DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Two Mental Health Patients Who Died by Suicide

William S. Middleton Memorial Veterans Hospital Madison, Wisconsin

HEALTHCARE INSPECTION | REPORT #17-02643-239 | AUGUST 1, 2018

OIG MISSION

To serve veterans and the public by conducting effective oversight of the programs and operations of the Department of Veterans Affairs (VA) through independent audits, inspections, and investigations.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

Report suspected wrongdoing in VA programs and operations to the VA OIG Hotline:

www.va.gov/oig/hotline

1-800-488-8244

Executive Summary

At the request of Senators Tammy Baldwin and Ron Johnson, the VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the care of a patient (Patient 1) who committed suicide less than 48 hours after being discharged from the William S. Middleton Memorial Veterans Hospital (Facility), Madison, Wisconsin. In addition, Senator Baldwin asked the OIG to address the following questions:

- Because Patient 1 was receiving VA care less than 72 hours before his death, is the VA classifying his death as a sentinel event?[1] If so, has The Joint Commission been notified and are there further reporting requirements?
- If VA is classifying Patient 1's death as a sentinel event, will that trigger further review?
- Was a 72-hour hold required for Patient 1? If so, why was it not ordered?
- Did the Facility consider initiating a 72-hour hold for Patient 1? If so, why was it not ordered? If not, why was it not considered?

Facility managers classified Patient 1's death from suicide as a sentinel event. When a suicide occurs, Veterans Health Administration (VHA) requires the facility to complete: a peer review[2] if a VA provider saw the patient within 30 days of death, a Behavioral Health Autopsy Program (BHAP) Chart Review,[3] and an Issue Brief.[4] Veterans Integrated Service Network (VISN) 12 additionally requires a root cause analysis[5] (RCA) and The Joint Commission (TJC)[6]

---

[1] Sentinel event is a patient safety event that results in death, permanent harm, or severe temporary harm where an intervention is required to sustain life. https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. (The website was accessed on August 1, 2017).

[2] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. Peer review is an organized process used to evaluate a provider's performance; The OIG reviewed the Facility's peer reviews related to the patients discussed in this report and found Facility managers complied with VHA Directive 2010-025. Because the Facility's peer review process complied with VHA policy, the OIG did not go into detailed discussion of peer reviews in this report.

[3] BHAP Chart Review is a systematic EHR review that includes demographic characteristics, risk and protective factors, use of mental health (MH) and crisis services, diagnoses and symptoms, and clinician notes. https://catalog.data.gov/dataset/behavioral-health-autopsy-program-bhap. (The website was accessed on October 25, 2017).

[4] VHA Directive 1145.01, *Survey Procedures For State Veterans Homes Providing Nursing Home Care and/or Adult Day Health Care*, November 2, 2016. An issue brief is a written form of communication used by the VA medical facilities for immediate notification of specific and unexpected events.

[5] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. Root cause analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls.

notification. The OIG found that required reporting was completed. However, OIG staff found deficiencies in the RCA process that compromised the analysis and recommended actions. The OIG found that the RCA process violated VHA policy by including staff directly involved in Patient 1's care under review by the RCA team. The RCA team included the Nurse Manager (NM) of the mental health inpatient unit (MH IPU) from where Patient 1 was discharged 48 hours prior to his suicide. Further, the OIG found that the MH IPU NM interviewed supervisees and not all staff with knowledge of the events were interviewed. While the OIG understands that having the MH IPU NM on the RCA team would lend insight into the MH IPU's operation, it is possible that, as a process owner, the MH IPU NM's ability to recognize unit problems might have been limited.

Additionally, OIG staff identified concerns with the BHAP Chart Review. In 2015, the Center of Excellence for Suicide Prevention removed two critical BHAP Chart Review questions: patient's barriers to care and possible preventative actions.[7] Therefore, information essential to VHA's identification of barriers to patient care and suicide preventative actions was not collected following Patient 1's death. Given OIG's ongoing monitoring of corrective actions related to *Alleged Inadequate Mental Health Care,* Iowa City VA Health Care System, Iowa City, Iowa, August 3, 2017, the OIG did not make a similar recommendation in this report.

The OIG confirmed that a 72-hour hold was not required for Patient 1 although the Facility's MH IPU psychiatrist could have initiated a treatment director's hold[8] (TDH) for emergency detention. Based on the interview with the MH IPU psychiatrist, OIG staff found that the MH IPU psychiatrist considered a TDH but instead decided to discharge Patient 1. The OIG found that the MH IPU psychiatrist used a medically acceptable rationale in the decision-making process that included consideration of the following factors:

- The resident psychiatrist asked Patient 1's mother to remove all guns from the home.
- Patient 1 agreed to return to the Transitions Clinic[9] (TC) for follow up.
- The MH IPU offered fewer activities and treatment groups over the weekend.

---

[6] TJC is an independent, not-for-profit organization that accredits and certifies nearly 21,000 health care organizations and programs in the United States. https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. (The website was accessed on August 1, 2017).

[7] The Center of Excellence for Suicide Prevention removed the questions and inserted language that staff from the Center of Excellence may place a call to facility SPCs within two weeks of receipt of the Behavioral Health Autopsy Chart Review to ask these questions.

[8] A TDH is an emergency involuntary detention that is initiated by a physician when an MH inpatient is at risk for harm or potential harm to self or others.

[9] TC is an intensive outpatient MH clinic that provides a combination of individual and group therapy sessions three days a week over a four-week treatment course.

- Patient 1 might have a negative reaction to being detained involuntarily on a locked unit and thus become less likely to return to the MH IPU voluntarily in the future if he needed help.
- Patient 1 described his mood as unchanged from his baseline.
- Patient 1 appeared motivated to follow through with his surgery after returning home.

In addition to evaluating the processes that Senator Baldwin requested, OIG staff reviewed Patient 1's first hospitalization that occurred two weeks prior to the hospitalization that closely preceded his death.

The OIG identified additional areas of concern related to his first and second hospitalizations:

- Ethically questionable enrollment in a research study. During Patient 1's first hospitalization, Psychiatrist D initiated a TDH that resulted in a court Settlement Agreement (SA).[10] The SA allowed for discharge to a less restrictive environment but required Patient 1 to comply with MH treatment recommendations for 90 days both while hospitalized and upon discharge. Prior to Patient 1's discharge from this first hospitalization, while under the SA, he was enrolled in a research study. The OIG identified an ethical concern regarding whether Patient 1's consent for research participation could be truly voluntary because he may have considered his participation in the research protocol to be a required part of his treatment.
- Failure to inform the monitoring agency of SA violations. Had staff at the county human services department been notified that Patient 1 violated the terms of the SA, they likely would have petitioned the court the same day for an order continuing hospital detention pending a formal involuntary commitment hearing.
- Deficiencies in discharge planning. Neither Patient 1's family nor the county human services department was involved in Patient 1's discharge planning during his second hospitalization. On the day of Patient 1's discharge (Friday), the social worker left a voice mail informing the county human services department of Patient 1's discharge that day. However, the voicemail was not retrieved until the following Monday. Even if the county human services department agreed with the decision to discharge Patient 1, department staff would have offered services not available at VA such as welfare checks

[10] An SA is an agreement between a patient on a TDH and the court whereby the patient waives his/her right to a probable cause hearing and a final commitment proceeding for up to 90 days, in return for release from detention. As a condition for release, the patient must agree to a MH treatment in a lesser restrictive care setting per the SA.

including suicide risk assessments during the weekend. These resources were not considered in the development of Patient 1's discharge plan. In addition, the OIG found that the Facility's MH IPU policy did not include the VHA requirement for family involvement, if the patient consents, in discharge planning.

- Inadequate post discharge follow-up. On the same day as his discharge from his second hospitalization, Patient 1 complied with the discharge plan and attended several therapy sessions at the TC. The OIG identified that staff missed opportunities to assess Patient 1's MH needs during these clinical encounters. TC staff were reluctant to address Patient 1's behaviors during group sessions for fear of him walking out, and the possibility that he might need to be pursued by staff, which would result in inadequate coverage for the ongoing group session. Prior to and during Patient 1's TC visit, the MH IPU psychiatrist and TC staff were in frequent contact with each other discussing Patient 1's behaviors. In response to the TC staff concerns, the MH IPU agreed to go to the clinic and see Patient 1; however, a personal matter prevented the visit. Although there was an on-duty clinic psychiatrist present, TC staff did not seek further psychiatric consultation and did not complete a suicide risk assessment despite Patient 1's withdrawn behaviors, sullen mood, and high-risk for suicide status.

Patient 1 had a longstanding history of MH problems, and in 2014, another VA facility psychiatrist diagnosed him with a MH disorder. Patient 1's MH disorder predisposed him to suicidal thinking. Patient 1 reported a history of suicidal ideation and attempts dating back to early adolescence and again in 2014. Following Patient 1's treatment at another VA facility, he moved and transferred his healthcare to the Facility.

OIG staff reviewed Patient 1's outpatient MH care at the Facility and evaluated the quality of his outpatient MH care in the 15 months prior to his death. The OIG found deficiencies in his care that may have contributed to the worsening of his MH disorder prior to his suicide.

The OIG identified the following deficiencies by psychiatric clinical pharmacists (PsychCP)[11] in Patient 1's outpatient MH care:

- PsychCP 1 changed a psychiatrist's plan of care for Patient 1 in a way that reduced the specified close level of follow-up and monitoring appropriate for his mood disorder and suicidality.
- PsychCPs 1 and 2 did not schedule Patient 1 per the frequency of standard clinical practice and the psychiatric medication black box warnings.

[11] The three PsychCPs discussed in this report are identified as PsychCP 1, PsychCP 2, and PsychCP 3.

- PsychCPs 1, 2, and 3 did not fully assess Patient 1's MH symptoms or symptom severity. Therefore, sufficient evaluation of Patient 1's response to psychiatric medication did not occur.

The OIG learned of another death by suicide (Patient 2) that occurred 13 months prior to Patient 1's death. In a review of Patient 2's electronic health record, OIG staff found similar MH care deficiencies whereby a PsychCP documented insufficient clinical assessments and management of suicidality.

During the course of the inspection, OIG staff identified system factors underlying these deficiencies. The OIG determined that the Facility did not have a methodology for assigning patients with complex MH care needs to more highly trained psychiatrists. Patients were assigned arbitrarily to a PsychCP or a psychiatrist. For patients with unstable major psychiatric diagnoses, complex presentations, and/or significant dangerousness, a psychiatrist would be the more appropriate primary MH prescriber. Additionally, the Facility did not provide policy or guidance for collaboration between an assigned PsychCP and a psychiatrist when

- Patient care management was beyond the PsychCP's scope of practice,
- Changes occurred in the patient's condition. or
- Referrals to higher levels of care were required.

Further, the OIG found that PsychCPs acted outside of their scope of practice in changing diagnoses and providing psychotherapy. Although PsychCPs described informal collaboration with psychiatrists, the collaboration was insufficient to meet the requirements of PsychCPs' scope of practice. The PsychCPs' independent decision-making without sufficient psychiatrist collaboration or supervision (using supervisory tools such as Ongoing Professional Practice Evaluations) may have contributed to deficient MH care for Patients 1 and 2.

The Facility did not have the VHA requisite relationship and communication infrastructure such as collaborative agreements or consultative arrangements with psychiatrists for the PsychCPs. The OIG determined that the Facility leaders' confidence in the PsychCPs' skills and abilities was because the Facility selected PsychCPs who did well in their programs and who trained at the Facility. Based on the PsychCPs Facility training, managers believed they knew PsychCPs' capabilities.

The OIG made two recommendations to the VISN Director related to institutional disclosures for Patients 1 and 2 as well as an ethics review of Patient's 1 participation in a research study.

The OIG made nine recommendations to the Facility Director related to an expanded evaluation of Patient 1's death, court settlement agreements, revision of the MH unit policy, prescribing practices including adherence to black box warnings, the use of collaborative agreements and assignment of prescribers for patients with complex MH needs, and strengthening the PsychCPs' supervision through Ongoing Professional Practice Evaluations processes.

Comments

The VISN and Facility Directors concurred with recommendations 1–6, 7 (concur in principle), 10, and 11 and provided action plans. The Directors non-concurred with recommendations 8 and 9. (See Appendixes A and B, pages 36–64 for the Directors' comments.) Based on information received from the Facility, the OIG considers recommendation 6 closed. The OIG does not consider recommendations 1–5 and 7–11 closed and will follow-up on the Facility's recently implemented and planned actions until they are completed.

OIG Response to VISN and Facility Directors' Comments

This report addresses the MH care provided to a veteran who died by suicide. The OIG team who conducted and were on site for the review of this veteran's clinical care included experts in MH treatment and consisted of two experienced psychiatrists, one experienced psychologist, one experienced social worker, and one lawyer. This team is fully qualified to review and report on the MH care of veterans. The OIG's efforts are primarily directed at reviewing the quality of care provided to veterans, and in this case the OIG highlighted several deficiencies. In the 15 months prior to the veteran's death, the OIG found deficiencies in the treatment of this patient who received psychiatric medications. These deficiencies in care may have set the stage for progressive worsening of this veteran's MH disorder that ultimately was a factor in his death by suicide. The OIG also found fault in the discharge planning process in that neither the family nor representatives from the county human services department were involved in the process. VA staff failed to notify the local monitoring agency of the patient's settlement agreement violations. There was inadequate post discharge management and follow-up planning given the veteran's mental state at the time of discharge. In addition, the OIG asked VA to review the propriety of enrolling a mentally ill patient in a pharmacologic research study while the patient was under a court-ordered settlement agreement.

During the course of this review and discussions with the clinical pharmacists who were active in this case, the OIG team was surprised to find VA clinical pharmacists making psychiatric diagnostic decisions, deviating from the psychiatrist's recommended treatment strategy, and providing psychotherapy to this patient without supervision from the MH care team documented or reported in the OIG interviews. The Facility did not have a methodology for assigning patients based on complexity of MH care needs, so that patients with unstable psychiatric diagnoses or significant dangerousness can be seen by either a pharmacist or a psychiatrist. Clinical pharmacists have a scope of practice and are not licensed independent practitioners. Wisconsin law anticipates the use of Collaborative Practice Agreements by clinical pharmacists and psychiatrists; the OIG found no indication that these agreements were in use at the Madison VA at the time of the inspection or the events leading up to it. There is no dispute as to the value of clinical pharmacists in the delivery of MH care in general, and the appropriate use of teams of clinicians to address veterans' MH needs is to be applauded. However, the lack of documented effective oversight when combined with a lack of precision in defining which licensed

independent provider will team with the clinical pharmacist(s) assigned to a particular patient, as in this case, can and did result in less than satisfactory medical care.

The VISN Director's response (item 8, pages 37–38) raises an important issue concerning the inspection but, in OIG leadership's view, characterizes the underlying circumstances inaccurately and proposes a response that is not commensurate to the conduct. During the course of OIG's inspection, one of the OIG staff members made an inappropriate, gendered comment before an interview of a panel of female clinical pharmacists. The comment came to the attention of OIG leadership after the clinical pharmacists subsequently complained to the Council of Inspectors General for Integrity and Efficiency (CIGIE). The OIG investigated the matter, confirmed the comment was made, and the staff member was counseled and agreed to attend workplace sensitivity training. The OIG and the staff member involved apologized to the clinical pharmacists for the comment. Although the OIG disagrees with the legal conclusion in your response that the comment constituted an act of harassment, the OIG again expresses regret that the comment was made and apologizes for the distress that it caused to those involved. To provide context to your comments regarding that incident, the OIG includes the letters issued by the OIG and staff member in response to the CIGIE complaint (see pages 65–68).

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

Contents

Abbreviations

BHAP	Behavioral Health Autopsy Program
COS	Chief of Staff
DoD	Department of Defense
ED	emergency department
EHR	electronic health record
FDA	Food and Drug Administration
FY	fiscal year
IPU	Inpatient Unit
MH	mental health
MH IPU	mental health inpatient unit
NCPS	National Center for Patient Safety
NM	nurse manager
OIG	Office of Inspector General
PCP	Primary Care Provider
PsychCP	psychiatric clinical pharmacist
RCA	root cause analysis
SA	Settlement Agreement
SPC	Suicide Prevention Coordinator
SW	social worker
TC	Transitions Clinic
TDH	treatment director's hold
TJC	The Joint Commission
UW	University of Wisconsin
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
WSM	William S. Middleton

Introduction

Purpose

At the request of Senators Tammy Baldwin and Ron Johnson, the VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the care of a patient who committed suicide less than 48 hours after being discharged from the William S. Middleton Memorial Veterans Hospital (Facility), Madison, Wisconsin.

Background

The Facility is located in Madison, Wisconsin, and is part of Veterans Integrated Service Network (VISN) 12. The 129-bed Facility provides tertiary medical, surgical, neurological, and psychiatric care; a full range of outpatient services; and a community living center for approximately 130,000 patients from 15 counties in south-central Wisconsin and 5 counties in northwestern Illinois. This 1b level complexity[12] Facility also operates a primary care clinic, the West Clinic, located in Madison at Research Park,[13] and community based outpatient clinics at Janesville, Baraboo, Beaver Dam, Wisconsin, and Rockford and Freeport, Illinois. The Facility supports a Vet Center in Madison. The Facility is affiliated with the University of Wisconsin's (UW) School of Medicine and Public Health, and is physically connected to the UW's Science Center, which includes the UW Hospital and Clinics.

The Facility offers mental health (MH) services at its main campus, the five community based outpatient clinics, and the West Clinic. These MH services include substance use disorder treatment, inpatient unit (IPU) treatment, integrated care,[14] medication management, and psychotherapy. The Facility offers a psychiatric specialty residency program affiliated with the UW School of Pharmacy. This residency program provides training to become a psychiatric clinical pharmacist (PsychCP) with a focus in the psychiatric treatment of patients in integrated care, outpatient MH, and substance use disorders. The program is accredited by the American Society of Health-System Pharmacists.[15]

---

[12] The facility complexity model is a data driven model that relies on data from VHA corporate databases along with information from VA central office program offices to identify workload and programs at each facility for the purposes of comparing facility complexity. Level 1a facilities are the most complex, and level 3 the least complex.

[13] Research Park is located about three miles from the Facility.

[14] Integrated care is the integration of MH prevention and treatment services into primary care clinics.

[15] American Society of Health-System Pharmacists (ASHP) is an organization with members that include pharmacists, student pharmacists, and pharmacy technicians in all practice settings. Its mission is to help people achieve optimal health outcomes. https://www.ashp.org/About-ASHP. (The website was accessed on December 6, 2017); Post graduate year (PGY) refers to a resident's current year of accredited graduate medical education. The year or grade of the resident is denoted with a numeral after the PGY designation.

Front Door Clinic

The Front Door Clinic is an outpatient MH triage clinic open Monday–Friday from 8 a.m. until 5 p.m. The Front Door Clinic is staffed with three social workers (SW), one prescriber[16] (psychiatrist or PsychCP), and one nurse. The team conducts phone triage and schedules patient intakes; and assesses and treats walk-in patients, Emergency Department (ED) patients, and patients with urgent needs. Patients with substance use and dual diagnosis[17] disorders, however, are seen by the Addictive Disorders Treatment Program triage clinician. Additionally, patients presenting to the Front Door Clinic already assigned to MH teams may be seen by their assigned MH team prescribers. The on-duty Front Door Clinic SW or psychologist completes patient psychosocial intakes. The on-duty prescriber conducts further intakes and provides medication management. The Front Door Clinic staff also facilitate admissions to the MH IPU and substance abuse residential rehabilitation treatment program, as appropriate.[18]

Transitions Clinic

This intensive outpatient MH clinic provides a combination of individual and group therapy sessions that meet three days a week over a four-week treatment course. The Transitions Clinic (TC) is an alternative to MH IPU treatment for patients with acute to sub-acute symptoms of mental illness. Clinic staff consists of two psychiatrists, one PsychCP, one nurse, and two SWs. Group topics include skill building, medication education, and sleep hygiene. In addition to regularly scheduled groups, patients meet weekly with a case manager and a prescriber.

Involuntary Civil Commitment

According to Veteran Health Administration (VHA) policy,[19] "…the Federal Government does not have civil commitment laws…" While involuntary hospital commitment laws vary from state to state, VA facilities must follow the state law where the VA hospital is located for guidance regarding civil commitment laws.

[16] A prescriber is a health care provider whose state licensure and professional scope of practice authorizes the use of medicine for a patient.

[17] Dual diagnosis (also referred to as co-occurring disorders) is a term for when someone experiences a mental illness and a substance use disorder simultaneously. https://www.nami.org/Learn-More/Mental-Health-Conditions/Related-Conditions/Dual-Diagnosis. (The website was accessed on January 8, 2017.)

[18] Substance Abuse Residential Treatment Program (SARRTP) is a residential program designed to provide specialized, intensive treatment for substance use disorders.

[19] VHA Handbook 1160.6, *Involuntary Mental Health Treatment*, September 16, 2013.

The Wisconsin MH Act and Emergency Detention Orders

Chapter 51 of the Wisconsin Statutes ("Mental Health Act" or "Act")[20] governs when a person may be detained involuntarily in a hospital to protect him/her from self-harm, pending formal commitment proceedings. A physician may initiate an emergency involuntary detention, also referred to as a director's hold[21] or a treatment director's hold (TDH), on patients admitted to an IP treatment facility when all of the following conditions are met:

1. The patient is "mentally ill,"
2. The patient is "dangerous" (as defined by statute), and
3. The facility Director, or Designee, reasonably believes the patient is unable or unwilling to cooperate with voluntary treatment.

A patient is considered "dangerous" when there is evidence of any of the following:

- A substantial probability of physical harm to the patient or to others,
- Impaired judgment with a substantial probability of physical impairment or injury to the patient or to others, or
- Behaviors due to mental illness whereby the patient is unable to satisfy basic needs for subsistence so that a substantial probability exists that death, serious physical injury, serious physical debilitation, or serious physical disease will imminently ensue.

When a physician approves emergency detention, the patient may be detained "for a period not to exceed 72 hours after the individual is taken into custody…exclusive of Saturdays, Sundays and legal holidays."[22] A physician must provide a statement that the patient meets the standard for commitment and file a notification of detention with the county court in which the patient was taken into custody. The filing of the statement and notification of detention to the court has the same effect as a petition for commitment. Otherwise, the patient must be released immediately.

[20] Wisconsin Statutes, *Chapter 51 State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act.* Updated July 22, 2017).

[21] According to Facility Memorandum No. 116A-15-09, *Legal Procedures For Involuntary Treatment Of Patients*, April 15, 2015, a Directors Hold is a procedure instituted by the director of a designated psychiatric unit or his/her designee. If an already hospitalized psychiatric inpatient demands to leave, or is not participating in treatment, and/or is judged as having an emergency need for MH treatment regardless of consent, a TDH detains the patient on the locked unit.

[22] Wisconsin Statutes, *Chapter 51 State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act,* Section 51.15 (4) (b). Updated July 22, 2017).

Court Settlement Agreement

A patient detained for self-harm behaviors by a TDH may enter into a court Settlement Agreement[23] (SA) whereby the patient waives his/her right to a probable cause hearing and a final commitment proceeding for up to 90 days, in return for release from detention. As a condition for release, the patient must agree to MH treatment as specified in the SA. The SA conditions must provide for treatment in the least restrictive manner, consistent with the patient's needs. If the patient fails to comply with a term of the SA, the designated county department must notify the county's corporation counsel.[24] The corporation counsel may file a statement of non-compliance with the court, and the court may issue an order of detention, pending a final commitment proceeding.

Commitment Proceeding

After considering evidence at the final commitment proceeding, the court may dismiss the petition and order the patient released, or commit the patient to the care and custody of the county health department for IP or outpatient treatment.

Jefferson County Human Services and Corporation Counsel

In Wisconsin, Jefferson County Human Services provides services for individuals with mental illness and/or alcohol or drug problems within Jefferson County. These services include crisis intake, assessment and treatment planning, counseling and psychotherapy, medication management, monitoring of court SAs, case management, and follow up. Jefferson County's crisis MH team is staffed with a psychiatrist and crisis managers 24 hours per day, 7 days per week. Corporation Counsel is the legal advisor to the County Board; the County Administrator; all County Board committees, commissions and boards; and all department heads. One of Corporation Counsel's governmental responsibilities includes providing legal counsel for the County in MH commitments and guardianship proceedings.

[23] An SA is an agreement between a patient on a TDH and the court whereby the patient waives his/her right to a probable cause hearing and a final commitment proceeding for up to 90 days, in return for release from detention.

[24] County corporation counsel is the legal advisor to the County Board, the County Administrator, all County Board committees, commissions and boards, and all department heads. One of Corporation Counsel's governmental responsibilities includes providing legal counsel for the County in MH commitments and guardianship proceedings.

Sentinel Events

The Joint Commission (TJC)[25] defines a sentinel event as a patient safety event that results in death, permanent harm, or severe temporary harm where an intervention is required to sustain life.[26] TJC considers a sentinel event as "Suicide of any individual...receiving care, treatment, or services in a staffed around-the-clock care setting or within 72 hours of discharge…"[27] TJC requires that organizations review all sentinel events.[28] Although not required, TJC encourages accredited organizations to report sentinel events to TJC.[29] If TJC becomes aware of a sentinel event, the facility is expected to submit a comprehensive systematic analysis and action plan within 45 business days of the event or of becoming aware of the event.

VHA policy requires the facility to immediately investigate and respond to sentinel events and report sentinel events to the National Center for Patient Safety (NCPS)[30] and to the VISN, if required by VISN policy.[31]

Root Cause Analysis

A root cause analysis (RCA) is a specific process used to review all adverse events[32] or close calls.[33] Through interviews and analysis of relevant information, the RCA team aims to identify the basic or contributing performance factors associated with adverse events or close calls. By addressing these identified performance factors, facility managers strive to prevent the same or similar situations from reoccurring.

---

[25] TJC is an independent, not-for-profit organization that accredits and certifies nearly 21,000 health care organizations and programs in the United States. TJC is recognized nationwide as a symbol of quality that reflects an organizations commitment to meeting certain performance standards.

[26] TJC, *Comprehensive Accreditation Manual for Behavioral Health*, January 2017. https://www.jointcommission.org/assets/1/6/SE_2017_CAMBHC.pdf. (The website was accessed on July 19, 2017.)

[27] TJC, *Comprehensive Accreditation Manual for Behavioral Health*.

[28] TJC, *Comprehensive Accreditation Manual for Behavioral Health*.

[29] TJC, *Comprehensive Accreditation Manual for Behavioral Health*.

[30] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired on the last working day of March 2016 and has not yet been updated. The National Center for Patient Safety or NCPS develops and implements VHA's patient safety programs. Authorization for the NCPS is further described in the handbook.

[31] VHA Handbook 1050.01.

[32] Adverse events are unfavorable incidents, therapeutic misadventures (caused by medical mismanagement), iatrogenic (caused by a doctor) injuries, or other adverse occurrences directly associated with health care or healthcare services.

[33] Close calls are events or situations that could have resulted in adverse events but did not, either by chance or through timely intervention.

To ensure integrity of the RCA process, VHA requires facility leaders

> Exclude individuals directly involved in the adverse event or close call under review. In the interest of objectivity, these individuals must not be part of the RCA Team…[34]

However, these individuals should be interviewed because they are likely to have information and knowledge to inform the RCA process.

Clinical Pharmacists

In VHA, the role of the clinical pharmacist may differ substantially based on qualifications, assignment, or scope of practice.[35] VHA clinical pharmacists provide medication management to patients in a variety of clinical settings. Although not independent practitioners, clinical pharmacists function as health care providers[36] with a high level of autonomy and exercise independent decision-making within their scope of practice. However, clinical pharmacists do not diagnose health conditions. Clinical pharmacists may perform comprehensive medication management including prescribing medication (the ability to initiate, modify, continue, and discontinue medication regimens); ordering related laboratory tests and diagnostic studies; and performing physical measurements and objective assessments.[37]

VHA requires that clinical pharmacists' scopes of practice include collaborative medication management agreements with physicians or other independent licensed practitioners.[38] VHA also requires that the clinical pharmacist consult with the collaborating physician when

- Patient care management is beyond the clinical pharmacist's scope of practice,
- Changes occur in the patient's condition, or
- Referrals to higher levels of care are required.

---

[34] VHA Handbook 1050.01.

[35] A provider's scope of practice is a generally defined by state law and outlines what health professionals are permitted to do in their professional practice. Scope of Practice Archive Database (2017). http://www.ncsl.org/research/health/scope-of-practice-overview.aspx. (The website was accessed on December 12, 2017.)

[36] A health care provider is a doctor of medicine or osteopathy, podiatrist, dentist, chiropractor, clinical psychologist, optometrist, nurse practitioner, nurse-midwife, or a clinical social worker who is authorized to practice by the State and perform within the scope of their practice as defined by State law. *Who is considered a Health Care Provider/Practitioner?* https://hr.berkeley.edu/node/3777. (The website was accessed on December 12, 2017.)

[37] VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended June 29, 2017.

[38] VHA Handbook 1108.11(1); An independent licensed practitioner is any individual permitted by law and the facility to provide patient care services independently, such as without supervision or direction, within the scope of the individual's license, and in accordance with individually-granted clinical privileges.

PsychCP

Psychiatric clinical pharmacy is a specialty practice that began in the 1990s with the establishment of a board certification process. Eligibility for certification requires an applicant's graduation from an accredited school of pharmacy; a current active pharmaceutical license; completion of a residency program in psychiatric pharmacy with one additional year of practice or a minimum of four years of practice in psychiatric pharmacy; and passing of a specialty certification examination.[39]

As of January 2016, VHA employed 280 pharmacists with scopes of practice in MH. Of those 280, 82 were board certified as PsychCPs, and 215 completed a residency program[40] in psychiatric pharmacy.[41] PsychCPs were working in psychiatric acute care units, clozapine clinics, primary care MH integration, triage, medication management, and behavioral health interdisciplinary teams.

Psychiatrists

A psychiatrist is a medical doctor who specializes in MH and is qualified to assess both the mental and physical aspects of MH problems. Psychiatric education and clinical training focus on specialized knowledge of the complex relationship between emotional and medical illnesses and the relationships with genetics and family history. Psychiatrists are educated in the evaluation of medical and psychological data, diagnosis, and treatment planning. Psychiatrists diagnose MH conditions using the *Diagnostic and Statistical Manual of Mental Disorders,*[42] which contains descriptions, symptoms, and other criteria for diagnosing mental disorders. Psychiatrists can order or perform a full range of medical laboratory and psychological tests that, combined with discussions with patients, help to understand a patient's emotional, mental, and physical status. Psychiatrists treat patients with a variety of methods including talk therapy, medications, and physical treatments involving electrical or magnetic stimulation.

---

[39] Psychiatric Pharmacists. *American Journal of Psychiatry*, 158(12), p. 2090. https://ajp.psychiatryonline.org/doi/abs/10.1176/appi.ajp.158.12.2090. (The website was accessed on August 3, 2017.)

[40] PGY-2 or second year pharmacy residency programs build on the competencies achieved in PGY-1 residency over 12 months. A PGY-2 residency increases the depth of knowledge related to medication therapy and clinical leadership in the specific area of practice studied. A review of American pharmacy: education, training, technology, and practice. *Journal of Pharmaceutical Health Care and Sciences.* 2016 2:32. (The website was accessed on August 3, 2017.)

[41] Clinical Pharmacy Services In Behavioral Health in the VA

[42] *American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.* Arlington, VA, American Psychiatric Association, 2013.

Training Differences between Psychiatrists and PsychCPs

Length and Type of Training (see Table 1). The practice of psychiatry generally requires four years of undergraduate college education, four years of medical school, and four years of psychiatry residency training. Many psychiatrists obtain additional post-residency fellowship training in subspecialty areas such as substance use disorders or forensics. For accreditation by the Accreditation Council for Graduate Medical Education,[43] psychiatry residencies must provide training that includes at least 12 months full time equivalent of organized, continuous, and supervised outpatient clinical experience. Furthermore, each resident's training must include experience treating specific individual outpatients longitudinally for at least one year.[44] This latter requirement facilitates intensive training in the doctor-patient relationship. Comparatively, the training of PsychCPs includes two–four years of undergraduate college education, four years of pharmacy school, one year general clinical pharmacy internship, and one year of residency in psychiatric clinical pharmacy. There is no specific accreditation requirement as to the amount of time devoted to outpatient practice during the year of psychiatric pharmacy residency.

Table 1: Comparison of Required Minimum Education/Training Years Between Clinical Pharmacists and Psychiatrists

	Psychiatrist	Pharmacist
Undergraduate	4 years	2−4 years
Graduate	4 years	4 years
Clinical Pharmacy Residency	0 years	1 year
Psychiatry Residency	4 years	1 year
Outpatient Full Time Equivalent Clinical Experience	1 year	No specific requirement for accreditation

Source: American Society of Health-System Pharmacists Accreditation Standard for Postgraduate Year Two Pharmacy Residency Programs and Accreditation Council for Graduate Medical Education Program Requirements for Graduate Medical Education in Psychiatry

[43] Accreditation Council for Graduate Medical Education (ACGME) is an independent, not-for-profit, physician-led organization that sets and monitors the professional educational standards for physicians. http://www.acgme.org/About-Us/Overview. (The website was accessed on August 17, 2017.)

[44] ACGME Program Requirements for Graduate Medical Education in Psychiatry, Accreditation Council for Graduate Medical Education. July 1, 2017. https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/400_psychiatry_2017-07-01.pdf. (The website was accessed on December 12, 2017.)

Differences in Specific Elements of Prescriber[45]Training

The focus of outpatient training also differs between psychiatry and psychiatric clinical pharmacy programs, as specified by the respective accreditation requirements. Specifically, the longitudinal outpatient experience required by Accreditation Council for Graduate Medical Education includes "…initial evaluation and treatment of ongoing individual psychotherapy patients...participation in multiple treatment modalities that emphasize developmental, biological, psychological, and social approaches to outpatient treatment,[and]...application of psychosocial rehabilitation techniques..."[46] Psychiatry residents must also receive training in geriatrics, substance use disorders, forensics, and emergency and community psychiatry.[47] The psychiatrist student's ability to formulate a clinical diagnosis is guided by the following requirements:

> The program must formally conduct a clinical skills examination for each resident. This examination should include an annual evaluation of the resident's...ability to provide a relevant formulation, differential diagnosis, and provisional treatment plan…The program must monitor clinical records on major rotations to assess resident competence to...organize a comprehensive differential diagnosis and discussion of relevant psychological and sociocultural issues...[48]

In contrast, the American Society of Health System Pharmacists requirements for second year psychiatric clinical pharmacy residency programs include the following general training activities:

> …participation in the development of individualized medication regimens and treatment plans, ...implementation and monitoring of treatment plans for patients, ...identification and responsibility for resolution of medication-related problems, ...participation as a provider of individual and population-based patient care services and disease state management, initiating and modifying drug therapy based on collaborative practice agreements or other treatment protocols, ... [and] documentation of significant patient care recommendations and resulting actions,

[45] A prescriber is a healthcare provider who has legal and state authority as well as facility privileging to order the use of a medicine or other treatment.

[46] ACGME Program Requirements for Graduate Medical Education in Psychiatry, Accreditation Council for Graduate Medical Education. July 1, 2017, p. 19. https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/400_psychiatry_2017-07-01.pdf. (The website was accessed on December 12, 2017.)

[47] Community psychiatry training includes treatment of persistently and chronically mentally ill patients.

[48] "ACGME Program Requirements for Graduate Medical Education in Psychiatry", Accreditation Council for Graduate Medical Education. July 1, 2017, p. 23. (The website was accessed on December 12, 2017.)

treatment plans, and progress notes in the appropriate section of patients' permanent medical records.[49]

Psychotherapy

Psychotherapy is the treatment of mental illness by talking about problems rather than by using medication. Psychotherapy can also be directed at specific problem behaviors such as nonadherence with prescribed medication regimens that interferes with treatment. Central to most types of psychotherapy is the therapeutic relationship between a patient and a licensed MH professional whereby scientifically validated techniques are applied in an interpersonal context to help patients work through their problems. Cognitive behavioral therapy is a psychotherapeutic treatment with substantial scientific evidence of efficacy in MH disorders. If these treatments do not reduce symptoms, psychiatrists may consider other treatment options such as electroconvulsive therapy.[50]

Suicide Risk

VA/Department of Defense (DoD) *Clinical Practice Guideline for Assessment and Management of Patients At Risk For Suicide*, June 2013 (VA/DoD clinical practice guidelines) state, "Because of the strong association between mental illness and suicide risk, some research suggests that the effective treatment of MH conditions reduces the risk of suicide and may decrease suicide rates."[51] Medications and various psychotherapy treatments have shown effectiveness in reducing MH disorder symptoms and suicidality risk. The VA/DoD clinical practice guidelines[52] state, "Admission to a psychiatric IPU is one of the strongest predictors of subsequent suicide death," and caution that "The risk of suicide in the four weeks after psychiatric IP hospitalization is around 100 times greater than that for the general population." Therefore, it is critical that discharged patients receive immediate, effective, and ongoing follow-up care. VHA requires a patient record flag be placed on the electronic health record (EHR) of patients that providers

[49] ASHP Accreditation Standard for Postgraduate Year Two (PGY2) Pharmacy residency programs, ASHP Pharmacists Advancing Healthcare (2017). https://www.ashp.org/-/media/assets/professional-development/residencies/docs/pgy2-residency-accreditation-standard-June2017.ashx?la=en&hash=FA375984733CEA67F705CB327A635777515EE65E (The website was accessed on December 12, 2017.)

[50] Electroconvulsive therapy (ECT) is a procedure in which small electric currents are passed through the brain, intentionally triggering a brief seizure. ECT seems to cause changes in brain chemistry that can quickly reverse symptoms of certain mental illnesses. http://www.mayoclinic.org/tests-procedures/electroconvulsive-therapy/basics/definition/prc-20014161 (The website was accessed on August 14, 2017.)

[51] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline For Assessment and Management of Patients At Risk For Suicide*, Version 1.0 –June 2013, p. 11.

[52] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline For Assessment and Management of Patients At Risk For Suicide*, Version 1.0 –June 2013, p. 71.

determine to be at high risk for suicide. The purpose of the flag is to communicate to VA staff that the patient is high-risk for suicide when making treatment decisions.[53]

Psychiatric Medications[54]

Specific psychiatric medications can be effective for treating patients with moderate, severe, and chronic MH disorders. These medications reduce symptoms, such as melancholy and exhaustion, and relieve symptoms, such as restlessness, anxiety, sleep problems, and suicidal thoughts. Since 2007, the Food and Drug Administration (FDA) [55] has assigned certain psychiatric medications a black box warning[56] that the medication is associated with an increased risk of suicidality in adults aged 18–24 years during initial treatment (generally the first one–two months).[57] The FDA black box warning does not discourage the prescription of these psychiatric medications as clinically needed; however, it emphasizes that prescribers should both inform patients about the risk of increased suicidality and monitor patients closely during the initial phase of treatment or during a dose change.

Congressional Request

In March 2017, the OIG received inquiries from Senators Tammy Baldwin and Ron Johnson asking for an assessment of the care that a patient received who committed suicide less than 48 hours after being discharged from the Facility. In addition, Senator Baldwin requested evaluation of the following:

- Because the patient was receiving VA care less than 72 hours before his death, is the VA classifying his death as a sentinel event? If so, has TJC been notified and are there further reporting requirements?
- If the VA is classifying the patient's death as a sentinel event, will that trigger further review?

---

[53] VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008. This directive expired July 31, 2013 and has not yet been replaced.

[54] Specific psychiatric medications relieve MH disorders by affecting neurotransmitters—especially serotonin norepinephrine and dopamine, which are brain chemicals. Various psychiatric medications work in slightly different ways and have different side effects. http://www.mayoclinic.org/. (The website was accessed on August 4, 2017.)

[55] FDA is a federal government agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also provides accurate, science-based health information to the public. https://www.usa.gov/federal-agencies/food-and-drug-administration. (The website was accessed on July 10, 2017.)

[56] Black box warning is a type of warning that appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks. https://www.fda.gov/downloads/forconsumers/consumerupdates/ucm107976.pdf. (The website was accessed on July 10, 2017.)

[57] Simon G. An article in *UpToDate.* Last literature review version 19.3: September 30, 2011.

- Was a 72-hour hold required for the patient? If so, why was it not ordered?
- Did the Facility consider initiating a 72-hour hold for the patient? If so, why was it not ordered? If not, why was it not considered?

Scope and Methodology

The OIG initiated the healthcare review on April 10, 2017 and conducted a site visit June 5-8, 2017.

OIG staff reviewed pertinent clinical, administrative, and court documents. OIG staff reviewed applicable medical examiner's laboratory reports and non-VA hospital records. OIG staff reviewed Wisconsin statutes related to emergency detention and civil commitment of MH patients, MH and pharmacy practice regulations, state pharmacists' collaborative practice laws, FDA approved drug labeling, and medical professional journals. OIG staff reviewed accreditation standards for second year resident (PGY-2) pharmacy residency programs and graduate medical education programs. OIG staff reviewed the VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide and the VA's National Center for Ethics in Health Care guidance for informed patient consent.

OIG staff interviewed the subject patient's family; Jefferson County Corporation Counsel; Jefferson County Crisis Services Supervisor; Jefferson County Crisis Case Manager; VA Central Office Clinical Pharmacy Practice Office staff including the Deputy Chief Consultant; and the VISN 12 Pharmacy Executive. OIG staff interviewed the following Facility staff: Chief of Staff; Chief of MH; Associate Chief of Pharmacy; MH Medical Director; MH IPU Director; PGY-2 Psychiatric Pharmacy Director; MH IPU Nursing Manager (NM); MH Psychiatrists; MH SWs; MH Clinical Pharmacists; MH IPU RN; Suicide Prevention Coordinators (SPC); Pharmacy and Therapeutics Chair; Credentialing and Privileging Coordinators; Risk Manager; Patient Safety Manager (PSM); and Organizational Improvement Chief.

OIG staff reviewed VHA and Facility policies and procedures, Facility staffing data, position descriptions, MH clinical pharmacist scope of practice and personnel records, applicable committee meeting minutes, relevant email and instant messages, and the EHRs of Patients 1 and 2. OIG staff reviewed the Facility's internal review[58] documents, Behavioral Health Autopsy Program (BHAP) Chart Review, and communications related to the reporting of the patient's death to TJC and the Facility's corresponding action plan. OIG staff reviewed Facility Strategic Analytics for Improvement and Learning[59] metrics and Facility Suicide Prevention Applications Network[60] data from spring 2015 through spring 2017.

[58] The OIG reviewed the Facility's peer reviews for the patients discussed in this report and found Facility managers complied with VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. Because the Facility's peer review process complied with VHA policy, the OIG did not go into detailed discussion of peer reviews in this report.

[59] Strategic Analytics for Improvement and Learning (SAIL) is a performance model used by VHA with nine quality domains and one efficiency domain. The SAIL model uses a star ranking system to designate a facility's performance in individual measures, domains, and overall quality as compared to other facilities.

[60] Suicide Prevention Applications Network receives data from VHA SPCs in relation to suicide ideation and suicidal behavior of veterans.

OIG staff reviewed Corporate Data Warehouse[61] data from 2015 through 2017; identified patients flagged as high-risk for suicide, patient deaths, hospital admissions, and patient panels of clinical pharmacists and psychiatrists; and evaluated clinical care through EHR review.

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

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

[61] Corporate Data Warehouse is a centralized data repository that contains VHA clinical, administrative, and financial data.

Inspection Results

Issue 1: Did the Facility classify Patient 1's death as a sentinel event because he received VA care less than 72 hours before his death? If so, is further review required?

Facility managers classified Patient 1's death from suicide as a sentinel event.[62] When a suicide occurs, VHA requires the facility to complete: a peer review[63] if a VA provider saw the patient within 30 days of death, a Behavioral Health Autopsy Chart Review,[64] and an Issue Brief.[65] TJC[66] and VA National Center for Patient Safety[67] require an RCA[68] for sentinel events. Facility policy requires the Facility Director and the Organizational Improvement Manager to make a decision about reporting to TJC. The OIG found that Facility managers completed the required reporting and notified TJC of the sentinel event. However, the OIG found deficiencies in the Facility's RCA process that compromised the analysis and recommended actions.

[62] Sentinel event is a patient safety event that results in death, permanent harm, or severe temporary harm where an intervention is required to sustain life. https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. (The website was accessed on August 1, 2017.)

[63] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive expired June 30, 2015 and has not yet been updated. Peer review is an organized process carried out by an individual health care professional or select committee of professionals, to evaluate the performance of other professionals.

[64] BHAP Chart Review is a systematic EHR review that includes demographic characteristics, risk and protective factors, use of MH and crisis services, diagnoses and symptoms, and clinician notes. This data is managed by the VA Suicide Prevention Program and used to inform recommendations for program modifications and identify potential barriers to care. https://catalog.data.gov/dataset/behavioral-health-autopsy-program-bhap. (The website was accessed on October 25, 2017.)

[65] VHA Directive 1145.01, *Survey Procedures for State Veterans Homes Providing Nursing Home Care and/or Adult Day Health Care*, November 2, 2016. Issue brief is a written form of communication used by the VA medical facilities for immediate notification of specific and unexpected events.

[66] TJC is an independent, not-for-profit organization that accredits and certifies nearly 21,000 health care organizations and programs in the United States. TJC is recognized nationwide as a symbol of quality that reflects an organizations commitment to meeting certain performance standards. https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. (The website was accessed on August 1, 2017.)

[67] VA National Center for Patient Safety develops and nurtures a culture of safety throughout VHA, and its goal is the nationwide reduction and prevention of inadvertent harm to patients as a result of their care. https://www.patientsafety.va.gov/. (The website was accessed on December 14, 2017.)

[68] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired the last working date of March 2016 and has not yet been updated. RCA is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls.

Facility policy states that the RCA process[69]

> ...focuses primarily on systems and processes rather than individual performance and digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are analyzed.

The OIG found that the Facility violated VHA and Facility policy.[70] By failing to interview key staff members whose direct knowledge of Patient 1 and the MH IPU's operations were essential to a thorough analysis of factors that preceded Patient 1's death, a process failure occurred.

Behavioral Health Autopsy Program Chart Review

VHA requires that SPCs complete a BHAP Chart Review of all deaths from suicide.[71] BHAP Chart Reviews provide VA's Suicide Prevention Program Office with comprehensive data for tracking and analysis which drives the development of mental health and suicide prevention policy and procedures.

Although Facility leaders reviewed and submitted the BHAP Chart Review as required, the OIG found that in November 2015, the Center of Excellence for Suicide Prevention removed two questions from the review template critical for data analysis and suicide prevention policy development. These two questions inquired about barriers to patient care and possible preventative actions. The template stated that a member of the BHAP national team might call the SPC within two weeks to ask these questions. The Facility SPCs reported that they were not contacted. Therefore, this information was not collected following Patient 1's death.

In August 2017, the OIG published *Alleged Inadequate Mental Health Care, Iowa City VA Health Care System, Iowa City, Iowa*. In this 2017 report, the OIG recommended that the Acting Under Secretary for Health ensure that Facility staff conduct thorough post-suicide reviews to include all information that provides valuable context and details related to the event. Given the OIG's ongoing monitoring of corrective actions related to *Alleged Inadequate Mental Health* Care, Iowa City VA Health Care System, Iowa City, Iowa, August 3, 2017, the OIG did not make a similar recommendation in this report.

[69] Facility Memorandum No. 00-15-05, *Patient Safety Improvement Program*, February 15, 2015.
[70] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired on the last working day of March 2016 and has not yet been updated; Facility Memorandum No. 00-15-05.
[71] Deputy Under Secretary for Health for Operations and Management Memorandum, *Behavioral Autopsy Program Implementation*, December 11, 2012.

Issue 2: If Patient 1's death was a sentinel event, did the Facility notify TJC? If so, are there further reporting requirements?

Facility policy requires that a sentinel event be reported to TJC within five calendar days of knowledge of the event.[72] The OIG found that Facility managers reported Patient 1's death to TJC within one day of their knowledge of the event and later submitted an action plan. TJC required the Facility to provide an update on sustained improvement and reduction of risk during Quarter 4, fiscal year 2017. As of October 2017, the Facility completed one of three follow-up actions and received an extension to complete the other two actions. The Facility also reported Patient 1's death to the NCPS and VISN 12, as required.

Issue 3: Was a 72-hour hold required and/or considered during Patient 1's hospitalization preceding his death?

Although not required, a 72-hour hold may be initiated to involuntarily detain a patient to protect the patient from self-harm. The OIG found that the psychiatrist who discharged Patient 1 (Psychiatrist D) considered a TDH and ultimately determined that a 72-hour hold was clinically contraindicated.

Psychiatrist D's Diagnostic Approach and Rationale for Discharge

Psychiatrist D diagnosed Patient 1 with a severe MH disorder upon his discharge from his first MH IPU hospitalization. Fifteen days later, upon discharge from his second MH IPU hospitalization, Psychiatrist D diagnosed Patient 1 with a different MH condition. Psychiatrist D told OIG staff that this shift in diagnostic perspective was based on the perceived inconsistency of Patient 1's behaviors during his participation in TC compared to his behavior during his second hospitalization, and his unrealistic demands during the hospitalization. Specifically, Psychiatrist D noted that Patient 1 was cooperative and positive in the 1.5 weeks of his TC participation between admissions. However, during the second hospitalization, Patient 1 was angry, isolative, and demanding (for example, wanting wrist surgery that day). Further, Psychiatrist D believed that Patient 1's reason for coming to the MH IPU was fundamentally manipulative in nature, specifically, to get his wrist surgery scheduled more quickly.

During Patient 1's second MH IPU hospitalization, Psychiatrist D contacted the Orthopedics Service in an effort to expedite a surgery appointment. Orthopedics Service staff told Psychiatrist D that Patient 1 had to meet certain conditions for at least six weeks prior to a surgery appointment. The Orthopedics Service staff reported that they had informed Patient 1 about this requirement the month before and assured him that staff would be in contact. Psychiatrist D said that Patient 1 was angry about the Orthopedic Service response and perceived

[72] Facility Memorandum No. 00-15-05.

it as unfair because he had previously received surgery at VHA without meeting certain conditions. MH IPU staff discussed a referral to an IP substance use treatment program with Patient 1 and submitted a consult request to the Facility's outpatient Specialized Outpatient Treatment Program. Patient 1 declined to participate in IP or specialized outpatient treatment programs.

Throughout Patient 1's second MH IPU hospitalization, he reported continued suicidal ideation and did not appear to be responding to IP treatment. Patient 1 remained in his room most of the time and did not participate in therapeutic activities and groups. On the day of discharge, Patient 1 refused to come out of his room to meet with the interdisciplinary team. The Specialized Outpatient Treatment Program SW (SW D) evaluated Patient 1 in his room on the day of discharge. SW D reported that Patient 1 lay in bed with a blanket covering his face for most of the interview. SW D assessed Patient 1 at high-risk for suicide and informed Psychiatrist D prior to Patient 1's discharge.

Psychiatrist D described consideration of the following factors in the decision to discharge Patient 1:

- The resident psychiatrist asked Patient 1's mother to remove all guns from the home.
- Patient 1 agreed to return to TC for follow up.
- The MH IPU offered fewer activities and treatment groups over the weekend that was approaching.[73]
- Patient 1 might have a negative reaction to being detained involuntarily on a locked unit and thus become less likely to return to the MH IPU voluntarily in the future if he needed help.
- Patient 1 described his mood as unchanged from his baseline.[74]
- Patient 1 appeared motivated to follow through with his surgery after returning home.

Therefore, instead of initiating a TDH, Psychiatrist D gave Patient 1 the option to stay through the weekend or to be discharged home that day. Patient 1 chose discharge agreeing to attend his scheduled TC counseling sessions later that day following his discharge.[75] Upon discharge, he complied with the discharge plan, attended the scheduled TC counseling sessions following his release, and then returned home. The following day Patient 1 killed himself.

[73] Patient 1 was admitted on a Wednesday.

[74] The OIG EHR review showed evidence that Patient 1's mood was unstable over the long term.

[75] Patient 1 was discharged on a Friday.

Psychiatrist D considered implementing a TDH, and decided not to do so based on medical judgment. Although with hindsight, it would have been better not to discharge Patient 1, Psychiatrist D had a clear and medically acceptable rationale for doing so. There was no requirement for the TDH apart from Psychiatrist D's best judgment.

Issue 4: Concerns Related to Patient 1's Research Study Enrollment

During Patient 1's first MH IPU hospitalization (nearly three weeks prior to his death) OIG staff identified ethical concerns with Patient 1's enrollment in a medication research study. The OIG found that Psychiatrist D encouraged Patient 1's participation in the research study while Patient 1 was under a TDH. Further, Patient 1's consent for participation in the research study occurred while he was under an SA that required his cooperation with treatment including taking medications as recommended. Because of these circumstances, it was difficult to be confident that Patient 1's consent to the research study was truly voluntary.

For enrollment in clinical treatment research, VHA requires a practitioner to promote a patient's voluntary decision-making during the informed consent process with an absence of undue pressure or coercion in the consent process. Specifically, the patient should be informed he/she is "...free to choose among any recommended treatments and procedures, including no treatment...."[76] However, the patient may have believed that refusing to participate in the research study would be a violation of the SA, which required him to cooperate with medication recommendations of his treating psychiatrist.

Psychiatrist D told OIG staff that Patient 1's first Facility MH IPU hospitalization was a pre-planned admission with SW B and that one of the main objectives was for evaluation of medications. Specifically, Patient 1 was being considered for a specific medication (Medication A) to treat his impulsivity. Following his admission, Patient 1 reported he felt trapped on the MH IPU and wanted to leave. In response to Patient 1's desire to leave, his ongoing suicidal ideation, and suicide attempt three weeks prior, Psychiatrist D initiated a TDH. Psychiatrist D stated that the following morning, Patient 1 began negotiating with the treatment team regarding how to leave the MH IPU as quickly as possible. He was offered Medication A treatment and refused. Psychiatrist D later presented Patient 1 with the option of entering the research study that involved the possibility of taking the same medication, to which he agreed.

Psychiatrist D encouraged Patient 1's participation in the research study while Patient 1 was on the TDH. The OIG also found that the research study coordinator began the research study enrollment process with Patient 1 on the day the SA was signed. OIG staff were unable to determine whether the research study screening occurred before or after Patient 1 signed the

[76] VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, (revised May 22, 2017).

SA.[77] The following day, he was discharged from the MH IPU. Although the SA allowed Patient 1 to receive treatment in the less restrictive environment of an outpatient setting, it required him to comply with all MH treatment recommendations including medications. If Patient 1 did not cooperate with the SA conditions, he would be in violation of the court mandate and would risk involuntary commitment to the MH IPU. Patient 1 may have perceived that the SA required him to participate in the research study because it involved a medication that was being recommended by his treating psychiatrist. As such, Patient 1's ability to provide truly voluntary consent to research participation may have been compromised.

The OIG concluded that offering Patient 1 research study participation while under mandated treatment and after he had already declined Medication A included as one option in the research treatment may have constituted undue pressure for his participation agreement. Furthermore, because Patient 1 knew that his treatment providers wanted him to take Medication A and the SA required him to cooperate with treatment, Patient 1 may have thought his agreement to the research study became a means for him to achieve discharge.

Issue 5: Deficiencies in Discharge Planning and Follow-Up for Patient 1's Second Hospitalization

VHA requires that MH IPU staff initiate and coordinate the discharge plan and follow-up care.[78] Further, if the patient consents, the family must be included in discharge planning. Patient 1's discharge plan for his second MH IPU admission (preceding his death) failed to notify and to involve community stakeholders and family in the discharge planning despite Patient 1's consent to his family's involvement.[79]

Failure to Notify Jefferson County Human Services of Patient 1's Discharge and SA Violations

On the day of discharge (Friday), SW D left a voice mail informing the Jefferson County Case Manager[80] of Patient 1's discharge that day. However, the voicemail was not retrieved until the following Monday. Therefore, the Jefferson County monitoring agency team (including a psychiatrist) for the Patient 1's SA did not have the opportunity to participate in discharge planning. As such, Patient 1's discharge plan did not include services that the county monitoring

[77] The research coordinator documented in the EHR the day after Patient 1 signed the SA that he visited him the day prior to screen for the research study with no notation of time for the first screening visit.

[78] VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013.

[79] The OIG's EHR review showed that the treatment team communicated with Patient 1's mother during his second hospitalization and interviews demonstrated her involvement in Patient 1's episode of care.

[80] The case manager was part of the county monitoring team for Patient 1's SA.

agency could have provided such as case manager welfare checks, medication management assistance, transportation, and suicide risk assessments.

Wisconsin's Assistant Corporation Counsel told OIG staff that the county monitoring agency should be notified when a patient violates SA conditions so that the team can follow-up appropriately, and when indicated, Corporation Counsel can petition for a court hearing to determine if the violation merits hospital detention.

On the day of Patient 1's second hospitalization (the SA was in effect), he cancelled his TC counseling appointment earlier in the day, and the Facility contacted the local police who conducted a welfare check. The police did not report safety concerns, and Patient 1 planned to voluntarily return to the Facility for MH IPU admission that evening. The Facility notified the county agency of Patient 1's appointment cancellation and his plan for voluntary admission. If Patient 1 failed to show for admission, Facility staff reportedly planned to contact the county agency to pursue court action to hospitalize Patient 1. The Assistant Corporation Counsel told OIG staff that Patient 1's cancellation of his TC counseling appointment was not necessarily a violation of the conditions of his SA because the county agency considers extenuating circumstances when appointments are missed.

However, Facility staff did not inform the county agency of other violations of Patient 1's SA. Specifically, neither the TC staff nor the MH IPU providers informed the county agency about Patient 1's SA violations during the week leading up to his second MH IPU hospitalization. As such, Corporation Counsel did not have the opportunity to consider filing a statement of non-compliance with the Court that might have resulted in an order of temporary detention for breach of the SA.

The Assistant Corporation Counsel told OIG staff that Patient 1's SA violations the week prior to his second hospitalization was a "material breach" of his SA conditions. An order of detention on this basis would have obviated the need to prove dangerousness, a showing that would have been required in order to obtain court approval of a second TDH. Had the Jefferson County Human Services been informed of Patient 1's SA violations during Patient 1's second hospitalization, the Corporation Counsel's Office likely would have sought a court order of temporary detention for breach of the SA.

Lack of Family Involvement in Discharge Planning

The MH IPU resident psychiatrist spoke with Patient 1's mother by telephone the day before his discharge and "[r]equested that [the] mother assist with getting guns out of family homes and [ensure] that for the foreseeable future [the] patient does not have access to them." While the resident psychiatrist documented the mother's concern for Patient 1, she did not document any discussion about the specifics of Patient 1's upcoming discharge. In a separate EHR note on the same day, the resident psychiatrist documented meeting with Patient 1, the plan for discharge the following morning, and having spoken to Patient 1's mother about removing guns from the

home. The resident psychiatrist did not document that Patient 1's mother was informed of the planned discharge.

Patient 1's mother learned of her son's planned discharge from a nurse when she visited him the evening prior to his release. According to Patient 1's mother, the nurse informed her that her son was being discharged because Psychiatrist D felt he "was only there to speed up his surgery." Patient 1's mother explained that she was "surprised" about the impending discharge because earlier that day when she called to check on Patient 1 she was told that he only came out of his room to get his medications and that most of the day he remained in bed staring at the ceiling. Patient 1's mother stated that when she went to check on her son after work that night she found him in his room in bed in the dark still staring at the ceiling.

The nurse confirmed telling Patient 1's mother of her son's planned discharge on the evening before his release. The nurse stated that Patient 1's mother did not disagree with the plan for discharge but expressed worry about her son. The nurse reported that Patient 1's mother stated she "had not given up" but that "she made plans for his funeral." The nurse suggested that she call the psychiatrist or a SW the following morning. The nurse reportedly informed the oncoming nurse[81] about Patient 1's mother's concerns. The nurse's shift summary documentation for that evening did not note any concerns raised by Patient 1's mother.

The OIG found that the Facility MH IPU policies did not include guidance for family involvement in patient discharge planning.[82] During the course of the healthcare inspection, OIG staff learned that subsequent to Patient 1's death, the Facility revised the MH IPU practice to include family in the discharge planning process.

Missed Opportunities in Post-Discharge Follow-Up

Patient 1 attended TC counseling sessions the afternoon of his discharge. Around the time of discharge, Psychiatrist D sent a secured electronic message to select TC staff informing them that Patient 1 was being discharged; the threshold for encouraging Patient 1's readmission to the MH IPU should be low; and Psychiatrist D would go to the TC, if needed. One TC staff member wrote back with concern that there was limited staff and should Patient 1 get up and walk out of group for some reason there was no one there to help. Psychiatrist D asked that she be notified when Patient 1 arrived and that she would leave her appointment and be present for the group session. TC staff and Psychiatrist D stayed in close communication as Patient 1 attended counseling sessions that afternoon. TC staff electronically informed Psychiatrist D that although Patient 1 was in session attendance, he appeared angry, watched videos, and looked at

[81] An oncoming nurse is a nurse who is reporting to work for the next shift. The oncoming nurse receives verbal patient reports from the nurse who was on the prior shift duty.

[82] Facility Memorandum No. 116A-15-11, *Inpatient Mental Health Unit (2B) Policies and Procedures*, August 15, 2015.

FaceBook™ on his mobile phone. Psychiatrist D planned to attend the TC group session, but she later electronically communicated with TC staff that a personal matter had prevented her attendance. TC staff informed her that they did not confront Patient 1 in the counseling group for concern that he would leave angrily and there were no staff available to follow him.

Prior to Patient 1's departure from the TC on the day of his discharge, SW C contacted Psychiatrist D with a procedural question and asked if a suicide risk assessment was needed. Psychiatrist D responded "...i [sic] think likely should though I will be otherwise commenting on his discharge paperworks about it." TC staff did not complete a suicide risk assessment that day despite Patient 1's categorization as a high-risk for suicide patient, sullen and isolative behaviors during TC sessions, and recent discharge from MH IPU. Psychiatrist D did not come to the TC to meet with Patient 1 despite her communication of intention to do so. Further, the OIG found no evidence that TC staff sought consultation about their concerns with Patient 1's behaviors with Psychiatrist E who was present at the TC that day and was the assigned covering TC physician.

Issue 6: Deficiencies in Patient 1's Long Term MH Outpatient Care

Patient 1's MH disorder was a longstanding problem that preceded his hospitalizations by nearly two years. This MH disorder can predispose individuals to suicidal thinking and behaviors. The quality of treatment provided over the longer term may have contributed to the progressive worsening of his illness, and the subsequent unsuccessful efforts to manage his MH disorder in more intensive treatment settings.

The OIG found that earlier in the course of his MH outpatient treatment, the PsychCPs assigned as Patient 1's primary MH prescribers did not adequately evaluate his MH disorder or follow up with him at the recommended visit frequency for effective monitoring of his psychiatric medication protocol. Further, PsychCP 1 and SW B did not adhere to Psychiatrist C's original plan of care for Patient 1, and this may have been detrimental to the effectiveness of his MH disorder treatment.

Changed Plan of Care

In September 2015, Psychiatrist C diagnosed Patient 1 with an MH disorder, assessed his suicide risk as high, and recommended "...close f/u [follow-up] during this vulnerable period." Psychiatrist C's plan of care for monitoring Patient 1's mood and suicidality through close follow-up was altered two weeks later when his prescribers changed and PsychCPs were assigned as his prescribers.

Care Deficiencies

- **Incomplete mood assessment**. A psychiatric clinical pharmacy resident (resident) and PsychCP 1 (who was supervising the resident) met with Patient 1. The resident did not fully assess Patient 1's MH disorder. Specifically, the

resident did not assess specific syndromal elements[83] of the MH disorder or the overall severity and/or change since Patient 1's previous visit.

- **Inadequate prescriber follow-up.** The PsychCP resident changed Psychiatrist C's plan of care and scheduled Patient 1 to be seen again in six weeks notwithstanding the recommendation by Psychiatrist C for close follow-up.
- **Inadequate monitoring of a psychiatric medication**. The PsychCP resident increased Patient 1's psychiatric medication dose (Medication B) "to target mood." Despite the black box warning for Medication B[84] and FDA recommendations that call for frequent monitoring through visits after a psychiatric medication dosage change for young adults,[85] Patient 1 was scheduled to be seen again nearly seven weeks later. (See Table 2.)

Additional MH Outpatient Care Deficiencies

- Incomplete Clinical Assessments
    - In early 2016, MH care was provided by PsychCP 2, who met with Patient 1 for the first time and documented, "Vet is 20 minutes late for 30 minute appt. I see him since he has no-showed multiple app[ointmen]ts, but we have very limited time. Choose to discuss his CC [chief complaint] of sleep and address med[ication] non-compliance." In the 30-minute visit, although the patient was being treated with a psychiatric medication, PsychCP 2 did not evaluate the MH disorder being treated other than a notation of "dysthymic" mood on the mental status exam.[86] Patient 1's suicide risk was assessed as moderate.

[83] Syndromal elements are clinical features that define a disorder and include a cluster of symptoms and signs which tend to occur together and are assumed to reflect a common pathophysiology.

[84] Medical literature recommends that clinicians monitor and observe young adults (18–24 years old) with suicidality every one or two weeks after they are started on specific psychiatric medications, and that all patients initiating psychiatric medication therapy should receive follow-up within two to four weeks.

[85] At the time of the events discussed in this report, the FDA recommended that after a psychiatric medication dosage change, patients have seven monitoring visits in the following 12 weeks for youths and adults with major MH disorders. For young adults started on Medication D, the drug labeling recommended weekly monitoring during the first four weeks of treatment, then every other week for the next four weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. http://www.pdr.net. (The website was accessed on July 2017.)

[86] "The mental status exam is a structured assessment of the patient's behavioral and cognitive functioning." *Clinical Methods: The History, Physical, and Laboratory Examinations*. 3rd edition, Chapter 207, David C. Martin, The Mental Status Exam, https://www.ncbi.nlm.nih.gov/books/NBK320/. (The website was accessed on July 10, 2017.)

- In early 2017, two days after Patient 1 presented to the ED, PsychCP 2 telephoned Patient 1 for follow-up. He reported active suicide ideation with no intent or plan. PsychCP 2 offered hospitalization, but Patient 1 declined. PsychCP 2 documented that Patient 1 was unsure what triggered the increase in his suicide ideation and worsening mood and that he denied any specific changes in stressors. PsychCP 2 did not complete a full assessment of Patient 1's MH disorder including an evaluation of specific syndromal elements of the MH disorder or the overall MH disorder severity and/or change since his last visit. PsychCP 2 prescribed Medication C. (See Table 2.)
- Two weeks after prescribing Medication C, PsychCP 2 met with Patient 1 but did not evaluate the MH disorder severity or fully assess the MH disorder's collateral symptoms. PsychCP 2 continued Medication C and prescribed Medication D "for insomnia and possible mood augmentation." (See Table 2.) PsychCP 2 documented that Patient 1 should return to the clinic in one month.
- Nearly two weeks after PsychCP 2 prescribed Medication D for Patient 1, he met with SW B and reported worsening of his MH disorder. SW B assessed Patient 1's suicide risk as high and documented collaboration with PsychCP 2 during the visit. Although an increased dose of Medication C was ordered on the day of Patient 1's visit with SW B, PsychCP 2 did not document collaboration with SW B, an evaluation of Patient 1, or an assessment of MH disorder symptoms.

Table 2: Prescriber Follow-Up Appointments after Antidepressant Dosage Change or Dosing Start

Prescriber	Psychiatric Medication	Dosage Change or Start (Date)	Days Before Follow-Up Appointment with Prescriber	Complete Assessment of MH Disorder
Pharmacy Resident and PsychCP 1	Medication B	Dosage change (Late 2015)	47 days	No
PsychCP 2	Medication C	Medication start (Early 2017)	13 days	No
PsychCP 2	Medication D	Medication start (Early 2017)	30 days	No

Source: VA OIG EHR Reviews

Issue 7: Deficiencies in MH Outpatient Care of an Additional Patient

During the course of the healthcare review, the OIG learned that 13 months prior to Patient 1's death, another Facility patient (Patient 2), a male in his late 40s, died by suicide. Patient 2's MH care was primarily managed by a PsychCP (PsychCP 3), and the OIG found MH care deficiencies similar to those identified in Patient 1's case.

In early 2015, Psychiatrist G evaluated Patient 2 initially and focused on treatment of two MH disorders. Patient 2 told Psychiatrist G that a non-VA psychiatrist diagnosed him with a MH condition and prescribed Medication A, which he was taking at that time. Unable to identify a history of specific behavior, Psychiatrist G questioned the MH diagnosis but continued Medication A due to Patient 2's treatment preference and started a medication (Medication E) for symptoms of an additional MH disorder. Over the next two months, Psychiatrist G saw Patient 2 two more times. In both of these visits, Patient 2 reported suicidal thoughts (ranging from occasional to persistent) although he consistently denied a suicide plan. Patient 2 reported marital strain, which increased his stress and increased his suicide risk level. Two months later during his third visit with Psychiatrist G, Patient 2 stated he was living in a motel with persistent thoughts of suicide. Psychiatrist G assessed Patient 2's suicide risk as moderate and started him on Medication B for depressed mood.

In summer 2015, Patient 2's MH care was reassigned from Psychiatrist G to PsychCP 3 with no documented reason for transfer of care. During his summer visits with PsychCP 3, Patient 2 reported no benefits from Medication B, which was discontinued. He was started on a new medication (Medication G), and then started on another psychiatric medication (Medication F). During Patient 2's visit with PsychCP 3 the following month, he reported no improvement in mood, and PsychCP 3 increased the Medication F dosage and discontinued Medication G.

Patient 2 met with PsychCP 3 three months later. The OIG identified inconsistencies in PsychCP 3's clinical assessment of Patient 2's mood and suicidal ideation during the visit. Patient 2 reported feeling better but with variable sleep. The documentation of the Patient 2's mood and suicidality included:

- Mood was "a little better."
- "…notes no change in mood."
- "Denies SI [suicide ideation]. Some passive thoughts about not being here anymore."
- "…no increase in SI [suicide ideation]…no recent SI [suicide ideation]."

MH care deficiencies during Patient 2's fall 2015 PsychCP visit:

- **Incomplete mood assessment.** PsychCP 3 did not evaluate MH disorder collateral symptoms or complete an assessment of severity of the MH disorder.

- **Insufficient clinical assessment and medication management**. PsychCP 3 provided psychotherapy for 25 of 30 minutes. Psych CP 3 documented that "The therapy (both 1:1 & group) piece of his care seems to be the most important to his recovery at this time—will focus on that while keeping meds [medications] the same for now."
- **Inadequate follow-up**. Patient 2 had reportedly stopped taking Medication A on his own with no indication of how long he had been off this medication prior to this visit. PsychCP 3 discontinued the Medication A prescription, continued Medication F and Medication E with no dosage changes, and assessed Patient 2's suicide risk as low. Despite discontinuation of a medication for mood, suicidal ideation, and Patient 2's reported marital stressors, PsychCP 3 scheduled the follow-up visit for three months later.

Three months later, Patient 2 returned for follow-up with PsychCP 3. During the visit, he described his mood as "blah" and affect was documented as "flat, restricted." Patient 2 reported feeling bored, exhausted, and having difficulty staying asleep.

MH care deficiencies in Patient 2's early 2016 PsychCP visit:

- **Incomplete mood assessment**. No assessment of collateral symptoms of the MH disorder or mood severity was documented.
- **Inadequate suicide assessment**. PsychCP 3's documentation regarding Patient 2's suicidal ideation included inconsistencies such as: "Constant thoughts about hoping it will end soon; Denies any active SI." His suicide risk was assessed as moderate.
- **Inadequate medication management**. PsychCP 3 started a psychiatric medication intended to help with sleep, continued Medication F at the same dose despite worsening mood and flat and restricted affect, and discontinued Medication E due to intermittent compliance.
- **Inadequate follow-up and monitoring of symptoms**. Despite Patient 2's MH disorder presentation, unmanaged symptoms, psychosocial stressors, chronic suicidal ideation, moderate suicide risk, and initiation of medication, PsychCP 3 scheduled the follow-up appointment for "two to three months."

Twelve days after Patient 2's visit with PsychCP 3, Patient 2 died by suicide.

Issue 8: Absence of a Methodology for Prescriber Assignments for Patients with Complex MH Care Needs

During the course of the healthcare inspection, the OIG found that the Facility did not have a methodology for assigning patients with complex MH care needs to more highly trained psychiatrists.

VHA offers specialty care services for particular areas of care in which staff have extensive training and education, such as MH. While the Facility's MH service did offer specialized treatment teams for patients with geriatric needs, addiction disorders, and intensive MH case management needs, OIG staff found that other patients with complex MH disorders might be assigned to PsychCPs as their primary MH care prescribers. Based on psychiatrists' higher level of education and training, the OIG concluded that psychiatrists would be a more appropriate prescriber for patients with complex MH care needs, in particular, Patients 1 and 2.

The VISN 12 Pharmacy Executive stated that having a mechanism in place for acuity changes in MH patients was critical and expressed surprise that the Facility did not have a policy or procedure in place for MH prescriber assignments. The VISN 12 Pharmacy Executive told OIG staff that facilities usually define the patient populations for clinical pharmacists and that in a primary care setting, patients retain their primary care provider (PCP) and are also assigned a clinical pharmacist.

The Facility's Chief of MH told OIG staff that there was not a "system" that determines prescriber assignment of MH patients based on clinical factors such as diagnosis, illness severity, or other care needs. The MH Service Chief told OIG staff that distinguishing between prescribers is not necessary because PsychCPs work closely with MH teams, and psychiatrists are available for consultation, as needed. The MH Service Chief asserted confidence in PsychCPs' skills due to the Facility's hiring process, which primarily selects graduates from the UW training program. The Chief of Staff told OIG staff that PsychCPs followed the direction of care from psychiatrists; that they do not make diagnoses or perform diagnostic work; and that they conduct follow-up work based on a psychiatrist's recommendations.

During the course of the healthcare inspection, the OIG found that in the spring of 2016, the Chief of Staff asked the Chief of MH to develop a Standard Operating Procedure (SOP) to delineate when PsychCPs should seek psychiatrist involvement in a patient's care. The Chief of MH responded that the MH service structure, including opportunities for PsychCP collaboration with psychiatrists, was adequate and therefore declined to develop the SOP. However, the OIG found no evidence that PsychCPs collaborated with psychiatrists as the symptoms of Patients 1 and 2 worsened.

Issue 9: PsychCPs' Non-Adherence to Scope of Practice, Inconsistent Psychiatrist Collaboration, and Lack of Psychiatrist Supervision

The OIG found PsychCPs routinely acted outside of their scope of practice by: (1) modifying or adding a psychiatric diagnosis, and (2) providing psychotherapy. Further, the OIG found that PsychCPs treated patients with complex MH conditions without psychiatrist collaboration or supervision.

PsychCPs Acting Outside of Scope of Practice: Patient 1 and Additional Patients

Diagnosis changes. In fall 2015, Psychiatrist C diagnosed Patient 1 with Psychiatric Disorder 1. Two weeks later, the resident pharmacist and PsychCP 1 amended Patient 1's current primary diagnosis to include Psychiatric Disorder 2 as an alternative diagnosis. All five Facility PsychCPs, including the PGY-2 Psychiatric Pharmacy Residency Director, told OIG staff that changing or adding patient diagnoses was within their scope of practice. To evaluate if PsychCPs were changing psychiatric diagnoses, OIG staff randomly selected and reviewed 10 EHRs of patients assigned to PsychCPs. The OIG found that PsychCPs changed or added a psychiatric diagnosis in three of the 10 patients' EHRs.

Providing psychotherapy. The OIG determined through EHR reviews that PsychCPs documented the provision of psychotherapy to Patients 1 and 2 (see Table 3), a practice that is not within the PsychCPs' scope of practice. Furthermore, PsychCPs documented the provision of psychotherapy for a majority of the time they spent with these patients. (See Table 3.)

Table 3: Psychotherapy and Time Durations Documented by PsychCPs and a PsychCP Resident for Patient 1 and Patient 2

	Prescriber	Dates	Time Spent in Psychotherapy
Patient 1	PsychCP 2	Early 2017	16+ of 30 minutes
	Resident PsychCP	Early 2017	16 of 30 minutes
Patient 2	PsychCP 3	Summer 2015	20 minutes
		Mid-Summer 2015	20 minutes
		Late Summer 2015	25 minutes
		Fall 2015	25 minutes
		Early 2016	25 minutes

Source: VA OIG EHR Reviews

PsychCPs' Role in the Facility's MH Service

The COS stated the Facility had a long history of using Clinical Pharmacists and that he was one of the first people to fully support the integration of the UW Clinical Pharmacist residency program into the MH service. The Chief of MH acknowledged the service's reliance on PsychCPs and the benefit of filling psychiatrist vacancies with PsychCPs. Although previously considered by the Facility, there was not a system in place or a policy to differentially assign patients to psychiatrists or PsychCPs based on MH diagnosis or condition severity. The Chief of MH explained that a system was not necessary because the PsychCPs worked closely with the MH team and had psychiatrists available to consult. The Chief of MH attributed confidence in PsychCPs abilities because the Facility selects "…people who do well in their [training] programs…," who have all trained at the Facility, and that managers are in a "good position to know their capabilities." Based on this perceived confidence, they granted the PsychCPs independence in their clinical practice.

The OIG found that PsychCPs were not assigned particular psychiatrists for collaborative or supervisory relationships as might be expected with similar clinician roles, such as physician assistants. The Chief of MH told OIG staff that Facility leaders had previously reached a consensus that a PsychCP could identify patient concerns and raise them with a psychiatrist. This strategy seems inconsistent with the PsychCPs' limited clinical psychiatric training as well as VHA's guidance[87] that states clinical pharmacists are not considered independent practitioners.

Inconsistent psychiatrist collaboration and consultation. VHA requires that the clinical pharmacist communicate with a collaborating physician, for example, when the patient's condition changes. VHA also requires that a relationship and communication infrastructure exists with collaborating providers.[88] PsychCPs told OIG staff that they might include collaborative information in a progress note and/or add a consulted colleague as a co-signer to the EHR progress note. Furthermore, some PsychCPs told OIG staff that they sought informal consultation at weekly interdisciplinary team meetings when they were unsure about a patient's diagnosis; however, attendance at these meetings was encouraged but not mandatory. The OIG found no evidence in the EHRs examined of this type of informal consultation. With respect to Patient 2, the OIG found that the PsychCP 3 did not attend the weekly team meetings because of scheduling conflicts.

OIG staff spoke with the VISN 12 Pharmacy Executive, who stated that instead of collaborative practice agreements, VA clinical pharmacists may have agreements with individual services such as PC or MH, and that the agreements may be between pharmacists and multiple physicians. The OIG found that the Facility did not have a service agreement between MH and Pharmacy Services. The Facility did not have the formal infrastructure for communication as required by

[87] VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended June 29, 2017.
[88] VHA Handbook 1108.11(1).

VHA policy.[89] Collaborative practice terms were also not included in the PsychCPs' scope of practice.

Lack of PsychCP supervision. The OIG did not find regulatory body, VHA, or Facility requirements for psychiatrists to supervise PsychCPs. Facility MH managers used peer reviewed chart audits, completed as part of PsychCPs' Ongoing Professional Practice Evaluations, as a supervisory evaluation tool.[90] Approximately two years ago, because of an increased PsychCP staff, the Facility psychiatrists discontinued peer reviewing PsychCPs' work.

In the cases of Patients 1 and 2, the OIG did not find documentation of psychiatrists' collaboration in the care provided by PsychCPs, nor was there evidence of regular psychiatric supervision of the PsychCPs' clinical work. The OIG determined that the PsychCPs' independent decision-making without sufficient psychiatrist collaboration or supervision may have contributed to the deficient MH care for Patients 1 and 2.

[89] VHA Handbook 1108.11(1).

[90] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012. Ongoing Professional Practice Evaluation is the ongoing monitoring of privileged providers to confirm the quality of care delivered and to ensure patient safety. Activities such as direct observation, clinical discussions, and clinical pertinence reviews are incorporated into this process.

Conclusion

Patient 1's death was classified as a sentinel event, and the Facility notified TJC within the appropriate time frame. The Facility completed VHA and VISN required reviews in response to a suicide. However, the OIG found that the RCA process violated VHA policy and deficiencies in the RCA process compromised its analysis and recommended actions. Additionally, the OIG identified concerns with the BHAP Chart Review. In 2015, the Center of Excellence for Suicide Prevention removed two critical questions, patient's barriers to care and possible preventative actions, from the BHAP Chart Review. Therefore, information essential to VHA's identification of barriers to patient care and suicide preventative actions was not collected following Patient 1's death. Given OIG's ongoing monitoring of corrective actions related to this same topic in *Hotline Inspection—Alleged Inadequate Mental Health Care, Iowa City VA Health Care System, Iowa City, Iowa*, August 3, 2017, the OIG did not make a similar recommendation in this report.

During Patient 1's second Facility MH IPU admission, a 72-hour hold was not required, although Psychiatrist D could have initiated a TDH. Using a medically acceptable rationale, the MH IPU psychiatrist considered a TDH and decided to discharge Patient 1.

The OIG identified additional areas of concern related to his first and second hospitalizations:

- During Patient 1's first hospitalization, Psychiatrist D initiated a TDH that resulted in a court SA. The SA allowed for discharge to a less restrictive environment but required Patient 1 to comply with MH treatment recommendations for 90 days both while hospitalized and upon discharge. Prior to Patient 1's discharge from this first hospitalization, while under the SA, he was enrolled in a research study. The OIG identified an ethical concern regarding whether Patient 1's consent for research participation could be truly voluntary because he may have considered his participation in the research protocol to be a required part of his treatment.
- The Facility failed to inform the county monitoring agency of SA violations. Had staff at the county monitoring agency been notified of the SA violations, they likely would have petitioned the court the same day for an order continuing hospital detention pending a formal involuntary commitment hearing.
- Deficiencies occurred in Patient 1's discharge planning whereby neither Patient 1's family nor the county agency responsible for monitoring his SA was involved in discharge planning. On the day of Patient 1's discharge (Friday), the social worker left a voice mail informing the county human services department of Patient 1's discharge that day. However, the voicemail was not retrieved until the following Monday. Even if the county human services department agreed with the decision to discharge Patient 1, department staff would have offered

services not available at the Facility such as welfare checks, including suicide risk assessments, during the weekend. These resources were not considered in the development of Patient 1's discharge plan. In addition, the OIG found that the Facility's MH IPU policy did not include the VHA requirement for family involvement, if the patient consents, in discharge planning.

- Inadequate post-discharge follow-up resulted in the failure to evaluate and address Patient 1's MH needs. TC staff did not address Patient 1's behaviors during group sessions for fear of him walking out; the possibility that he might need to be pursued; and not having adequate staff coverage for the group. Prior to and during Patient 1's TC visit, the MH IPU psychiatrist and TC staff were in frequent contact with each other discussing Patient 1's behaviors. In response to TC staff concerns, the MH IPU agreed to go to the clinic and see Patient 1; however, a personal matter prevented the visit. Although there was an on-duty clinic psychiatrist present, TC staff did not seek further psychiatric consultation and did not complete a suicide risk assessment despite Patient 1's withdrawn behaviors, sullen mood, and high-risk for suicide status.
- Patient 1's mood disorder was a longstanding problem that preceded his hospitalizations by many months and predisposed him to suicidal thinking. The quality of his outpatient MH care in the 15 months prior to his death may have contributed to the progressive worsening of his illness prior to his suicide.

A PsychCP changed a psychiatrist's plan of care for Patient 1 in a way that reduced the close level of follow-up and monitoring appropriate for his mood disorder and suicidality. PsychCPs did not schedule Patient 1 per the frequency of standard clinical practice and psychiatric medication black box warnings. PsychCPs' clinical assessments of the MH disorder symptoms and severity were not complete or comprehensive. For Patient 1, MH care deficiencies contributed to inadequate monitoring and evaluation of Patient 1's response to a psychiatric medication.

Patient 2 died by suicide 13 months prior to Patient 1's death with similar MH care deficiencies. His care was managed by a PsychCP whose documentation was insufficient for clinical assessments and management of Patient 2's suicidality. The Facility did not have a methodology for assigning patients with complex MH care needs to more highly trained psychiatrists. Patients were assigned arbitrarily to a PsychCP or a psychiatrist. For patients with unstable major psychiatric diagnoses, complex presentations, and/or significant dangerousness, a psychiatrist would have been the more appropriate assigned prescriber.

The VA has an extensive history of using clinical pharmacists in a variety of clinical settings. Although not independent practitioners, clinical pharmacists function as health care providers with a high level of autonomy and exercise independent decision making within their scope of practice. However, VHA requires that clinical pharmacists' scope of practice includes

collaborative medication management agreements with physicians or other independent licensed practitioners and that clinical pharmacists consult with the collaborating physician when

- Patient care management is beyond the clinical pharmacist's scope of practice,
- Changes occur in the patient's condition, or
- Referrals to higher levels of care are required.

The Facility did not have the VHA requisite relationship and communication infrastructure such as collaborative agreements or consultative arrangements with psychiatrists for the PsychCPs. The OIG found that PsychCPs acted outside of their scope of practice in changing diagnoses, providing psychotherapy, and treating patients with insufficient documentation of collaboration with psychiatrists. The PsychCPs' independent decision-making without sufficient psychiatrist collaboration or supervision may have contributed to the deficient MH care for Patients 1 and 2. Further, the Facility did not provide policy or guidance for collaboration between an assigned PsychCP and a psychiatrist when patient care management was beyond the PsychCPs' scope of practice; changes occurred in the patient's condition; and referrals to higher levels of care were required.

The OIG determined that the Facility leaders' confidence in the PsychCPs' skills and abilities was because the Facility selected PsychCPs who did well in their training programs and who trained at the Facility. Based on the PsychCPs Facility training, managers believed they knew their capabilities. While the OIG acknowledges the value of PsychCPs in MH settings, as with other licensed independent practitioners, physician oversight and collaborative agreements are not only required but also essential to the assurance of quality of patient care.

Recommendations 1–11

1. The Facility Director expands the Facility's Root Cause Analysis of Patient 1's death to include interviews of all key staff by individuals who are not their supervisors; and if additional deficiencies are identified, ensures that Facility managers complete an action plan and monitor compliance.

2. The Veterans Integrated Service Network Director ensures that the Facility Director consult with the Office of Chief Counsel regarding Patient 1 and Patient 2 whether an institutional disclosure is appropriate.

3. The Veterans Integrated Service Network Director ensures an ethics review is completed regarding Patient 1's participation in the research study and provision of guidance on the voluntary participation of patients under court treatment mandates.

4. The Facility Director strengthens processes to ensure that timely notification to county monitoring agencies occurs in cases of court Settlement Agreement violations.

5. The Facility Director strengthens processes to ensure that Facility staff speak directly with and notify the county monitoring agency staff before an inpatient with a court Settlement Agreement is discharged.

6. The Facility Director revises the mental health inpatient unit policy to include family notification with patient consent in discharge planning and ensures that Facility policy is consistent with Veterans Health Administration policy.

7. The Facility Director strengthens processes to ensure that mental health clinical assessments are complete and comprehensive to include a symptom inventory and severity assessment, and monitors compliance.

8. The Facility Director strengthens processes to ensure that prescribers are prescribing psychiatric medications safely including adherence to the black box warnings, and that managers complete electronic health record reviews to monitor compliance.

9. The Facility Director ensures the development of a methodology for the assignment of psychiatrists as prescribers for patients with complex mental health care needs, including patients flagged as high-risk for suicide.

10. The Facility Director strengthens the Ongoing Professional Practice Evaluation process to ensure that psychiatric clinical pharmacists practice within their scope of practice, and monitors compliance.

11. The Facility Director ensures the development of a collaborative agreement and/or policy to address specific conditions that require oversight of psychiatric clinical pharmacists by psychiatrists in the Mental Health Service.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: July 10, 2018

From: Director, VA Great Lakes Health Care System (10N12)

Subj: OIG Draft Report, Healthcare Inspection— Review of Two Mental Health Patients Who Died by Suicide, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

To: Director, Baltimore Office of Healthcare Inspections (54BA)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Healthcare Inspection, Review of Two Mental Health Patients Who Died by Suicide, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin.

2. We are deeply saddened by the deaths of the patients reviewed in this draft report. Patient 1 had an extensive history of moderate to severe MH disorders in his youth. He was loved by his family and friends. He was followed by a multidisciplinary team of licensed health care providers. The professionals who cared for him included a psychiatrist, a social worker, a clinical pharmacist, a nurse, and psychologists. During the two years prior to his death, his healthcare providers called or saw him 40 times (Attachment A). His clinical pharmacist had recently, and correctly, started him on a new medicine that the inpatient psychiatrist reviewed, approved, and did not alter.

3. We take the death of all patients very seriously and have robust processes to review each case with the goal of learning and improving our care. We appreciate the OIG review of the discharge planning process and, after careful review, have revised our policy to ensure staff include family members in discharge planning to the extent patients' consent to their involvement. We appreciate OIG's suggestion for strengthening our Root Cause Analysis (RCA) process and have already interviewed the recommended staff. We will carefully scrutinize membership on future RCAs for potential conflicts of interest. Subsequent to our consultation with the Office of General Counsel, we conducted an institutional disclosure to Patient 1's family. We have asked the Office of Research Oversight – Human Research Protection to review the informed consent process for the research study; the consultation is underway.

4. We acknowledge that documentation in the electronic health record needs to be improved. Missing documentation led the OIG to conclude that a psychiatrist was not actively involved and did not have direct input into the patient's treatment plan. Our experience at Madison is that psychiatrists are integral members of our Mental Health teams, and the treatment plans for all patients are an interdisciplinary team effort

5. Our review of Patient 1's outpatient mental health care demonstrated that his team provided him with comprehensive mental health care. Neither his health care team nor the OIG will ever know all of the factors that set the stage for his worsening MH disorder during the winter of 2017. We understand from the OIG report, the lack of documented collaboration between Mental Health team members and the team psychiatrist led to the impression that the psychiatrist was not involved in his care. We have implemented processes to ensure these documentation gaps are corrected moving forward.

6. The Madison Behavioral Health Interdisciplinary Program (BHIP) provides continuous access to ongoing recovery-oriented, evidence-based, mental health (MH) care for Veterans already receiving MH care, and Veterans new to the VA. The collaborative teams assure same day access and continuity of care for Veterans within established panels using staff who practice at the top of their licensure, and utilize the expertise of all team members. In Madison each BHIP team consists of psychiatrists, psychologists, MH Social workers and Clinical Pharmacy Specialists. We have two large teams consisting of 10-12 FTE each. The two teams share Front Door access and consultation coverage. Veterans are assigned based upon national directives. Each team is co-located for ease of communication. Each team has daily huddles and weekly team meetings. Each team cares for approximately 2000 patients. We agree with the OIG that improved documentation of team decision-making is appropriate.

7. We believe the OIG team would have been enhanced with the addition of a Clinical Pharmacy Specialist (CPS). It seemed the team focused solely on criticism of the work done by the Clinical Pharmacists. Care provided by every other category of clinician was presented without criticism. There is a multitude of evidence to support and define the role of the CPS in team based mental health settings and multiple other practice settings (Attachment B1, B2, B3). In a psychiatric population, the benefits of adding a CPS for both access and quality of care to Mental Health patients has been extensively supported in the literature. A complete summary of clinical pharmacy mental health practice can be found in the VA Pharmacy Benefits Management's (PBM) White Paper entitled *Pharmacist Advanced Practice in Mental Health* (Attachment B-1).

8. Finally, I am disturbed that one of the OIG team members harassed the female clinical pharmacists during the interview process. Inappropriate sexist and demeaning comments by this team member left these professional women feeling demeaned, intimidated, and distressed and set a negative and confrontational tone for the remainder of the review. We believe the impact of this interaction was detrimental to the interview process, and the meeting should have been immediately stopped and rescheduled. None of the OIG team members on the interview panel intervened to

stop the harassment, and they allowed the interview to proceed, despite the obvious intimidation. This conduct is unacceptable.

9. I can be contacted at 708-492-3900 if there are additional questions or if further clarification is needed.

Renee Oshinski
Director, VA Great Lakes Health Care System (VISN 12)

Attachments A, B

Attachment A

Between early 2013 and early 2016, Patient 1 had a total of 20 visits including 11 visits with a Mental Health Social Worker, 2 visits with a Psychologist, 1 visit with a Mental Health RN, 3 visits with a Mental Health Clinical Pharmacist, 2 visits with a Psychiatrist and 1 visit with a Vocational Rehab Counselor. Patient 1 then disengaged with the VA and came back in early 2017. From the start of 2017 until his passing a month and a half later, Patient 1 had a total of 23 visits including 3 visits with a Mental Health Social Worker, 4 visits in the Emergency Department, 4 visits with a MH Clinical Pharmacist, 3 visits with a Psychiatrist, 3 visits with Research, 1 visit with the Addictive Disorders Treatment Program, and 5 visits in Transitions Clinic (multiple disciplines attend), for a total of 43 patient encounters.

Between early 2015 and his passing in early 2016, Patient 2 had 21 visits with a Mental Health Social Worker, 14 visits with a Psychologist, 3 visits with a Psychiatrist, 5 visits with a Mental Health Clinical Pharmacist and 1 Telephone Triage visit for a total of 44 patient encounters.

Attachment B-1

Department of Veterans Affairs
Veterans Health Administration

VHA Pharmacist Advanced Practice in Mental Health

This paper was developed to provide education about VHA Pharmacist Advanced Practice and the history of Clinical Pharmacy Specialist (CPS) integration into outpatient mental health teams. We specifically address concerns raised in the ongoing Office of the Inspector General (OIG) assessment regarding VHA Clinical Pharmacists Practicing in Mental Health (MH). We highlight the history of MH clinical pharmacy practice to include education and training of the clinical pharmacist as well as current trends in practice in VHA and the private sector. VHA has long been recognized as an innovator in clinical pharmacy practice and it is common for practice in specific diseases to first begin in VHA and then slowly expand to the private sector. Although some historical examples of MH pharmacy practice are provided below, unfortunately private sector MH clinical pharmacy practice has not yet caught up to VHA practice. Given the previous willingness of the private sector to adopt successful VHA clinical pharmacy practice models once they have been demonstrated to provide benefit, we are confident VHA's MH practice model will be more widespread outside of VHA at some point in time. This is a critical point that may be unappreciated if attempts are made to validate the appropriateness of VHA clinical pharmacist MH practice using external benchmarking.
NOTE: All hyperlinks contained in this document are internal VA links.

What evidence exists to support advanced patient care roles for pharmacists?
There is extensive literature and validated studies demonstrating that clinical pharmacists deliver equivalent, or in some cases (e.g., anticoagulation) superior, medication management services to patients than some other disciplines.[1-6] These studies, and the long history and experience of VA providers who have worked with clinical pharmacists, have resulted in tremendous confidence and support for the clinical pharmacist to perform complex medication management autonomously, but collaboratively.[6,7] In addition, 50 out of 53 United States jurisdictions grant pharmacists prescribing authority in state pharmacy practice acts, further supporting current VA practice and policy.[8]

What is the history of MH clinical pharmacy practice?
Mental health clinical pharmacy practice was implemented in the late 1960s and early 1970s.[9] From the beginning, MH CPS have demonstrated benefits in both the inpatient and outpatient settings through consultative and direct patient care roles while collaboratively working with members of the MH team. In 1971, the US Public Health Service assigned a clinical pharmacist to a psychiatric unit in Alaska.[10] The psychiatric pharmacist worked with psychiatrists to complete medication histories, educate the treatment team, assist in the selection of optimal medications, and monitor/manage the bothersome side effects of psychotropics commonly used at the time, such as chlorpromazine and lithium. Clinical pharmacists were working not only in psychiatric inpatient and outpatient settings, but also in methadone and disulfiram clinics and mental retardation centers. The clinical pharmacists provided medication management, including the completion of prescriptions, which were pre-signed by psychiatrists.[10,11] Over a 3-year period in eight rural mental health clinics, MH clinical pharmacists successfully maintained large numbers of stabilized psychiatric patients within their communities. The MH clinical pharmacist was a direct provider post-discharge which included comprehensive medication management and prescriptive responsibilities.[12] During this time, business models describing these practice paradigms were developed. This treatment paradigm mirrored some of the collaborative drug therapy management and medication therapy management (MTM) systems commonly employed today. Additional summary of MH clinical pharmacy practice can be found in Appendix A.

Background on VHA Clinical Pharmacy Practice

VHA Clinical Pharmacist Practice is outlined in VHA Handbook 1108.11 Clinical Pharmacy Services. For over 40 years, clinical pharmacists have provided comprehensive medication management and cognitive clinical pharmacy services. VA set national policy for the advanced roles of clinical pharmacists authorized to prescribe medications in 1995. VA Directive 10-95-019, General guidelines for establishing medication prescribing authority for clinical nurse specialists, nurse practitioners, clinical pharmacy specialists, and physician assistants established medication prescriptive authority for CPS along with Advanced Practice Nurses and Physician Assistants. Since this time the role of the CPS has grown into that of a core team member that improves access through the provision of medication management services. CPSs are actively involved in prescribing medications and providing medication management services in key areas where high risk medications are utilized and/or where provider shortages are apparent. Expansion of CPS roles in new and existing areas results in improved system-wide patient access to care. This is achieved by diverting appointments from primary care and specialty care providers, at a lower pharmacist cost, in areas where it has been difficult to locate and hire physician providers. Currently VA employs approximately 8,800 clinical pharmacists, of which 3,910 (45%) possess a Scope of Practice (SOP) with prescriptive privileges serving as an Advanced Practice Provider (APP). The VA pharmacists who possess a SOP are superbly trained with the majority having a doctorate of Pharmacy degree (PharmD), 70% of them having advanced residency training, 39% with advanced board certification and another 11% with additional certifications (such as geriatrics or diabetes certifications). In summary, over 79% have advanced clinical practice training and experience. Throughout VA, clinical Pharmacy Encounters encompassed over 5.6 million direct patient care visits in FY2017. The following statements below describe pharmacist SOP and its authority within VA.

What is included in the VA Pharmacist Scope of Practice (SOP)?

VA Pharmacist SOP is described in Subsection 10 of the VHA Handbook 1108.11 Clinical Pharmacy Services defined for the individual pharmacist by the facility Executive Committee of the Medical Staff (ECMS). The SOP permits a high level of autonomy and independent decision-making when performing the authorized duties and the clinical pharmacist is responsible and accountable for the patient care provided. To be granted prescriptive authority and responsibility, the clinical pharmacist must have experience and expertise in the practice areas and functions, including, but not necessarily limited to, medication management of patients with defined diagnoses, management of medication-related adverse events, ongoing and acute medication monitoring, and collaboration with other healthcare providers for management of new diagnoses. Collaborative medication management entails an agreement wherein pharmacists may perform all facets of comprehensive medication management including the ability to autonomously, as an advanced practice provider under their SOP, initiate, modify, and continue medication regimens, order related laboratory tests and diagnostic studies, perform physical measurements and objective assessments, take independent corrective action for identified drug-induced problems and order consults (e.g., dietician, social work, specialty provider), as appropriate, to maximize positive drug therapy outcomes.

What qualifies the CPS for their position and how is SOP determined at the facility level?

The CPS SOP is obtained through careful review of a pharmacist's qualifications, training, and demonstration of skills and allows for collaborative medication management. The credentialing, but not privileging requirements of VHA Handbook 1100.19 Credentialing and Privileging Handbook apply to the pharmacist with a SOP. Therefore, the clinical pharmacist with a SOP is credentialed in the same manner as other prescribers at the medical center level under the ECMS. CPS are recognized by the facility medical staff bylaws as Advanced Practice Providers (APP) and a highly trained and capable clinical work force. It is important to note that the CPS must meet standards set forth in VA Handbook 5005 [Staffing], Part II [Appointments], Chapter

3[Title 38 Appointments], And Appendix II-G15 [Licensed Pharmacist Qualification Standard]. This Handbook states *"The clinical pharmacy specialist (CPS) functions at the highest level of clinical practice, works independently under their scope of practice as defined by the individual medical center to directly care for patients. A CPS plays a defined role in budgetary execution and serves as a mid-level provider who functions to initiate, modify or discontinue medication therapy and as a consultant for intensive medication therapy management services. This includes, but is not limited to, the following: designing, implementing, assessing, monitoring and documenting therapeutic plans utilizing the most effective, least toxic and most economical medication treatments; helping achieve positive patient centric outcomes through direct and indirect interactions with patients, providers, and interdisciplinary teams in assigned areas; performing physical assessments; and ordering laboratory and other tests to help determine efficacy and toxicity of medication therapy."* The qualifications that each CPS possesses to meet the position standards will differ amongst CPS and will include past clinical experience, board certification, and/or post-graduate residency training. It is important to note that there is no requirement for the CPS to possess a particular type or quantity of qualifications for this position (e.g., there is not a requirement for them to possess board certification or residency training to meet standards of the position), but rather the individual CPS SOP is based on review of all credentials and experience that prepare them for the direct care role.

What type of training and education does the MH CPS possess to prepare them for their role in direct patient care?

There are a wide variety of training and education options that prepare the MH CPS for their role to provide comprehensive medication management services to patients. Many MH CPS have Post Graduate pharmacy residency training that provides them with additional experience in patient assessment, medication management and monitoring beyond their Doctor of Pharmacy degree. The first psychiatry residency was established in 1972 at the University of California San Francisco.[9] Currently, there are approximately 69 Post-Graduate Year 2 (PGY-2) specialty residency programs in psychiatric pharmacy in the United States.[13] Of these, 37 are within the VA. Additionally, there are approximately 4 psychiatric pharmacotherapy-related fellowships (usually 2-year programs) that have a research emphasis.[14] PGY2 training provides the MH CPS with added experience in psychiatric disorders includes clinical problem solving, judgement and decision making, communication and education, medical information evaluation and management, management of patient populations, and therapeutic knowledge. For a detailed timeline of psychiatric residency training, refer to Appendix B. It is important to note and as previously stated, that a CPS is not required to complete a pharmacy residency program for their position but this program will be used as evidence of knowledge and skills in the practice setting.

Is there a recognized board certification program for the MH CPS?

Since 1992, psychiatric pharmacy has been recognized as a specialty by the Board of Pharmacy Specialties (BPS), an independent post licensure specialty certification agency affiliated with the American Pharmacists Association.[9] MH CPS can be considered board eligible or board certified by the BPS. Pharmacists who earn this certification may use the designation of Board Certified Psychiatric Pharmacist (BCPP). Psychiatric pharmacy activities have been defined in detail by BPS under the following key domains: patient management, information management, and health policy and practice management. Each domain is further divided into specific tasks and knowledge requirements. Currently, more than 1,000 pharmacists have earned the BCPP designation.[15] Once this designation has been earned, certification must be maintained by a rigorous requirement of 100 hours of BCPP recertification courses within a 7-year period or by reexamination every 7 years.

Through education, training, clinical experience, and lifelong learning, psychiatric pharmacists become experts in psychiatric pharmacotherapy and possess clinical skills that enable them to independently provide specialized direct patient care that promotes rational medication use. It is important to note and as previously stated, that a CPS is not required to possess board certification for their position but this certification will be used as evidence of knowledge and skills in the practice setting.

What is the role of the MH CPS as a part of the larger MH team?
Mental Health CPS are utilized as mental health providers in general and specialty mental health clinics, behavioral health clinics embedded in primary care, residential rehabilitation facilities, specialty mental health programs, and on inpatient mental health units to improve access, quality and safety. The Patient-Centered Primary Care Collaborative published a resource guide in 2012 entitled "Integrating Comprehensive Medication Management to Optimize Patient Outcomes."[16] This guide outlines how pharmacists promote the safe, appropriate, and effective use of medications with a demonstrated return on investment by providing effective medication management. Specific to a psychiatric population, the benefits of incorporating a MH CPS to improve both access and the quality of care to patients with mental illness has extensively been reported in the literature.[17-27]

In March 2017, the National Council Medical Director Institute, authorized by the National Council for Behavioral Health, published a report titled "The Psychiatric Shortage, Causes and Solutions".[28] The report concluded that the shortage of psychiatrists, training new psychiatrists and increasing the number of psychiatrists by itself, will not be sufficient to improve access and the quality of care. The expanded use of other providers, including MH CPS, who prescribe psychiatric medications is a necessary strategy in the face of the declining number of psychiatrists. Mental Health CPS are another emerging workforce that has special expertise in patients with complex medications regimens, such as those in community mental health. For complex patients and in team-based care, the MH CPS represents a key resource for managing multiple medications. Additional recommendations were related to training programs to incorporate telepsychiatry, integrated behavioral health, team-based care, population health management, collaboration with other psychiatric prescribers, leadership, team building and management. These topics have been well integrated into PGY2 Psychiatric Pharmacy Residency Programs. As part of the psychiatric team or as the psychiatric specialist on a primary care or medical home team, psychiatric pharmacists can provide additional manpower or capacity for an overburdened system, while substantially improving patient care and medication-related outcomes.

How are patients referred for care to the MH CPS?
Referrals for care are outlined in Subsection 8 of VHA Handbook 1108.11 Clinical Pharmacy Services. The method of referral may differ based on the role of the CPS within the specific practice area and facility. The referral method may include standardized templates (e.g., formal chart consults), care coordination agreements (CCA) (formerly known as service agreements), referral of patients from providers or team members through email communication, team or interdisciplinary meetings, clinical chart consults, and population management databases (e.g., clinical dashboards). When a patient is identified for CPS comprehensive medication management services, the patient continues care with their designated primary care provider as well entire MH Team. The MH CPS does not manage the patient independently but rather works as a member of the MH team to manage and treat the conditions of the patient. Their emphasis as a part of the team is in evaluating the appropriateness of the medications prescribed for their MH condition and making appropriate adjustments to the medication treatment plan to ensure the patient meets the overall treatment goals. The facility may delineate the types and ways by which a patient is referred for care through

their facility CCA. This will generally include the method by which communication and referral back to the team will occur once the services are complete.

What is the requirement for collaboration between the MH CPS and other providers caring for the patient?
There is not a requirement for the MH CPS to consult or contact the psychiatrist for patient care that is within the scope of services or functions. For example, the CPS is not required to alert the provider prior to performing medication management actions (e.g., initiating a medication, discontinuing a medication, or changing a medication). In addition, there is not a requirement to designate a specific collaborating provider (or physician) on the individual pharmacist's SOP document nor is there a requirement to have a physician or psychiatrist co-sign the CPS progress notes or orders. Oversight for the CPS SOP is provided through the facility ECMS, therefore the CPS practices in accordance with the processes outlined in the facility medical staff bylaws and in collaboration with the medical staff who reports to the facility Chief of Staff. The CPS however must communicate with the appropriate provider (e.g., psychiatrist on the MH team or referring provider as appropriate) in cases when patient assessment requires a referral to higher levels of care. This would include when any significant changes in the patient's condition occur, the patient requires additional assessment that is outside of the SOP and expertise of the CPS, or when new diagnoses present. During treatment, the CPS uses their clinical judgement and training to communicate relevant information about the condition of referral, generally medication management, in the electronic medical record. However, whenever the CPS comes across issues that are beyond their SOP, they consult in an appropriate fashion with the collaborating provider (e.g., primary or specialty care provider) who is assigned to that patient. This communication maybe through a variety of modalities such as telephone, face to face, or co-signature on progress notes, among other methods. These methods are the same as any other healthcare professionals who provide patient care services as a part of the collaborative team (e.g., social workers, psychologists, nurses, etc.). In addition, the requirements for medical record documentation are the same as other providers as described below.

Does the CPS assess the diagnosis of the patient?
The CPS provides appropriate assessment of the patient's disease states or conditions when they present for patient care. This may include reviewing and ordering appropriate labs to monitor the patient's diseases or conditions, or making objective or subjective assessments of the condition. The Office of Mental Health Services Qualified Levels of Personnel describes the types of services and activities of each team member and how they contribute to the overall care of the Veteran. From this document it is apparent that the CPS performs several different assessments for the Mental Health patient to determine that their treatment plan is appropriate and effective. In the event a change in diagnosis or a new diagnosis is suspected, the CPS is responsible for collaborating with an appropriate team member to determine next steps for management.

How are CPS evaluated for the quality of care they provide (e.g. what are the peer review requirements of the CPS)?
The ongoing quality of care provided by the CPS along with appropriate oversight is outlined in the professional practice evaluation (PPE) (otherwise known as peer review) process delineated in Subsection 17 of VHA Handbook 1108.11 Clinical Pharmacy Services. Pharmacist PPE includes the initial focused professional practice evaluation (FPPE) and ongoing professional practice evaluation (OPPE) and mirrors the process for privileged providers in VHA Handbook 1100.19 Credentialing and Privileging. In addition, the CPS as other clinicians participate in the VA facility VHA Directive 2010-025, Protected Peer Review for Quality Management process when questions regarding the quality of care are identified. These elements hold the CPS to a higher level of accountability than that of clinical pharmacist practicing in the private sector.

What are the medical record documentation requirements for a CPS?
CPS, as with other healthcare providers, are responsible for documenting their patient care encounters to include any review, assessment and plans as appropriate into the patient electronic medical record. CPS, similar to other healthcare providers, abide by VA policy and procedures set forth in VHA Handbook 1907.01, Health Information Management and Health Records, in addition to other relevant VHA and facility policies.

How would limiting CPS practice impact VHA?
In the event VA decided to limit or reduce CPS MH practice under a SOP, PBM believes this would have disastrous consequences with little to no benefit to patient care. PBM is not aware of any evidence that supports claims that there is a lack of communication between clinical pharmacists and their collaborating providers resulting in negative consequences for our Veterans. Currently VA policy does not define MH team based care as each facility must determine how to best accommodate the patient care needs based on the type of team members available as well as their individual expertise and role on the team. While VHA Handbook 1160.01, Uniform Mental Health Services in VA outlines standards for ambulatory mental health care and other MH care services, it does not delineate individual team members roles as a part of the collaborative care team. Teams are expected to leverage the expertise of individual members to provide recovery-oriented, evidence-based treatments for all mental health issues presented by Veterans.

In the event restrictions or reductions of pharmacist SOP occurs, some of the potential impacts would be:

1. If requirements were made to notify the psychiatrist of the care decisions made under the CPS with each encounter, this would result in a significant number of notifications that would negatively impact physician job satisfaction, burnout and time available to see patients. There is no reason to expect this would improve the quality of care.
2. Physicians who work closely with CPS in VA have broad acceptance and reliance on the ability of the CPS to autonomously support for Chronic Medication Management. Mandating additional review requirements will be a disincentive to fully utilize this valuable resource.
3. Scaling back the 6 million patient care visits currently performed by the VA CPS would have tremendous cost implications. These visits have been deemed by providers to be needed to care of the patient and if the CPS was not available to perform these tasks, it would result in providers having to perform these 6 million visits. This could cost the VA an estimated additional $81.7M to $203M dollars annually "If" VA could even hire additional MH providers. (Methodology is cost difference in 30-minute encounter by CPS=$40.50, PCP =$55.63 and Specialist = $78.13)
4. The anticipated costs of additional oversight to the VA system would be staggering to VA and require the VA to divert patient care needs away from specialists and primary care providers with no documented benefits compared to the current system of oversight that is consistent with that of other prescribers. A rough cost estimate if physicians were required to be alerted on all CPS encounters, read and cosign notes = 6M encounters x 3-5 min per note = 300,000 hours = 144 FTEE x $300,000 (avg. salary primary care and specialists) = $43M to the VA

Conclusions
PBM is confident that the current VHA policies and processes which delineate pharmacist SOP and its oversight through the facility medical staff bylaws hold VA pharmacists to a high level and increased frequency of quality review standards as compared to most state practice acts. In addition, PBM has not received any documented evidence that systemic problems exist. As such, PBM recommends no action to be taken to restrict VHA's authority related to pharmacist SOPs nor to require additional documentation of the communication between the pharmacist and the collaborating provider. The PBM Clinical Pharmacy Practice

Office (CPPO) will continue to work with individual facilities to support development of facility CCAs which promote communication and collaboration between the VA CPS and the teams and patients they serve.

Pharmacy Benefits Management Services
March 29, 2018

References

1. Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Miscellaneous%20Documents/USPHS_Report_USSG.PDF
2. Perez A, Doloresco F, Hoffman JM, et al, Economic Evaluations of Clinical Pharmacy Services: 2001–2005. Pharmacotherapy 2008; 28: 285e–323e.
3. Chisholm-Burns MA, Kim Lee J, Spivey CA, Slack M, Herrier RN, Hall-Lipsy E, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. Med.Care 2010 Oct;48(10):923-933.
4. Touchette DR, Doloresco F, Suda KJ, et. al. Economic Outcomes of Clinical Pharmacy Services: 2006-2010. Pharmacotherapy 2014; 34: 771-793
5. Greer N, Bolduc J, Geurkink E, Rector T, Olson K, Koeller E, et al. Pharmacist-Led Chronic Disease Management: A Systematic Review of Effectiveness and Harms Compared With Usual Care. Ann Intern Med. 2016; 165:30-40. doi: 10.7326/M15-3058
6. Rose AJ, McCullough MB, Carter BL, Rudin RS. The Clinical Pharmacy Specialist: Part of the Solution. J Gen Intern Med 2016 DOI: 10.1007/s11606-016-3958-x.
7. Patterson et al. Perceptions of pharmacists' integration into patient-centered medical home teams. Research in Social and Administrative Pharmacy 11 (2015) 85–95.
8. Hill JD, Hill JM, Gentile NJ. A Review of State Pharmacist Collaborative Practice Laws. Am J Health-Syst Pharm. 2016; 73: 1467-72.
9. Stoner SC, Ott CA, Dipaula BA. Psychiatric pharmacy residency training. Am J Pharm Educ. 2010;74(9):163.
10. Chadwick GI. Psychiatric pharmacy residency and services. Military Med. 1976;141(8):537-539.
11. Coleman JH, Evans RL, Rosenbluth SA. Extended clinical roles for the pharmacist in psychiatric care. Am J Hosp Pharm. 1973;30(12):1143-1146.
12. Rosen CE, Holmes CE. Pharmacists' impact on chronic psychiatric outpatients in community mental health. Am J Hosp Pharm 1978;35:704–8.
13. American Society of Health-System Pharmacists. Residency directory [Internet]. Bethesda (MD):American Society of Health-System Pharmacists;2018 [cited 2018 Feb 8]. Available from: https://accred.ashp.org/aps/pages/directory/residencyProgramSearch.aspx
14. College of Psychiatric and Neurologic Pharmacists. Neuropsychiatric fellowships [Internet]. Lincoln (NE):College of Psychiatric and Neurologic Pharmacists;2013 [cited 2018 Feb 8]. Available from: http://cpnp.org/career/fellowships.
15. Board of Pharmaceutical Specialties. BPS psychiatric pharmacy fact sheet [Internet]. Washington (DC):Board of Pharmaceutical Specialties;2018 [cited 2018 Feb 8]. Available from: http://www.bpsweb.org/news/BPSPsychiatricPharmacyFactSheet.pdf.
16. McInnis T, Strand LM, Webb CE. The Patient Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2nd ed. Washington, DC: Patient Centered Primary Care Collaborative, 2012.
17. Al-Jumah KA, Qureshi NA. Impact of pharmacist interventions on patients' adherence to antidepressants and patient-reported outcomes: a systematic review. *Patient Prefer Adherence* 2012; 6: 87-100.
18. Rubio-Valera M, Chen TF, O'Reilly CL. New roles for pharmacists in community mental health care: a narrative review. Int J Environ Res Public Health. 2014;11(10):10967-90.
19. Arterbury A, Bushway A, Goldstone LW. Effect of a pharmacist-led medication education group on hospital readmissions due to medication non-adherence for patients with previous inpatient psychiatric admissions. J Pharm Pract. 2014; 27: 279.

20. Herbert C, Winkler H, Moore T. Outcomes of mental health pharmacist-managed electronic consults at a Veterans Affairs health care system. Mental Health Clinician. 2017; 7 (3): 131-136.
21. Lynum KB, Hill AM. Psychiatric Services: a platform for MTM. *J Pharm Pract* 2015;28:13-20.
22. McKee J, Lee K, Cobb C. Psychiatric pharmacist integration into the medical home. Primary Care Companion CNS Disorders 2013;15(4).
23. Tallian, KB, Hirsch, JD, Kuo, GM. Development of a pharmacist-psychiatrist collaborative medication therapy management clinic. J Am Pharm Assoc (2003). 2012;52(6).
24. Wang I, Dopheide JA, Gregerson P. Role of a psychiatric pharmacist in a Los Angeles "Skid-Row" safety-net clinic. J Urban Health. 2011 Aug; 88(4): 718–723.
25. Nazarian PK, Dopheide JA. Psychiatric Pharmacist Management of Depression in Patients With Diabetes. Prim Care Companion CNS Disord. 2013; 15(5).
26. Cobb CD. Optimizing medication use with a pharmacist-provided comprehensive medication management service for patients with psychiatric disorders. Pharmacotherapy. 2014 ;34(12): 1336-40.
27. Harms M, Haas M, Larew J, DeJongh B. Impact of a mental health clinical pharmacist on a primary care mental health integration team. Mental Health Clinician. 2017; 7(3): 101-105.
28. National Council for Behavioral Health. The Psychiatric Shortage: Causes and Solutions. 2017 Mar 28.

Attachment B-2

Impact of the Mental Health Clinical Pharmacy Specialist

Mental Health Clinical Pharmacy

Role of the Pharmacist in Mental Health and Substance Abuse Disorders. White Paper Draft. Substance Abuse and Mental Health Services Administration Expert Panel. Pending release July 31, 2017.

- **Description:** The Substance Abuse and Mental Health Services Administration (SAMSHA) outlines the need for improving outcomes in mental health care including stigma, access, transitional care, and disparity in mental health services in rural areas. The extensive literature demonstrates numerous ways that pharmacists have been positively involved in providing mental health care to patients as essential members of healthcare teams through a variety of collaborative and interdisciplinary models. The inclusion of a pharmacist on healthcare teams provides benefits in supporting the Triple Aim for improving patient outcomes, patient experiences when encountering healthcare and driving value for medical expenditures. Care delivery models are changing in an effort to improve care for patients with mental illness and substance abuse. This opens up opportunities for pharmacists to provide comprehensive medication management including the Assertive Community Treatment and Behavioral Health Home team-based care models.

National Council for Behavioral Health. The Psychiatric Shortage: Causes and Solutions. 2017 Mar 28.

- **Description:** In March 2017, the National Council Medical Director Institute, authorized by the National Council for Behavioral Health, published a report titled "The Psychiatric Shortage, Causes and Solutions". The report concluded that the shortage of psychiatrists, training new psychiatrists and increasing the number of psychiatrists by itself, will not be sufficient to improve access and the quality of care. The expanded use of other providers, including MH Clinical Pharmacy Specialist (CPS), who prescribe psychiatric medications is a necessary strategy in the face of the declining number of psychiatrists. Mental Health CPS are another emerging workforce that has special expertise in patients with complex medications regimens, such as those in community mental health. For complex patients and in team-based care, the MH CPS represents a key resource for managing multiple medications. Additional recommendations were related to training programs to incorporate telepsychiatry, integrated behavioral health, team-based care, population health management, collaboration with other psychiatric prescribers, leadership, team building and management. These topics have been well integrated into PGY2 Psychiatric Pharmacy Residency Programs

Goldstone LW, DiPaula BA, Caballero J, Park SH, Price C, Slater MZ. Improving medication-related outcomes for patients with psychiatric and neurologic disorders: value of psychiatric pharmacists as part of the health care team. Ment Health Clin [Internet]. 2015;5(1):1-28. DOI: 10.9740/mhc.2015.01.001.

- **Description**: The purpose of this paper is to discuss the impact of psychiatric pharmacists and the ways in which they, as part of a collaborative team, can improve medication related outcomes for patients with psychiatric or neurologic disorders. We describe the expertise and skills of psychiatric pharmacists and the associated positive outcomes for patients with these disorders. Psychiatric pharmacists have **specialized knowledge, skills, and training or substantial experience working with patients with psychiatric or neurologic** disorders. As part of the collaborative team with a physician, psychiatric pharmacists can provide comprehensive medication management (CMM), a direct patient care service, to patients with psychiatric or neurologic disorders. CMM is a standard of care in which all medications for an individual patient are assessed to determine appropriateness, effectiveness, safety, and adherence. Studies have shown that when psychiatric pharmacists are included as part of the collaborative team with a physician, medication-related outcomes for patients with psychiatric or neurologic disorders improve.

McKee J, Lee K, Cobb C. Psychiatric pharmacist integration into the medical home. Primary Care Companion CNS Disorders 2013;15(4).

- **Description:** The purpose of this paper is to describe the importance of integration of psychiatric pharmacists into primary care practices to provide comprehensive medication management as part of an integrated health care team to improve access to care, improve quality of care, decrease costs, and improve provider and patient satisfaction for patients with both serious mental illnesses and chronic medical conditions. Psychiatric pharmacists provide added clinical, economic, and humanistic value to management of diseases that often lead to treatment nonadherence, high resource utilization, and overall poor quality of life.

VA MH Clinical Pharmacy Outpatient Published Literature

Bond CA, Salinger RJ. Fluphenazine outpatient clinics: a pharmacist's role. J Clin Psychiatry 1979;40:501–3.

- **Design:** Retrospective chart review with historic control (before-after design) of twenty-five schizophrenic patients in a VA psychiatric outpatient clinic over a one-year period.
- **Practices:** Pharmacists provided drug monitoring services for approved patients; drug adjustments required psychiatrist approval.
- **Outcomes:**
  - Decrease in hospital readmissions (42 admissions 1 year before intervention vs 3 admissions 1 year after)
  - Decrease of 1332 days of hospitalization
  - Estimated $230,000 savings in inpatient utilization over one year
  - Decrease in side effects reported (38 before intervention vs 4 after)
  - Average decline of 39% in fluphenazine dosage requirements
  - 42% decline in anticholinergic use

Gray DR, Namikas EA, Sax MJ, et al. Clinical pharmacists as allied health care providers to psychiatric patients. Contemp Pharm Pract 1979;2:108–16.

- **Design:** Retrospective chart review with historic control (before-after design) of nineteen psychiatric patients in a VA psychiatric outpatient clinic over a three-month period.
- **Practices:** Pharmacists provided drug monitoring and weekly drug groups; pharmacists permitted to adjust or prescribe drugs under protocol.
- **Outcomes:**
  - Nonsignificant improvement in clinical outcomes
  - Significant decrease in adverse effects (61 before intervention vs 20 after)
  - Significant decrease in number of prescribed drugs (decrease of 1.32 drugs/patient/month)
  - Improvement in patient's drug knowledge (53% score before intervention vs 77% score after)

Parikh M, Ebong EE, Harris E, et al. Evaluation of clinical pharmacy services within the primary care mental health integration model at the Tuscaloosa Veterans Affairs Medical Center. Mental Health Clinician. 2016;6(5):260-5.

Design: Retrospective chart review was conducted on 2 groups of patients. The first group identified veterans enrolled in the PCMHI clinic prior to CPS addition, from April 1, 2012, to March 31, 2013. This group was primarily seen by the behavioral health provider and medication therapy was initiated by the PCP. The second group consisted of patients enrolled in the PCMHI clinic upon fully implementing the Clinical Pharmacy Specialist, from August 1, 2013, to July 31, 2014. This group was seen by both the BHP and the CPS.

- **Practices:** MH CPS provider in VA PCMHI
- **Outcomes:**
  - 60% increase in the number of patients who achieved therapeutic goal
  - 32% decrease in the number of patients discharged to specialty MH clinic post-incorporation of CPS into PCMHI as compared to pre-incorporation of CPS (P = 0.024)

Harms M, Haas M, Larew J, DeJongh B. Impact of a mental health clinical pharmacist on a primary care mental health integration team. Mental Health Clinician. 2017; 7(3): 101-105.

- **Design:** Retrospective chart review looked at 50 patients referred to Primary Care Mental Health Integration (PCMHI) medication management from July 2014 to March 2015.
- **Practices:** Clinical Pharmacy Specialist (Advanced Practice Provider with scope of practice) in Primary Care Mental Health Integration providing comprehensive medication management.
- **Outcomes:**
  - The analysis included 50 patients, which resulted in a total of 156 contacts between July 2014 and March 2015.
  - The mean change in PHQ-9, GAD-7, and PCL-C scores at week 12 as compared to baseline were a decrease of 10 (95% confidence interval [CI], 6.2-13.8, P 0.001), 8 (95% CI, 3.1-12.9, P 0.006), and 14.5 (95% CI, –17.3-46.3, P 0.109).
  - A total of 336 treatment interventions were made, and the overall medication adherence rate was 82.9%.

Herbert C, Winkler H, Moore T. Outcomes of mental health pharmacist-managed electronic consults at a Veterans Affairs health care system. Mental Health Clinician. 2017; 7 (3): 131-136.

- **Design:** This quality improvement project assessed the effectiveness of the e-consult service. Information was collected through a retrospective chart review of STVHCS veterans with the corresponding consult note placed in their chart from May 2014 through December 2015. Numbers of recommendations implemented and veterans maintained in primary care were analyzed as markers of effectiveness. Time and cost savings were secondarily explored.
- **Practices:** Consults to Mental Health Clinical Pharmacy Specialists (advanced practice providers with a scope of practice) manage veterans with uncomplicated mental health conditions in primary care, making specialty mental health providers more available for those who need such services.
- **Outcomes:**
  - A total of 361 consults were submitted for 353 unique patients.
  - Of the 322 patients included in analyses, a total of 301 unique patients (93.5%) were maintained in primary care for at least 3 months.
  - Of the 21 not maintained in primary care, 15 recommendations were implemented; of those maintained in primary care, 271 recommendations were implemented.

Non-VA MH Clinical Pharmacy Outpatient Published Literature

Rosen CE, Copp WM, Holmes S. Effectiveness of a Specially Trained Pharmacist in a Rural Community Mental Health Center. Public Health Reports. 1978; 93:464-467.

- **Design:** Retrospective chart review of thirty outpatients with chronic psychiatric illness in eight community mental health clinics over a three-year period.
  - Control group (148 patients) was treated by other mental health professionals.
- **Practices:** Pharmacist provided case management services such as drug monitoring and educational services, and was permitted to adjust or prescribe drugs under protocol.
- **Outcomes:**
  - Patients reported greater improvement in overall health, with a trend toward greater patient satisfaction.
  - Cost of psychiatrist services was 2.5 times greater than pharmacist services.

McInnis T, Strand LM, Webb CE. The Patient Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2nd ed. Washington, DC: Patient Centered Primary Care Collaborative, 2012.

- **Description:** The Patient-Centered Primary Care Collaborative published a resource guide in 2012 entitled "Integrating Comprehensive Medication Management to Optimize Patient Outcomes." This guide

outlines how pharmacists promote the safe, appropriate, and effective use of medications with a demonstrated return on investment by providing effective medication management.

Finley PR, Rens HR, Pont JT, et al. Impact of a collaborative pharmacy practice model on the treatment of depression in primary care. Am J Health Syst Pharm 2002;59(16):1518-26.

- **Design**: Mental health CPS were included in a multidisciplinary collaborative practice model, working at the juncture between primary care and Psychiatry. In this model, designated PCPs could refer patients with depression to a MH CPS immediately after initiation of an antidepressant. 91 patients received care from CPS while 129 patients received usual care from their PCPs.
- **Practices**: Clinical pharmacy specialists provided medication maintenance (with limited prescribing authority), modified doses under protocol, and provided follow-up patient care services at a clinic.
- **Outcomes**:
  - Higher medication adherence rates (mpr 0.81 vs 0.66; p=0.0005)
  - Greater medication switch rates (24% vs. 5%; p=0.0001)
  - Fewer PCP visits (39% vs 12%; p=0.029)

Finley PR, Rens HR, Pont JT, et al. Impact of a collaborative care model on depression in a primary care setting: a randomized controlled trial. Pharmacotherapy 2003;23(9):1175-85.

- **Design**: Patients in primary care found to have depression were randomized to receive either care from a MH CPS as part of a collaborative care model (n=75) or usual care through their PCP (n=50) over a six-month period.
- **Practices**: Clinical pharmacists provided patient education, drug therapy management, and treatment follow-up.
- **Outcomes**:
  - Higher medication adherence in collaborative care model (76% vs 48%; p=0.038.)
  - Significantly improved patient satisfaction in collaborative care model

Nazarian PK, Dopheide JA. Psychiatric Pharmacist Management of Depression in Patients With Diabetes. Prim Care Companion CNS Disord. 2013; 15(5).

- **Design:** Prospective evaluation of effect of psychiatric pharmacist interventions in 15 patients with depression and diabetes, as reflected by change in PHQ9.
- **Practices:** Psychiatric medication management by a psychiatric pharmacist delivered over 30-60 minute appointments.
- **Outcomes:** Mean change of -9.5 in PHQ9. Response achieved in 89% (9) patients not LTFU, and one-third (3) patients achieved remission.

Wang I, Dopheide JA, Gregerson P. Role of a psychiatric pharmacist in a Los Angeles "Skid-Row" safety-net clinic. J Urban Health. 2011 Aug; 88(4): 718–723.

- **Design:** Retrospective review of records of 48 patients referred to the psychiatric pharmacist over 7 months. PHQ9, CGI-S and CGI-I analyzed.
- **Practices:** One day of clinic per week. Treatment plan coordinated with PCP. 60-75 min initial appointments with 30-45 min follow up appointments.
- **Outcomes:**
  - Two patients achieved remission of depression.
  - Mean change in PHQ9 was -5.7± 5.7 (p=0.02) at the end of the study period.
  - 77% showed improvement (CGI-I score of 1-3) and 11.5% of patients achieved CGI-I score of 1.
  - Two patients worsened and self-D/C'd their medications.
  - PCPs accepted all recommendations made by the psychiatric pharmacist

Tallian KB, Hirsch JD, Kuo GM, et al. Development of a pharmacist-psychiatrist collaborative medication therapy management clinic. J Am Pharm Assoc 2012;52(6):e252-8.

- **Design:** A pharmacist-run Medication Therapy Management clinic was established in collaboration with the Outpatient Psychiatric Services at the University of California San Diego. Analysis included number of patients comanaged, dropout rates, visit duration, and billed minutes over a 20-month period.
- **Practices:** Two board-certified psychiatric pharmacists provided direct patient care three days a week in a clinic setting using a collaborative practice protocol that included pharmacotherapy management, laboratory monitoring, medication counseling, and psychosocial referrals to other providers.
- **Outcomes:**
  - The two pharmacists effectively co-managed 68 patients with major depressive disorder, schizophrenia, schizoaffective disorder and/or bipolar disorder.
  - 82.3% of patients were clinically stable and remained on the pharmacist caseload for the entire 20-month period.
  - Patients had an average of 7.7 visits (total of 491 visits), averaging 26 minutes per visit. Billing was done at $4.82/minute which equaled $84,542.80.

Cobb CD. Optimizing medication use with a pharmacist-provided comprehensive medication management service for patients with psychiatric disorders. Pharmacotherapy. 2014 ;34(12): 1336-40.

- **Design:** Retrospective review and analysis of medication-related data and a return on investment cost analysis. 154 patients with psychiatric disorders referred to pharmacist for comprehensive medication management.
- **Practices:** Medications reviewed by pharmacists and recommendations mailed to patient and physician within 1 week. Patients could follow up as many times as required to resolve medication issues.
- **Outcomes:**
  - 256 CMM visits completed
  - 5.6 drug therapy problems per patient identified
  - Total net cost savings estimated at $90,484.00 with mean savings of $586.55 per patient
  - Cost of providing service estimated at $32,185.93. Return on investment was $2.80 for every dollar spent providing the service.

MH Clinical Pharmacy Inpatient Published Literature

Inoue F. A clinical pharmacy service to reduce psychotropic medication use in an institution for mentally handicapped persons. Ment Retard 1982;20:70–4.

- **Design:** Retrospective chart review with historic control (before-after design) of 680 patients with behavioral disturbances in an institution for mentally handicapped persons over a five-year period.
- **Practices:** Pharmacists performed drug management review (drug monitoring, treatment recommendations), and were permitted to order laboratory tests under protocol.
- **Outcomes:**
  - 45% decrease in number of psychotropic drugs prescribed
  - 50% of patients with improved cognitive function after treatment changes
  - 8% of patients with symptom worsening after treatment changes

Stimmel GL, McGhan WF, Wincor MZ, et al. Comparison of pharmacist and physician prescribing for psychiatric inpatients. Am J Hosp Pharm 1982;39:1483–6.

- **Design:** Retrospective cohort study of 158 prescriptions (120 control) for hospitalized psychiatric patients with various disorders in a small inpatient HMO psychiatric facility.
  - Expert clinical judges graded pharmacist/physician prescribing practices based on prescribing quality guidelines by the American Psychological Association.

- **Practices:** Pharmacists were allowed to prescribe under protocol with the supervision of a physician (certified as prescribers).
- **Outcomes:** Pharmacist prescribing was comparable to physician prescribing for anticholinergics, but significantly better for antipsychotics and antidepressants.

Canales PL, Dorson PG, Crismon ML. Outcomes assessment of clinical pharmacy services in a psychiatric inpatient setting. Am J Health Syst Pharm. 2001;58(14):1309–16.

- **Design:** Prospective cohort study of 45 acute psychiatric inpatients (48 control) in a state psychiatric facility over a six-month period.
- **Practices:** Pharmacists were responsible for attending treatment team meetings, performing baseline assessments and weekly reviews, monitoring for adverse reactions, making pharmacological treatment recommendations, patient/provider education, and discharge counseling.
- **Outcomes:**
  - Improved clinical outcomes
  - Decreased rates of drug-induced adverse effects

Shaw H, Mackie CA, Sharkie I. Evaluation of effect of pharmacy discharge planning on medication problems experienced by discharged acute admission mental health patients. Int J Pharm Pract. 2000;8(2):144–53.

- **Design:** Randomized controlled trial of 51 acute care psychiatric patients (46 control) at a large psychiatric hospital over a 12-week period post-discharge.
- **Practices:** Pharmacists educated patients about their medications, developed discharge summaries for use by community pharmacist, and conducted follow up visits.
- **Outcomes:**
  - Drug knowledge improved and maintained at 12 weeks
  - Increased compliance and fewer medication problems at 12 weeks

Virani A, Crown N. The impact of a clinical pharmacist on patient and economic outcomes in a child and adolescent mental health unit. Can J Hosp Pharm. 2003;56(3):158–62.

- **Design:** Prospective evaluation and retrospective cost analysis of 48 pharmacist interventions in a pediatric mental health setting.
- **Practices:** Pharmacists conducted clinical interventions.
- **Outcomes:**
  - 98% of pharmacist recommendations were implemented.
  - 86% of interventions were assessed as having a positive effect on patient care.
  - 14% decrease in drug cost per patient-day
  - 21% decrease in total drug costs

McKee J, Cleary S. High-risk, high-alert medication management practices in a regional state psychiatric facility. Hosp Pharm. 2007;42(4):323–30.

- **Design:** Historical control study of 551 patients taking lithium, clozapine, or warfarin in a state psychiatric facility over a 21-month period.
- **Practices:** Pharmacists performed enhanced clinical monitoring of laboratory results for high-risk patients taking lithium, clozapine, or warfarin.
- **Outcomes:**
  - Adverse drug reactions decreased from 6% to 3% for lithium, from 2% to 1% for clozapine, and increased from 0 to 0.5% for warfarin.

Dorevitch A, Perl E. The impact of clinical pharmacy intervention in a psychiatric inpatient hospital. J Clin Pharm Ther. 1996;21:45–8.

- **Design:** Prospective evaluation of 109 physician-initiated consultations with a clinical pharmacist over a one-year period.
- **Practices:** Clinical pharmacists provided recommendations regarding drug therapy changes, dosing schedule changes, preventative measures, medication side effects, and laboratory tests or monitoring parameters.
- **Outcomes:**
  - 67.9% of patients exhibited a very satisfactory or satisfactory response to clinical pharmacist recommendations.

Morton WA, Mendenhall AR, Windsor PG, Lydiard B. Clinical psychopharmacy consultations: acceptance of recommendations on an adult inpatient psychiatric unit. Hosp Pharm. 1995;30(9):786–90.

- **Design:** Retrospective evaluation of 135 pharmacist interventions in an adult psychiatric hospital following referral by a physician.
- **Practices:** Pharmacist conducted clinical interventions.
- **Outcomes:**
  - 79% of pharmacist recommendations were implemented.

Attachment B-3

Timeline for the Development of the Mental Health Pharmacy Specialty

Date	Event
1971	Psychiatric pharmacy experiential electives developed – UCSF and University of Tennessee
1972	First psychiatric residency program - UCSF
1973	First psychiatric pharmacy program precepted by a psychiatric pharmacist - UCSF
1973	Two-year postgraduate residency in psychiatric pharmacy created with the US Public Health Service
1974	ASHP established the Advisory Panel on Pharmacy Services in Mental Health Services
1974	ACPE requires all pharmacy colleges and schools to begin offering PharmD degrees
1975	ASHP established the Special Interest Group on Mental Health Pharmacy
1976	Board of Pharmaceutical Specialties (BPS) was created (now called Board of Pharmacy Specialties)
1992	Psychiatric Pharmacy recognized as a specialty by BPS with support from ASHP
1996	Board Certification examination for psychiatric pharmacists (BCPP) administered for the first time
1997	ACPE requirements for PharmD program went into effect
1998	College of Psychiatric and Neurologic Pharmacists (CPNP) founded
2002	The American College of Physicians and the American Society of Internal Medicine jointly published a position paper on the scope of practice for pharmacists.
2005	ASHP Board of Directors approved new Accreditation Standards for Specialized T training
2007	Revised ASHP Psychiatric Pharmacy Practice Standards go into effect, requiring participation in the National Matching Service (NMS) and that all Psychiatric Pharmacy Residency programs be PGY2

VISN Director Comments to OIG's Report

Recommendation 2

The Veterans Integrated Service Network 12 Director ensures that the William S. Middleton Memorial Veterans Hospital Director consult with the Office of Chief Counsel regarding Patient 1 and Patient 2 whether an institutional disclosure is appropriate.

Concur.

Target date for completion: Completed: March 5, 2018

Director Comments

The Office of Chief Counsel was consulted and the Madison VA Hospital completed institutional disclosure. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the Veterans Integrated Service Network 12 Director to ensure that corrective actions have been effective and sustained.

Recommendation 3

The Veterans Integrated Service Network 12 Director ensures an ethics review is completed regarding Patient 1's participation in the research study and provision of guidance on the voluntary participation of patients under court treatment mandates.

Concur.

Target date for completion: August 30, 2018

Director Comments

VISN 12 Network Director requested an ethics review by The VHA Office of Research Oversight Human Research Protections. They have completed a preliminary review of the enrollment of Patient 1 in the study and are completing the findings of their review.

.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: July 10, 2018

From: Director, William S. Middleton Memorial Veterans Hospital (607/00)

Subj: OIG Draft Report, Healthcare Inspection— Review of Two Mental Health Patients Who Died by Suicide, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

To: Director, VA Great Lakes Health Care System (10N12)

1. The following Facility Director's comments are submitted in response to the recommendations in the draft OIG report.
2. I can be contacted at 608-280-7091 if there are additional questions or if further clarification is needed

John J. Rohrer
Director
William S. Middleton Memorial Veterans Hospital

Facility Director Comments to OIG's Report

Recommendation 1

The William S. Middleton Memorial Veterans Hospital Director expands the Root Cause Analysis of Patient 1's death to include interviews of all key staff by individuals who are not their supervisors; and if additional deficiencies are identified, ensures that William S. Middleton Memorial Veterans Hospital managers complete an action plan and monitor compliance.

Concur.

Target date for completion: Completed March 30, 2018

Director Comments

The staff who were not included in the interviews were interviewed. No additional deficiencies were identified. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained.

Recommendation 4

The William S. Middleton Memorial Veterans Hospital Director strengthens processes to ensure that timely notification to county monitoring agencies occurs in cases of court Settlement Agreement violations.

Concur.

Target date for completion: Completed: September 7, 2017

Director Comments

The process change has been implemented as part of the recommendations of the Hospital's Root Cause Analysis. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained.

Recommendation 5

The William S. Middleton Memorial Veterans Hospital Director strengthens processes to ensure that William S. Middleton Memorial Veterans Hospital staff speak directly with and notify the county monitoring agency staff before an inpatient with a court Settlement Agreement is discharged.

Concur.

Target date for completion: Completed: September 7, 2017

Director Comments

The process change has been implemented as part of the recommendations of the local Root Cause Analysis performed on case of Patient 1. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained.

Recommendation 6

The William S. Middleton Memorial Veterans Hospital Director revises the mental health inpatient unit policy to include family notification with patient consent in discharge planning and ensures that the William S. Middleton Memorial Veterans Hospital policy is consistent with Veterans Health Administration policy.

Concur.

Target date for completion: Completed: March 6, 2018

Director Comments

The mental health inpatient unit policy was revised based on the recommendations of the local Root Cause Analysis performed on case of Patient 1. We have included the updated MH Inpatient Unit policy. We request closure of this recommendation**.**

OIG Comments

Based on information received from the Facility, the OIG considers this recommendation closed.

Recommendation 7

The William S. Middleton Memorial Veterans Hospital Director strengthens processes to ensure that mental health clinical assessments are complete and comprehensive to include a symptom inventory and severity assessment, and monitors compliance.

Concur in principle.

Target date for completion: Completed

Director Comments

While we did not note deficiencies in our internal review, there is a National approach to standardize assessments, particularly with respect to suicide risk and severity assessment, and a consistent approach across the enterprise. We judge the quality of mental health assessments through the OPPE/FPPE process and adherence to the national standards for mental health care. It is the judgment of the Mental Health service line, outside reviewers, and the national program office that there were no deficiencies. If the national program office issues new guidelines, we will certainly comply.

It is worth noting that Patient 1 received a documented suicide risk assessment at every one of his 37 clinical visits between 2015 and 2017. The MH screen is performed every 6 months per clinical reminder, it is not required nor is it standard of practice to be performed at every visit. The American Psychiatric Association clinical guidelines do not outline standards for use of systematic inventories of MH disorder symptoms or quantitative assessment of MH disorder severity rating scales and they note that "...the use of rating scales is not yet common practice in clinical settings..."

Patient 2 had 44 patient contacts in the one year he was followed in MH. Each one of his face-to-face visits included a suicide risk assessment. Standard templates were used for the notes. This patient had an MH screening tool administered three times in 2015. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained. Templated standardized assessments are designed to support clinical management decisions. However, the OIG is concerned that overreliance on such tools to the exclusion of other clinical information is detrimental to patient care.

Recommendation 8

The William S. Middleton Memorial Veterans Hospital Director strengthens processes to ensure that prescribers are prescribing psychiatric medications safely including adherence to the black box warnings, and that managers complete electronic health record reviews to monitor compliance.

Non-concur.

Target date for completion: N/A

Director Comments

The Madison VA is committed to the highest standards of medication safety and has many processes already in place to address the intent of the recommendation, which include the use of automated tools in VA's electronic health record (EHR), complying with Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategies (REMS), conducting facility-level Medication Use Evaluations (MUEs) monitoring the use of pain medications as part of VA's Opioid Safety Initiative, ensuring pharmacists are an integral part of the medication use process, conducting peer review activities and various other techniques.

However, in our assessment, the recommendations to 1- ensure adherence to "black box warnings" and 2- to use the electronic health record (EHR) to monitor compliance are neither advisable, nor can they be implemented. A Boxed Warning is part of a drug's official labeling approved by the Food and Drug Administration (FDA). It is designed to call attention to the possibility that a drug can cause serious injury, including death. A Boxed Warning does not mean that a drug cannot be used in a particular way; it is only intended to highlight the possibility that a serious Adverse Drug Event (ADE) can occur.

The use of any drug can result in an ADE and the Boxed Warning serves to alert prescribers to take this possibility into account when making prescribing decisions. Because this specific warning has no prescribing requirements, there is nothing for which provider can "adhere to". Further, because providers take Boxed Warning information into account during the cognitive prescribing decision-making process, there is nothing to extract from the EHR which can be used to conduct a compliance review. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained. The FDA black box warning does not discourage the prescribing of these medications as clinically needed; however, it emphasizes that prescribers should both inform patients about the risk of increased suicidality

and monitor patients closely during the initial phase of treatment or during a dose change. The OIG is concerned that without policy requiring such education and close monitoring, compliance cannot be assured.

Recommendation 9

The William S. Middleton Memorial Veterans Hospital Director ensures the development of a methodology for the assignment of psychiatrists as prescribers for patients with complex mental health care needs, including patients flagged as high-risk for suicide.

Non-concur.

Target date for completion: N/A

Director Comments

This is a National policy issue and not in the Facility Director's control. The methodology for assignment of the prescriber or Mental Health Treatment Coordinator (MHTC) who coordinates the Veteran's treatment plan is defined by VHA Handbook 1160.01 and DUSHOM (10N) Memorandum March 26, 2012, Assignment of Mental Health Treatment Coordinator. These policies were being followed by the Madison VAH staff during the course of Patient 1 and Patient 2's care. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained. The OIG believes that based on our findings at *this Facility*, local leadership should modify processes for patient assignment based on the complexity of the patients' diagnoses.

Recommendation 10

The William S. Middleton Memorial Veterans Hospital Director strengthens the Ongoing Professional Practice Evaluation process to ensure that psychiatric clinical pharmacists practice within their scope of practice, and monitors compliance.

Concur.

Target date for completion: Completed: June 11, 2018

Director Comments

We conduct our OPPEs for clinical pharmacists according to the same standards and processes used for OPPE for all clinical providers. We have reviewed the OPPE process and validated that the method is strong and appropriate. Following the initial OPPE by a clinical pharmacist, the OPPE is reviewed by the mental health service line, including psychiatry. In addition, we have adjusted the OPPE form to have peer assessment of whether care was delivered within the psychiatric clinical pharmacists' scope of practice. We will monitor compliance within the OPPE process. We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained.

Recommendation 11

The William S. Middleton Memorial Veterans Hospital Director ensures the development of a collaborative agreement and/or policy to address specific conditions that require oversight of psychiatric clinical pharmacists by psychiatrists in the Mental Health Service.

Concur.

Target date for completion: Completed: August 2017

Director Comments

Creation of a Care Coordination Agreement was in process beginning April 2017 (prior to the OIG visit), and was finalized August 2017. The Care Coordination Agreement exists with the purpose of establishing the responsibilities, accountability, team collaboration, and resources for the professional activities of the Mental Health CPS. The agreement includes verbiage in accordance with the National Clinical Pharmacy Directive that the Mental Health CPS works within the interdisciplinary team and communicates with a "mental health team member if significant changes in the mental health treatment course occurs, when referrals to higher levels of care are needed, when additional care is needed, or advanced practice patient care management is required that is outside the Mental Health CPS scope." Patients within the mental health service are cared for by a team of Psychiatrists, Social Workers, Psychologists, and Mental Health CPS. We agree that a collaborative agreement between the Pharmacy service line and the Mental Health service line is important for clear delineation of roles and good clinical care. After discussion with Pharmacy and MH Leadership, the Care Coordination Agreement was further revised in February 2018.

In addition, each Mental Health Clinical Pharmacist has a collaborative relationship defined in their scope and signed by the Chief of Mental Health per VHA Handbook 1108.11(1). We request closure of this recommendation.

OIG Response

The OIG does not consider this recommendation closed and will follow up on the recently implemented actions provided by the William S. Middleton Memorial Veterans Hospital Director to ensure that corrective actions have been effective and sustained.

OIG Correspondence[91]

DEPARTMENT OF VETERANS AFFAIRS
INSPECTOR GENERAL
WASHINGTON DC 20420

March 12, 2018

By Email and First-Class Mail

[redacted]
William S. Middleton Memorial Veterans Hospital
2500 Overlook Terrace
Madison, WI 53705

Re: *Complaint Filed with CIGIE Integrity Committee*

Dear Drs. [redacted] and [redacted]:

I write in response to your letter to the Council of the Inspectors General for Integrity and Efficiency (CIGIE) regarding certain comments made by an Office of Inspector General (OIG) employee in advance of your interview with this office in June 2017. It is the policy of the OIG to treat witnesses with appropriate dignity and respect as we conduct our work. I apologize on behalf of our entire organization that we did not meet that standard in this instance.

By letter dated January 11, 2018, the Chair of CIGIE's Integrity Committee forwarded to our office a complaint filed by you and several of your colleagues on December 22, 2017. Inspector General Michael Missal directed me to investigate and respond to your complaint. In turn, I requested that investigators from the OIG's Analysis and Oversight Division (AOD) assist me in researching and responding to your complaint.

Your complaint concerns a statement made by [redacted] an OIG [redacted] who participated in an interview with all of you at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin in June 2017. Your complaint refers to and expands on a similar complaint that Dr. [redacted] previously had filed with CIGIE's Integrity Committee in September 2017. CIGIE forwarded that complaint to the OIG the same month. In October 2017, in response to Dr. [redacted] initial complaint, I spoke with [redacted] and [redacted] acknowledged making a statement about "bachelorettes"—an allusion to the 1970s television program *The Dating Game*—in reference to the three of you that was consistent with the statement described by Dr. [redacted] in her complaint.[1] At that time, I counseled [redacted] about the importance of avoiding any language that is or may be viewed by others as inappropriate or demeaning and to always consider how [redacted] statements may be heard by and impact others.

Following receipt of your more detailed and expanded complaint in January, I again spoke to [redacted] about the interview and requested that [redacted] provide a written statement of the events

[1] [redacted] said that [redacted] comment was made in an attempt, albeit misguided, to light-heartedly explain that, because the interview was going to be audio-recorded and there were three interviewees, it was important that each interviewee identify herself by name before answering so that the record was clear.

[91] The redactions applied to this document are pursuant to *Freedom of Information Act* exemptions 6 and 7(C), which protect personal privacy. The public interest in the conduct of government operations was balanced against the identifying information of third parties. The information was on an issue collateral to the report, which was sufficiently disclosed without identifying the third parties.

[redacted]

at issue. Joe Oliver, the Director of AOD, also contacted each of you by telephone on February 21, 2018 to obtain any additional relevant information, and AOD obtained statements from each of the OIG staff other than [redacted] who participated in the interview. This process confirmed the basic facts concerning [redacted]'s statement as alleged in your complaint and adduced no additional relevant information.

Your December 2017 complaint to CIGIE also alleged that the interview was conducted in an "unnecessarily intimidating way" and showed "clear personal bias and impairment … and lack of respect" for pharmacists and non-MD professionals. These allegations do not appear to be directly related to the statement made by [redacted] Moreover, I understand the substance of the interview was conducted by team members other than [redacted] Your complaint does not provide detail concerning the aspects of the interview itself that you found to reflect a bias in favor of physicians over pharmacists. Of course, it is the nature of the OIG's work sometimes to ask difficult questions, and a core issue in this inspection involved the appropriate role of non-MD professionals in prescribing medications in certain mental health contexts. AOD staff reviewed the audio recording of the interview itself and found it to be conducted in a professional and respectful manner. The OIG is therefore unable to address those aspects of your complaint further.

That said and to be clear, the OIG agrees that reference to VA professionals in any context, particularly in the context of a potentially difficult OIG inspection interview, as "bachelorettes" is inappropriate and we regret that it happened.

In light of the additional detail and context of your recent complaint concerning [redacted]'s inappropriate comments, and in addition to the counseling conducted with [redacted] in the fall of 2017, [redacted] has agreed to complete a workplace sensitivity training course. Also, enclosed is a letter of apology from [redacted] In order to help ensure that a similar issue does not recur, Inspector General Missal will remind all OIG staff at an upcoming town hall meeting of his expectation that OIG employees treat all VA employees with dignity and respect in connection with our oversight duties.

The OIG regrets and apologizes for the comments [redacted] made during your OIG interview and we thank you for bringing this matter to our attention.

Regards,

C. A. Wilber

Christopher A. Wilber
Counselor to the Inspector General

[redacted]

March 12, 2018
Page 3 of 3

Enclosure

cc (by email only): [redacted] Chair, CIGIE Integrity Committee
[redacted]

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington DC 20420

March 9, 2018

[redacted]
Department of Veterans Affairs
William S. Middleton Memorial Veterans Hospital
2500 Overlook Terrace
Madison, WI 53705

Dear Doctors:

I am very sorry for the bachelorette comment I made at the beginning of your OIG interview. That was a very poor and misguided attempt to lighten the mood in advance of what I anticipated could be a challenging interview. After much introspection, I understand that any unnecessary reference to the gender or marital status of an interviewee is not acceptable. I also understand that game show references are beneath your dignity and the dignity of formal OIG interviews. Please know that I never intended to disrespect or demean any of you, or to cause any of you discomfort or added stress. You all are very accomplished professionals and valued members of the VA mental health treatment community. I have learned a valuable lesson from this incident and will not repeat my mistake in the future. I hope each of you can accept my heart-felt apology.

Best Wishes,
[redacted]

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Inspection Team	Lauren Olstad, MSW, LCSW Team Leader Medina Hudson-Odoi, RN, MSN, CNM Terri Julian, PhD Alan Mallinger, MD Vanesa Masullo, MD Misty Mercer, MBA Andrew Waghorn, JD
Other Contributors	Felicia Burke Nicholas DiTondo, BA Laura Dulcie, BSEE Jason Reyes Natalie Sadow, MBA Elizabeth Whidden, ARNP Michele Wilt, MBA, BSN

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Great Lakes Health Care System (10N12)
Director, William S. Middleton Memorial Veterans Hospital (607/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Tammy Baldwin, Ron Johnson
U.S. House of Representatives: Sean P. Duffy, Mike Gallagher, Glenn Grothman, Ron Kind, Gwen Moore, Mark Pocan, Paul D. Ryan, James F. Sensenbrenner

OIG reports are available at www.va.gov/oig.