VA COMMUNITY CARE

Veterans Health Administration Office of Community Care Patient Safety Guidebook

February 2018

VETERANS HEALTH ADMINISTRATION OFFICE OF COMMUNITY CARE PATIENT SAFETY GUIDEBOOK

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EXECUTIVE SUMMARY

The goal of the Veterans Health Administration (VHA) Office of Community Care (OCC) is to align quality and patient safety policies across the spectrum of care for Department of Veterans Affairs (VA) beneficiaries, to include both internal VHA (direct) and purchased care. This VHA OCC Patient Safety Guidebook and its associated community care (CC)-related patient safety reporting, investigation, and improvement processes were developed to resolve identified gaps in information sharing, reporting structure, and feedback to stakeholders for patient safety events (adverse events and close calls) that occur when Veterans are receiving care on behalf of VA in the community.

The VHA OCC conducted a gap analysis of the policies and practices related to patient safety for Veterans receiving care in the community. The gap analysis identified:

- A lack of transparency, communication, and information sharing about how issues pertaining to quality and patient safety in CC are addressed
- A need for additional guidance and structure regarding the reporting of quality and/or safety concerns involving CC to VHA health care contractors
- Feedback regarding the outcomes of reviews involving quality and patient safety concerns is not consistently being provided to VHA stakeholders.

The VHA OCC Patient Safety Guidebook, built on existing VHA patient safety reporting and investigation processes, provides the tools and processes to report, disclose, investigate, and improve patient safety for Veterans who receive care in the community and supports VHA's goal of preventing inadvertent harm to Veterans consequent to their medical care. The Guidebook and its associated processes increase communication and collaboration between VHA and its community partners. Developed in collaboration with VA Medical Center (VAMC) Patient Safety Managers (PSMs), Veterans Integrated Service Network (VISN) Patient Safety Officers (PSOs), and the National Center for Patient Safety (NCPS), the Guidebook is intended to provide clear roles, responsibilities, and procedures to explore vulnerabilities in the CC system and emphasize prevention through collaboration with community partners to mitigate system vulnerabilities and improve patient safety.

A CC patient safety event is defined as an adverse event or close call (see Glossary) that occurs at a facility outside VA that is providing care on behalf of VA via a contractual relationship. While the focus of this Guidebook is on community care events occurring involving third-party administrators (TPAs, contractual relationships established under the Veterans Choice Program [VCP] network, Patient-Centered Community Care [PC3] network, or the Community Care Network [CCN]), non-TPA community care providers are also expected to investigate events and implement corrective actions. Any patient safety concerns, whether with TPA or Non-TPA community care providers, should be shared with your PSM, VAMC CC coordination staff, or VHA OCC at CC-PatientSafety@va.gov.

POLICY

The VHA Handbook 1050.01 directs VA employees on the procedures needed to accomplish the VHA's goal of preventing inadvertent harm to patients consequent to their medical care. VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, directs VA employees on the procedures required to fulfill our ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their care. Under its Organizational Excellence Program Office, VHA implemented a four-step approach to patient safety and respect for patients based on the principles of a high reliability organization that includes:

1. Understanding the health care continuum as a system, and exploring system vulnerabilities that can result in patient harm
2. Reporting of adverse events and close calls
3. Emphasizing prevention rather than punishment to mitigate system vulnerabilities
4. Disclosure of adverse events to patients

KEY TERMS

For the purposes of the VHA OCC Patient Safety Guidebook, please see the Table of Key Terms below for CC-related terms used throughout the Guidebook. For additional definitions, please refer to the Glossary at the end of the Guidebook.

Table of Key Terms

VHA OCC Patient Safety Guidebook Key Terms	
Community Care (CC)	Care that is provided to veterans in the community through regional contracting vehicles, provider agreements, individual authorizations, and/or other memorandums of understanding (MOU's)
Third-party Administrator (TPA)	A company that is contracted by VHA to create a regional network of providers that provide care to Veterans Examples of Veteran programs which incorporate TPA's include: Veterans Choice Program (VCP), Patient-Centered Community Care (PC3), and the Community Care Network (CCN) *TPA's are responsible for ensuring that safe medical care is provided to Veterans by providers in their network. Each TPA is responsible for investigating adverse events and close calls that occur to Veterans who see a provider in their network through the VCP, PC3, or CCN programs and to ensure that appropriate follow up actions are taken when necessary.
TPA Quality and Patient Safety Representative	An assigned representative from the TPA's quality and patient safety team who coordinates with VISN PSOs, PSMs, VAMC CC coordination staff, and VHA OCC for CC-related patient safety issues that occur within the TPA's network
Non-TPA Community Care (CC)	All other CC services supported by VHA that are not provided through TPA contracts (examples include care delivered through individual authorizations, provider agreements, home health services, dialysis, etc.)
VHA Office of Community Care (OCC) staff	Staff employed by the VHA Program Office supporting the CC program
VAMC Community Care (CC) coordination staff	VAMC staff directly supporting the coordination of care for Veterans receiving care in the community

ROLES AND RESPONSIBILITIES

Roles and responsibilities for CC-related adverse event and close call reporting and investigation processes are outlined in detail in Appendix A. Those roles considered "key" are called out in the following table, featuring specific CC-related patient safety tasks for these roles.

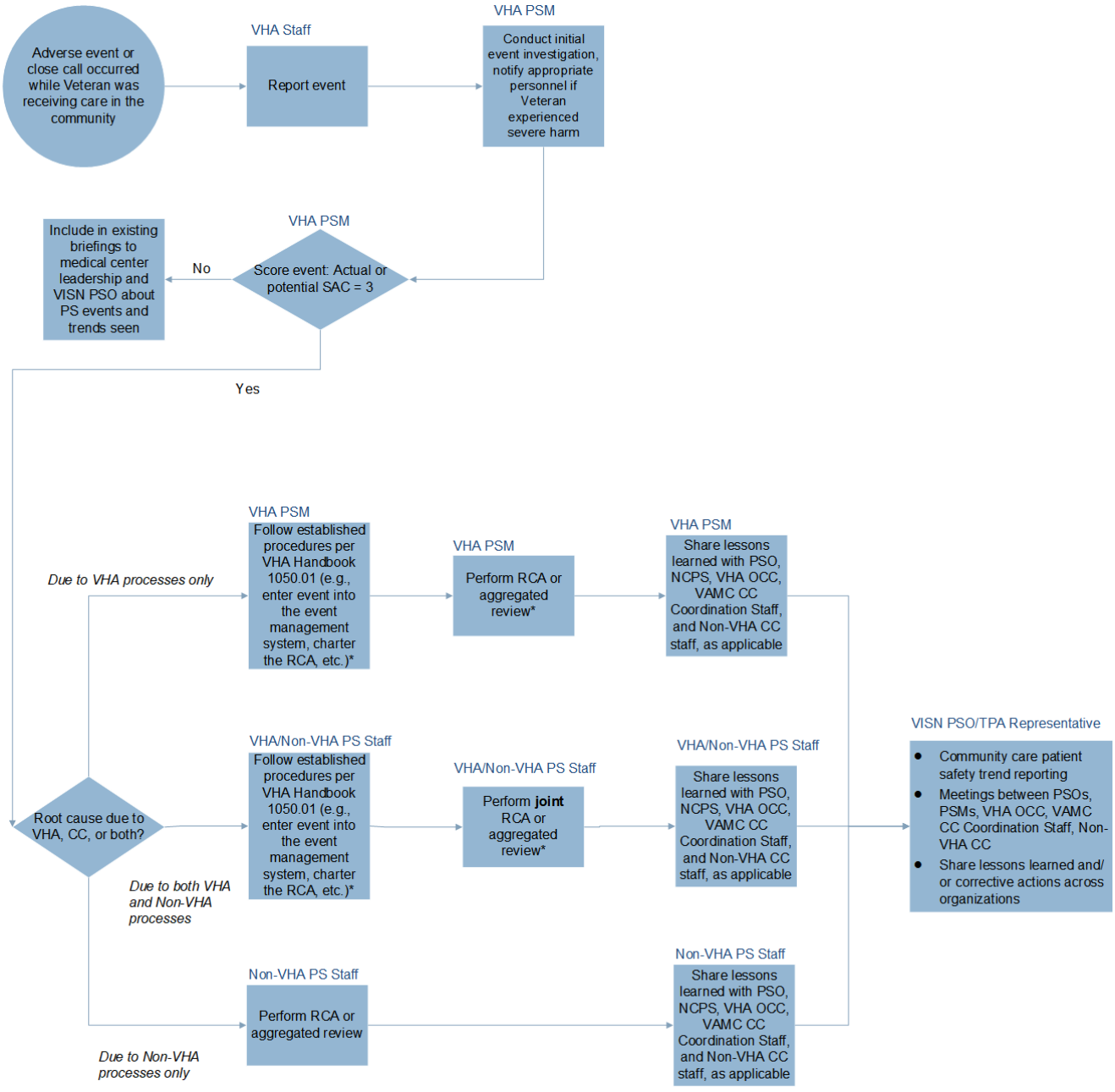
Responsible Entities and CC-related Patient Safety Tasks

CC-related Patient Safety Tasks		Responsible Entity			
		VISN PSO	VAMC PSM	VAMC CC Coordin-ation Staff	Non-VHA CC Staff (e.g., TPA Quality and Patient Safety Representa-tive)
Patient Safety Reporting	Follow patient safety reporting procedures as outlined in the Guidebook	✓	✓	✓	✓
	Initial review of submitted patient safety event reports and completion of any immediate action needs		✓		
	For high severity/probability patient safety events (with the potential to be scored a safety assessment code [SAC] = 3), notify appropriate personnel as outlined in the Guidebook	✓	✓	✓	✓
	Sign a non-disclosure agreement (NDA)				✓
	Follow established procedures per VHA Handbook 1050.01	✓	✓	✓	
Patient Safety Investigation	Follow patient safety investigation procedures as outlined in the Guidebook	✓	✓	✓	✓
	Conduct initial event investigation for CC-related patient safety events, when applicable		✓	✓	✓
	Complete RCA facilitation training (one-time training)			✓	
	Participate on RCA Teams (when applicable)			✓	✓
	Facilitate joint RCAs or Aggregated Reviews (when applicable)		✓	✓	✓

CC-related Patient Safety Tasks		Responsible Entity			
		VISN PSO	VAMC PSM	VAMC CC Coordin-ation Staff	Non-VHA CC Staff (e.g., TPA Quality and Patient Safety Representa-tive)
	Facilitate facility RCAs or Aggregated Reviews, when applicable		✓	✓	✓
	Provide support to VAMC PSMs	✓			
	Follow established procedures per VHA Handbook 1050.01	✓	✓	✓	
Patient Safety Improvement	Follow patient safety improvement procedures as outlined in the Guidebook	✓	✓	✓	✓
	Include CC as a standing agenda item at designated meetings (at discretion of VISN PSO)	✓			
	Include discussions about CC event reports and lessons learned as part of regular VISN- or VAMC-level patient safety discussions	✓	✓		✓
	Provide an attestation of completion of an RCA or quality improvement initiative, when applicable, or explanation of non-completion				✓

PROCESS FLOW

Note: The process flow below is an overview of the process. Please use the procedures starting on the following page for each step in CC-related reporting, investigation, and improvement processes. Please see Appendix B for detailed process flows.



PROCEDURES FOR PROCESSING CC-RELATED PATIENT SAFETY EVENTS

Patient Safety Reporting:

1. Staff member identifies patient safety event that occurred in CC
   - VHA staff member creates patient safety event report (within 24 hours) using facility-specific tool, identifies location as “contracted care”, and submits
2. Notification sent by system (once event report submitted) to, or paper report received, by VA Facility PSM
3. VA Facility PSM reviews event report and determine any immediate action needs, to include clinical needs of the injured Veteran, based on type, severity, and probability of the event, and the notification distribution requirements for the event
   - For administrative issues not classified as a patient safety event (no potential or actual harm occurs to the patient), report the issue through the appropriate venue
   - For adverse events and close calls with the **potential** to be scored with a SAC = 3 or classified high severity/probability (pre-SAC scoring/assessment, based on initial assessment of event), complete notifications and procedures per the tables on the following pages referencing CC-related tasks for events reported by VHA staff

High Severity/Probability (pre-SAC scoring) Events

Patient Safety Reporting CC-related Patient Safety Tasks (High Severity/Probability only – expected to be very low in frequency)	For adverse events and close calls identified by a VHA staff member, with the potential to be scored with a SAC = 3 (pre-SAC scoring), and potentially resulting from errors and/or systems flaws involving:				
	TPA Care Processes Only	Processes involving both TPA and VHA	Non-TPA CC Processes Only	Processes involving both Non-TPA CC and VHA	VHA Processes Only
PSM notifies VISN PSO and VHA OCC (CC-PatientSafety@va.gov) of event by telephone or electronically	✓	✓	✓	✓	
PSM notifies VAMC CC coordination staff of event by telephone or electronically	✓	✓	✓	✓	✓
PSM notifies TPA Quality and Patient Safety Representative of event by telephone or electronically	✓	✓			
VAMC CC coordination staff notifies Non-TPA CC staff of event by telephone or electronically			✓	✓	
TPA Quality and Patient Safety Representative or Non-TPA CC staff initiate further action per established organizational procedures and contractual requirements	✓	✓	✓	✓	
For adverse events that resulted in serious harm to the Veteran or could result in serious harm in the foreseeable future, facility leader(s) coordinate an institutional disclosure per VHA Handbook 1004.08	✓	✓	✓	✓	✓
Refer to VHA Handbook 1050.01 for established procedures regarding compensation to injured patients and voluntary reporting of patient safety events to The Joint Commission	✓	✓	✓	✓	✓
Follow established procedures per VHA Handbook 1050.01		✓		✓	✓

Patient Safety Investigation:

1. Review event and conduct initial investigation
   - VA Facility PSM reviews reported event and requests that appropriate VAMC CC coordination staff review case, engage with other VAMC CC coordination staff and/or TPA Quality and Patient Safety Representative if needed, conduct an initial investigation, perform any needed immediate actions, to include addressing clinical needs of the injured Veteran, and provide a summary of findings to the PSM
   - Non-VHA staff (TPA or Non-TPA CC) follow established organizational procedures and contractual requirements to investigate event and perform appropriate follow-up actions
2. Assess event's severity/probability
   - VA Facility PSM scores event using SAC matrix from VHA Handbook 1050.01, enters event data into patient safety event management system, and performs appropriate action based on SAC score per VHA Handbook 1050.01
   - Non-VHA staff perform appropriate action based on organizational procedures, contractual requirements, and this Guidebook
3. For adverse events and close calls deemed high severity/probability and/or scored with an actual or potential SAC = 3, complete procedures per the below table

SAC=3 Events

Patient Safety Investigation CC-related Patient Safety Tasks (SAC = 3 only – expected to be very low in frequency)	For events scored with an actual or potential SAC = 3 (high severity/probability), and potentially resulting from errors and/or systems flaws in:				
	TPA Care Processes Only	Processes involving both TPA and VHA	Non-TPA CC Processes Only	Processes involving both Non-TPA CC and VHA	VHA Processes Only
Actual SAC=3 *only*: VHA and TPA or Non-TPA CC staff, as applicable, complete a joint (both VHA and non-VHA staff) RCA within 45 days (e.g., delay in care and unclear where process gap occurred)		✓		✓	
Potential SAC=3 *only*: VHA and TPA or Non-TPA CC staff, as applicable, complete a joint (both VHA and non-VHA staff) RCA within 45 days (e.g., delay in care and unclear where process gap occurred) or an Aggregated Review will be completed		✓		✓	
Actual SAC=3 *only*: VHA patient safety staff complete an RCA within 45 days on the VHA components of the process (e.g., wrong provider type consulted)					✓
Potential SAC=3 *only*: VHA patient safety staff complete an RCA within 45 days on the VHA components of the process or an Aggregated Review will be completed					✓
TPA Quality and Patient Safety Representative or Non-TPA CC staff, as applicable, complete an RCA or other quality improvement initiative within 45 days	✓		✓		
TPA Quality and Patient Safety Representative or Non-TPA CC staff, as applicable, provides the PSM, PSO, and VHA OCC with an attestation by e-mail that an investigative analysis and/or quality improvement initiative was completed and appropriate corrective actions taken (see Appendix D). If an analysis/initiative was not completed, a statement of non-completion with an explanation is provided.	✓		✓		
VAMC CC coordination staff facilitate or serve on the RCA Team, if appropriate		✓	✓	✓	✓

Patient Safety Investigation CC-related Patient Safety Tasks (SAC = 3 only – expected to be very low in frequency)	For events scored with an actual or potential SAC = 3 (high severity/probability), and potentially resulting from errors and/or systems flaws in:				
	TPA Care Processes Only	Processes involving both TPA and VHA	Non-TPA CC Processes Only	Processes involving both Non-TPA CC and VHA	VHA Processes Only
VAMC CC coordination staff provide summary findings from the RCA to the Facility PSM, if applicable		✓		✓	✓
If overall care processes may be improved by sharing lessons learned and/or corrective actions, the PSM or PSO will share these with the TPA Quality and Patient Safety Representative					✓
TPA Quality and Patient Safety Representative or Non-TPA CC staff, as applicable, shares lessons learned and/or corrective actions with the PSM, PSO, VHA OCC, and VAMC CC coordination staff	✓		✓		
For adverse events that resulted in serious harm to the Veteran or could result in serious harm in the foreseeable future, facility leader(s) coordinate an institutional disclosure per VHA Handbook 1004.08	✓	✓	✓	✓	✓
Follow established procedures per VHA Handbook 1050.01		✓		✓	✓

Note: If insufficient Non-TPA CC staff exist to support an investigative analysis and/or quality improvement initiative, VAMC CC coordination staff will facilitate the RCA or Aggregated Review and provide summary findings, to include corrective actions and lessons learned, to the appropriate PSM, VISN PSO, VHA OCC, and NCPS, as applicable

Patient Safety Improvement:

1. It is recommended that VISN PSOs and TPA Quality and Patient Safety Representatives brief combined CC event trends, lessons learned, corrective actions, and/or de-identified case studies, when overall care processes may be improved, at VISN PSO-designated meetings on a quarterly basis, at minimum, with the PSO, TPA Quality and Patient Safety Representative, and NCPS, VHA OCC, and VAMC CC coordination staff in attendance
2. For events attributable to a process error(s) on the part of the **TPA**, VISN PSOs follow up with TPA Quality and Patient Safety Representatives to ensure an investigative analysis and/or quality improvement initiative was completed (attestation provided) and corrective actions implemented
3. For events attributable to a process error(s) on the part of **Non-TPA CC** facility/provider, VAMC CC coordination staff or PSO's follow up, as appropriate, with the applicable Non-TPA CC facility/provider to ensure an investigative analysis and/or quality improvement initiative was completed (attestation provided) and corrective actions implemented
4. PSMs or designees (e.g., VAMC CC coordination staff supporting CC patient safety efforts) may brief CC trend reports, lessons learned, and/or corrective actions at VA CC Oversight Council meetings, at applicable facilities
5. TPA Quality and Patient Safety Representatives, or other designated staff, provide patient safety performance metrics (as outlined per contract requirements) to the NCPS and VHA OCC
6. Non-TPA CC staff provide patient safety performance metrics (as outlined per contract requirements) to the NCPS and VHA OCC

GLOSSARY

Source: VHA Handbook 1050.01, VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK (see Appendix C)

Adverse Event: Adverse events that may be candidates for a root cause analysis (RCA) are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided to a Veteran in the community on behalf of the VA. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment). Some examples of more common adverse events include: patient falls, adverse drug events, procedural errors or complications, and missing patient events. All adverse events, including those occurring in CC, require reporting and documentation in the patient safety event management system. The type of review required is determined through the SAC Matrix scoring process (see Appendices).

Aggregated Review: The Aggregated Review process is a method of analyzing a group of similar incidents or event types to determine common causes, thereby facilitating coordinated actions to prevent recurrences. Issues and incidents reviewed via Aggregated Reviews are those that do not require individual RCAs. The determination of common causes using Aggregated Reviews provides the opportunity to correct minor issues before they lead to serious adverse events.

Close Call: A close call is an event or situation that could have resulted in an adverse event, but did not, either by chance or through timely intervention. Such events have also been referred to as “near miss” incidents. An example of a close call would be a surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification, but caught prior to the procedure. Close calls are opportunities for learning and afford the chance to develop preventive strategies and actions; they receive the same level of scrutiny as adverse events that result in actual injury. They require reporting and documentation in the patient safety event management system. NOTE: Just as for adverse events, the SAC Matrix scoring process and score determines the type of review (see Appendices).

Disclosure of Adverse Events: Disclosure of adverse events refers to the forthright and empathetic discussion of clinically-significant facts between providers or other personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future directly associated with care or services provided to a Veteran in the community on behalf of the VA.

Institutional Disclosure of Adverse Events: Institutional disclosure of adverse events is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care in the community on behalf of the VA that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse. Serious injury (e.g., SAC = 3) may include significant or permanent disability, injury that leads to prolonged hospitalization, injury requiring life-sustaining intervention, or intervention to prevent impairment or damage, including, for example “sentinel events” as defined by the Joint Commission.

Patient Safety: Patient Safety is ensuring freedom from accidental or inadvertent injury during health care processes.

Patient Safety Event: An adverse event or close call.

Root Cause Analysis: RCA is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. An RCA is a specific type of focused review that is used for all adverse events or close calls requiring analysis. Consistent use of RCAs further refines the implementation and increases the quality and consistency of focused reviews. To avoid confusion, the term RCA is used to denote this type of focused review and must adhere to the procedures provided in the VHA Handbook 1050.01. RCAs must be initiated with a specific charter memorandum, and the term “Root Cause Analysis” must be used in documents so that they are protected and deemed confidential under 38 U.S.C. 5705 and it’s implementing regulations.

APPENDICES

Appendix A. Detailed Roles and Responsibilities

Appendix B. Detailed Process Flows

Appendix C. References (Laws, Standards, Guidance, etc.)

- VHA Handbook 1050.01: VHA NATIONAL PATIENT SAFETY IMPROVEMENT HANDBOOK
- 38 U.S.C. 5705 - Confidentiality of medical quality-assurance records
- Reporting Potential Quality of Care Issues and Serious Reportable Events (Health Net)
- Operations and Medical Management: Veterans Safety Event (TriWest)
- Patient Safety Event Reporting Guidance
- Frequently Asked Questions

Appendix D. Forms

- VHA OCC Patient Safety Non-Disclosure Agreement and Release of VHA Data
- Attestation of Completion of Investigative Analysis and Improvement Initiative(s)

REVISION HISTORY

The development and maintenance of this document is the responsibility of the VHA OCC. Questions regarding, or proposed changes to this document, including supporting rationale, should be submitted to CC-PatientSafety@va.gov. For additional resources related to patient safety in CC, please go to the VHA OCC Field Guidebook SharePoint Page.

1. Revision: v1

   Date: 6/15/2017

   Description of Changes: Initial draft

   Requested By: VHA OCC

2. Revision: v2

   Date: 2/21/2018

   Description of Changes: Updated per end-user feedback

   Requested By: VHA OCC

3. Revision:

   Date:

   Description of Changes:

   Requested By: