Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-01498-318

Healthcare Inspection

An Unexpected Death in a Mental Health Treatment Program
VA New Jersey Health Care System
Lyons, New Jersey

September 17, 2013

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to a request by the Office of Inspector General, Office of Investigations to review the care of a patient receiving post-traumatic stress disorder (PTSD) treatment at the Mental Health Residential Rehabilitation Treatment Program (MH RRTP) at the VA New Jersey Health Care System (facility), Lyons, NJ.

The patient, who was middle-aged, had a prior history of poorly controlled blood pressure and coronary artery disease with a myocardial infarction (heart attack) in his late thirties. On Day 70 of participation in the residential PTSD program, a nurse found the patient pulseless and unresponsive in his room. Cardiopulmonary resuscitation efforts were unsuccessful.

The Office of the State of New Jersey Medical Examiner autopsy report listed "Acute intoxication due to the combined effects of cyclobenzaprine, tramadol, gabapentin, sertraline, hydroxyzine, and amlodipine" as the cause of death. Final diagnoses also included hypertensive and atherosclerotic cardiovascular disease affecting the coronary arteries, aorta, and kidney vasculature, and evidence of a remote history of having had surgery for fasciitis due to a gunshot wound. The manner of death (suicide, homicide, accidental) was listed as undetermined. No recent thrombus was found on examination of the cardiovascular system during autopsy.

The VHA MH RRTP Handbook specifies that veterans in MH RRTP programs are able to learn and practice safe management of their medication regimens in order to achieve independent medication administration. Each or MH RRTP Program Manager must develop a local policy for Safe Medication Management (SMM) within the unit. A patient's ability to safely manage medications must be assessed by a clinician upon admission into an MH RRTP.

The level of independence for each veteran must be assessed as either:

- Dependent-veteran requires additional education and varying levels of medication supervision which includes direct involvement for observing and administering each medication

- Semi-independent-veteran is able to assume partial responsibility for storage, security, and safe administration of medications. For these patients professional staff may assume an indirect role in the veteran's medication management by documenting the results of periodic reviews of veteran's safe medication practices, a visual count of Veteran's medications, or clinical observations of their responses to medications or

- Independent-veteran is able to assume complete responsibility for the storage, security, and safe administration of medications. These patients understand the purpose of each medication with a general understanding of their common side effects, and can consistently demonstrate independent medication management.

Patients' abilities to manage their own medication may change throughout participation in the MH RRTP. SMM is to be incorporated into the individual treatment plan for MH RRTP patients and is to be reviewed as part of treatment planning updates. VHA's MH RRTP Handbook also specifies that clinical monitoring of a patient's response to medication must be evaluated and recorded in the patient's medical record at least on a monthly basis. This monitoring should include: (1) identification of target symptoms (2) evaluation of the efficacy of medication on the target symptoms including any adverse events, and patient perception of efficacy and side effects (3) review of relevant laboratory results and (4) an evaluation of educational needs and barriers.

During the inspection, we found that program staff did not comply with Veterans Health Administration and facility requirements for an effective, safe medication management program or document the resident's care sufficiently or timely.

We also found that leadership did not provide sufficient professional support for a MH RRTP advanced practice registered nurse.

We recommended that the Health Care System Director ensure that the facility:

- Complies with MH RRTP safe medication management requirements.
- Completes MH RRTP electronic health record documentation that is individualized, timely, and includes required elements.
- Provides appropriate follow-up to requests for professional support by MH RRTP mid-level providers.

Comments

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendations and provided acceptable action plans. (See Appendixes A and B, pages 15-18 for the Directors' 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 Department of Veterans Affairs (VA) Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an inspection at the request of OIG investigators following the unexpected death of a resident in the VA New Jersey Health Care System (VA NJ HCS) Post Traumatic Stress Disorder (PTSD) Mental Health (MH) Residential Rehabilitation Treatment Program (RRTP). We reviewed the care of this patient and compliance with safe medication management protocol by staff.

Background

VA NJ HCS consists of two campuses, one in Lyons, and the other in East Orange, NJ. A 381-bed tertiary care center, VA NJ HCS provides comprehensive health care through inpatient and outpatient services in medicine, surgery, MH, substance abuse, and homeless services. The Lyons Campus (facility) includes a 300-bed community living center, an 85-bed domiciliary, a 25-bed PTSD RRTP, and a 10-bed Women's Trauma unit. VA NJ HCS has 10 community based outpatient clinics located throughout New Jersey and is part of Veterans Integrated Service Network (VISN) 3.

MH RRTP

The facility's 25-bed unit is one of 40 Veterans Health Administration (VHA) PTSD-specific MH RRTPs.[1] In 1995, VHA established the MH RRTP bed level of care for patients with mental illnesses and/or addictive disorders who do not warrant acute psychiatric inpatient admission but require additional structure and support to address multiple and severe psychosocial deficits. In addition to individual psychotherapy, the facility's program includes psychiatric (medication) treatment, psycho-educational[2] and process[3] treatment groups. The two tracks of PTSD treatment offered at the facility were PTSD and substance abuse (45-days) and general PTSD (50-days).

VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)* (Handbook), published December 22, 2010, established procedures and reporting requirements for this level of care.

Safe Medication Management

VHA requires MH RRTPs to emphasize rehabilitative approaches that promote education and practice of self-care skills, including residents' self-management of their

[1]Northeast Program Evaluation Center, *Mental Health Residential Rehabilitation and Treatment (MH RRTP)* FY 2011 Power Point, NEPEC VHA Website, accessed April 29, 2013.
[2]Psychoeducational groups are structured therapeutic sessions to include the presentation of didactic material to enhance psychological functioning and coping.
[3]Process groups are unstructured therapeutic sessions that allow group members to address any psychological issue of concern to them at the time of group. Process groups may focus on specific topics, such as trauma coping, substance abuse, or relationship issues.

medication regime. VHA also requires the MH RRTP manager to develop and implement a local policy for safe medication management (SMM) that addresses medication administration, assessment, education, monitoring, and secure storage, and that a pharmacist serves on the MH RRTP team.[4] Beginning on the day of admission, SMM is required to be an active ongoing interactive assessment and education process between MH RRTP staff and the program participant.

Assessment and Education

Upon admission to a MH RRTP, a provider, such as a physician, advanced practice registered nurse (APN), physician's assistant, or registered nurse (RN) must conduct medication reconciliation (MR)[5] and assess the resident's current level of knowledge, understanding, and management of their medication regime.[6] Staff who complete the assessment must document this information in the electronic health record (EHR). Using this assessment, a provider must enter an EHR order designating a patient's specific SMM level.

Based on the assessment, residents are classified as Level I (dependent), II (semi-independent), or III (independent). Following assessment, a provider is to educate the resident about each prescribed medication and document the resident's learning needs, education, and understanding. VHA outlines that residents on more than three medications per day might benefit from the use of an assistive device, such as a pillbox, reminder alarm, signage, and/or pictorial chart of medications.[7] Responsibilities for administration, management, and medication education are defined by the assigned level, as shown in Table 1.[8]

Level I - Dependent	Level II – Semi-Independent	Level III – Independent
Staff stores, dispenses, and supervises every medication dose.	Staff stores, dispenses, and supervises some medication doses.	Staff stores and dispenses controlled substances only.[9]
Resident does not self-administer any medication.	Resident self-administers some medications and stores 1-30 day medication supply in a locked location.	Resident self-administers medications and stores 1-30 day medication supply in a locked location.
Staff reinforces medication education with each dose.	Staff provides medication education initially and periodically.	Staff provides medication education initially and periodically.

Table 1. Overview of VHA MHRRTP SMM Levels

[4]VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010.
[5]Medication reconciliation is a process of validating all prescribed, over-the-counter, and other medications and supplements reportedly taken by a patient.
[6]VHA Directive 2011-012, Medication Reconciliation, March 9, 2011.
[7]VHA Handbook 1162.02.
[8]*ibid*.
[9]Medication independent patients in Compensated Work Therapy Transitional Residence (CWT-TR) programs may be dispensed up to a 7-day quantity or less of a controlled substance.

Monitoring

SMM is to be incorporated into an MHRRTP patient's individual treatment plan (ITP) and must be reviewed as part of ITP updates. VHA requires ITPs include any history of medication-related high-risk behaviors, such as suicide attempts with overdoses or treatment resistance, and high-risk-alert medications, and reflect the most current SMM level.[10]

Assessment of the patient's medication knowledge is a process by which a veteran's ability to accurately and safely manage the medication regimen is determined. Reassessment must take place as deemed appropriate by the medical provider, but at least monthly, and all findings documented in the patient's medical record. VHA's MH RRTP Handbook specifies that clinical monitoring should include: (1) identification of target symptoms (2) evaluation of the efficacy of medication on the target symptoms including any adverse events, and patient perception of efficacy and side effects (3) review of relevant laboratory results and (4) evaluation of educational needs and barriers.

In addition, staff must monitor and review a resident's response to the first dosage(s) of a new medication and upon a resident's return from an authorized absence (pass), staff must inventory residents' medication, document medication use, and return excess pass medication to the pharmacy.

Storage and Security

VHA requires that for residents with independent or semi-independent SMM status, the resident's medications be kept in a locked location accessible only to the resident and qualified staff and that the resident must agree, in writing, to comply with all MH RRTP medication security requirements. The written agreement must include a statement that the resident is responsible for the security of medication(s) in a designated locked area with security code or key. Inspections of all residents' rooms must occur daily to detect unsecured medications. In addition, the facility policy must include a process to address any difficulty the resident might exhibit in securing medication.

APN Scope of Practice

APNs are RNs who have obtained a postgraduate nursing degree, typically a master's degree. National policy outlines scope of practice (now called the core elements of practice)[11] and the privileges appropriate for APNs. In 2012, the majority of states required physician involvement in APNs' practices of diagnosis, treatment, and medication prescription.[12] New Jersey is one of nine states that require physician involvement to prescribe medications but not to diagnose or treat residents. VHA recognizes APNs as independent practitioners although requires a collaborating

[10]*High-risk-alert medications are drugs that bear a heightened risk of causing significant harm when they are used in error*. Source http://www.ismp.org/tools/highalertmedications.pdf, accessed April 16, 2013.
[11]Office of Nursing Services, APRN Facts and Background as of February 2012, accessed February 14, 2013.
[12]*Health Affairs, Health Policy Brief*, Robert Wood Johnson Foundation, October 25, 2012, source Health Policy Brief, accessed April 11, 2013.

physician for the prescription of controlled substances.[13,14] In addition, the APN's clinical service chief is responsible for the healthcare provided by that APN. VISNs and facilities may have local policies to address the scope of practice, including expectations regarding physician collaboration.

Scope and Methodology

We consulted with OIG investigators and reviewed the subject patients EHR, relevant facility and national policies, and relevant reports including autopsy, Mathematica Follow-Up Quality Review, a root cause analysis on the subject case, patient incident, patient advocacy, safety, and quality. During our February 11 – 13, 2013, site visit we interviewed facility managers and staff. We reviewed APN scope of practice and physician collaborator agreements, and resident monitoring documentation, including SMM resident agreements, daily sign in/sign out logs, and daily inspection records

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.

Case Summary

The patient was a middle-aged male who began care at the facility in 2004. His medical history included poorly controlled blood pressure and coronary artery disease with a myocardial infarction (heart attack) in his late thirties. He had a history of alcohol-related admissions in 2008, 2009, and 2010, and he engaged intermittently in outpatient substance use treatment. In the time frame leading up to admission to the MH RRTP the patient was participating in a substance abuse treatment program (SATP) at the facility prior to admission and attending groups that focus on treatment of concomitant substance use and PTSD issues.

In the early spring of 2012, the patient showed up unscheduled at the office of an SATP psychologist and expressed his belief that he needed more intensive PTSD treatment. He was subsequently referred and 1 week later screened and accepted into the PTSD MH RRTP. Prior to admission, he had been residing with his ex-wife.

His outpatient medication regimen consisted of seven standing (daily) medications including amlodipine for high blood pressure; omeprazole, a medication used to treat gastroesophageal reflux; naproxen, a non-steroidal, non-opiate, anti-inflammatory medication used to treat pain; Zoloft, an anti-depressant medication; prazosin, an anti-hypertensive medication that has shown efficacy in some patients treated for problematic nightmares associated with PTSD; hydroxyzine, an anti-histamine

[13]Office of Nursing Services, *APRN Facts and Background as of February 2012*, source http://vaww.va.gov/nursing/aprnPractice.asp#visn, accessed February 14, 2013.
[14]VHA Nursing Handbook 1180.03-Draft, VHAnursingHandbookDRAFT_PENDINGSep2012, accessed April 11, 2013.

medication used by some patients for anxiety related symptoms; and trazadone, an older anti-depressant medication that is also frequently used by clinicians to treat insomnia.

Within the first week of admission, a history and physical were performed, a psychosocial history was completed, and he was assessed for suicidality. During his treatment in the MH RRTP, he participated in individual sessions and group activities focused on PTSD and substance use recovery.

Throughout the resident's treatment course, he had problems with elevated blood pressure, pain, and sleep disturbance, including nightmares. In response to ongoing medical issues, the APN submitted several medical specialty consultation requests.

During the course of treatment, providers made multiple changes in the subject resident's medication regimen. For example, the APN added gabapentin on Day 5 and, per the resident's request, doubled the dosage on Day 9. Gabapentin is an anti-convulsant medication that is also FDA approved to treat pain that can follow healing of shingles. Some clinicians use gabapentin off-label to manage other pain conditions. On Day 17, the APN discontinued trazodone; but did not document the reason for this change.

A week later (Day 24), the psychiatrist increased the patient's prazosin dosage to address nightmares and, per the resident's request, increased sertraline dosage. On Day 30, the cardiologist recommended starting hydrochlorothiazide (a diuretic medication used to treat high blood pressure), re-checking the patient's blood lipid level in 2 weeks,[15] and adding medication if lipid levels warranted, however, there was no documented re-check of lipid levels.

On Day 45, a psychiatric resident increased the prazosin dosage but did not document an explanation for that change. Notes in the EHR show that the patient's treatment admission was extended beyond the expected 45-day stay. MH RRTP staff did not document the clinical justification for this extension nor update the ITP to reflect the change.

On Day 51, the APN prescribed cyclobenzaprine per the resident's complaint of pain and request for that specific medication. Cyclobenzaprine is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Three days later, Physical Medicine and Rehabilitation Services evaluated the resident's pain and prescribed time-limited steroid treatment and physical therapy. We did not find that a referral to physical therapy had been submitted. On Day 59, the APN evaluated the resident for pain and increased the gabapentin dosage, added baclofen (a medication used to treat muscle spasms caused by certain

[15]Lipid levels refer to blood fats that circulate in the blood, and they can be measured by a laboratory analysis.

conditions) and ibuprofen.[16] The APN did not document a pain level. Five days later, the APN discontinued the ibuprofen. On Day 65, the APN prescribed tramadol to treat the resident's pain from a back injury that occurred during a recreational sports activity.

During his time in the program, the resident went on six weekend-authorized passes. Although granted a weekend pass from Days 68–70, the resident did not leave the unit. On Day 68, he attended two scheduled group treatment sessions and evening nursing staff observed the resident was "...vissible [sic] on the unit; he is pleasant and in compliant [sic] with the unit and medication regime. Mood and affecct [sic] euthymic. No complaints voiced and no distress noticed." On Days 69 and 70, the resident signed the "Daily Sign-In/Out Log" in the morning listing his destination as "Front." Staff informed OHI inspectors that the resident was known to suntan outside. Also on both days, nursing staff obtained the resident's blood pressure[17] (145/79 and 136/70, respectively) and, after conducting mid-day room inspections, noted that they did not find any unsecured medications in the resident's room.

On the day of his death, the resident received several unanswered phone calls from his ex-wife, with whom he had reportedly been arguing in the days preceding his death. The resident had also posted a handwritten sign on his room door that read, "1510 ~~Taking Nap~~ Am Sleeping Pls do not Disturb Thank you." There is no other documentation of the resident's status or discussion of his decision to remain at the facility for the weekend.

In the late afternoon on Day 70, the patient interacted with a nurse however; 2 hours later, the nurse found him unresponsive and with no pulse on the floor of his room. A plant appeared to have been knocked over. Cardiopulmonary resuscitation efforts were unsuccessful. On the day of his death, the patient's standing medication regimen consisted of amlodipine, hydrochlorothiazide and lisinopril for high blood pressure; sertraline, prazosin, hydroxyzine for psychiatric symptoms; omeprazole for gastric reflux; and baclofen, cyclobenzaprine, gabapentin, and tramadol for pain. Investigators did not find the patient's medication bottles present at the scene or stored in his locker and when interviewed staff were unable to account for the whereabouts of the medications.

The Office of the State of New Jersey Medical Examiner performed an autopsy, and the report's final diagnoses included:

I. Acute intoxication due to the combined effects of cyclobenzaprine, tramadol, gabapentin, sertraline, hydroxyzine, and amlodipine.

II. Hypertensive and atherosclerotic cardiovascular disease

[16]Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used for pain relief, fever reduction, and against swelling. NSAIDs may increase the risk of heart attack or stroke and are contraindicated for patients with a history of heart disease, WebMD Ibuprofen, accessed May 6, 2013.

[17]Blood pressure is considered normal when the top number (systolic) is less than 120 and the bottom number (diastolic) is less than 80, National Heart, Lung, and Blood Institute, accessed June 4, 2013.

III. Status post-surgery performed for treatment of fasciitis due to gunshot wound, remote.

The medical examiner listed the "manner of death" (suicide, homicide, or accidental) as undetermined.

Inspection Results

Medication Regimen

At the time of death the patient was on three medications for his blood pressure, one for depression, one for nightmares, one for reflux, and four for pain and spasm. The dosages were within normal range. Following the resident's death, his medication vials were not observable in his room nor were they found locked in the medication storage area. Serial investigations were unable to determine the whereabouts of the medication vials. The New Jersey Medical Examiner reportedly indicated mildly elevated levels of sertraline, tramadol, and flexeril but of questionable clinical significance. These levels were not suggestive of intentional overdose. Tramadol and flexeril can interact to lower seizure threshold however; the resident did not have a seizure history nor did the autopsy indicate seizure as cause of death. The patient's blood pressure had been monitored the day before and the day of his death and he was not found to be hypotensive.

Compliance with MH RRTP Program Policies and Procedures

There were problems with the MHRRTP program's compliance with program policies and procedures. The facility initiated a comprehensive root cause analysis under their quality management program and an administrative investigation board to address issues related to this case. We found specific concerns related to SMM practices, EHR documentation, and APN-physician collaboration.

A. SMM

In 2010, VHA contracted with Mathematica Corporation[18] to conduct on-site quality reviews at RRTPs. The purpose of these reviews was to determine if facilities were meeting the transformation plan goals and VHA requirements for access, quality of care; safety, security, privacy; and program operations.

VHA's Mathematica *Follow-Up Quality Review Report*, dated July 26, 2011, identified deficiencies in the facility's SMM program. These deficiencies included insufficient policy, absence of initial SMM level assessments, and absence of providers' orders for residents' SMM level. In addition, the report notes:

> The program must conduct and document an initial assessment of veterans' medication management level rather than automatically

[18]Mathematica Policy Research Inc. is a non-governmental research organization.

determine that all veterans admitted to the program are dependent for medication administration.

Although the local policy included VHA's SMM requirements and guidelines, in practice, the program did not fully implement these procedures, including some areas identified as non-compliant in the Follow-Up Quality Review Report.

1. Assessment and Education

We found discrepancies between documentation of provider orders and the staff-assigned SMM levels. For example, on the day of the subject resident's MH RRTP admission (Day 1), the APN entered medication orders that included the notation of "level 1 privileges" for some of the medications, but made no privilege-level notation on others. Although facility practice was to treat all newly admitted patients as level I, VHA requires assessment upon admission to promote individualized SMM levels. The APN initiated a progress note documenting medication education and "reinforce[ment of] self-medication agreement" on Day 4, but did not sign the note until Day 22. Without signature, other staff could not view the note and the resident's SMM level remained unclear. It was not until Day 23 that a staff RN completed the required initial SMM assessment with a designation of level III. Staff said that he was being treated as a level 2 throughout his admission.

On Day 32, the APN medication orders again listed the resident at level I for some medications but entered no level for other medications. Later that day, an RN completed a SMM evaluation and designated the resident at level III; however, there were no corroborating orders for level III. On Days 43 and 58, the APN noted that the resident should continue on level II; with an addendum on Day 58 that stated "LEVLE [sic] 3 ALL DAILY."

VHA policy requires education upon medication changes. Facility staff did not consistently document in the EHR that the resident was educated when a medication was added, changed, or altered. Additionally, we did not find evidence that a pillbox or other assistive device was offered or in place for the patient's use with his multiple medications or that the MH RRTP pharmacist reviewed medications with the resident, as required by VHA policy.

2. Monitoring

Although staff monitored the patient's blood pressure, they did not document his response to addition of new medications as required, including the first dose. Nurses completed SMM evaluation templates with indication that the resident had no barriers to medication compliance and learning, and that he understood the frequency, route, dosage, and common adverse events of all his medications. However, the staff did not document individualized information regarding the resident's educational needs and perceptions about medication effectiveness and side effects. There were multiple days when the resident fell asleep during group sessions and, on one occasion, a rehabilitation technician noted that the resident attributed his sleepiness to the "new

medication." Documentation indicated that the patient gained 18 pounds by Day 51. There was no documentation of follow-up by staff to evaluate these issues.

Although staff obtained urine drug screen specimens upon the resident's return from weekend passes, they did not complete medication inventories, document medication use while on pass, or return excess medications to the pharmacy, as required by VHA policy.

3. Storage and Security

We found that the facility did not obtain the subject resident's written agreement of compliance with all MH RRTP medication security requirements as required by VHA and facility policy. We evaluated 48 resident admissions during a 3-month period, during which the patient's admission occurred. We found only three signed written compliance and none of the three forms were completed with all necessary information, such as SMM level.

Facility records indicate that inspections of all residents' rooms did occur daily to detect unsecured medications, including an inspection on the day of the resident's death.

B. EHR Documentation

We found that MH RRTP staff did not document thoroughly or timely in the subject resident's EHR. For example, ITPs, ITP updates, and SMM evaluations were lacking required information and not compliant with timeframes required. Although initiated on Day 3, staff did not complete the initial ITP in the EHR until Day 33 and did not include SMM level as required. On Day 36, the APN entered an addendum to the ITP listing the resident's medications and level I designation. Approximately 4 weeks later, staff documented an ITP update without any SMM information.

Staff also did not consistently document the resident's pain levels, medication changes and additions, SMM level orders, and the therapeutic reason for his extended program stay. Although the SMM evaluation indicates that nursing staff "verbally endorsed" the level designation to the provider, there was no documentation to indicate that the APN received this information.

C. APN Physician Collaboration

In the course of our inspection, we found that leadership did not provide sufficient professional support for a MH RRTP advanced practice registered nurse.

We found that all seven APNs in mental health services had collaborative agreements with at least one or more physicians, and that they had completed the required 15 annual APN-collaborating physician EHR quality documentation reviews in the 2-year period prior to this inspection. The PTSD RRTP APN had a formal collaborative agreement with the RRTP psychiatrist. Because of the medical complexity of the MH RRTP resident population, the APN requested in 2010 through Lyons MH leadership,

that a formal collaboration agreement be arranged with a primary care physician. This arrangement had not been established at the time of this inspection.

Conclusions

The Office of the State of New Jersey Medical Examiner autopsy report's final diagnoses included acute intoxication due to the combined effects of cyclobenzaprine, tramadol, gabapentin, sertraline, hydroxyzine, and amlodipine.

We found that staff did not consistently assess or assign SMM levels for each medication prescribed for the subject resident. Staff also did not document timely or all required elements, including the resident's perceptions about pain, medication effectiveness, and side effects. Further, clinical managers had not arranged requested MH APN primary care physician collaboration to further support comprehensive management of medical conditions and medications.

Recommendations

1. We recommended that that the Health Care System Director ensures that the Mental Health Residential Rehabilitation Treatment Program complies with local and VHA Mental Health Residential Rehabilitation Treatment Program Safe Medication Management policy requirements.

2. We recommended that the Health Care System Director ensure that Mental Health Residential Rehabilitation Treatment Program documentation is individualized, timely, and includes required elements.

3. We recommended that the Health Care System Director ensure that Mental Health leadership provides appropriate professional support for Mental Health Residential Rehabilitation Treatment Program mid-level providers.

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 6, 2013

From: Director, VA New York/New Jersey Veterans Healthcare Network (10N3)

Subject: **Healthcare Inspection – An Unexpected Death in a Mental Health Treatment Program, VA New Jersey Health Care System, Lyons, NJ**

To: Director, Baltimore Office of Healthcare Inspections (54BA)

Acting Director, Management Review Service (VHA 10AR MRS OIG CAP CBOC)

I have reviewed the above report by the Office of the Inspector General and concur with its finding. I further concur with the VA NJHCS Director's clarifying comments. Please contact Pam Wright, VISN3 QMO, at 718-741-4143, if you require any further information.

Michael A. Sabo, FACHE

Appendix B

System Director Comments

Department of Veterans Affairs **Memorandum**

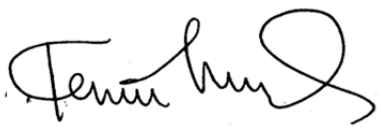
Date: August 5, 2013

From: Director, VA New Jersey Health Care System (561/00)

Subject: **Healthcare Inspection – An Unexpected Death in a Mental Health Treatment Program, VA New Jersey Health Care System, Lyons, NJ**

To: Director, VA New York/New Jersey Veterans Healthcare Network (10N3)

I have reviewed the above report by the Office of Inspector General Healthcare Inspections (OIG) and concur with its findings. Any unexpected death that occurs in one of our programs is of great concern and requires that we search for answers in order to identify issues in care that need to be improved. This death on the PTSD Unit at Lyons underwent several reviews including a Root Cause Analysis, a review by a clinical pharmacist and a review by a physician toxicologist. While system issues in the Safe Medication Management Program and with the collaborative process for Advanced Practice Nurses emerged from these reviews, a link between those deficiencies and this death was never established. As noted in the above report, the blood levels of the Veteran's medications that were found on autopsy are of questionable clinical relevance. None of the reviews drew the conclusion that the medication levels explained this Veteran's death. This report by the OIG reinforces our local findings and provides us an organized summary of issues that we will continue to address, as outlined in our actions in response to the OIG recommendations.



KENNETH H. MIZRACH

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that that the Health Care System Director ensures that the Mental Health Residential Rehabilitation Treatment Program complies with local and VHA Mental Health Residential Rehabilitation Treatment Program Safe Medication Management policy requirements.

Concur

Target date for completion: March 2014

Facility response: Meeting the full intent of the Safe Medication Management Process that is outlined in the VHA Mental Health RRTP policy requires the development of detailed processes including outlining specific roles and responsibilities. We have convened an interdisciplinary Task Force to review all aspects of the Safe Medication Management process inclusive of assessment, education, monitoring medications, safe medication agreements, storage of medication and documentation. The Task Force will review roles of the various professional staffs and will revise the existing process and policy to explicitly outline roles and responsibilities. Initial action that was already taken includes removal of Tramadol as a medication that can be prescribed as a Level 3 medication (independent medication administration). A checklist will be developed to track the progress of the Task Force as well as to serve as a quality assurance tool to insure that all required and key structures and processes are included. These steps and staff education to the revised processes are targeted to be done by November 1, 2013. Follow up monitoring of key process steps (e.g. assessment, education, medication monitoring) will occur until there is a minimum of three months of 95% compliance. Our target for achieving the full three months of compliance is March 2014.

Recommendation 2. We recommended that the Health Care System Director ensure that Mental Health Residential Rehabilitation Treatment Program documentation is individualized, timely, and includes required elements.

Concur

Target date for completion: March 2014

Facility response: As one component of the revisions identified in Recommendation 1, the Task Force will establish standardized documentation via templates or other mechanisms that insures full and appropriate clinical documentation of the Safe Medication Management process. In addition, Mental Health leadership will define standardized documentation requirements that address deficiencies noted in this report including integration of medication management into the treatment plan, justification for

extending length of stay in the program, response of patients who are on pass, etc. Chart monitoring for these elements will be done in conjunction with the Safe Medication Management process monitoring starting in December and will continue until there is three months of 90% compliance.

Recommendation 3. We recommended that the Health Care System Director ensure that Mental Health leadership provides appropriate professional support for Mental Health Residential Rehabilitation Treatment Program mid-level providers.

Concur

Target date for completion: October 2013.

Facility response: The facility has reviewed the collaborative agreement in place for the Advanced Practice Nurse (APN) assigned to PTSD as well as all APNs assigned to Mental Health whose role crosses over to medical care of the patient. The APN on PTSD was identified as having only one collaborative agreement in place with a psychiatrist. A medical physician has been identified to serve as an additional collaborator and a new collaborative agreement is being drafted. This is due to be completed by August 15. In addition, a work group has been convened co-chaired by an APN and a physician to review the overall manner in which APNs and physicians collaborate and to make suggestions for improvements that will enhance clinical collaboration. That group's work is expected to be completed and recommendations presented by October of this year.

Appendix C

OIG Contact and Staff Acknowledgments

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Appendix E

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