



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Mental Health
Clinical Pharmacists in
Veterans Health
Administration Facilities



The mission of the Office of Inspector General is to serve veterans and the public by conducting effective oversight of the programs and operations of the Department of Veterans Affairs through independent audits, inspections, reviews, 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

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess Veterans Health Administration (VHA) facilities' utilization of clinical pharmacists who work under a scope of practice in a mental health outpatient care setting.¹ On August 1, 2018, the OIG published a report that identified risks to patients if mental health care provided by clinical pharmacists is not properly monitored.² In that report, the OIG made recommendations pertaining to clinical oversight of clinical pharmacists and formal collaborating agreements between clinical pharmacists and independent providers at one medical facility. The seriousness of the risks identified in the prior report led the OIG to initiate a broader review of clinical pharmacists' practice in mental health outpatient care settings.

Clinical pharmacists have advanced specialized education and training that allows them to provide comprehensive medication management that includes resolving patient medication nonadherence and assisting patients in achieving medication-related therapeutic goals.

Clinical pharmacists are not licensed independent practitioners (LIPs) and therefore must work in collaboration with LIPs who have prescriptive authority. Collaboration is outlined in a collaborative practice agreement, which identifies the collaborating LIP(s) with prescriptive authority. The types of services clinical pharmacists may provide are requested within a scope of practice by the individual clinical pharmacist, reviewed and recommended by the relevant service chief(s) and by a facility's executive committee of the medical staff, and then approved by the medical facility director.

The role of clinical pharmacists with a scope of practice in the mental health specialty practice area has been a focus of expansion for VHA in recent years. The OIG acknowledges the value of clinical pharmacists in the delivery of health care in general and the inclusion of clinical pharmacists within teams of clinical providers to address veterans' mental health needs. As VHA expands and increases its use of mental health clinical pharmacists (MHCPs), it is imperative that there are collaborating agreements in place and that scopes of practice clearly delineate duties and are standardized to maximize patient safety and reduce potential vulnerabilities. A lack of collaborating agreements, or nonspecific or unstandardized scopes of practice, may allow MHCPs to provide care independently for patients, leading to increased risk to patients' safety.

¹ Not all VHA clinical pharmacists work under a scope of practice due to types of duties performed. However, in this report, the OIG focuses on clinical pharmacists who work under a scope of practice.

² VA OIG Report, *Review of Two Mental Health Patients Who Died by Suicide, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin* (Report No.17-02643-239).

OIG staff randomly sampled 19 of 119 VHA facilities with at least one MHCP, reviewed relevant national and facility policies, and interviewed MHCPs, chiefs of pharmacy and mental health services lines, as well as VHA Pharmacy and mental health national policy leaders.

The OIG identified the following issues regarding MHCPs:

- Facility Pharmacy and mental health chiefs, as well as MHCPs, misidentified the autonomy (independence level) of MHCPs. Additionally, facilities' bylaws lacked clarity regarding MHCPs' independence levels.
- VHA policy and program office instruction conflicted regarding whether collaborating agreements were required at facilities, which resulted in a lack of formalized processes for MHCPs to collaborate and communicate with LIPs for clinical support.
- VHA policy requires an oversight structure, and individual facilities determine how to utilize MHCPs. VHA leaders acknowledged there was no provision in VHA policy for MHCP oversight by a specific physician who reviewed an MHCP's care.
- Facilities' scopes of practice were inconsistent in describing delegated duties that were specific to the mental health outpatient practice area.
- VHA policy is insufficient to ensure that the chief of the mental health service reviews and endorses MHCPs' scopes of practice when MHCPs who deliver patient care are not organizationally aligned under mental health services.
- Facilities generally lacked a process that included documentation of the mental health chiefs' review and recommendation of MHCP's scopes of practice as evidenced by the absence of signature lines in 14 of 19 facilities.
- Facilities lacked a clear and standardized referral process that would ensure, prior to treatment, that a defined diagnosis for treatment was conveyed to the MHCP and that involvement of an LIP with prescriptive authority was considered during assessment of a patient to determine appropriateness for referral to an MHCP.
- VHA policy does not require that a process is defined to consider a patient's clinical complexity or when it is appropriate to refer patients to MHCPs.
- VHA and facilities policies lacked guidance to instruct MHCPs on when or how to refer patients to a higher level of mental health care.

The OIG made nine recommendations to the VHA Under Secretary for Health related to issues of MHCP autonomy, collaboration and communication with a collaborating provider, scope of practice, and patient referrals.³

Comments

The Under Secretary for Health concurred with recommendations 1, 3, 5–7; concurred in principle with recommendations 4 and 9; and provided action plans. The Under Secretary for Health non-concurred with recommendations 2 and 8. (See Appendix A, pages 28–37 for the Executive in Charge’s comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.

OIG Response to Executive in Charge, Office of the Under Secretary for Health, Comments

The Under Secretary for Health’s non-concurrence of recommendations 2 and 8 is due primarily to a different viewpoint of the oversight needed to ensure MHCPs stay within their scope of practice. A principal finding in this report is that an MHCP must be part of a team, that the team leader needs to be a licensed independent mental health care provider, and that there needs to be a formal collaborating agreement between the MHCP and the team leader. Clinical pharmacists have scopes of practice, not independent clinical privileges, and thus the clinical management of a patient is ultimately the responsibility of the team leader, guided by the expertise and input of all team members. The team leader should hold regularly scheduled meetings and medical management reviews with all team members to ensure the provision of quality care.

The Under Secretary for Health, on the other hand, believes that the mere presence of a Mental Health Care Coordination Agreement is sufficient to ensure MHCPs stay within their scope of practice. The OIG disagrees with this position as a Mental Health Care Coordination Agreement is only a service level agreement between the chief of mental health, the chief of pharmacy, and the chief of staff that addresses aspects of the role of a clinical pharmacist. This agreement does not formally align a clinical pharmacist to any particular team or define the relationship. The clinical pharmacist and mental health team leader are not required to sign this agreement.

The OIG reviewed state law and noted that with an expansion of the roles and responsibilities of the clinical pharmacist from the traditional pharmacy role, a written agreement must define the relationship between the clinical pharmacist and a licensed physician. More clearly stated, the law places the clinical team under the direction of a licensed mental health provider. VA’s Mental Health Care Coordination Agreement also expands the roles and responsibilities of the

³ Recommendations directed to the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

clinical pharmacist, and by assigning them to a team led by a licensed provider, this enhanced role will result in higher level direct supervision. The Mental Health Care Coordination Agreement is not adequate as it simply asserts a collegial relationship with mutual consultation and referral between the clinical pharmacist and the collaborating provider(s).

The OIG recognizes the value of increasing the number of MHCPs in patient care. A temporizing solution to the nation-wide shortage of mental health providers should be to enhance and integrate mental health care teams with the variety of expertise needed to support the complexity of patients with mental health care needs. MHCPs should be properly supervised and in a setting consistent with their education, training, and scope of practice. Clinical pharmacists are not permitted by their scopes of practice to make a diagnosis, perform a physical examination, or provide psychotherapy, and the OIG recommends clarifying their role as team members, while complementing with appropriate supervisory expertise.



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

Contents

Executive Summary	i
Abbreviations	vi
Introduction	1
Scope and Methodology	10
Inspection Results	12
Issue 1: Inconsistent Facility Policies	12
Issue 2: MHCPs’ Scopes of Practice	20
Issue 3: Referrals	21
Conclusion	25
Recommendations 1–9	27
Appendix A: Executive in Charge, Office of the Under Secretary for Health Comments	28
OIG Contact and Staff Acknowledgments	38
Report Distribution	39

Abbreviations

CDC	Centers for Disease Control and Prevention
CPPO	Clinical Pharmacy Program Office
LIP	licensed independent practitioner
MHCP	mental health clinical pharmacist
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management
VHA	Veterans Health Administration



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess Veterans Health Administration (VHA) facilities' utilization of clinical pharmacists who work under a scope of practice in a mental health outpatient care setting.

Background

Clinical Pharmacists

Clinical pharmacists are healthcare professionals whose efforts can enhance patient care and promote wellness.⁴ Specific responsibilities vary among the different areas of pharmacy practice; however, all pharmacists have a knowledge base and set of clinical skills relating to comprehensive medication management. The principal goal of pharmaceutical care is to achieve positive outcomes from the use of medication, improving patients' quality of life with minimum risk.

The American College of Clinical Pharmacy describes clinical pharmacists as

...practitioners who provide comprehensive medication management and related care for patients in all health care settings. They are licensed pharmacists with specialized advanced education and training who possess the clinical competencies necessary to practice in team-based, direct patient care environments.⁵

VHA clinical pharmacists who have scopes of practice play an important role in the care of patients in multiple healthcare settings. They manage a large range of disease states, provide

⁴ Pharmacists are described using terminology that varies even for similar functions, both by VHA and among professional organizations such as the American Pharmacists Association. For the purposes of this report, the OIG will be discussing only clinical pharmacists as defined by VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, amended June 29, 2017; *Journal of the American Pharmacists Association*, Consortium recommendations for advancing pharmacists' patient care services and collaborative practice agreements. March/April 2013: e132–e141.

⁵ The American College of Clinical Pharmacy is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in practice, research, and education. <https://www.accp.com/about/index.aspx>. (The website was accessed on June 26, 2018.)

direct patient care, and function at the highest level of clinical practice with autonomy and independent decision-making within the parameters of their scopes of practice.⁶

This inspection focuses on VHA policies and processes that guide the practice of clinical pharmacists specific to the mental health specialty practice area within outpatient settings. In March 2018, VHA reported a total of 4,021 clinical pharmacists, 372 (9 percent) of whom had requested a scope of practice in the mental health practice specialty.

VHA established guidance for clinical pharmacy services with oversight by VHA Pharmacy Benefits Management (PBM) Service and the PBM Clinical Pharmacy Program Office (CPPO).⁷ As reported by CPPO, VHA utilizes clinical pharmacists in various patient care settings, educating patients and managing disease states such as diabetes, hyperlipidemia, and hypertension. VHA mental health clinical pharmacists (MHCPs) provide interventions including medication management therapy for mental health conditions such as mood, anxiety, trauma-related, or psychotic disorders.⁸

Most VHA policies and state laws regarding clinical pharmacy services address clinical pharmacist responsibilities without specifying practice areas. VHA and professional practice guidelines refer to terms such as: scope of practice, collaboration and collaborative care agreements (collaborating agreements), collaborative medication management, and autonomy; more detail on these terms follows.

Education

A clinical pharmacist possesses at a minimum, a baccalaureate degree in pharmacy and may complete a graduate degree at the doctoral level, postgraduate residency training, and/or attain certification in a specialty practice area, such as mental health; however, the additional training

⁶ Not all VHA clinical pharmacists work under a scope of practice due to the types of duties performed. However, in this report, the OIG uses the term clinical pharmacist to indicate clinical pharmacists who do work under a scope of practice; VHA Handbook 1108.11(1).

⁷ VHA Handbook 1108.11(1); CPPO provides written clinical practice guidance that is overseen by PBM. VA Pharmacy Benefits Management Clinical Pharmacy Program Office, Advancing Clinical Practice Annual Report fiscal year 2017.

⁸ Mood disorders such as major depressive disorder and bipolar disorder; anxiety disorders such as generalized anxiety disorder; trauma-related disorders such as posttraumatic stress disorder; and psychotic disorders such as schizophrenia or schizoaffective disorder. *APA*, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, <https://dsm.psychiatryonline.org/doi/book/10.1176/appi.books.9780890425596>. (The website was accessed on December 12, 2018.)

or certification is not required by VHA for clinical pharmacist practice.⁹ Facilities determine what qualifies a clinical pharmacist for a practice area by evaluating the individual clinical pharmacist's education and experience.

Autonomy and Collaboration

Autonomy

VHA allows clinical pharmacists to work with autonomy and independent decision-making, without designation of a specific supervising or managing physician, noting that clinical pharmacists work with multiple providers simultaneously, as opposed to working with a single provider. If patients' care needs require services beyond those granted to the clinical pharmacist (for example, making a diagnosis¹⁰), then the clinical pharmacist would consult with an unspecified collaborating provider as described previously, consistent with facility policies for collaboration and referral.

Collaboration

Expectations for collaboration between clinical pharmacists and other providers have been established by professional organizations and within VHA, as described below.

American College of Clinical Pharmacy standards for clinical pharmacy practice state “Clinical pharmacists work in collaboration with other providers to deliver comprehensive medication management that optimizes patient outcomes.”¹¹

The American College of Clinical Pharmacy defines collaboration as “collaborative and cooperative practice activities performed by the clinical pharmacist as authorized by (i) state practice acts and (ii) formal collaborative drug therapy management agreements with other providers...”¹²

⁹ VHA Handbook 5005/55, *Staffing*, June 7, 2012; Established in 1932, the Accreditation Council for Pharmacy Education is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education (until 2003 it was known as the “American Council on Pharmaceutical Education”). “State boards of pharmacy require that licensure applicants from the United States have graduated from an accredited pharmacy degree program to be eligible to sit for the North American Pharmacist Licensure Examination.TM” Accreditation Council for Pharmacy Education, *Accreditation Standards and Key Elements for The Professional Program in Pharmacy Leading to The Doctor of Pharmacy Degree: Standards 2016*, July 1, 2016.

¹⁰ VHA Handbook 1108.11(1).

¹¹ American College of Clinical Pharmacy: *Comprehensive Medication Management in Team-Based Care*. <https://www.accp.com/docs/positions/misc/CMM%20Brief.pdf>. (The website was accessed on May 17, 2018.)

¹² American College of Clinical Pharmacy, “Standards of Practice for Clinical Pharmacists.” <https://www.accp.com/docs/positions/guidelines/standardsofpractice.pdf>. (The website was accessed on January 23, 2018.)

The American College of Clinical Pharmacy states, “A collaborative practice agreement . . . in accordance with state regulations, should serve as the regulatory framework for the clinical pharmacist’s delivery of CMM [comprehensive medication management].”¹³ Collaborating agreements can provide a framework for broader treatment of both acute and chronic disease by allowing a physician to delegate the ability to manage certain medications to a clinical pharmacist.¹⁴

The American Pharmacists Association Foundation also emphasized the importance of collaboration, stating “Collaboration is the cornerstone of the success of this [clinical pharmacist practice] model. Pharmacists are a healthcare solution and can dramatically help to improve patient outcomes when integrated into healthcare teams.”¹⁵

The Centers for Disease Control and Prevention (CDC) also promotes a practice model that includes effective implementation of collaborative care agreements within “well-informed . . . teams” with “meaningful communication between providers.”¹⁶ The CDC along with other professional healthcare organizations developed and endorsed a template and explanatory materials as a resource for implementing collaborating agreements for clinical pharmacy services within healthcare teams.¹⁷ The template identifies the roles and responsibilities of all parties involved and the process for collaboration during patient care. Collaborating agreements define patient populations served under the agreement and establish parameters conducive to delivery of evidence-based care.¹⁸

¹³ American College of Clinical Pharmacy White Paper, “Collaborative Drug Therapy Management and Comprehensive Medication Management—2015.” <https://www.accp.com/docs/positions/whitePapers/CDTM%20CMM%202015%20Final.pdf>. (The website was accessed on July 3, 2018.)

¹⁴ CDC. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, Georgia: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017.

¹⁵ The American Pharmacists Association Foundation is a not for profit 501(c)(3) organization and is affiliated with the American Pharmacists Association, the oldest and largest national professional society of pharmacists in the United States established in 1852. <http://www.aphafoundation.org/about-us>. (The website was accessed on June 26, 2018.)

¹⁶ CDC Translational Tools. Collaborative Practice Agreements and Pharmacists’ Patient Care Services, A Resource for Pharmacists, October 2013. https://www.cdc.gov/dhds/pubs/docs/Translational_Tools_Pharmacists.pdf. (The website was accessed on June 26, 2018.)

¹⁷ The following organizations collaborated with CDC to develop the resource and endorsed its use: National Alliance of State Pharmacy Associations, American Pharmacists Association, American Medical Association, the American Association of Nurse Practitioners, the Network for Public Health Law – Eastern Region, and University of Maryland Francis King Carey School of Law. CDC. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, Georgia: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017.

¹⁸ Alex J. Adams, et al. Physician-Pharmacist Collaborative Practice Agreements: A Strategy to Improve Adherence to Evidence-Based Guidelines. *Evid Based Med Public Health* 2015; 2: e923. doi: 10.14800/emph.923. pages 1–2.

Further, U.S. state laws regulate the practice authority given to clinical pharmacists. Most states allowed for a limited scope of practice that restricted the practice of clinical pharmacists to certain patient care activities, and as of 2015, 48 states granted pharmacists the ability to practice collaboratively with other health care providers.¹⁹

Licensed Independent Practitioner

In VHA, a licensed independent practitioner (LIP) is a health care provider who is permitted by law (in the state of licensure) and by the facility to provide patient care services without supervision or direction, within the limits approved by state licensure regulations, and in accordance with clinical privileges that the facility grants to an individual practitioner.²⁰

Credentialing is a facility's systematic process of screening and evaluating a practitioner's qualifications, including but not limited to: licensure, the practitioner's relevant training and experience, current competence, and health status. VHA requires that both LIPs (who provide services independently without supervision) and non-LIPs such as clinical pharmacists and physician assistants (who provide services with supervision) undergo the credentialing process.²¹

Clinical privileging is the process of granting a practitioner the ability to provide services for direct patient care without supervision, as permitted by the facility and state law. Only LIPs may be granted clinical privileges; clinical pharmacists are not independent practitioners and do not receive privileges from the facility. Instead, the facility director approves a scope of practice, which outlines delegated clinical duties.²²

VHA Expectations for Collaboration Between Clinical Pharmacists and LIPs

VHA clinical pharmacists practice Collaborative Medication Management, which VHA defines as a multidisciplinary approach to healthcare delivery which utilizes pharmacists' medication expertise to contribute to patient care in a designated practice area within their scopes of practice. Healthcare organizations, professional organizations, and state laws establish collaboration expectations for patient care delivery between clinical pharmacists and providers. Facilities are

¹⁹ American College of Clinical Pharmacy White Paper, Collaborative Drug Therapy Management and Comprehensive Medication Management—2015. <https://www.accp.com/docs/positions/whitePapers/CDTM%20CMM%202015%20Final.pdf> (The website was accessed on July 3, 2018.); CDC. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, Georgia: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017.

²⁰ VHA Handbook 1100.19 *Credentialing and Privileging*, October 15, 2012. This handbook expired October 31, 2017, and has not been recertified or updated.

²¹ VHA Handbook 1100.19.

²² VHA Handbook 1100.19; VHA Handbook 1108.11(1).

to provide “comprehensive, collaborative, and patient-centered pharmaceutical services.”²³ VHA policy describes collaborative relationships and communication infrastructure as “imperative...for continuity of care” when a clinical pharmacist is performing patient care.²⁴

VHA Collaborating Agreements

Collaborative Medication Management “entails collaborating agreements between physicians or other independent practitioners and clinical pharmacists.”²⁵ A collaborating agreement is an agreement between one or more physicians and clinical pharmacists that permits the clinical pharmacist to assume responsibility for performing physical assessments; ordering drug therapy-related laboratory tests; administering drugs; and managing drug regimens.²⁶ In VHA, the clinical pharmacist is to collaborate with an LIP (a collaborating provider) when a patient requires a referral to a higher level of care, when any significant changes in a patient’s conditions occur, or when patient care needs exceed those approved within the clinical pharmacist’s scope of practice.²⁷

By outlining permissible duties of a clinical pharmacist, collaborating agreements assist with maximizing the clinical functioning of MHCPs in alignment with their education and training.²⁸

Collaborating agreements

...may include the authority to 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.²⁹

Scope of Practice

A scope of practice is a document in which the clinical pharmacist requests permissions for patient care duties relevant to a particular practice area (for example, diabetes, hypertension, or

²³ VHA Handbook 1108.07, *Pharmacy General Requirements*, March 10, 2017.

²⁴ VHA Handbook 1108.11(1).

²⁵ VHA Handbook 1108.11(1).

²⁶ Sarah E. McBane, Anna L. Dopp, Andrew Abe, Sandra Benavides, Elizabeth A. Chester, Dave L. Dixon, Michaelia Dunn, Melissa D. Johnson, Sarah J. Nigro, Tracie Rothrock-Christian, Amy H. Schwartz, Kim Thrasher, and Scot Walker. *American College of Clinical Pharmacy White Paper. “Collaborative Drug Therapy Management and Comprehensive Medication Management—2015.”*

²⁷ VHA Handbook 1108.11(1).

²⁸ Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority. A Report of the Collaborative Practice Workgroup Convened by the National Alliance of State Pharmacy Associations. July 2015.

²⁹ VHA Handbook 1108.11(1).

mental health) and setting (inpatient medical facility, or outpatient clinic).³⁰ VHA requires a scope of practice for clinical pharmacists with direct patient care responsibility for collaborative medication management, described as the authority of the clinical pharmacists “to initiate, modify, renew, or discontinue” medications.³¹ The scope of practice describes patient care duties including executing therapeutic plans; ordering, reviewing and acting on appropriate laboratory tests and diagnostic studies; and prescribing medications, devices, and supplies, relevant to the patient’s drug therapy.³²

VHA requires that the “scopes of practice must be standardized across VA medical facilities for clinical pharmacists with similar practice areas, training, and experience” by containing required elements such as a description of activities or duties based on the clinical pharmacist’s area of practice or responsibility (for example domiciliary, telemedicine, or mental health).³³ The requested duties are reviewed by the chief of pharmacy service and the chief of another clinical service in instances when the clinical pharmacist is aligned with that service (the mental health service for the purposes of this review). In this latter case, the respective chiefs of pharmacy and mental health must each review and endorse the requested duties in the scope of practice, specifically, “there will be two service chief recommendations” prior to submission to the medical staff executive body, which makes the final recommendation for approval by the medical facility director.³⁴ However, VHA policy does not require the chief of mental health to provide input, review, or endorse the MHCPs’ scopes of practice when the MHCPs are not organizationally aligned under mental health services, even though they are delivering care within the mental health services specialty care area.

Referrals

VHA policy requires facilities to develop local policies for “clear and standardized” processes for referring patients to pharmacy-managed clinics, to ensure that referred patients are appropriate for management by clinical pharmacists. Facility policy should also outline which referrals could be appropriately made by the clinical pharmacist, in consultation with a collaborating provider. VHA requires facilities to establish “infrastructure” for clinical pharmacists to use when referring patients to higher levels of mental health care, although VHA policy did not describe standards or expectations for such a framework, giving individual facilities the ability to design systems of infrastructure based on facility needs and processes.³⁵

³⁰ VHA Handbook 1108.11(1).

³¹ VHA Handbook 1108.11(1).

³² VHA Handbook 1108.11(1).

³³ VHA Handbook 1108.11(1).

³⁴ VHA Handbook 1108.11(1).

³⁵ VHA Handbook 1108.11(1).

Mental Health Treatment Considerations

Treatment provided in general outpatient mental health settings differs from that in some other medical settings, such as specialty clinics for hyperlipidemia or hypertension, where providers often make clinical decisions based on standardized, objective measures and protocols.³⁶ In mental health, while providers may utilize standardized psychiatric assessment tools, treatment decisions rely more heavily on the pairing of scales with a provider's clinical impressions based on his/her experience and training.³⁷ The complexity of assessment in the mental health practice area underscores the importance of establishing collaborating agreements to ensure that an LIP is available to support the MHCP and provide supplemental evaluation of a patient as clinical changes occur.

Components of psychiatric assessments include but are not limited to: mental health history; social, cultural, and environmental factors; family history; childhood history; occupational and/or military history; and legal history. These factors may be explored during an initial assessment prior to referral to an MHCP; however, additional related details are often subsequently disclosed in treatment with the development of patient-provider rapport.³⁸ Furthermore, diagnoses often become clearer over time as a result of illness progression or remission. When such new clinical information becomes available, it is important that a provider utilize it to inform mental health treatment decisions.³⁹ If ongoing evaluation remains limited to medication assessment while a patient is under the care of the MHCP (who is not authorized to perform diagnostic assessments), treatment decisions may fail to address additional factors impacting patient stability.⁴⁰

Prior OIG Reports

On August 1, 2018, the OIG published a report that discussed issues similar to the ones outlined in this inspection.⁴¹ The 2018 report was issued in response to requests by Wisconsin Senators Tammy Baldwin and Ron Johnson concerning the care of a patient who committed suicide less than 48 hours after being discharged.

³⁶ Tewksbury et al., 2018. Development of Collaborative Drug Therapy Management and Clinical Pharmacy Services in an Outpatient Psychiatric Clinic. *Journal of Pharmacy Practice*, Vol. 31(3), page 272–278.

³⁷ *American Psychiatric Association*, 2006. Practice Guideline for the Psychiatric Evaluation of Adults, Second Edition.

³⁸ *American Psychiatric Association*. 2006. Practice Guideline for the Psychiatric Evaluation of Adults, Second Edition. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/psychevaladults.pdf (The website was accessed on June 5, 2018.); Aboraya, A., et. al. The Reliability of Psychiatric Diagnosis Revisited: The Clinician's Guide to Improve the Reliability of Psychiatric Diagnosis. *Psychiatry*, January 2006:45.

³⁹ *American Psychiatric Association*, 2006. Practice Guideline for the Psychiatric Evaluation of Adults, Second Edition.

⁴⁰ VHA Handbook 1108.11(1).

⁴¹ VA OIG Report, *Review of Two Mental Health Patients Who Died by Suicide, William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin* (Report No.17-02643-239).

In the 2018 report, three deficiencies are relevant to this inspection:

- William S. Middleton Memorial Veterans Hospital did not have a methodology for assigning patients with complex mental health care needs to more highly trained psychiatrists.
- William S. Middleton Memorial Veterans Hospital did not provide policy or guidance for collaboration between an assigned Psychiatric Clinical Pharmacist (referred to in this report as MHCP) and a psychiatrist when (1) patient care management was beyond the Psychiatric Clinical Pharmacist's scope of practice, (2) changes occurred in the patient's condition, or (3) referrals to higher levels of care were required.
- William S. Middleton Memorial Veterans Hospital Psychiatric Clinical Pharmacists acted outside of their scope of practice in changing diagnoses and providing psychotherapy.

For the 2018 report, the OIG made 11 recommendations, and one is closed. The following two recommendations addressed the three deficiencies:

- 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.
- 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.

Scope and Methodology

The OIG initiated a healthcare inspection on January 4, 2018, and conducted interviews by telephone from March 15 through May 11, 2018.

OIG staff reviewed professional practice guidelines from the American Association of Nurse Practitioners, Accreditation Council for Pharmacy Education, American College of Clinical Pharmacy, American Medical Association, American Pharmacists Association, American Pharmacists Association Foundation, and CDC.

OIG staff interviewed the Mental Health Services Deputy Chief Consultant, PBM Deputy Chief Consultant, PBM Assistant Chief Consultant for Clinical Pharmacy Services and Healthcare Services and Research, PBM Program Manager (regarding Clinical Pharmacy Practice Policy and Standards and Clinical Pharmacy Practice Program and Outcomes Assessment), National Clinical Pharmacy Practice Program Manager, 19 chiefs of pharmacy, 18 chiefs of mental health, 50 MHCPs, and other facility leaders.

OIG staff requested VHA documents and PBM guidance related to clinical pharmacist practice; clinical pharmacist scope of practice related to mental health; clinical pharmacist experience, education, or training requirements; collaborating agreements related to mental health care; and guidance related to clinic set-up and/or encounter documentation relevant to MHCPs. The OIG reviewed documents provided by VHA: VHA Handbook 1108.11, Clinical Pharmacy Services, June 29, 2017; PBM Guidance: Clinical Pharmacists Scope of Practice; PBM Guidance: Pharmacy Clinic Set-up and Stop Code Guidance. The OIG requested facilities provide facility level documents: medical staff bylaws; current list of MHCPs; scopes of practice for each MHCP; collaborating agreements related to MHCPs; service line agreements between Pharmacy and mental health services; Professional Standards Board minutes credentialing each MHCP; and any other facility policies or procedures related to the practice of MHCPs. All documents from VHA and facilities were reviewed, which included additional VHA policies and guidance obtained: Credentialing and Privileging, Clinical General Mental Health Services and Qualified Levels of Personnel, CPPO Fact Sheet-Clinical Pharmacist Specialist Role in Mental Health with Attachments, VHA Support Service Center Data Definitions Behavioral Health Interdisciplinary Program Panel Management Tool, General mental health Staffing Model Team Development: Behavioral Health Interdisciplinary Program Team-Based Care, and Primary Care-Mental Health Integration, Co-Located, Collaborative Care: An Operations Manual.

In March 2018, OIG staff retrieved data from the CPPO SharePoint site that reported 119 VHA facilities had a total of 372 clinical pharmacists who had requested a scope of practice in mental health settings. The OIG staff randomly sampled 20 (17 percent) of the 119 facilities reporting at least one MHCP. After initiating the review, the OIG staff determined that one of the 20 facilities did not have an MHCP at that time, and this facility was excluded from the review. OIG staff

reviewed documents and conducted interviews with staff at the remaining 19 facilities. All MHCPs interviewed worked in an outpatient mental health setting.

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.

Inspection Results

The OIG acknowledges the value of clinical pharmacists in the delivery of health care in general and the inclusion of clinical pharmacists within teams of clinical providers to address veterans' mental health needs. However, PBM's guidance provided facilities with latitude for decision-making but lacked national oversight of MHCPs' collaboration with LIPs with prescriptive authority, standardization of scopes of practice, and processes for referring patients to the MHCP for care and for MHCPs to refer patients to higher levels of mental health care. The OIG identified incongruities between VHA policy and guidance to facilities from CPPO for care provided by MHCPs, leading to varied implementation of policy by facilities. The varied facility implementation and absence of national oversight creates the potential for MHCPs to practice beyond the limits set by professional standards or state laws.

Issue 1: Inconsistent Facility Policies

The OIG determined that facility policies contained inconsistent descriptions regarding MHCPs' autonomy (independence level) and some facility staff misidentified MHCPs as LIPs. VHA policies provide inconsistent instruction to facilities regarding requirements for collaborating agreements, and VHA and facility policies insufficiently indicate to MHCPs when communication with an LIP with prescriptive authority is required.⁴²

Autonomy

Misidentification of MHCPs' Independence Level

VHA MHCPs practice autonomously, but do not practice as LIPs.⁴³ The OIG determined that facility staff lacked understanding regarding the difference between practicing autonomously and practicing as an LIP. This was evidenced by facility MHCPs, chiefs of mental health, and chiefs of pharmacy services misidentifying MHCPs as LIPs. The OIG determined that facility bylaws

⁴² VHA Handbook 1108.07, *Pharmacy General Requirements*, March 10, 2017. "Prescriptive authority is the ability to write prescriptions or orders for medications and supplies in accordance with the provider's individualized scope of practice or clinical privileges."

⁴³ "Clinical pharmacists with a scope of practice function as health care providers with a high level of autonomy and exercise independent decision-making within their scope of practice, although clinical pharmacists are not independent practitioners... This Handbook reconciles actual practice with published policy by ensuring the clinical pharmacist with a scope of practice is aligned with staffing procedures contained in the facility bylaws." VHA Handbook 1108.11(1).

may have contributed to confusion regarding an MHCP's independence level, as the bylaws lacked clarity regarding MHCPs' independence level.⁴⁴

During interviews, OIG staff asked facility staff if they considered MHCPs to be LIPs. Of the 19 chiefs of pharmacy, three (16 percent) misidentified MHCPs as LIPs and one other (5 percent) was unsure if MHCPs were LIPs. Of the 18 chiefs of mental health, two (11 percent) misidentified MHCPs as LIPs and four others (22 percent) were unsure if MHCPs were LIPs. Of the 50 MHCPs, eight (16 percent) misidentified themselves as LIPs and 14 (28 percent) could not provide definitive responses when asked if they were an LIP, such as "it depends on the leadership," "I am not technically a LIP, but I function like one," "yes but not for certain medications" or stated they were unsure.

VHA policy allows each facility to outline specific staffing procedures within their bylaws.⁴⁵ Bylaws designate locally which providers are considered LIPs, medical staff, and advanced practice professionals.⁴⁶ Although facilities are given this authority at the local level, VHA policy states bylaws are not to conflict with other VHA policies.⁴⁷ VHA policy states that clinical pharmacists are not LIPs; therefore, bylaws should not identify clinical pharmacists as LIPs.

Despite this guidance, the OIG determined during a review of 19 facility bylaws, four (21 percent) stated clinical pharmacists could practice independently if their state license permitted it and the facility authorized it.⁴⁸ This had the potential to create additional confusion, as at the time of the OIG review, none of the state laws where the sampled facilities were located permitted clinical pharmacists to function as LIPs. Another four (21 percent) of the facilities where bylaws were reviewed lacked adequate definition of the independence levels of clinical pharmacists within their bylaws. They either did not provide guidance to define the independence level of clinical pharmacists, made contradictory statements by listing clinical pharmacists under more than one category regarding independence level, or made conditional statements regarding the ability for a clinical pharmacist to practice as an LIP but did not define the conditions.⁴⁹ The lack of clarity within bylaws regarding MHCPs' level of independence may

⁴⁴ "The credentialing, but not privileging, requirements of this Handbook apply to... clinical pharmacy specialists who do not practice as licensed independent practitioners... Nothing in the VA medical facility Medical Staff Bylaws, Rules, and Regulations can be inconsistent with the law, Department of Veterans Affairs (VA) regulations, this Handbook's policies and procedures, or other VA policies." VHA Handbook 1100.19.

⁴⁵ VHA Handbook 1108.11(1).

⁴⁶ Pharmacy Benefits Management Service, PBM Guidance: Understanding Medication Prescriptive Authority, March 2016.

⁴⁷ The handbook term is also referred to as VHA policy; VHA Handbook 1100.19.

⁴⁸ VHA Handbook 1100.19.

⁴⁹ This set of bylaws used the terms pharmacist, clinical pharmacist, and clinical pharmacy specialist without definitions; One set of bylaws lists CPs as providers who "function within a Scope of Practice or may practice independently on defined clinical privileges as defined in these Bylaws," but do not further define those clinical privileges. Another set of bylaws state CPs will practice "under the supervision of a credentialed and privileged Licensed Independent Practitioner when required" but do not specify when this is required.

have contributed to chiefs of service and MHCPs misidentifying MHCPs as LIPs. By being misidentified as LIPs, there is an increased risk for MHCPs to function in an independent role without adequate collaboration with LIPs who have prescriptive authority, leading to patient safety concerns.

Collaboration and Communication with a Collaborating Provider

VHA Requirements

VHA policy and CPPO guidance to facilities is inconsistent regarding the need for collaborating agreements between clinical pharmacists and LIPs. OIG staff also identified inconsistent implementation of collaborating agreements at the facilities reviewed. Although VHA policy states that Collaborative Medication Management entails collaborating agreements, CPPO guidance indicates that they are not required, and that collaborating agreements are service level agreements, not agreements between clinical pharmacists and LIPs.⁵⁰ Guidance to facilities from CPPO includes a template for a care coordination agreement (CPPO template) specific to the mental health practice setting, with instructions to facilities to modify the document based on the role of the MHCP and individual facility needs.⁵¹ CPPO guidance informs facilities that an agreement is not required thus allowing facilities to opt out of its use.⁵²

The CPPO template describes communication differently than in VHA policy, giving responsibility for the MHCP to communicate “with a *mental health team member*” in instances when VHA policy requires communication specifically with a “physician or other independent provider.” Although MHCPs may collaborate with other team members, when MHCPs work within the prescriptive authority granted in a scope of practice, VHA requires the MHCP to collaborate with physicians or other independent practitioners.⁵³ The distinction between a team member and an LIP with prescriptive authority is not communicated to facilities in the guidance provided by CPPO, and the lack of specification of which discipline(s) is appropriate for collaboration contributes to the potential for MHCPs to (1) collaborate with non-prescribing providers on matters requiring the clinical expertise of an LIP with prescriptive authority, or (2) practice in an independent role for which they are not licensed, serving as the sole decision maker for prescribing practices in medication management, creating a patient safety risk by not ensuring continuity of care.⁵⁴

⁵⁰ Merriam-Webster defines the term entails as “to impose, involve, or imply as a necessary accompaniment or result.” Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/entail>. (The website was accessed on July 6, 2018.)

⁵¹ VHA PBM Guidance, Mental Health Clinical Pharmacy Specialist Care Coordination Agreement, undated.

⁵² VHA PBM Guidance, Clinical Pharmacist Scope of Practice, April 2017.

⁵³ VHA Handbook 1108.11(1).

⁵⁴ VHA PBM Guidance, Clinical Pharmacist Scope of Practice, April 2017.

PBM and CPPO leaders described MHCPs as working within teams, emphasized team-based management of patient mental health care, and noted that there is no standardized model for clinical pharmacist integration into the mental health practice setting in VHA; rather than PBM developing a model to be used across all VHA facilities, individual facilities determine how to utilize MHCPs. These leaders also noted that there is no provision for oversight by a specific physician's review of care by the MHCP.

They also stated that CPPO provides oversight of differing clinical pharmacy practice areas and relies upon other VHA staff for input into the mental health practice setting as PBM leaders who developed policy did not have mental health practice expertise. A VHA mental health leader described providing feedback for VHA policy on clinical pharmacists but acknowledged that relevant policy and guidance would be developed by CPPO rather than a mental health program office. The VHA mental health leader also described the team-based approach to patient management and emphasized collaboration when issues arise.

VHA practice regarding the use of MHCPs differed from that of other non-independent prescribers within VHA, such as physician assistants, as well as from practice guidance developed by acknowledged leaders in pharmacy practice and other professional organizations, including those collaborating with CDC: the National Alliance of State Pharmacy Associations, American Pharmacists Association, American Medical Association, the American Association of Nurse Practitioners, the Network for Public Health Law–Eastern Region, and the University of Maryland Francis King Carey School of Law.

In comparing clinical pharmacists with physician assistants, VHA's practice differed regarding autonomy and the level of involvement by a collaborating physician. In VHA, "Physician assistants function as health care providers with *varying levels of autonomy* and exercise independent decision-making within their Scopes of Practice;" whereas, "Clinical pharmacists with a scope of practice function as health care providers with a *high level of autonomy* and exercise independent decision-making within their scope of practice, although clinical pharmacists are not independent practitioners."⁵⁵

For VHA physician assistants, levels of autonomy (full, limited, or supervised) have varying degrees of involvement of the collaborating physician, "depending on the physician assistant's practice setting, clinical competence, complexity of the patients treated, and the nature of the assigned duties."⁵⁶ In contrast, for VHA clinical pharmacists, who work with "...multiple physicians, teams, and panels of patients simultaneously...the current structure for oversight by a single supervising physician does not fit the clinical pharmacy practice model used in VHA

⁵⁵ VHA Directive 1063; VHA Handbook 1108.11(1).

⁵⁶ VHA Directive 1063.

today.”⁵⁷ VHA policy for physician assistants describes responsibilities for the role of a collaborating physician; however, VHA policy for clinical pharmacists does not include this description.⁵⁸ Furthermore, PBM guidance to facilities advises that, “...they [clinical pharmacists] essentially have a collaborative practice with the [entire] medical staff and are not bound to 1 individual collaborating physician.”⁵⁹

The CDC guide describes collaborating agreements as the outcome of a process of building trust between the clinical pharmacist and physician, beginning with a pharmacist dispensing a physician’s prescription, through the physician accepting a pharmacist’s recommendations for medication therapy, and finally to a physician granting authority for medication therapy management to a pharmacist under a formal collaborating agreement.⁶⁰ Thus, a formal collaborating agreement would be established between the MHCP and the LIP with prescriptive authority only when the clinical pharmacist practices autonomously.

The sample collaborating agreement template developed by CDC and others lists the individual clinical pharmacist(s) and LIP(s) with prescriptive authority entering into the agreement, specific disease(s) the clinical pharmacist will manage, and the acceptable methods for communication (for example, in writing when the patient’s medication therapy is continued or changed).⁶¹ The CDC template provides for signatures of all individuals named in the agreement.

OIG concluded that VHA policy and guidance for MHCPs are conflicting, lack a requirement for collaborating agreements between MHCPs and LIPs with prescriptive authority, and do not outline the level of involvement by a collaborating physician when the MHCP practices autonomously.⁶² In these ways, VHA differs from its own established policy for another non-independent prescriber (such as a physician assistant) as well as from guidance from reputable professional entities (CDC and others). VHA policy notes, “it is imperative that a relationship and communication infrastructure exists with the collaborating provider(s) for continuity of care.”⁶³ OIG staff determined that without collaborating agreements in place, or some other method for establishing a relationship and communication between the clinical

⁵⁷ VHA Handbook 1108.11(1).

⁵⁸ VHA Directive 1063; VHA Directive 1082.

⁵⁹ VHA PBM Guidance, Clinical Pharmacist Scope of Practice, April 2017.

⁶⁰ CDC. *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*. Atlanta, Georgia: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017.

⁶¹ According to CDC, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*. Atlanta, Georgia, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017, CDC collaborators included the National Alliance of State Pharmacy Associations, American Pharmacists Association, American Medical Association, the American Association of Nurse Practitioners, the Network for Public Health Law—Eastern Region, and the University of Maryland Francis King Carey School of Law.

⁶² VHA PBM guidance, Mental Health Clinical Pharmacy Specialist Care Coordination Agreement, undated.

⁶³ VHA Handbook 1108.11(1).

pharmacist and a physician or other LIP, such continuity of care is at risk. Further, without an established relationship between a clinical pharmacist and a physician or other LIP, it would be difficult for a facility to ensure that the clinical pharmacist is not improperly practicing independently while providing patient care.

Facility Documentation

OIG staff determined VHA policies and instructions to facilities were inconsistent regarding collaborating agreement requirements for facilities, resulting in lack of formalized facility processes for MHCPs to collaborate with an LIP with prescriptive authority for support. The lack of collaboration creates the potential for MHCPs to provide care independently for patients leading to patient safety concerns when significant changes in mental health conditions occur.

VHA policy states, “Collaborative medication management entails collaborating agreements between physicians or other independent practitioners and clinical pharmacists with a scope of practice...”⁶⁴ Thus, collaborating agreements are a component of Collaborative Medication Management and should be present if an MHCP is providing such services. The CPPO template provides a semi-standardized collaborating agreement; however, the template is not required and allows facilities to opt out of its use.⁶⁵

In response to OIG staff’s document request from facilities, OIG staff determined that nine (47 percent) of the 19 facilities sampled did not provide a collaborating agreement and the remaining 10 (53 percent) facilities provided documents that had not been implemented or lacked essential components of a collaborating agreement, such as collaboration terms pertaining to specific MHCPs. (See Figure 1.) Additionally, during the interviews with chiefs of mental health, OIG staff determined that three (17 percent) of 18 were unsure if a collaborative practice agreement existed at their facility.

Facilities’ MHCPs’ scopes of practice provided limitations similar to those outlined in VHA policy, which requires collaboration “for advanced patient care management beyond the applicant’s scope of practice, when changes occur in the patient’s condition, and when referrals to higher levels of care are required as outlined in the medical center policy.”⁶⁶ However, beyond this statement there were no details provided of what was beyond the limits of clinical pharmacists’ delineated duties.

⁶⁴ VHA Handbook 1108.11(1).

⁶⁵ Mental Health Clinical Pharmacy Specialist Care Coordination Agreement (CCA). <https://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Mental%20Health.aspx>. (The website was accessed on May 17, 2018.)

⁶⁶ VHA Handbook 1108.11(1).

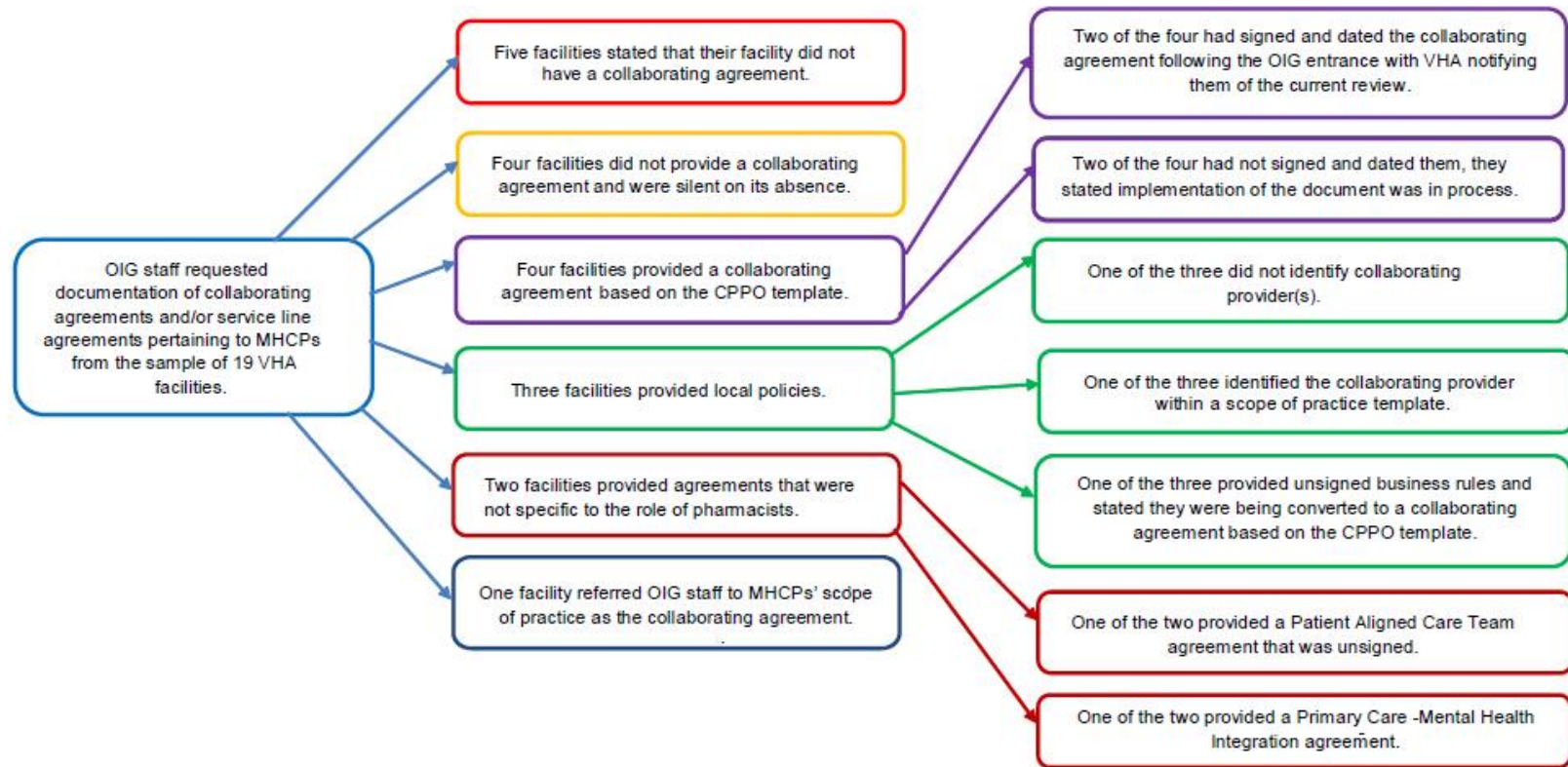


Figure 1: Facility Documentation of Collaborating Agreements⁶⁷

Source: VA OIG analysis

⁶⁷ It cannot be determined if VHA documents signed and dated after the OIG entrance were attributable solely to the current OIG review, as some interviewees indicated the implementation of collaborating agreements occurred as a requirement of VHA hiring clinical pharmacists under the Rural Health Initiative. The OIG entrance with VHA occurred on January 4, 2018.

Collaborating Agreements Versus Scopes of Practice

OIG staff determined that facilities' leaders misinterpreted collaborating agreements as interchangeable with scopes of practice. Further, VHA policy provided inconsistent guidance to facilities. Given that scopes of practice and collaborating agreements have distinct content and functions, their consolidation into one document has the potential to exclude elements critical to their purpose, particularly elements that set MHCP practice parameters and indicate when and how an MHCP collaborates with an LIP who has prescriptive authority.

Specifically, collaborating agreements serve to identify roles and responsibilities of the MHCPs and collaborating physicians and outline indicators and a process for MHCPs collaboration during patient care.⁶⁸ In contrast, scopes of practice serve to identify an individual MHCP's prescriptive authority, describe routine and non-routine professional duties, and describe the general areas of responsibility to be performed.⁶⁹

VHA policy indicates that both collaborating agreements and scopes of practice are required as components of Collaborative Medication Management, stating, "Clinical pharmacist scope of practice includes collaborative medication management, which entails collaborating agreements between physicians or other independent practitioners and clinical pharmacists..." and describes collaborating agreements as separate and distinct from scopes of practice.⁷⁰ CPPO guidance to facilities contradicts that policy, stating that the scope of practice is the collaborating agreement.⁷¹

MHCP interviewees expressed confusion regarding the differences between scopes of practice and collaborating agreements. Eleven (22 percent) of 50 MHCPs referred OIG staff to their scopes of practice when asked if a collaborating agreement existed at their facility, and only four (21 percent) of the 19 facilities provided documentation for collaborating agreements. The inconsistent guidance from VHA creates the potential for facilities to consider collaborating agreements interchangeable with scopes of practice. As noted above, consolidating a scope of practice and collaborating agreement into one document may exclude elements critical to each document's purpose, particularly the outlining of indicators for an MHCP to collaborate with an LIP with prescriptive authority.

⁶⁸ Alex J. Adams, et al. Physician-Pharmacist Collaborative Practice Agreements: A Strategy to Improve Adherence to Evidence-Based Guidelines. *Evid Based Med Public Health* 2015; 2: e923. doi: 10.14800/emph.923. page 1–2.

⁶⁹ VHA Handbook 1108.11(1).

⁷⁰ VHA Handbook 1108.11(1).

⁷¹ VHA PBM, Guidance Clinical Pharmacist Scope of Practice, April 2017.

Issue 2: MHCPs' Scopes of Practice

OIG staff determined there were inconsistencies among facilities in the description of practice area duties, and review and recommendation of the MHCPs' scopes of practice by the chiefs of mental health service.

Standardization of Mental Health-Specific Duties

OIG staff determined there were inconsistencies among facilities in describing the duties specific to the mental health outpatient care setting. VHA requires the scope of practice “be standardized across VA medical facilities for clinical pharmacists with similar practice areas...” by containing required elements including a description of patient care duties based on the clinical pharmacist’s area of practice (for example: domiciliary, telemedicine, or mental health).⁷² CPPO made available to facilities a standardized template; however, this template was not in use by facilities. During interviews, OIG staff determined that six (32 percent) of 19 facility chiefs of pharmacy and eight (44 percent) of 18 chiefs of mental health were unaware of VHA guidance specific to the practice of MHCPs.

In the scopes of practice reviewed, 15 (79 percent) of 19 facilities did not describe MHCP patient care duties specific to the mental health practice area, or the MHCPs’ role or function, although MHCPs provided patient care within the mental health service.

Service Chiefs’ Endorsement of Review and Recommendation

VHA policy assigns responsibility to the facility director to ensure that relevant service chiefs (as relates to this inspection, the chief of mental health and the chief of pharmacy) have reviewed and endorsed the scopes of practice requested by the MHCPs.⁷³ However, VHA policy does not require the chief of mental health to provide input, review or endorse the MHCPs’ scopes of practice when the MHCPs are not organizationally aligned under mental health services, even though they are delivering care within the mental health services specialty care area.⁷⁴

In this respect, VHA policy for clinical pharmacists differs from principles established in other VHA policies. VHA policy for LIPs requires that, “in instances where a practitioner is granted privileges in more than one service, the Service Chief from all services where privileges are granted must recommend the privileges specific to that service.”⁷⁵ VHA policy for physician

⁷² VHA Handbook 1108.11(1).

⁷³ VHA Handbook 1108.11(1); VHA PBM Guidance, Clinical Pharmacist Scope of Practice, April 2017.

⁷⁴ VHA Handbook 1108.11(1).

⁷⁵ VHA Handbook 1100.19. Quality of care includes focused and ongoing professional practice evaluation.; VHA Handbook 1108.11 (1).

assistants requires a collaborating provider to monitor the physician assistant's clinical activities to ensure the activities are within the authorized scope of practice and are medically appropriate.⁷⁶

At the majority of the facilities, the chiefs of mental health did not endorse the review and recommendation of MHCPs' scopes of practice. Signature lines were missing in 14 (74 percent) of 19 facilities. This lack of documentation of the review, recommendation, and endorsement made it difficult to assure that chiefs of mental health were aware of the extent of MHCPs' allowed practice and that meaningful clinical oversight was provided.

VHA policy states it is the responsibility of the medical facility director to ensure that both the chief of clinical service (mental health) and the chief of pharmacy have reviewed and endorsed the scopes of practice submitted by the MHCPs, only in the case when the MHCP is organizationally aligned with mental health, regardless of the fact that MHCPs provide service in the mental health area.⁷⁷ VHA policy is insufficient to address concerns about the chief of mental health providing input and clinical oversight of mental health specialty care scopes of practice, as noted above. A service chief is ultimately responsible for oversight of care delivered within the service line, yet MHCPs not aligned with mental health services do not necessarily have documented oversight by the chief of mental health. This applies not only to scope of practice issues as discussed here but also more generally to clinical care delivery.⁷⁸

Issue 3: Referrals

OIG staff determined that facilities lacked a clear and standardized referral process that would ensure that the diagnosis for treatment was conveyed to the MHCP and that involvement of an LIP with prescriptive authority was considered during assessment of a patient to determine appropriateness for referral to an MHCP. OIG staff also determined that VHA and facilities lacked guidance to instruct MHCPs when or how to refer patients to a higher level of mental health care.

⁷⁶ VHA Directive 1063.

⁷⁷ VHA Handbook 1108.11(1).

⁷⁸ VHA Handbook 1108.11(1); "Clinical service lines cut across both institutional and disciplinary boundaries to organize patient care around specific diseases, interventions, or populations." Service lines are widely used in VA, but their structures vary considerably. The term "service line" is not used consistently throughout VA. VA Health Services Research and Development Services website.

https://www.research.va.gov/resources/pubs/docs/service_line.pdf. (The website was accessed May 31, 2018.)

Referring Patients with Defined Diagnoses to MHCPs

Clinical pharmacists should address medication management needs of patients with defined diagnoses and collaborate with other health care providers for management of new diagnoses.⁷⁹ OIG staff determined VHA facilities lacked a “clear and standardized process” for referrals to the MHCP that would ensure communication of patients’ diagnosis(es).

Referrals to MHCPs can include: “standardized templates, collaborative care agreements, email communication from providers or team members, team or interdisciplinary meetings, clinical chart consults, and population management databases.”⁸⁰ Additionally, VHA permits other methods of referral, such as referrals from a scheduler or patients’ self-referrals. VHA policy does not define required components of a referral or how they are documented in the electronic health record. OIG staff determined that the referral process may not provide the MHCP with a defined diagnosis for patients’ treatment.

During interviews, some MHCPs reported obtaining a defined diagnosis for treatment by reviewing a formal consult or discussing the diagnosis with the referring provider when a direct hand-off occurred. However, other MHCPs stated they selected a diagnosis for treatment by referring to multiple diagnoses entered into the patients’ problem lists or searching for a diagnosis in other providers’ clinical progress notes within the electronic health record.⁸¹ Thirty-five (70 percent) of 50 MHCPs reported searching the electronic health record or the patients’ problem lists for identification of a diagnosis for patient treatment. Seven (14 percent) of the 50 MHCPs acknowledged that the problem list may not be current (up to date).⁸² In such instances, a diagnosis obtained from the problem list for MHCP treatment purposes may not be reliable. While MHCPs may have located a diagnosis using this process, it may not always result in identification of the correct diagnosis for treatment. If MHCPs provide treatment based on a patient’s diagnosis that is not reliable or accurate, the patient may not receive effective care.⁸³

⁷⁹ VHA Handbook 1108.11(1).

⁸⁰ VHA Handbook 1108.11(1).

⁸¹ VHA Computerized Patient Record System Problem List User Manual, December 2017. The problem list is used to document and track a patient’s problems and provides a view of current and historic health care problems. The problem list can be used by caregivers and others, including ward clerks and coding clerks.

⁸² According to interviews of chiefs of mental health and pharmacy services, as well as MHCPs.

⁸³ VHA Computerized Patient Record System, Problem List User Manual, December 2017. The problem list reflects a clinical diagnosis and a paired billing code.

Referring Complex Patients to MHCPs

VHA's referral process is intended to ensure referred patients are appropriate for management by MHCPs.⁸⁴ The OIG determined VHA guidance does not require that facilities incorporate a review by an LIP with prescribing authority to assess the clinical complexity of patients referred to an MHCP. While all settings and scenarios may not call for an LIP review, VHA guidance lacked consideration for patients who may warrant review by an LIP.⁸⁵

OIG staff determined that facility processes allowed for MHCPs to receive referrals for patients with varied clinical presentations, such as MHCPs being among a group of providers to which new patients were randomly assigned for medication management. OIG staff interviewed MHCPs who stated they did not consider clinical complexity a factor in the referrals that were appropriate for them to receive. Additionally, the CPPO template language indicates that it is the responsibility of MHCPs to determine whether a patient referral falls within a facility's clinic policies and MHCPs' scopes of practice. Of the 50 MHCPs, 20 (40 percent) stated that their criteria for receiving patient referrals consisted of a patient having a diagnosis and being prescribed medications within the MHCPs' scopes of practice. When scopes of practice lack defined permitted duties, and no requirement exists for a review to ensure that the referral is appropriate, MHCPs may accept patient referrals that require care beyond the limits of their expertise.

MHCPs Referring Patients to an LIP

OIG staff determined that VHA did not provide comprehensive guidance on processes for MHCPs on when or how to refer patients to a higher level of mental health care, such as an LIP with prescriptive authority. Further, facilities' leaders did not develop specific policies to ensure patients received the higher levels of care when needed.

VHA Handbook 1108.11(1) states “[i]nfrastructure must exist for a clinical pharmacist with a scope of practice to refer patients to higher levels of care when appropriate. [Facility] Policy must outline what referrals are appropriate to be made by the clinical pharmacist with a scope of practice... Referrals to higher levels of care include mechanisms for triaging urgent and acute cases (e.g., referral to urgent care or emergency department in patients with worsening of symptoms) and means for communication and care coordination when patient referrals are performed.”⁸⁶

The CPPO template provided a degree of guidance on when MHCPs are to refer to a higher level of care by stating the MHCP is responsible for, “Communicating with a mental health team

⁸⁴ VHA Handbook 1108.11(1).

⁸⁵ VHA Handbook 1108.11(1).

⁸⁶ VHA Handbook 1108.11(1).

member if significant changes in the mental health treatment course occurs, when referrals to higher levels of care (i.e. inpatient) are needed, when additional care (i.e. therapy, wellness, etc.) is needed, or advanced patient care management is required that is outside the MHCP's scope (i.e. transcranial magnetic stimulation)." However, this guidance had limited impact, as 15 (79 percent) of 19 facilities sampled had not implemented the CPPO template.

OIG staff interviewed chiefs of mental health and determined they had a lack of understanding regarding patients who were no longer a good fit for MHCPs. When asked to provide an example, three (17 percent) of 18 chiefs of mental health stated the onus was on the MHCP to determine the appropriateness of a patient. Of the three, two chiefs of mental health indicated that MHCPs were aware of their own limits and therefore knew when to seek support, and one stated not setting any thresholds or limits for the MHCP. When facility leaders do not provide referral policy and/or procedures and depend on MHCPs to independently determine which patients are appropriate for their care, there is a potential for increased risk to the patients when treatment needs exceed what an MHCP can provide.

OIG staff interviewed 50 MHCPs about what happened when a patient in the MHCP's care had a change in their mental health condition. OIG staff determined that six (12 percent) MHCPs were independently determining treatment needs when a change in condition occurred, rather than communicating with a mental health team member. OIG staff determined that five others (10 percent) limited involvement of an LIP with prescribing authority to cases when a patient was in need of referral for psychiatric admission or when a patient indicated suicidality. As a result of the lack of VHA and facilities' guidance to instruct MHCPs on when or how to refer patients to a higher level of mental health care, MHCPs may independently determine their ability to continue care for a patient based on their clinical comfort level. This may create the potential for inconsistent processes among MHCPs and increase patient risk as MHCPs continue care for patients whose mental health needs are beyond the limits of MHCPs' expertise.

Conclusion

Facility pharmacy and mental health chiefs, as well as MHCPs, misidentified the independence level of MHCPs. Additionally, facilities' bylaws lacked clarity regarding MHCPs' independence levels and may have contributed to confusion among facility staff regarding MHCPs' independence level. Facility staff lacked an understanding regarding the difference between practicing autonomously and practicing as an LIP, evidenced by interviews of facility MHCPs, chiefs of mental health, and chiefs of pharmacy services who misidentified MHCPs as LIPs.

VHA policy and program office instruction conflicted regarding whether collaborating agreements were required at facilities, which resulted in a lack of formalized processes for MHCPs to collaborate and communicate with LIPs for clinical support. OIG staff identified inconsistent implementation of collaborating agreements at the facilities reviewed, such as implementation of service level agreements, practitioner specific between the clinical pharmacist and licensed independent provider(s) or opting out of facility implementation. In addition, VHA policy also conflicted with program office instruction when defining communication responsibilities, either as between "clinical pharmacists to collaborate with physicians or other independent practitioners" versus a "mental health team member."

VHA policy requires an oversight structure, and individual facilities determine how to utilize MHCPs. VHA leaders acknowledged there was no provision in VHA policy for MHCP oversight by a specific physician who reviewed an MHCP's care. VHA policy and guidance for MHCPs lack a requirement for collaborating agreements between MHCPs and LIPs with prescriptive authority, and do not outline the level of involvement by a collaborating physician when the MHCP practices autonomously. OIG staff determined that without collaborating agreements in place, or some other method for establishing a relationship and communication between the clinical pharmacist and a physician or other LIP, such continuity of care is at risk. Further, without an established relationship between a clinical pharmacist and a physician or other LIP, it would be difficult for a facility to ensure that the clinical pharmacist is not improperly practicing independently while providing patient care.

Facilities' scopes of practice were inconsistent in describing delegated duties that were specific to the mental health outpatient practice area. VHA requires the "scopes of practice must be standardized across VA medical facilities for clinical pharmacists with similar practice areas..." by containing required elements including a description of activities or duties based on the clinical pharmacist's area of practice.

VHA policy is insufficient to ensure that the chief of the clinical service (mental health) provides review and endorsement of MHCPs' scopes of practice when those MHCPs, although delivering patient care within the mental health service, are not organizationally aligned under mental health services. This presents concerns when the chief of mental health does not have a system for providing input and clinical oversight of the MHCPs' specialty care scopes of practice. The

service chief is ultimately responsible for oversight of care delivered within the service line; yet, MHCPs not organizationally aligned with mental health services do not necessarily have documented oversight by the chief of mental health. This applies not only to scope of practice oversight but also more generally to clinical care delivery.

Facilities generally lacked a process that included endorsement of the mental health chiefs' review and recommendation of MHCP's scopes of practice as evidenced by the absence of signature lines in 14 of 19 facilities and thus at the majority of the facilities, leaders could not ensure that the chiefs of mental health provided input and clinical oversight of duties performed within the mental health service by MHCPs.

Facilities lacked a clear and standardized referral process that would ensure that the diagnosis for treatment was conveyed to the MHCP and that involvement of an LIP with prescriptive authority was considered during assessment of a patient to determine appropriateness for referral to an MHCP prior to treatment. VHA policy does not define required components of a referral or how they are documented in the electronic health record. Additionally, the referral process may not provide the MHCP with a defined diagnosis for patients' treatment. MHCPs may have located a diagnosis by self-selecting from the problem list or searching clinical notes of the medical record, resulting in potential misidentification of the correct diagnosis for treatment. When facility leaders do not provide referral policy and/or procedures and depend on MHCPs to independently determine which patients are appropriate for their care, there is a potential for increased risk to the patients when treatment needs exceed an MHCP's expertise.

VHA policy does not require that a process is defined to consider a patient's clinical complexity or when it is appropriate to refer patients to MHCPs. VHA policy does not require that facilities incorporate a review by an LIP with prescribing authority to assess the clinical complexity of patients referred to an MHCP. While all settings and scenarios may not call for an LIP review, VHA policy lacked consideration for patients who may warrant review by an LIP. Facility processes allowed for MHCPs to receive referrals for patients with varied clinical presentations, such as MHCPs who were among a group of providers randomly assigned new patients for medication management. MHCPs stated they did not consider clinical complexity a factor in the referrals that were appropriate for them to receive. Additionally, the CPPO template language indicates that it is the responsibility of MHCPs to determine whether a patient referral falls within a facility's clinic policies and MHCPs' scopes of practice.

VHA and facilities policies failed to instruct MHCPs on when or how to refer patients to a higher level of mental health care. VHA did not provide comprehensive guidance on processes for MHCPs on when or how to refer patients to a higher level of mental health care, such as an LIP with prescriptive authority. Further, facilities' leaders did not develop specific policies to ensure patients receive the higher levels of care when needed. Therefore, MHCPs may independently decide to continue care for a patient based on the MHCP's clinical comfort level creating the potential for inconsistent processes among MHCPs and increase patient risk as MHCPs continue care for patients whose mental health needs are beyond the limits of MHCPs' expertise.

Recommendations 1–9

1. The Under Secretary for Health ensures facility medical staff bylaws are consistent with Veterans Health Administration policy regarding clinical pharmacist practice as non-independent practitioners.
2. The Under Secretary for Health ensures collaborating agreements, also referenced as collaborative practice agreements, are in place for mental health clinical pharmacists who provide outpatient collaborative medication management.
3. The Under Secretary for Health ensures that the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews existing Veterans Health Administration guidance and provides assistance in outlining the mental health clinical pharmacist's responsibilities for communication with the collaborating licensed independent practitioner who has prescribing authority.
4. The Under Secretary for Health affirms allowable clinical duties within mental health clinical pharmacists' scopes of practice include comprehensive provisions related to mental health.
5. The Under Secretary for Health ensures a process is in place for chiefs of mental health service to document review, recommendation, and endorsement of all outpatient mental health clinical pharmacists' scopes of practice, regardless of whether the clinical pharmacist is aligned with the mental health service line, and monitor compliance.
6. The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews and provides input into the patient referral process to mental health clinical pharmacists with consideration for ensuring that accurate diagnoses can be reliably identified by and conveyed to the mental health clinical pharmacists.
7. The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews the patient referral process to mental health clinical pharmacists and provides input with consideration for clinical settings or scenarios in which a review of the clinical complexity of the referral by a licensed independent practitioner with prescribing authority would be appropriate, prior to treatment.
8. The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director establishes guidance and provides assistance in outlining when and how mental health clinical pharmacists are to refer patients to a higher level of mental health care.
9. The Under Secretary for Health initiates a risk assessment of outpatient mental health clinical pharmacists' practice and establish mitigation plans; and includes the Veterans Health Administration Office of Mental Health and Suicide Prevention Director in the design, implementation, and analysis processes.

Appendix A: Executive in Charge, Office of the Under Secretary for Health Comments

Department of Veterans Affairs Memorandum

Date: May 2, 2019

From: Executive in Charge, Office of the Under Secretary for Health (10)⁸⁷

Subj: OIG Draft Report, Review of Mental Health Clinical Pharmacists in Veterans Health Administration Facilities (VIEWS 00199326)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the draft report on the practice of Mental Health (MH) Clinical Pharmacy Specialist (CPS) in the Veterans Health Administration (VHA). I appreciate the Office of Inspector General (OIG) concerns about safety risks in VHA outpatient mental health team-based care. VHA will conduct a risk assessment to determine the extent of any risks and will manage them appropriately. VHA has already established Care Coordination Agreements for MH CPSs at each facility. Future policy clarification on MH team-based care is underway, and facilities are updating medical staff bylaws with respect to CPS' scopes of practice.
2. I am pleased that OIG did not find any cases of patient harm throughout the course of their review and found that MH CPSs followed VHA policy. Giving Veterans access to MH CPSs pushes VA mental health care toward excellence and is supported by numerous studies that validate the significant clinical, economic, and humanistic benefits of pharmacist-directed patient care in a variety of settings. For nearly 40 years, VHA Clinical Pharmacists and CPSs have demonstrated dedication, clinical expertise, and professional integrity that positively impacts the care and clinical outcomes of Veterans.
3. Many facilities are facing the conundrum of providing mental health care in a national environment of health professional shortages. The U.S. Health and Human Services Report titled *Shortage Definition: Health Professional Shortage Areas & Medically Underserved Areas/Populations* described an expected 25 percent deficit in psychiatrists in the United States by the year 2025. Since July 2017, the VHA Mental Health Hiring initiative has achieved a net gain of over 1,000 mental health providers. Of these hires,

⁸⁷ Recommendations directed to the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

115 are MH CPSs bringing the total to over 426 licensed CPSs practicing in Mental Health at over 119 VA facilities.

4. Team-based care is a core component of VHA health care that leverages the expertise and licensure of each team member to provide the best care for Veterans. MH CPSs, as a member of the team, work closely with their colleagues to optimize medication therapy as part of comprehensive care. CPSs contribute to comprehensive medication management by assessing medication therapy, prescribing medications consistent with their prescriptive authority, monitoring medications, addressing medication nonadherence, and assisting patients in achieving therapeutic goals. MH CPSs provide services in general and specialty mental health clinics, behavioral health clinics, primary care, residential rehabilitation facilities, and on inpatient mental health units.
5. There are several concerning aspects in OIG's review.
 - a. It is concerning that the OIG does not have a Clinical Pharmacist on the health care inspection team. Without such representation, the OIG team risks bias toward the preferences of its psychiatrist who may infuse his or her own professional biases into the review. VHA commented on this concern during open discussions with the OIG team about this report and an earlier report on Madison, Wisconsin VA. We note again that OIG found no patient harm from the care of CPSs in this report or in the Madison report.
 - b. VHA policy is clear that clinical pharmacists are not designated as Licensed Independent Practitioners (LIPs). OIG's questions to interviewees focused on the definition of the term LIP as opposed to clinical pharmacists' processes of care in a team care environment.
 - c. The draft report incorrectly concludes that VHA lacks formalized processes for MH CPSs to collaborate and communicate with appropriate MH clinicians for clinical support. VHA clinical pharmacist practice is formally established in national policy (VHA Handbook 1108.11). Every VA facility has formal Care Coordination Agreements that require MH CPSs to collaborate with appropriate MH professionals for advanced care beyond the MH CPS's Scope of Practice.
 - d. The draft report incorrectly states that the MH CPS scope of practice lacks allowable clinical duties with comprehensive provisions related to mental health. VHA clinical pharmacists with a Scope of Practice are credentialed

by the executive committee of the medical staff relative to the clinical duties they are trained and experienced to perform.

- e. OIG's recommendation requiring documentation of the mental health Chief of Staff approval on a MH CPS scope of practice lowers, rather than raises the level of oversight and scrutiny. VHA insists upon maintaining a higher standard and will continue to require Clinical Pharmacist Scopes of Practice undergo review and approval by the facility's entire executive committee of medical staff. Membership of this august body includes chiefs of service from all essential clinical care areas (including mental health), and they are all responsible for ensuring the practice of any licensed provider is appropriate for the care of Veterans. Clinical Pharmacist Scopes of Practice undergo the same scrutiny by the same invested group of leaders as any and all licensed practitioners in the facility.
 - f. The draft report fails to explain to the reader that all licensed health care practitioners are expected to read and understand the health record, know the scope of their practice and expertise, and seek advice or refer the Veteran to the care of other health care professionals when needed. VHA holds CPSs to the same referral standards and processes as all other licensed health professionals. Referrals and consultation may occur in the moment, during a face-to-face encounter, by phone, and electronically in the health record. Providing practitioners with many ways to openly communicate removes unnecessary barriers, increases smooth transitions of care, improves care coordination, and increases care quality. OIG's recommendation with respect to referrals would impose unnecessarily burdensome constraints on communications with Clinical Pharmacists that would likely lower quality and frequency of communications among health professionals. Veterans cannot afford delays in care due to constrained communications.
6. If you have any questions, please email Karen Rasmussen, M.D., Director for GAO-OIG Accountability Liaison at VHA10EGGOALAction@va.gov.

(Original signed by:)
Richard A. Stone, M.D.
Executive in Charge

Comments to OIG's Report

The following Executive in Charge comments are submitted in response to the recommendations in the OIG report.

Recommendation 1

The Under Secretary for Health ensures facility medical staff bylaws are consistent with Veterans Health Administration policy regarding clinical pharmacist practice as non-independent practitioners.

Concur.

Executive in Charge Comments

Department of Veterans Affairs (VA) medical facilities are required to follow Veterans Health Administration (VHA) policy regarding clinical pharmacist practice. VHA policies, (VHA Handbook 1108.11 and VHA Handbook 1100.19) describe that a clinical pharmacist with a Scope of Practice is not a Licensed Independent Practitioner. VHA requires medical facilities to review and update their facility medical staff bylaws to ensure consistency with medical staff bylaws template found here <http://vaww.oqsv.med.va.gov/filedownload.ashx?fid=10228> [This website is an internal VA website and not accessible to the public]. The bylaws template correctly identifies the clinical pharmacist with a Scope of Practice or a Clinical Pharmacy Specialist (CPS) as an Advanced Practice Professional. VHA will provide education to key stakeholders (e.g., VA facility Chiefs of Staff, Credentialing and Privileging staff, Chiefs of Pharmacy and clinical pharmacists with a Scope of Practice) on this topic.

Status: In Process

Completion Date: July 2019

Recommendation 2

The Under Secretary for Health ensures collaborating agreements, also referenced as collaborative practice agreements, are in place for mental health clinical pharmacists who provide outpatient collaborative medication management.

Non-concur.

Executive in Charge Comments

To further clarify the role of the clinical pharmacist in the mental health setting, VHA has implemented Care Coordination Agreements (CCAs) at every VA facility with a Mental Health Clinical Pharmacy Specialist (MH CPS). The CCA was jointly developed by the Pharmacy Benefits Management Clinical Pharmacy Practice Office and the Office of Mental Health and

Suicide Prevention. This agreement describes that MH CPSs will collaborate with physicians or other licensed health care professionals for advanced care beyond their Scope of Practice. As of March 8, 2019, all VA medical facilities with MH CPS have reported they have implemented a MH CCA.

Status:

Completion Date:

Recommendation 3

The Under Secretary for Health ensures that the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews existing Veterans Health Administration guidance and provides assistance in outlining the mental health clinical pharmacist's responsibilities for communication with the collaborating licensed independent practitioner who has prescribing authority.

Concur.

Executive in Charge Comments

The Office of Mental Health and Suicide Prevention Director reviewed VHA guidance and concluded that the implemented mental health care coordination agreements (CCAs) are consistent with the expectation that Mental Health Clinical Pharmacy Specialists (MH CPS) communicate with collaborating providers, including physicians or other providers involved in advanced patient care. As of March 8, 2019, all VA medical facilities with MH CPSs have reported they have implemented a MH CCA.

Pharmacist Scope of Practice, Appendix B. "The clinical pharmacist with a scope of practice functions as a health care provider with a high level of autonomy and exercise independent decision making within their scope of practice. A collegial relationship with mutual consultation and referral exists with the collaborating provider(s) and the clinical pharmacist with a scope of practice. Consultation with a physician or appropriate provider is required for advanced patient care management beyond the applicant's scope of practice, when changes occur in the patient's condition, and when referrals to higher levels of care are required as outlined in medical center policy. A collaborating provider(s) is available at all times by telephone or in person for consultation."

Status: Complete

Completion Date:

Recommendation 4

The Under Secretary for Health affirms allowable clinical duties within mental health clinical pharmacists' scopes of practice include comprehensive provisions related to mental health.

Concur in principle.

Executive in Charge Comments

The Executive in Charge for VHA affirms allowable clinical duties within mental health (MH) Clinical Pharmacy Specialists' (CPS) scopes of practice, functional statements, and Care Coordination Agreements, as a body of documents, are accurate and reflect the expectations of VHA for comprehensive provisions related to mental health.

CPS functional statements further outline responsibilities for routine and non-routine duties as well as the care coordination agreements discussed previously. VHA Handbook 1108.11 outlines robust processes for pharmacist Scopes of Practice compared to state practice acts where variance exists from state to state. In the VHA, all clinical pharmacists with a Scope of Practice are credentialed by the executive committee of the medical staff (ECMS) and proficiency and professional practice evaluations are reviewed at a minimum of biannually by the ECMS, Chief of Pharmacy Services, and clinical service chief (as applicable). VHA Policy states:

“Required elements of a scope of practice include:

- a. The education, training, and experience the clinical pharmacist possesses to perform the functions identified.*
- b. The required skills and knowledge that the clinical pharmacist must possess in order to perform the requested functions identified.*
- c. The scope of practice statements, individual clinical pharmacist proficiency, and professional practice evaluation results are reviewed, at a minimum, biannually by the ECMS, Chief of Pharmacy Services, and clinical Service Chief (as applicable).*
- d. Identifying, as part of collaborative medication management, the clinical pharmacist's prescriptive authority, laboratory, diagnostic and referral responsibilities.*
- e. Describing the routine and non-routine professional duties.*
- f. Describing the general practice-based areas of responsibility for activities, to include the practice location of the clinical pharmacist (e.g., VA medical facility, CBOCs, contracted locations, Domiciliary, Telemedicine).*
- g. Outlining the clinical pharmacist's responsibility for communication with the collaborating physician such as when significant changes in the patient's condition occur, when referrals to higher levels of care are unclear, and advanced patient care*

management outside of the scope of practice and expertise of the clinical pharmacist is required.”

The Office of Mental Health and Suicide Prevention Director reviewed VHA guidance and concluded that the implemented mental health care coordination agreements (CCA) clearly describe the allowable clinical duties of the Mental Health Clinical Pharmacy Specialists (MH CPS) reflective of their practice setting. As of March 8, 2019, all VA medical facilities with MH CPS have reported they have implemented a MH CCA.

Status: Complete

Completion Date:

OIG Comment: The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 5

The Under Secretary for Health ensures a process is in place for chiefs of mental health service to document review, recommendation, and endorsement of all outpatient mental health clinical pharmacists’ scopes of practice, regardless of whether the clinical pharmacist is aligned with the mental health service line, and monitor compliance.

Concur.

Executive in Charge Comments

VHA finds both the Executive Committee of the Medical Staff (ECMS) review and approval process and the credentialing program ensure mental health clinical pharmacists’ scopes of practice are appropriately reviewed by facility clinical leadership and are appropriately monitored for compliance. Changing policy on facility documentation of review and approval of scopes of practice through the ECMS, and changing the national credentialing program are unnecessary.

The Executive in Charge for VHA ensured a process is in place for facility Chiefs of Mental Health, as members of the ECMS, to review, make recommendations, and endorse all clinical pharmacists’ scopes of practice during committee decision making. Chiefs of Mental Health contribute to ECMS approvals on clinical pharmacist scopes of practice regardless of whether the clinical pharmacist is aligned with the mental health service line. Approval of clinical pharmacists’ scopes of practice by the ECMS supersedes endorsement by any specific Chief of Service; ECMS decisions are documented in committee minutes. ECMS procedures and processes are established in section 5.02 of the medical staff bylaws template found at: <http://vaww.oqsv.med.va.gov/filedownload.ashx?fid=10228> [This website is an internal VA website and not accessible to the public].

The Executive in Charge for VHA ensured a process is in place for monitoring all licensed health care professionals for compliance with scopes of practice or privileges, including clinical pharmacists. VHA uses an enterprise-wide credentialing process, established through national policy, that requires evaluation of initial and ongoing competencies through standardized professional practice evaluation.

Status: Complete

Completion Date:

OIG Comment: The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 6

The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews and provides input into the patient referral process to mental health clinical pharmacists with consideration for ensuring that accurate diagnoses can be reliably identified by and conveyed to the mental health clinical pharmacists.

Concur.

Executive in Charge Comments

The Executive in Charge for VHA ensured that the VHA Office of Mental Health and Suicide Prevention Director will review and provide input into the patient referral process to Mental Health (MH) Clinical Pharmacy Specialists (CPS). Based on said review, the VHA Office of Mental Health and Suicide Prevention Director will determine whether updates are needed to VHA policy on Uniform Mental Health Services (VHA Handbook 1160.01).

VHA has already established requirements for MH care coordination agreements (CCA) for all facilities with MH CPS. The CCA describes referral processes and communication for the MH CPS and team. All VA medical facilities with MH CPS have implemented a MH CCA as of March 8, 2019. In addition, VHA Handbook 1108.11 outlines appropriate patients for management by the clinical pharmacist with a Scope of Practice and describes the provisions for collaborative medication management.

Status: In progress

Completion Date: December 2019

Recommendation 7

The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director reviews the patient referral process to mental health clinical pharmacists and provides input with consideration for clinical settings or scenarios in

which a review of the clinical complexity of the referral by a licensed independent practitioner with prescribing authority would be appropriate, prior to treatment.

Concur.

Executive in Charge Comments

As part of risk management, though we have no evidence of patient harm from MH CPS care, the Office of Mental Health and Suicide Prevention (OMHSP) will review the mental health referral process and, if needed, clarify national policy (VHA Handbook 1160.01, Uniform Mental Health Services).

All licensed health care professionals are expected to understand the complexity of any given patient's care needs and consult with other health care professionals, as needed, regarding the best care of the patient or when to refer to a higher level of care. VHA's national mental health policy already establishes requirements for team-based care to ensure mental health care is comprehensive in nature. These policy requirements apply to all members of the health care team, including the MH CPS. In March 2019, updates to the national policy were placed into formal concurrence. The national directive describes essential components of mental health programs to be implemented nationally to ensure that all Veterans have access to needed mental health services.

Status: In progress

Completion Date: December 2019

Recommendation 8

The Under Secretary for Health ensures the Veterans Health Administration Office of Mental Health and Suicide Prevention Director establishes guidance and provides assistance in outlining when and how mental health clinical pharmacists are to refer patients to a higher level of mental health care.

Non-concur.

Executive in Charge Comments

The Office of Mental Health and Suicide Prevention Director reviewed VHA guidance and concluded that the implemented mental health care coordination agreements (CCAs) are consistent with the expectation that Mental Health Clinical Pharmacy Specialists (MH CPS) communicate and refer to collaborating providers, including physicians or other providers, when advanced patient care is required. As of March 8, 2019, all VA medical facilities with MH CPS have reported they have implemented a MH CCA.

The individual Scope of Practice requires the mental health Clinical Pharmacy Specialist (MH CPS) to be competent in assessing a patient's condition and identify whenever the assessment identifies a change in the status (i.e. worsening, improvement, new problem). MH CPSs have extensive training to evaluate patient conditions and while they do not diagnose, their skills to assess the patient and ability to refer patients to a higher level of care is already established with the authorization of a Scope of Practice. Care coordination agreements (CCA) accurately outline advanced care management related to higher levels of care. VHA is confident in the skills and ability of this well-regarded and trained workforce to make sound decisions related to patient care and to collaborate with licensed health care professionals when advanced patient care is warranted. VHA will not be establishing any additional guidance outlining when and how mental health clinical pharmacists are to refer patients to a higher level of mental health care.

Status:

Completion Date:

Recommendation 9

The Under Secretary for Health initiates a risk assessment of outpatient mental health clinical pharmacists' practice and establish mitigation plans; and includes the Veterans Health Administration Office of Mental Health and Suicide Prevention Director in the design, implementation, and analysis processes.

Concur in principle.

Executive in Charge Comments

The report outlines some potential risks related to oversight in mental health outpatient care teams in general. In building a highly reliable organization, VHA needs to be vigilant about potential risks in all of our care systems. VHA agrees with conducting a risk assessment to identify potential safety risks in outpatient mental health team based care. VHA will apply appropriate risk management to any identified risks – which may include either risk tolerance or risk mitigation. A risk assessment team will lead the effort which will be informed by the Director of the Office of Mental Health and Suicide Prevention only to the extent the team needs clarification on VHA policy or expectations of the outpatient mental health team. Principal officials from all relevant program offices will be involved in development of VHA's response to risks.

Status: In progress

Completion Date: May 2020

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
----------------	---

Inspection Team	Katharine Foster, RN, Project Manager Laura Snow, MHCL, LCSW, Team Leader Kelli Crampton, LCSW Alan Mallinger, MD Vanessa Masullo, MD Laura Tovar, LSCSW Tammra Wood, LCSW
------------------------	--

Other Contributors	Josephine Andrion, MHA, RN Alicia Castillo-Flores, MBA, MPH Sami Cave, MA Limin X. Clegg, Ph. D Laura Dulcie, BSEE Erin Routh, CPA Natalie Sadow, MBA Emorfia Valkanos, RPh Robert Yang, MD, MHA
---------------------------	--

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and
Related Agencies
House Committee on Oversight and 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

The OIG has federal oversight authority to review the programs and operations of VA medical facilities. OIG inspectors review available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leadership on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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