psychologists, and nurse practitioners, when credentialed and privileged at a medical facility, are licensed independent practitioners. Clinical pharmacists are not licensed independent practitioners. This distinction is critical because it defines which provider is ultimately responsible for the clinical management of a patient and the decisions of the team. In this report, as in prior reports covering similar issues, the OIG highlighted instances involving siloed decisions made by a clinical pharmacist that had the potential to harm veterans.[9] Isolated decision-making challenges the concept of an integrated team and places veterans at risk because the layers of clinical training and expertise that strengthen the team are disregarded or bypassed entirely.

The Executive in Charge remarked on the expertise of the OIG team and an "apparent lack of knowledge" and "professional bias." These allegations are simply not based on the facts. It should be noted that two pharmacists served as consulting members of the OIG team. Moreover, the OIG interviewed eight VA pharmacists and a VA pharmacy information technologist, and viewed demonstrations during two of the interviews to become more knowledgeable about the software and processes that VA pharmacists used. The OIG facilitated and reviewed these discussions in exquisite detail to reach an unbiased, comprehensive, and shared understanding of the facts and the areas in need of improvement for the well-being of veterans. The OIG used this knowledge to show a Pharmacy Benefits Management leader how VPS pharmacists could access facility patients' electronic health records. The OIG is disappointed that those efforts were

[9] VA Office of Inspector General, *Review of Two Mental Health Patients Who Died by Suicide*, William S. Middleton Memorial Veterans Hospital Madison, Wisconsin, Report No. 17-02643-239, August 1, 2018; VA Office of Inspector General, *Review of Mental Health Clinical Pharmacists in Veterans Health Administration Facilities,* Report No. 18-00037-154, June 27, 2019.

viewed by the Executive in Charge as ill-spent time and not valued. The OIG team invested considerable time on all aspects of the inspection, including educating VHA personnel on the evidence, facts, and the reasons for conclusions.

The Executive in Charge stated that the Joint Commission of Pharmacy Practitioners met with the OIG regarding concerns about OIG inspections. In the meeting, the Joint Commission of Pharmacy Practitioners strongly lobbied in support of the role of clinical pharmacists in patient care. The OIG agreed with the Joint Commission of Pharmacy Practitioners regarding the importance of (1) the role of the clinical pharmacist, (2) the need for strong communication among clinical team members, and (3) state-based laws that guide non-VA clinical pharmacists' functional duties.

While the OIG respects the views of the Joint Commission of Pharmacy Practitioners, the meeting referenced by the Executive in Charge focused on a different report and did not address the specific program management and quality assurance deficiencies uncovered in this inspection. Furthermore, the meeting did not address this report, and the Executive in Charge's claim that the OIG report is based on speculation and professional bias is not supported by facts and evidence and is simply unfounded. Speaking with stakeholders and gaining all perspectives is critically important, and the OIG welcomes the opportunities for these discussions.

The Executive in Charge challenged the OIG for making recommendations based on one event. It is true that an error on the part of one pharmacist for one patient initiated this inspection. The inspection, however, uncovered gaps in VPS program management and quality assurance controls that were not identified by VHA prior to the OIG's inspection. Gaps in program management and quality assurance may affect services for many other veterans. The magnitude of the possible consequences related to a failed program management and quality assurance system in these circumstances was the impetus for the OIG's recommendation 5.

The Executive in Charge asserts that the patient's electronic health record "is replete with documentation by the Veteran's VA and non-VA providers alike, that during transitions in care, [the patient] was reported to be taking the medication in question." This is not a fair characterization of the evidence. While the OIG found that non-VA medical records in the days immediately prior to the patient's final VA episode of care included bupropion on templated medication lists, such lists do not confirm that the patient was taking the medication. At the same time period, during an episode of VA care, the integrated reconciled medication list does not include bupropion. When considering the date of the last 90-day refill of this prescription and the date of discontinuation by the VPS pharmacist, it is unlikely that the patient would have been taking this medication at the time of the non-VA care.

The Executive in Charge contested the facts of the case related to the availability of the medication that was canceled and characterized the VPS pharmacist's cancellation of the medication as a documentation error. The pharmacist made an intentional decision to cancel one of the patient's antidepressant medications without conferring with the prescribing psychiatrist and without accessing the electronic health record to understand the clinical intent of the

prescribed medication. Once canceled, the medication was removed from the patient's profile and subsequent review and comparison of the profile by pharmacists and providers with the list of current medications (medication reconciliation) would not have revealed a discrepancy. The VPS pharmacist's decision would have been identified and corrected had an effective quality management program been in place.

The OIG respects and appreciates the critical role of pharmacists in providing quality care to veterans. In order to provide effective oversight, the OIG conducted a thorough, fair, and unbiased review of the evidence and considered all perspectives, to make recommendations to VA leaders on how to improve patient care. The OIG will continue to engage productively with both VHA and clinical pharmacists to continue working on ways to achieve a shared goal of minimizing errors that can result in harm to veterans. However, when conditions exist that place veterans at risk of poor healthcare outcomes, the OIG will continue to present an unbiased and accurate description of those conditions, and when appropriate, recommend changes to improve the quality of health care provided to veterans.

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Abbreviations

OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VPS	Virtual Pharmacy Services

Introduction

The VA Office of Inspector General (OIG) conducted an inspection to evaluate concerns related to a Virtual Pharmacy Services (VPS) pharmacist's discontinuation of an antidepressant medication for a patient of the Minneapolis VA Health Care System (facility), which resulted in no medication prescribed for depression for approximately six weeks prior to the patient's death by suicide while a facility inpatient. The circumstances of the patient's death are discussed in a companion OIG report.[1]

Background

The facility is part of Veterans Integrated Service Network (VISN) 23 and includes 13 VA community clinics in both Minnesota and Wisconsin.[2] The facility provides primary, specialty, mental and behavioral health, and extended and rehabilitative care. From October 1, 2017, through September 30, 2018, the facility served 102,584 patients and had a total of 309 hospital operating beds, including 229 inpatient beds, and 80 community living center beds. The facility has professional and technical education affiliations with 63 universities and colleges, including the University of Minnesota Schools of Medicine and Dentistry, to provide health training in 36 programs.

Agency Relationships

Pharmacy Benefits Management leaders oversee Veterans Health Administration (VHA) pharmacy activities including the programs Meds by Mail and Consolidated Mail Outpatient Pharmacy.[3] Started in 2011, VPS is a Meds by Mail program that provides remote prescription verification processing. Meds by Mail provides VPS to VHA medical centers through specific interagency cross-servicing agreements (interagency agreements). VPS leaders told the OIG that

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[1] VA Office of Inspector General, *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System*, Minnesota, Report No. 19-00468-67, January 7, 2020.

[2] The community-based outpatient clinic locations are Hibbing, St. James, Mankato, Maplewood, Rochester, Ramsey, Albert Lea, Shakopee, and Ely, Minnesota, as well as Rice Lake, Hayward, Superior, and Chippewa Falls, Wisconsin.

[3] Pharmacy Benefits Management Services, VA. https://www.pbm.va.gov/. (The website was accessed on April 10, 2019.) Meds by Mail, in conjunction with the Office of Community Care, has two servicing centers that provide home delivery of routine maintenance medications. *Meds by Mail—Community Care VA.* https://www.va.gov/COMMUNITYCARE/programs/dependents/pharmacy/meds_by_mail.asp. (The website was accessed on April 10, 2019.) Consolidated Mail Outpatient Pharmacy has seven locations that provide direct home delivery of medication refills to patients. Consolidated Mail Outpatient Pharmacy pharmacists perform their own order verification processes for prescription fulfillment activities but may not change prescription information that they receive; the pharmacists may only fill the prescription as written or cancel the prescription and return it back to the facility pharmacy.

VPS performs outpatient prescription verification for VHA facilities when a medical center's outpatient pharmacy reaches a threshold of queued prescriptions, which is specified by the medical centers' interagency agreements. The facility's interagency agreement, in effect from October 1, 2016, through September 30, 2018, allowed VPS pharmacists to process prescriptions remotely when the queue reached 1,000 prescriptions for up to 5,000 prescriptions per week.[4] Meds by Mail employs VPS pharmacists directly and via contract with a third-party corporation, DLH Solutions, Inc (DLH), under DLH's staffing contract with Consolidated Mail Outpatient Pharmacy.[5] A Meds by Mail supervisor told the OIG that Meds by Mail hired DLH contracted pharmacists through an overarching Consolidated Mail Outpatient Pharmacy contract and assigned DLH contracted pharmacists to VHA medical centers based on staffing needs. Figure 1 depicts the relationship(s) among the various entities.

[4] According to the Associate Chief Consultant, Pharmacy Benefits Management, the facility consented to allow VPS to continue order processing until the establishment of a new agreement. The updated agreement was effective indefinitely beginning March 12, 2019.

[5] DLH "provides health technology-enabled business process outsourcing and program management solutions supporting large-scale Federal health and human services initiatives. DLH delivers professional healthcare and public services to several Government agencies including the U.S. Departments of Defense, Health and Human Services, and Veterans Affairs." DLH is among the top three health solution vendors to the U.S. Department of Veterans Affairs, supplying DLH doctors and pharmacists for the Federal telehealth market, including VPS. DLH capabilities. http://www.dlhcorp.com/dlh_capabilities_life_sciences.php. (The website was accessed on May 16, 2019.) The staffing contract is a blanket purchase agreement with the National Consolidated Mail Outpatient Pharmacy, which provides staffing to both Meds by Mail and Consolidated Mail Outpatient Pharmacy. Staff described this agreement as an "umbrella contract" for Pharmacy Benefits Management, which oversees both Meds by Mail and Consolidated Mail Outpatient Pharmacy.

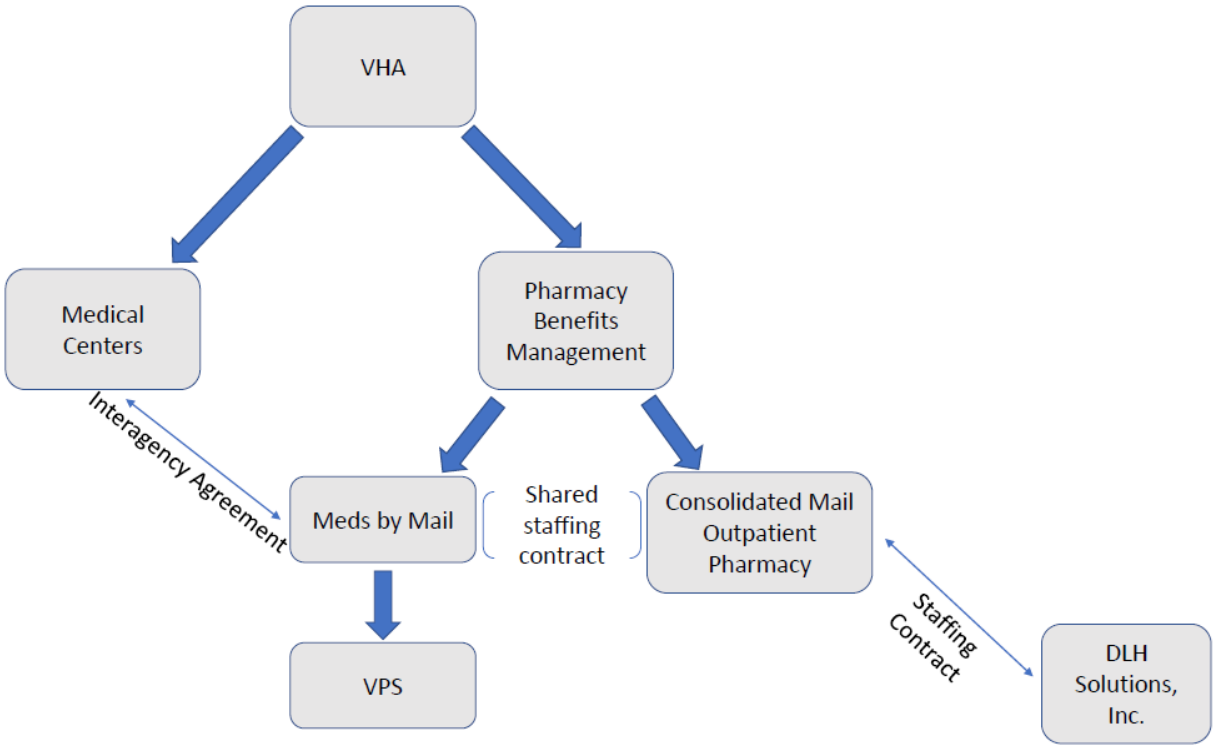

Figure 1. Relationships among medical centers, VPS, and DLH Solutions, Inc
Source: Pharmacy Benefits Management organizational chart and OIG team interviews

VPS Pharmacist Role and Responsibilities

VHA requires clinical pharmacists to have a functional statement or scope of practice that accurately delineates position responsibilities.[6] VPS leaders told the OIG that DLH pharmacists who are contracted by Meds by Mail for VPS operated under the Meds by Mail functional statement. The Meds by Mail functional statement included verification of prescriptions for processing and discontinuation of medications that either the patient was not taking or were duplicate therapies.[7] The functional statement also assigned responsibility to the VPS pharmacist to communicate relevant changes, including resolution of duplicate therapies to the prescribing provider. Although they have different functional statements, a Pharmacy Benefits Management leader reported that DLH contract pharmacists and VHA pharmacists are required to have the same qualifications and are held to the same performance standards.

[6] VHA Directive 1108.11 (1), *Clinical Pharmacy Service,* July 1, 2015, amended June 29, 2017. Meds by Mail VPS pharmacists are provided functional statements and not a scope of practice.

[7] Tosha Wetterneck, James Walker, et. al., "Factors Contributing to an Increase in Duplicate Medication Order Errors After CPOE Implementation," *Journal of the American Medical Informatics Association*, no. 6 (November/December 2011): 774-782. Duplicate therapies are two or more prescribed drugs in the same therapeutic class.

Each medical center is responsible for providing the VPS pharmacist with access, privileges, and training to its Veterans Health Information Systems and Technology Architecture (VistA) outpatient pharmacy software to process pending prescriptions remotely.[8] The VistA outpatient pharmacy information screen included a patient's eligibility, disabilities, outpatient narrative, allergies, and adverse medication reactions. Individual medical centers may restrict the type of prescriptions that can be processed by VPS pharmacists. For example, the facility's interagency agreement prohibited VPS pharmacists from processing prescriptions for "all antibiotics (except pre-dental and long term)" and prescriptions for patients enrolled in a specialty mental health program.

Prior OIG Report and Concerns

In the *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System* report, the OIG found deficiencies in care coordination, internal review effectiveness and sufficiency, and Patient Safety Committee and Quality Management Council documentation.[9]

During that healthcare inspection, the OIG found that a VPS pharmacist discontinued a patient's antidepressant medication without the treating psychiatrist's awareness. On April 16, 2019, Office of Healthcare Inspections leaders concluded that this concern was beyond the scope of the ongoing project and initiated a new hotline. This hotline inspection will

- Review potential impact of the pharmacist's actions on the patient's care;
- Review Meds by Mail VPS pharmacists' contractual responsibilities;[10] and
- Evaluate facility and VPS compliance with program management and quality assurance requirements.

[8] VistA is a comprehensive electronic health record made up of distinct applications or modules that include pharmacy packages, the Computerized Patient Record System, and Joint Legacy Viewer. VistA is used across VHA by all Veterans Affairs medical centers, community-based outpatient clinics, community living centers, and more than 300 vet centers. Following initial review of this report, VHA Pharmacy Benefits Management leaders informed the OIG team that the templated Interagency Cross-Servicing Support Agreement (VA Form 2269) has an administrative error stating it is the facility's responsibility to train VPS pharmacists on how to use the VistA outpatient pharmacy software. The Pharmacy Benefits Management leader clarified with the OIG team that Meds by Mail was responsible for the training. Pharmacy Benefits Management leaders said that they had plans to update the Interagency Agreement to accurately reflect Meds by Mail training responsibilities.

[9] VA Office of Inspector General, *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System, Minnesota*, Report No. 19-00468-67, January 7, 2020.

[10] Meds by Mail provides direct delivery of nonurgent, maintenance medications from two service centers located in Dublin, Georgia and Cheyenne, Wyoming. The VPS Program is staffed by pharmacists located at the Meds by Mail service centers.

Scope and Methodology

The OIG team reviewed the patient's electronic health record from summer 2017 through spring 2018. The OIG team interviewed facility leaders and pharmacy staff, Meds by Mail and VPS staff knowledgeable about the changes in the patient's medications, and Pharmacy Benefits Management leaders.[20]

The OIG team reviewed VHA directives and handbooks, pharmacy agreements and guidelines, facility policies and procedures in effect summer 2017 through spring 2018 related to oversight and management of pharmacy. The OIG team also reviewed relevant literature, training records, functional statements, personnel records, the facility's interagency agreement, and the DLH staffing contract.

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).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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.

[20] The OIG inspection team interviewed the facility Chief of Staff, Chief of Pharmacy, Pharmacy Program Manager, Outpatient Pharmacy Supervisor, Pharmacist, Pharmacy Automated Data Processing Application Coordinator, and Clinical Application Coordinator; Deputy Chief Consultant Pharmacy Benefits Management; Pharmacy Benefits Management Informatics Specialist; Associate Chief Consultant and Pharmacy Supervisor of Meds by Mail; and the VPS pharmacist.

Patient Case Summary

The patient met with the facility outpatient psychiatrist for the first time in late 2017. At that time, the patient was prescribed a pain medication as needed for chronic left shoulder and hip pain, two medications for anxiety, trazodone for insomnia, bupropion for depression, and a mood stabilizer medication. The psychiatrist diagnosed the patient with mild neurocognitive disorder, major depressive disorder recurrent moderate, delusional disorder, and substance use disorder in sustained remission. The psychiatrist ordered a renewal of the patient's bupropion in late 2017 and a 90-day supply of the medication was mailed to the patient. In early 2018, the psychiatrist increased the patient's trazodone dosage for sleep. The medication profile reflected the psychiatrist's orders to discontinue the previous dosage of trazodone and start taking the increased dosage of trazodone. The same day, the bupropion prescription was "discontinued by pharmacy."[21] The patient did not attend a scheduled follow-up appointment with the psychiatrist in spring 2018. Approximately two weeks later, the primary care physician evaluated the patient for benzodiazepine and opiate withdrawal symptoms in an unscheduled visit. The patient declined to go to the VA Emergency Department and later reported having gone to a non-VA hospital Emergency Department for management of withdrawal symptoms and being discharged to home the same day. The patient reportedly returned to the non-VA Emergency Department the next day for ongoing withdrawal symptoms and was again discharged to home after supportive management of withdrawal. The next day, the patient went to a non-VA physician and received medication for shoulder pain. That evening, the patient visited a different non-VA Emergency Department, received hydration, and was discharged home 12 hours later. The following day, the patient arrived at the facility's Emergency Department with suicidal ideation and withdrawal symptoms and was admitted to the facility inpatient medical service. The patient continued to present with depression, confusion, and cognitive impairment. Four days later, the patient died by suicide while hospitalized.[22]

[21] If the patient was taking the bupropion as prescribed prior to the early 2018 discontinuation, the ordered 90-day supply would have run out approximately six weeks before the patient's admission to the facility.

[22] For additional patient case summary details, see VA Office of Inspector General, *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System,* Minnesota, Report No. 19-00468-67; January 7, 2020. VHA concurred with all recommendations and provided acceptable action plans.

Inspection Results

1. Impact of a Medication Discontinuation on the Patient's Care

The OIG determined that the discontinuation of the patient's bupropion may have contributed to increased depressive symptoms, including suicidal ideation, in the six weeks following the patient's scheduled depletion of the medication. The OIG was unable to determine that the discontinuation of the medication contributed directly to the patient's death because other potential causal factors existed, such as cognitive impairment and withdrawal symptoms.

In late 2017, the psychiatrist performed an initial evaluation of the patient and documented a treatment plan that included continuation of bupropion for depression. In early 2018, the psychiatrist increased the patient's trazodone dosage to address ongoing sleep disturbance. In processing the prescriptions, a VPS-contracted DLH pharmacist (DLH pharmacist) was prompted with an order check that indicated the bupropion and trazodone were duplicate therapies.[23] The DLH pharmacist discontinued the bupropion prescription. The patient's dose of trazodone was consistent with dosing guidelines for the treatment of insomnia and not depression.[24]

During the patient's late spring care in a non-VA provider's office and two non-VA Emergency Departments, bupropion was included on medication lists although these lists did not confirm that the patient was taking the medication. According to available non-VA medical records, providers did not administer the medication to the patient at those visits. During the patient's final facility Emergency Department and inpatient medical service admission, providers did not document bupropion as a discontinued or an active medication nor did they prescribe it for the patient during that episode of care.

The OIG found that the DLH pharmacist did not access the patient's electronic health record or notify the psychiatrist of the discontinuation. The psychiatrist stated that the bupropion would not have been discontinued had the psychiatrist been notified. The OIG found that although the facility had granted the DLH pharmacist access to the patient's electronic health record, the DLH pharmacist was not aware of this capability. Pharmacy Benefits Management leaders noted that

[23] Embedded within the VistA software package is a second program, Medication Order Check Healthcare Application, an order check program that creates alerts for drug-drug interactions, drug dose exceeding maximum daily limitations, and duplicate drug therapy. Mayo Clinic, *Atypical Antidepressants*, June 25, 2016. Bupropion and trazodone are both atypical antidepressants. https://www.mayoclinic.org/diseases-conditions/depression/in-depth/atypical-antidepressants/art-20048208. (The website was accessed on September 20, 2019.)

[24] PDR.net, *Trazodone.* Trazodone is prescribed for depression and insomnia. For depression, dosing starts at 150 milligrams and can be increased up to 400 milligrams daily for outpatients and 600 milligrams daily for inpatients. Dosing for insomnia ranges from 25-150 milligrams. https://www.pdr.net/drug-summary/Trazodone-Hydrochloride-trazodone-hydrochloride-3033.1692?mode=preview. (The website was accessed on December 16, 2019.)

when VPS pharmacists had questions regarding a prescription, they could contact facility staff or return the prescription to the pending queue.[25] The DLH pharmacist should have reviewed the patient's electronic health record or consulted with the psychiatrist before discontinuing the bupropion.

2. Meds by Mail VPS Pharmacists' Contractual Responsibilities

VHA delineates the role of the clinical pharmacist in a functional statement used to provide management and oversight of professional activities.[26] The role of clinical pharmacists may differ based on their assignments and must be delineated in their functional statements as appropriate.[27] The OIG identified discrepancies between the Meds By Mail VPS pharmacist functional statement and the duties the VPS pharmacist could fully perform. VPS pharmacists' inability to fully execute functions may contribute to decisions that are not fully informed and may result in changes to the patient's medication regimen, such as in the case of the patient discussed above.

The OIG found that VPS pharmacists were unable to fully perform 20 of 27 clinical functions and 4 of 8 dispensing functions specified in the Meds by Mail functional statement (details of the clinical and dispensing functions are provided in appendix A). To fulfill the functions, VPS pharmacists need access to patient health information for informed clinical decision-making. A Pharmacy Benefits Management leader told the OIG that VPS pharmacists' ability to access patients' electronic health records differed based on medical center location. The Pharmacy Benefits Management leader acknowledged that VPS pharmacists did not receive training on how to navigate the necessary VistA menus even if they had been granted access to electronic health records.

VPS pharmacists' ability to comply with parameters in the interagency agreement are limited by lack of access and training on electronic health record systems. For example, the facility prohibited VPS pharmacists from processing antibiotic medications except for pre-dental procedures or long-term antibiotic therapy, and from processing prescriptions for patients enrolled in a specialty mental health program. A VPS pharmacist would need to access the patient's electronic health record to determine if processing a prescription for antibiotics was prohibited by the interagency agreement or if the patient was enrolled in a specialty mental health program. The OIG determined that the limited access to clinical information and to patients and caregivers may contribute to the inability of VPS pharmacists to fully perform the clinical pharmacy functions. Additionally, four items outlined in the functional statement required the pharmacist to consult with the prescribing provider. However, as noted above,

[25] The pending queue is the list of medication orders stored in the pharmacy system and awaiting order verification.

[26] VHA Handbook 1108.05, *Outpatient Pharmacy Services,* June 16, 2016, amended August 20, 2019; VHA Handbook, 1108.11 (1), *Clinical Pharmacy Services,* July 1, 2015, amended June 29, 2017.

[27] VHA Handbook 1108.05.

Pharmacy Benefits Management leaders acknowledged that VPS pharmacists returned prescriptions to the pending queue rather than contact the prescribing provider.

VPS Pharmacist Performance Metric

A 2015 study found that the rate of pharmacist errors during order verification increased with the number of orders verified per shift, and that more than 400 orders per shift was associated with the highest rate of errors.[28] During the period of the OIG's inspection from August 2017 through May 2018, Meds by Mail monitored only the VPS pharmacists' productivity with a benchmark goal of 95 prescriptions processed per hour. If VPS pharmacists processed 95 orders per hour that would total 760 order verifications in an eight-hour shift, almost double the threshold for the highest rate of errors identified in the study.

Determining an appropriate number of prescriptions to be processed per hour is dependent on the type of prescriptions being filled (new or refill). VPS pharmacists processed both new and renewal prescriptions. Based on these factors, the OIG concluded that the VPS productivity measure might be an unreasonable target and may contribute to an increased risk for pharmacist error. Further, Pharmacy Benefits Management leaders told the OIG that they did not ensure monitoring of VPS prescription processing accuracy.

3. Program Management and Quality Assurance Requirements

Program management and quality assurance monitoring systematically evaluate performance to ensure that program requirements and quality standards are met.[29] Deficiencies in program management and quality assurance monitoring may contribute to adverse patient outcomes. The OIG found that Pharmacy Benefits Management leaders failed to clearly outline program management and quality assurance monitoring objectives and processes in both the interagency agreement and staffing contract.

[28] Christy Gorbach et al., "Frequency of and risk factors for medication errors by pharmacists during order verification in a tertiary care medical center," *American Journal of Health-System Pharmacists* 72, (September 1, 2015): 1471-1474. The study reviewed three shifts (day, evening, night) per day. For purposes of this report, the OIG assumed that each shift was eight hours.

[29] Project Management Institute, *Program Management.* https://www.pmi.org/learning/featured-topics/program, August 1, 2019. (The website was accessed on September 25, 2019.) Merriam-Webster, *Quality Assurance*, 2019. https://www.merriam-webster.com/dictionary/quality%20assurance. (The website was accessed on September 25, 2019.)

Interagency Agreement

The interagency agreement listed the facility pharmacy as responsible for providing quality assurance feedback to VPS and to the facility's pharmacy "as appropriate."[30] The facility's interagency agreement did not establish quality assurance measures or define conditions in which feedback was warranted. Pharmacy Benefits Management leaders did not establish a standardized format by which the medical centers provided quality assurance monitoring to Meds by Mail and told the OIG that feedback provided to Meds by Mail varied by medical center, with feedback based on different time periods and conditions. The facility's Chief, Pharmacy Services, told the OIG that no regularly occurring audit or quality assurance monitoring was established and that supervisors addressed problems as they arose.

Staffing Contract

The Associate Chief Consultant, Pharmacy Benefits Management told the OIG that the staffing contract between Consolidated Mail Outpatient Pharmacy and DLH is an umbrella contract that extended to Meds by Mail and DLH since these programs are under Pharmacy Benefits Management. According to the staffing contract, DLH's program management and quality assurance performance objectives must be assessed including timeliness, accuracy of prescription order processing, and order verification.[31] The staffing contract identified methods of performance assessment such as operational logs, random monitoring, and review of records for the nine specified performance objectives. Only one of the nine performance objectives identified a responsible staff member ("third party, COR [contract officer representative] or designee"). Additionally, the staffing contract did not specify oversight responsibilities, reporting frequency, and format for quality assurance.

Conclusion

The OIG determined that the discontinuation of the patient's bupropion, which was ordered specifically for depression, may have contributed to increased depressive symptoms, including suicidal ideation, in the six weeks following the patient's scheduled depletion of the medication.[32] The OIG was unable to determine that the discontinuation of the medication contributed directly to the patient's death because other potential causal factors existed, such as

[30] *Interagency Cross-Servicing Support Agreement*, *Virtual Pharmacist Order Verification*, VA Pharmacy Benefits Management VPS Through Meds by Mail and the facility, Agreement Period October 1, 2016, through December 30, 2018.

[31] The staffing contract stated "Program Management involves all aspects of human resource management and policy compliance. Quality Assurance focuses on the accuracy and timeliness of services provided."

[32] While trazodone was continued, the patient's dose of trazodone was consistent with dosing guidelines for the treatment of insomnia, not depression.

cognitive impairment and withdrawal symptoms. The circumstances of the patient's death are discussed in a companion OIG report that was published January 7, 2020.[33]

The DLH pharmacist did not access the patient's electronic health record or notify the psychiatrist of the discontinuation. Although, the facility granted the DLH pharmacist access to the patient's electronic health record, the DLH pharmacist was not aware of this capability. The DLH pharmacist should have reviewed the patient's electronic health record or consulted with the psychiatrist before discontinuing the bupropion.

The OIG identified discrepancies between the Meds by Mail VPS pharmacist functional statement and the duties the VPS pharmacist could fully perform. The VPS pharmacists' inability to fully execute functions may contribute to decisions that are not fully informed and may result in changes to the patient's medication regimen, such as in the case of the patient discussed above. The OIG found that VPS pharmacists were unable to fully perform 20 of 27 clinical functions and 4 of 8 dispensing functions specified in the Meds by Mail functional statement. The OIG determined that the limited access to clinical information and to patients and caregivers may contribute to the inability of VPS pharmacists to fully perform the clinical pharmacy functions.

The OIG concluded that the VPS productivity measure of processing 95 prescriptions per hour might be an unreasonable target and may contribute to an increased risk for pharmacist error. Further Pharmacy Benefits Management leaders told the OIG that they did not ensure monitoring of VPS prescription processing accuracy. The OIG also found that Pharmacy Benefits Management leaders failed to clearly outline program management and quality assurance monitoring objectives and processes in both the interagency agreement and staffing contract.

Recommendations 1–5[34]

1. The Under Secretary for Health ensures a review of the pharmacy care provided for the patient and consults with the Human Resources Department regarding administrative action, if warranted.
2. The Under Secretary for Health develops a standardized Veterans Health Information Systems and Technology Architecture menu for Meds by Mail Virtual Pharmacy Services clinical pharmacists and ensures training and access to clinical information to perform the functional statement duties.

[33] VA Office of Inspector General, *Deficiencies in Care Coordination and Facility Response to a Patient Suicide at the Minneapolis VA Health Care System,* Minnesota, Report No. 19-00468-67, January 7, 2020.

[34] While the patient at issue received care at the Minneapolis VA Health Care System, the recommendations were directed to the Under Secretary for Health who oversees VHA Pharmacy Benefits Management. The recommendations were submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

3. The Under Secretary for Health ensures consistency between Virtual Pharmacy Services Meds by Mail clinical pharmacists' functional statements and position responsibilities.
4. The Under Secretary for Health evaluates the Meds by Mail Virtual Pharmacy Services performance metrics, determines a reasonable productivity benchmark, and establishes additional metrics as appropriate.
5. The Under Secretary for Health establishes program management and quality assurance objectives for Virtual Pharmacy Services that define the reporting frequency and structure, and monitors compliance with contract terms.

Appendix A: Clinical Pharmacist Clinical and Dispensing Functions

Table A.1. Clinical Functions*

1.	The pharmacist provides appropriate selection of drug therapy based upon the pharmaceutical principles of pharmacokinetics and pharmacodynamics; ***monitoring for efficacy, side effects and clinical outcome; and advises prescribers as appropriate.***
	Patient-specific therapeutic drug monitoring will include prospective review and intervention in:
2.	***Therapeutic appropriateness of a patient's drug regimen***
3.	***Therapeutic duplication in the patient's drug regimen***
4.	Appropriateness of the route and method of administration
5.	***Degree of patient compliance with the prescribed drug regimen***
6.	Drug-drug, drug-food, drug-laboratory, ***or drug-disease interactions***
7.	***Clinical and pharmacokinetic laboratory data to evaluate the efficacy of drug therapy and to anticipate side effects, toxicity, or adverse effects***
8.	***Physical signs and clinical symptoms relevant to the patient's drug therapy***
9.	***Performs continuous evaluation of prescribed medications to assure optimal drug therapy***.
10.	***Provides medication counseling to patients and/or caregivers***.
11.	***Completes medication histories including patient interviews***.
12.	***Serves as a drug information resource by providing up-to-date drug information to prescribers, other health care professionals, patients and caregivers***.
13.	***Participates in patient chart reviews, evaluates pertinent laboratory data,*** drug-drug and drug-nutrient interactions, monitors for adverse drug events, and screens for allergies.
14.	***Performs medication reconciliation updating the medication profile to reflect an accurate, active list of VA and non-VA medications. This may include adding non-VA medications or discontinuing duplicate medications or those the patient is not taking***.
15.	Assesses drug safety and ***efficacy, including evaluation of physical symptoms.***
16.	***Reports adverse drug events (ADE), near misses and medication errors in alignment with the Meds by Mail reporting program.***
17.	***Participates in medication utilization evaluation (MUE) program.***
18.	***Recommends approved alternatives when a medication is not available.***
19.	***Participates in medical emergencies and emergency preparedness activities.***
20.	***Manages recalls and medication shortage situations*** by substituting alternate dosage strengths and instructions of the same medication to equal the prescribed dose and schedule.
21.	Enters supply orders appropriate for patient care per Meds by Mail policy.
22.	Manages various actions, as appropriate for medication orders to include flagging prescriptions, ***managing view alerts***, and using the "hold medication" function.
23.	Serves as a role model and preceptor to pharmacy students and pharmacy technician students.
24.	Assumes an active role in staff development of peers and provides educational in-services.
25.	Assumes an active role in the overall pharmacy-training program consisting of students, externs, interns, residents and professional and non-professional staff members. Conducts on-the-job training and provides guidance through designated programs.
26.	Provides education to health care providers regarding medication use.
27.	The pharmacist is responsible for maintaining his/her professional competency by keeping abreast of current medical and pharmaceutical literature, new drugs and therapies, and applies this knowledge in his/her daily duties.

Source: The OIG's analysis of Meds by Mail Clinical Pharmacist Functional Statement and VHA Pharmacy organization and requirements.

**Note: Bold, italicized text indicates functions that VPS pharmacists were unable to perform.*

Table A.2. Dispensing Functions*[35]

1.	Reviews all medication orders for appropriateness, patient's allergy history, drug-drug, drug-nutrient, and ***drug-disease state interactions***, drug selection, dosage, route of administration and quantity, prior to dispensing.
2.	Contacts provider to resolve medication-related problems, ***documenting recommendations and interventions.***
3.	***Ensures all medication orders are entered into the electronic patient medical record***.
4.	***Reviews medication profiles and monitors for compliance or potential abuse; problems encountered shall be resolved***.
5.	Supervises the activities of support personnel.
6.	Processes prescriptions in assigned remote pending file site when scheduled.
7.	Assists pharmacy technicians and others with duties as assigned and deemed essential to the efficient operations of Meds by Mail.
8.	Regular attendance is an essential function of this position.

Source: The OIG's analysis of Meds by Mail Clinical Pharmacist Functional Statement and VHA Pharmacy organization and requirements.
**Note: Bold, italicized text indicates functions that VPS pharmacists were unable to perform.*

[35] "Verifies prescriptions entered in VISTA by pharmacy technician staff" is another dispensing function listed in the functional statement. However, the facility did not employ pharmacy technicians, so this function was not included in the OIG analysis.

Appendix B: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: May 14, 2020

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

Subj: Healthcare Inspection—Deficiencies in Virtual Pharmacy Services in the Care of a Patient

To: Director, Mental Health Programs, Office of Healthcare Inspections (54MH00)

1. Thank you for the opportunity to review the draft report on Deficiencies in Virtual Pharmacy Services in the Care of a Patient. The Virtual Pharmacy Service (VPS) Program operates under the direction of the Pharmacy Benefits Management (PBM) Meds-by-Mail (MbM) Program and is dedicated to providing high quality care for our Veterans.
2. While the Veteran's Health Administration (VHA) understands the important role the Veterans Affairs Inspector General plays in reviewing VA programs, its focused review of the profession of clinical pharmacy as it relates to mental health seems marked by an apparent lack of knowledge and indicates a professional bias. We again note our concern that the Office of Inspector General did not include a pharmacist on the inspection team, on interviews with subject matter experts, or on calls and discussions with VHA. This resulted in the VHA's Pharmacy Benefits Management Services Office and the Office of Mental Health expending countless precious hours clarifying Inspector General misinterpretations and misunderstandings of pharmacy practice in this and other reviews.
3. I understand the leading professional pharmacy societies in the United States, organized as the *Joint Commission of Pharmacy Practitioners* (https://jcpp.net/about/), met with the Inspector General and his staff to express their concerns about its approach to assessing mental health pharmacy practices and to offer assistance. We hope that the feedback provided by these professional groups will help inform and shape future Inspector General reviews of pharmacy practice so that they are consistent with contemporary pharmacy practice in the United States and are based on fact, not speculation nor professional bias.
4. VHA officials have thoroughly reviewed the facts of this case and the contents of this draft report.
5. I acknowledge the VPS pharmacist's designation of the non-refillable antidepressant prescription as "discontinued" in the Electronic Health Record (EHR) was not consistent with prescription processing guidelines. As the Inspector General's review team is aware, VHA took prompt action to identify contributing factors for this inconsistency in EHR documentation and to clarify its guidelines for processing prescriptions for mental health medications in the VPS setting. The VPS program has successfully helped local VA medical center pharmacies process routine, mail-delivery prescriptions since 2011 and in FY2019, VPS pharmacists processed over 4 million prescriptions for Veterans. It would be irresponsible for OIG or management to base broad conclusions about the high quality of this program on the actions of one VPS pharmacist and a single patient.
6. The facts of this case simply do not support the premise that an EHR documentation error which was not visible to the Veteran nor ever communicated to [the patient], in any way contributed negatively to [the patient's] care and I unequivocally reject that premise. In actuality, the facts support a lack of evidence the Veteran was ever without medication due to the "discontinued" designation of the non-refillable antidepressant prescription in the EHR. The facts support that the

EHR is replete with documentation by the Veteran's VA and non-VA providers alike, that during transitions in care, [the patient] was reported to be taking the medication in question.

7. Regarding the recommendations, VHA concurs in principle with recommendation 1 and concurs with recommendations 2 and 4 regarding a review of the pharmacy care provided, standardization of VistA menus for VPS pharmacists, evaluation of VPS productivity benchmarks. VHA does not concur with recommendations 3 and 5 for the reasons stated in the action plans.
8. If you have questions, please email Karen Rasmussen, M.D., Director, GAO-OIG Accountability Liaison at VHA10EGGOALAction@va.gov.

(Original signed by:)

Richard A. Stone, M.D.

Executive in Charge Response

Recommendation 1

The Under Secretary for Health ensures a review of the pharmacy care provided for the patient and consult with the Human Resources Department regarding administrative action, if warranted.

Concur in principle.

Target date for completion: Complete

Executive in Charge Comments

The Pharmacy Benefits Management Services office will conduct a review of the care provided by the Meds by Mail (MbM) pharmacist. Since the MbM pharmacist is a contract employee, not a VA employee, it is unnecessary to refer the issue to Human Resources. Corrective actions have been taken to address the deviation from established procedures by the contract employee and other administrative changes were made to the MbM agreements and Virtual Pharmacy Service (VPS) Guidelines to reduce the likelihood of future events. These changes include the development of VPS staff guidance specifically addressing duplicate therapy scenarios for mental health drug products. The revised guidelines were shared with all VPS staff and apply to all VPS sites.

Recommendation 2

The Under Secretary for Health develops a standardized Veterans Health Information Systems and Technology Architecture menu for Meds by Mail Virtual Pharmacy Services clinical pharmacists and ensures training and access to clinical information to perform the functional statement duties.

Concur.

Target date for completion: June 2020

Executive in Charge Comments

The Pharmacy Benefits Management Services office will work with VA medical centers which utilize Virtual Pharmacy Services to standardize to the extent possible, the outpatient pharmacy VistA menus used by VPS pharmacists. VHA accepts that some variation in VistA menus is expected due to the different needs of individual VA medical centers.

Recommendation 3

The Under Secretary for Health ensures consistency between Virtual Pharmacy Services Meds by Mail clinical pharmacists' functional statements and position responsibilities.

Non-Concur.

Target date for completion: Not Applicable

Executive in Charge Comments

Meds by Mail uses a very detailed VPS Guideline document to delineate specific duties and expectations for VPS pharmacists. The VPS Guideline establishes the parameters of the VPS Program and is the primary source document for program implementation. Every VA pharmacist, regardless of whether they work in the VPS Program, also has a general employment document called a functional statement. The functional statement establishes the broad range of activities that any licensed pharmacist should be qualified to perform, but it does not establish specific job duties of a given position. VHA does not agree with revising the functional statement because it is not the appropriate document for establishing specific duties for VPS pharmacists. VHA has agreed to review and clarify duties in the VPS Guideline.

OIG Comment

The OIG supports VHA efforts to clarify virtual pharmacist duties and considers this recommendation open. The OIG will follow up on the plan to review and clarify virtual pharmacist duties.

Recommendation 4

The Under Secretary for Health evaluates the Meds by Mail Virtual Pharmacy Services performance metrics, determines a reasonable productivity benchmark, and establishes additional metrics as appropriate.

Concur.

Target date for completion: July 2020

Executive in Charge Comments

Pharmacy Benefits Management Services will evaluate the need for any changes in metrics as it relates to the primary role of the Meds by Mail-VPS pharmacist in conformance with established *VPS Guidelines*. The Pharmacy Benefits Management Services office seeks to improve the quality of the VPS Program and will provide the Senior Leadership with an evaluation of VPS performance metrics.

Recommendation 5

The Under Secretary for Health establishes program management and quality assurance objectives for Virtual Pharmacy Services that define the reporting frequency and structure, and monitors compliance with contract terms.

Non-Concur.

Target date for completion: Not Applicable

Executive in Charge Comments

VHA holds the VPS Program to the same rigorous quality assurance standards and objectives as facility-based pharmacy programs. This ensures all VA and contract pharmacists provide the same quality of care to Veterans regardless of whether or not they work in a virtual setting. Quality assurance standards and objectives are located in the staffing contract; performance and productivity standards are located in the interagency agreements. Performance and productivity metrics are based on a thorough evaluation of pharmacist processing levels that Meds by Mail (MbM) conducted prior to initiating the VPS Program. The MbM's pharmacist supervisor oversees and manages the VPS Program and constantly monitors productivity and reported errors for each VPS pharmacist. MbM uses the same data sources as local facilities for oversight of pharmacist performance. The MbM pharmacist supervisor conducts competency assessments on every VPS pharmacist to ensure they understand and are capable of performing assigned duties. MbM has appropriate program management oversite and quality assurance activities in place to validate the clinical and operational integrity of the VPS Program. These existing quality assurance activities mirror the same ones used at VA medical centers, which is appropriate since the Virtual Pharmacy Services staff perform the same functions as local staff, only the VPS staff do it remotely.

OIG Comment

The OIG considers the current VPS quality assurance to be ineffective. While VPS staff may be expected to perform similar tasks as facility staff, the OIG found VPS staff did not have the same tools available to accomplish similar tasks. For example, VPS staff did not have or were not aware of their ability to access patient electronic health records that would inform their decision-making when refilling or canceling medications. VHA and facility-based pharmacy leaders were unaware of the VPS pharmacists' lack of access to patient care information. If the existing quality assurance monitoring system were effective, this access failure could have been discovered and remedied.

Glossary

anxiety. An expected part of life that involves worry or fear. For individuals with an anxiety disorder, it can get worse over time and can interfere with daily activities to include job performance, schoolwork, and relationships.[1]

benzodiazepines. Central nervous system depressants that may be prescribed for the treatment of anxiety disorders.[2]

bupropion. An antidepressant medication approved for treatment of moderate and severe depression.[3]

delusional disorder. A psychotic disorder defined by the presence of one or more delusions (fixed, false beliefs that are not impacted by the presentation of conflicting evidence) for longer than a month in the absence of meeting other criteria for schizophrenia.[4]

depressive disorders. A diagnostic category that encompasses several illnesses, including major depressive disorder, that share "the presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual's capacity to function."[5]

insomnia. A common sleep disorder that can make it hard to fall asleep, hard to stay asleep, or wake up too early and not be able to get back to sleep.[6]

mild neurocognitive disorder. A deficit or decline in cognitive functioning that was not present early in life.[7]

trazodone. An antidepressant medication that is used off label to treat insomnia.[8]

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[1] National Institute of Mental Health, *Anxiety.* https://www.nimh.nih.gov/health/topics/anxiety-disorders/index.shtml. (The website was accessed on May 22, 2019.)

[2] Mayo Clinic, https://www.mayoclinic.org/drugs-supplements/lorazepam-oral-route/description/drg-20072296. (The website was accessed on May 22, 2019.)

[3] National Institutes of Health, *Bupropion*, updated July 1, 2019. https://livertox.nlm.nih.gov/Bupropion.htm. (The website was accessed on August 16, 2019.)

[4] American Psychiatric Association. (2013). Schizophrenia Spectrum and Other Psychotic Disorders. *Diagnostic and statistical manual of mental disorders* (5th ed.).

[5] Diagnostic and Statistical Manual of Mental Disorders. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm04. (The website was accessed on August 16, 2019.)

[6] Mayo Clinic, *Insomnia.* https://www.mayoclinic.org/diseases-conditions/insomnia/symptoms-causes/syc-20355167. (The website was accessed on May 22, 2019.)

[7] Diagnostic and Statistical Manual of Mental Disorders. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm17. (The website was accessed on August 16, 2019.)

[8] Merck Manual Professional Version, *Trazodone.* https://www.merckmanuals.com/professional/resources/brand-names-of-some-commonly-used-drugs, 2019. (The website was accessed on August 16, 2019.)

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