

OFFICE OF THE STATE INSPECTOR GENERAL

**FY2017 Unannounced Inspections of
Facilities Operated by the Virginia Department of
Behavioral Health and Developmental Services**

March 2018



**Michael C. Westfall, CPA
Acting State Inspector General
Report No. 2018-BHDS-001**



COMMONWEALTH OF VIRGINIA
Office of the State Inspector General

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March 26, 2018

Jack Barber, M.D., Interim Commissioner
Department of Behavioral Health and Developmental Services
1220 Bank Street
Richmond, VA 23219

Dear Dr. Barber:

The Office of the State Inspector General (OSIG) performed unannounced inspections at all facilities operated by the Department of Behavioral Health and Developmental Services (DBHDS) during fiscal year 2017 (FY2017) pursuant to *Code of Virginia* § 2.2-309.1[B](1). The overall goal of unannounced inspections is to review the quality of services provided and make policy and operational recommendations to prevent problems, abuses and deficiencies, as well as improve the effectiveness of programs and services. OSIG's FY2017 unannounced inspections focused on significant events occurring in DBHDS-operated facilities. Attached, please find the final report and recommendations.

By copy of this letter, OSIG requests agency management provide a corrective action plan within 30 days to address this report's recommendations.

On behalf of OSIG, I would like to express our appreciation for the assistance provided by DBHDS and facility directors and staff during these inspections. If you have any questions, please contact me at (804) 625-3255 or michael.westfall@osig.virginia.gov. I am also available to meet with you in person to discuss this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Westfall".

Michael C. Westfall, CPA
Acting State Inspector General

CC: Clark Mercer, Chief of Staff to Governor Northam
Suzette P. Denslow, Deputy Chief of Staff to Governor Northam
Daniel Carey, M.D., Secretary of Health and Human Resources
Mira Signer, Chief Deputy Commissioner, DBHDS
Daniel Herr, J.D., Deputy Commissioner of Behavioral Health Services, DBHDS
Connie Cochran, Deputy Commissioner of Developmental Services, DBHDS
Dev Nair, Assistant Commissioner, Quality Management and Development, DBHDS
The Honorable R. Creigh Deeds, Chair, Joint Subcommittee, Mental Health Services in the 21st Century
The Honorable Robert B. Bell, Vice Chair, Joint Subcommittee, Mental Health Services in the 21st Century

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Executive Summary

Pursuant to *Code of Virginia* § [2.2-309.1](#), the Office of the State Inspector General (OSIG) conducted unannounced inspections at all facilities operated by the Virginia Department of Behavioral Health and Developmental Services (DBHDS) for fiscal year 2017 (FY2017), focusing on significant events that primarily relate to patient injury and death.

OSIG's review identified a number of recommendations with potential to improve patient safety, the goal of any robust event management system. In support of that goal, OSIG also provided recommendations to improve the quality of risk management in DBHDS-operated facilities, as well as to minimize risks faced by DBHDS, facilities and individuals served.

As a leading cause and concern, OSIG found the current DBHDS event reporting and response system as defined in Departmental Instruction (DI) 401(RM)03 Risk and Liability Management (DI401) to be inadequate and in need of a comprehensive revision. DI401, last revised in 2012, is an outdated policy that contains areas of ambiguity and lacks definitions for key terms and criteria or specific requirements for key processes. The lack of clearly defined criteria and guidelines limits facilities' ability to take advantage of opportunities for quality reporting, analysis and performance improvement. Application of DI401 across the system, along with its supporting infrastructure, including the age and utility of existing databases, has the potential to, and in some cases does, cause a variety of harmful errors, inefficiencies, waste and redundancies.

To mitigate risk and improve processes for reporting and responding to significant events, OSIG recommends DBHDS commit to the following action items:

1. Perform a comprehensive review and revision of DI401, including the DMH 158. This review should include input from relevant stakeholders, including facility directors, facility risk managers and direct-care staff.
2. Once revised, develop a standardized training curriculum. Facilities should have the option to customize the document to suit their needs.
3. Implement the Virginia Center for Behavioral Rehabilitation (VCBR) event database (including event reporting form) at all facilities not currently slated for closure.
4. Study the possibility of updating facility event databases to include the capability of reporting events as required in Code § [37.2-709](#) (48-hour requirement) and § [37.2-304.7](#) (15 working-day requirement).
5. Develop and require a standardized significant event review process. Upon development, DBHDS should train facility risk management staff on its use (including annual refreshers) and monitor implementation to determine fidelity and evaluate quality of reviews and outcomes.
6. Following a specified number (or percentage) of significant events, develop a system to evaluate case review performance, including policy compliance, quality of documentation, reviews and outcomes.

Purpose and Scope

The Office of the State Inspector General (OSIG) conducted unannounced inspections of the following 14 facilities operated by the DBHDS for FY2017:

- Seven behavioral health facilities serving adults;
- One behavioral health facility serving children and adolescents;
- One behavioral health facility serving elder adults;
- Three training centers serving the intellectually and developmentally disabled;
- One medical facility; and
- One behavioral rehabilitation center serving civilly committed adult sexually violent predators.

The annual unannounced inspections were performed pursuant to *Code of Virginia* § 2.2-309.1, whereby the State Inspector General shall have power and duty to:

“Provide inspections of and make policy and operational recommendations for state facilities ... in order to prevent problems, abuses, and deficiencies in and improve the effectiveness of their programs and services. The State Inspector General shall provide oversight and conduct announced and unannounced inspections of state facilities and ... shall conduct unannounced inspections at each state facility at least once annually.”

These inspections were not designed to be comprehensive reviews of facilities operated by DBHDS. For FY2017, the unannounced inspections focused specifically on reporting and responding to significant events. Departmental Instruction 401(RM)03 Risk and Liability Management (DI401, Appendix I) defines facility risk and liability standards and, specifically, the standards for reporting and responding to significant events.

The scope of these inspections was developed after a review of DBHDS data concerning significant events, including injuries requiring acute care hospitalization and deaths in DBHDS-operated facilities. OSIG identified a sample of these event types by focusing on those that occurred most often at each facility type during the timeframe for review, FY2016 through FY2017, quarter two (July 1, 2015 to December 31, 2016).

Objectives of these inspections included:

1. Conduct a quantitative analysis of significant events occurring in DBHDS-operated facilities to identify patterns and trends.
2. Determine the consistency of application of DI401.
3. Assess the quality of DBHDS and facility reviews of significant events, data management and current quality management processes utilized to drive performance improvement and lessen risks of future events.

4. Conduct case reviews of individuals who experienced significant events to identify potential risk points and opportunities for improvement.

Background

Code of Virginia § [37.2-304](#) establishes the DBHDS commissioner as the individual responsible for the supervision and management of DBHDS and the facilities it operates. These 14 facilities include nine behavioral health facilities, three training centers, one medical facility and a rehabilitation center for civilly committed adult sexually violent predators as follows:

Table 1: DBHDS-operated Facilities

Facility	Capacity	Location	Service Populations	Forensic Admissions	Accreditation/Certification
Catawba Hospital (CAT)	110	Catawba	Adults and elder adults with behavioral health needs	No	The Joint Commission (TJC), hospital standards (hospital), August 2015
Central State Hospital (CSH)	277	Petersburg	Adults with acute behavioral health needs	Yes, maximum security	TJC (hospital) October 2016
Central Virginia Training Center (CVTC)	228	Madison Heights	Individuals with intellectual and developmental disabilities (ID/DD)	No	Recertified by Centers for Medicare and Medicaid Services (CMS); intermediate care facility for individuals with intellectual disabilities (ICF/IID), June 2017
Commonwealth Center for Children and Adolescents (CCCA)	48	Staunton	Individuals 18 and under with behavioral health needs	Yes	TJC, behavioral health standards, May 2015
Eastern State Hospital (ESH)	302	Williamsburg	Adults and elder adults with behavioral health needs	Yes, medium security	TJC (hospital), May 2015
Hiram Davis Medical Center (HDMC)	84	Petersburg	Individuals with behavioral health and acute medical or nursing home-level needs	No	TJC (hospital), June 2016; TJC (nursing care center), December 2016; CMS (skilled nursing facility/nursing facility)(distinct part), October 2016
Northern Virginia Mental Health Institute (NVMHI)	134	Fairfax	Adults with behavioral health needs	Yes, medium security	TJC (hospital), October 2015
Piedmont Geriatric Hospital	123	Burkeville	Elder adults with behavioral health needs	Yes, medium security	TJC (hospital), June 2016
Southeastern Virginia Training Center (SEVTC)	75	Chesapeake	Individuals with ID/DD	No	CMS (ICF/IID), May 2017
Southern Virginia Mental Health Institute (SVMHI)	72	Danville	Adults with behavioral health needs	Yes, medium security	TJC (hospital), February 2015

Southwestern Virginia Mental Health Institute (SWVMHI)	179	Marion	Adults and elder adults with behavior health needs	Yes	TJC (hospital), April 2017
Southwestern Virginia Training Center (SWVTC)	120	Hillsville	Adults with ID/DD	No	CMS (ICF/IID), April 2017
Virginia Center for Behavioral Rehabilitation (VCBR)	450	Burkeville	Civilly committed adult sexually violent predators	No	None
Western State Hospital (WSH)	246	Staunton	Adults with behavioral health needs	Yes, medium security	TJC (hospital), October 2015

Patient Safety

The event that seems to have brought patient safety into national focus was the 1999 publication of the Institute of Medicine’s, *To Err is Human: Building a Better Health System*. The report claimed at least 44,000, and possibly as many as 98,000, patients died annually in hospitals as the result of preventable medical errors. Patient safety was also the focus of a 2010 report by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) entitled *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. It found that 13.5 percent of Medicare beneficiaries discharged during October 2008 experienced an adverse event that resulted in temporary harm, and 44 percent of those adverse events were deemed reasonably preventable with the implementation of evidence-based guidelines. A 2012 HHS OIG report, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, continued this focus on patient safety, reporting that hospital staff do not report 86 percent of events to incident-reporting systems, partially because of misconceptions about what actually constitutes patient harm.

In 2016, the National Patient Safety Foundation (NPSF) released Version 2.0 of its report, *RCA²: Improving Root Cause Analyses and Actions to Prevent Harm*, the purpose of which is to ensure root cause analyses (RCAs) result in the identification and implementation of sustainable systems-based improvements that lead to safer patient care. The report includes methodologies and techniques to facilitate more effective RCAs, as well as tools to evaluate them to identify and remediate flaws so they may better meet objectives. The report defines the purpose of an RCA as identifying vulnerabilities in a system so they can be mitigated or eliminated. It makes clear RCAs are *not* to be used to address individual staff performance as the primary cause of an adverse event; to do so would be ineffective in preventing future events. Instead, an effective RCA looks for the underlying systems-level causative elements that were manifested in staff-related performance issues. It is often difficult for providers to determine how to respond to events that are clearly precipitated by an egregious act, malicious intent, patient abuse or substance abuse. If this occurs or comes to light during an RCA², the burden is on a provider to make appropriate referrals in response, but not abandon the opportunity to learn from the event and/or identify other systems issues that should be addressed.

To identify systems-level causative elements, the NPSF outlines five general rules of causation that can be used:

1. Clearly show the “cause and effect” relationship;
2. Use specific and accurate, rather than negative or vague, descriptors for what occurred;
3. Human errors must have a preceding cause;
4. Violations of procedure are not root causes, but must have a preceding cause; and
5. Failure to act is only causal when there is a pre-existing duty to act.

Once causative elements are identified, the NPSF highlights the most important step in the RCA² process as, “the identification and implementation of actions to eliminate or control system hazards or vulnerabilities... identified...” These actions must take into account process and outcome measures so their effectiveness can be determined, including specific target dates for completion and the individual(s) responsible for ensuring completion. Corrective actions are classified as stronger, intermediate or weaker, and teams performing RCAs “should identify at least one stronger or intermediate strength action for each RCA² review.” Examples of strengths of corrective actions include:

- Stronger – Standardization of a process, tangible involvement by leadership and physical plant changes;
- Intermediate – Software enhancements, increase in staffing/decrease in workload, standardized communication tools and enhanced documentation/communication; and
- Weaker – Double checks, warnings, revised or new policies or procedures, and training or re-education.

The NPSF also provides a list of warning signs that indicate an organization’s RCA process is failing and needs to be revised. These signs include:

- No contributing factors identified in the RCA;
- Individuals are identified as causal factors;
- No corrective actions identified, or those identified do not appear to address the causal factors;
- No stronger or intermediate corrective actions identified; and
- Corrective actions do not have completion dates or meaningful measures.

Accreditation and Compliance Requirements

DEPARTMENT OF JUSTICE SETTLEMENT AGREEMENT

In 2008, the Department of Justice (DOJ) initiated an investigation of conditions at CVTC pursuant to the Civil Rights of Institutionalized Persons Act (CRIPA). In 2010, DOJ notified the Commonwealth that it was expanding its investigation to focus on the Commonwealth’s compliance with the Americans with Disabilities Act’s (ADA) integration mandate and the United States Supreme Court’s Olmstead ruling, which requires states to eliminate unnecessary segregation of persons with disabilities and ensure that the same receive services in the most integrated setting

appropriate to their needs. In 2011, DOJ issued its findings letter, concluding that the Commonwealth, “... fails to provide services to individuals with intellectual and developmental disabilities in the most integrated setting appropriate to their needs as required by the ADA and *Olmstead*.” In 2012 the United States and the Commonwealth, in the United States District Court for the Eastern District of Virginia, reached a [settlement agreement](#) (SA) intended to ensure the Commonwealth’s compliance with ADA and *Olmstead*. The SA target population includes those served in training centers in the Commonwealth, and states both parties anticipate compliance will be achieved by June 30, 2021.

The SA includes a specific focus on quality and risk management to ensure services delivered under the SA are of good quality and help individuals achieve positive outcomes and greater independence. Under section V.E.1, “Providers,” the SA holds the Commonwealth responsible for requiring all providers (including training centers and community services boards [CSBs]), “to develop and implement a quality improvement (“QI”) program, including root cause analyses, that is sufficient to identify and address significant service issues and is consistent with the requirements of the DBHDS Licensing Regulations.”

The SA identified an Independent Reviewer (IR) to determine whether the Commonwealth is in compliance with the SA, and issue reports every six months to update the Court on progress towards compliance. The most recent IR report that provides updates on compliance is the ninth IR report, which covers the period April 7, 2016 – September 30, 2016 (the IR did not include compliance updates in the 10th report due to private matters). Released in December 2016, this report indicated the Commonwealth was noncompliant with section V.E.1.

THE JOINT COMMISSION

In 2013, Mark R. Chassin, president and chief executive officer of TJC, and Jerod M. Loeb, executive vice president for healthcare quality evaluation at TJC, identified three variables on which health care organizations would have to focus in order to advance in a meaningful way toward high reliability: leadership commitment; encouraging staff throughout the organization to “speak up;” and installation of a systematic, data-driven approach to performance improvement.

TJC relies on the World Health Organization definition of patient safety as the prevention of errors and adverse events to patients associated with healthcare. Its Comprehensive Accreditation Manual for Hospitals (CAMH) includes entire chapters dedicated to patient safety and a Sentinel Event Policy (SEP, Appendix II). TJC defines a patient safety event as an, “event, incident, or condition that could have resulted or did result in harm to an individual served.” It further defines a sentinel event as, “...a patient safety event (not primarily related to the natural course of an illness or underlying condition of an individual served) that reaches an individual served” and results in death, permanent harm or severe temporary harm (defined as “critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time”). Other events considered sentinel include, but are not limited to:

- Suicide of an individual receiving services in a staffed, around-the-clock setting or within 72 hours of discharge;
- Any elopement that leads to death, permanent harm or severe temporary harm; or
- Rape, assault or homicide of any individual receiving services or any staff member while on site.

While no longer required to report sentinel events directly to TJC at the time of discovery, organizations accredited by TJC are expected to respond appropriately to all sentinel events and to present their response to TJC during survey or intra-cycle monitoring, if requested. Appropriate responses to sentinel events include:

- Identification of a formalized response team that stabilizes the individual served, discloses the event to family members and supports the individual, family and staff member involved;
- Notification of organization leadership;
- Immediate investigation;
- Completion of a comprehensive systematic analysis to identify causal and contributing factors;
- Development of a corrective action plan; and
- A timeline for implementation of “strong corrective actions” that produce systemic improvement.

The SEP states that an RCA is the most common form of comprehensive systematic analysis, but recognizes organizations may use other tools to conduct this analysis. The analysis and corrective action plan must be completed within 45 business days of the event or of becoming aware of the event.

DBHDS

The policies, procedures and responsibilities for reporting, responding to and investigating events at DBHDS-operated facilities are set forth in DI401, last revised in 2012, and reissued in 2013. Following are several definitions from DI401:

DI401 purpose:

“...to establish requirements and guidance for a comprehensive and uniform system-wide risk management program aimed at achieving the optimum degree of risk reduction, elimination and control through the identification, analysis, and treatment of those exposures that may result in harm to individuals receiving services, employees, visitors, volunteers, students and contractors, or a loss.”

Risk management:

“...an integrated system-wide program to ensure the safety of individuals receiving services, employees, visitors, volunteers, contractors and students through prevention, monitoring, early detection, evaluation and control of risks.”

DI401 states that through its risk management program, DBHDS intends to “enhance safety and to minimize the potential liability exposure and financial loss to the Department and the Commonwealth of Virginia.”

Event:

“... any occurrence, accidents [sic] or experience and situations that either do or could alter or change the status or condition of an individual receiving service, employee, volunteer, visitor, contractor or student, or the routine operations of the organization...”

Sentinel event:

“... any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to an individual receiving services, not related to the natural course of an individual's illness. Sentinel events specifically include loss of a limb or gross motor function, and *any event for which a recurrence would carry a risk of a serious adverse outcome (emphasis added).*”

Unexplained injury:

“... an injury to an individual receiving services that is discovered after an un-witnessed event where, upon initial discovery, the surrounding facts and circumstances provide no apparent reasonable or logical explanation sufficient to determine its cause.”

DI401 provides detailed instruction regarding the duties and responsibilities for parties involved in the process of reporting, responding to, and investigating significant events. In the DBHDS Central Office (CO), the director of clinical quality and risk management is responsible for developing and maintaining DBHDS risk management procedures and guidelines, overseeing and monitoring facility risk management programs, and reporting system-wide trend data. The assistant commissioners for Behavioral Health Services and Developmental Services are, in collaboration with the director of clinical quality and risk management, responsible for ensuring facility compliance with recommended operational risk reduction strategies.

Each facility director is responsible for implementing a comprehensive and integrated risk management program managed by a risk manager qualified by training or professional designation; developing and implementing risk reduction plans following event analyses; and implementing “as deemed appropriate all corrective action plans and risk reduction strategies recommended by the facility Risk Manager or the [Quality] Committee, or both...”

DI401 defines a risk manager as “the designated person responsible for coordinating, managing and implementing the facility's risk management program and activities.” Each facility’s risk manager develops and implements the facility’s risk management program, ensures all events are reported and reviewed using the DMH 158, assigns clinical severity levels and risk index codes, takes the necessary steps to ensure investigations and follow-up reviews are conducted, and monitors the status of corrective action plans. DI401 states risk managers must maintain documentation of:

- “Commonwealth of Virginia *Risk Management Plan*;
- Reference list of risk management-related department instructions, memoranda and guidelines;
- Facility risk management-related policies, procedures and protocols;
- Facility risk management plan;
- Facility annual risk management evaluations;
- Risk manager's EWP consistent with this DI;
- Other information, as appropriate (e.g., laws relevant to the care of individuals receiving services, operations, employment, current literature on risk management topics); and
- Incident management procedures in the absence of the risk manager.”

DI401 requires each facility to develop a risk management plan that outlines the risk management program’s goals and objectives, essential program components, processes for corrective action and integration of risk management with key departments and functions. DI401 states risk management plans “will be reviewed and updated annually by the facility staff and senior management. The Office of Clinical Quality and Risk Management shall be informed of any changes to such plan.” The risk management plan is also to include an event management protocol and a proactive risk identification and assessment process to reduce or mitigate the impact of future events. This process is to include evaluating the potential adverse impact of events and routine assessments of the facility, its high-risk areas and periodic reviews of facility policies and procedures for risk identification.

While facility risk managers are responsible for assuring all events are reported on the Facility Event Report form (DMH 158, included in Appendix I), DI401 allows for facilities to utilize a form other than the DMH 158 “to facilitate the capture of certain, high frequency events, when that form is approved by the facility Risk Manager.” However, it does not grant permission to disregard the requirement to utilize the DMH 158 to report all events. Risk managers are to ensure all employees receive training on DI401 and DMH 158.

Regarding initial reporting of events, DI401 is clear in its requirement that *all personnel* – employees, volunteers, contractors or students – who witness or discover any event that causes or has the potential to cause harm or injury to any individual, or an event that poses risks or liability to the facility, complete a DMH 158 and submit it to his or her immediate supervisor or staff person in charge. Employees must document the date and time of the event, their observations, individuals involved and other facts. DI401 prohibits any employee from editing the submitted DMH 158, except the risk manager, who may only write an addendum for the purpose of clarifying or updating an event.

Supervisors are responsible for reviewing completeness, clarity and legibility of the completed DMH 158. If the event is an unexplained injury, supervisors must document the injury type, shape and location; clinical outcome of the injury; ability/probability of the individual self-inflicting the injury; and the frequency and pattern associated with the injury. DI401 mandates supervisors submit the

DMH 158 to the risk manager, “no later than twenty-four business hours from occurrence or discovery of the event.”

Upon receipt of the DMH 158, the risk manager assures clinical outcome severity levels and risk index codes (Tables 2 and 3) are assigned, and facilities enter the event into their facility event tracking database.

Table 2: Severity Level Definitions (per DI401)

Severity Level	Description	Distinguishing Feature
00	No injury occurred	None
01	Minor injury occurred; no specific area of the body required any special attention; no medical treatment by a physician or physician extender required; possibly first aid administered, but no increased monitoring of the individual is required	None
02	Moderate injury occurred involving a relatively small and/or minor area of the body; no medical treatment beyond first aid by a physician or physician extender required; possibly first aid administered; increased monitoring warranted, no ultimate harm or loss of bodily function(s)	<i>Injuries in this category are distinguished from those in category 01 in that all injuries here require some increased monitoring, but no medical treatment as described below</i>
03	Injury requiring medical treatment beyond first aid (no hospitalization) by a physician or physician extender; possible temporary loss of bodily function(s); includes loss of consciousness	<i>The injury received requires treatment of the individual by a licensed physician, podiatrist or dentist or physician extender (e.g., physician's assistant or nurse practitioner), but the treatment required is not serious enough to warrant or require hospitalization. The treatment may be provided within the facility or provided outside the facility</i>
04	Injury or loss of consciousness requiring hospitalization; possible temporary loss of bodily function; possible major/permanent loss of bodily function(s)	<i>The injury received requires medical treatment as well as care of the injured individual at a general acute care hospital. Regardless of the length of stay, this severity level requires the injured individual be formally admitted as an inpatient to the hospital and assigned to a bed on a unit outside of the emergency room</i>
05	Injury received was so severe it resulted in death, or complications from the injury led to death of the individual	None
06	Deaths involving no injury	None

Table 3: Risk Index Code Definitions

Risk Code	Description	Distinguishing Feature
N	No risk or liability identified	None
L	Low/minor risk of liability	The event has little or no impact or requires comparatively little attention or concern
M	Moderate/some risk of liability	The event has reasonably manageable risks or requires minimal reduction/preventive efforts
H	High/significant risk or liability	These events include: <ul style="list-style-type: none"> ▪ incidents with actual, or the potential for high levels of public scrutiny; ▪ incidents where claims are anticipated, threatened or initiated;

		<ul style="list-style-type: none"> ▪ incidents involving criminal activity; ▪ deaths with a clinical outcome severity level of 05; ▪ all suspicious unexplained injuries, regardless of clinical outcome severity level; or ▪ incidents of any clinical outcome severity level where historical data on that individual indicates a trend suggesting a high-risk impact
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For events with severity levels 03 through 06, including deaths within 21 days of discharge, the risk manager shall report the event to the disAbility Law Center of Virginia (dLCV) pursuant to *Code of Virginia* § [37.2-709](#) via the Patient Advocacy Incident Reporting System (PAIRS). This reporting must occur within 48 hours of event occurrence or, if not witnessed, event discovery. *Code of Virginia* § [37.2-304.7](#) requires a written report of the event to dLCV be submitted within 15 *working* days of a critical event, serious injury or death. While the *Code* does define “days,” DI401 provides no clarification whether “days” refers to calendar, business or working days. Events reportable to PAIRS include any allegations of sexual abuse or sexual assault/rape, and all events including a loss of consciousness.

For events with severity levels 04 through 06, or any event with a risk code of H, the risk manager must “assess the need to initiate an RCA and performance improvement plan.” Risk managers are responsible for ensuring employees implement additional reviews for all events, to include medical consultation, medication review or safety committee review. For events with severity levels 05 through 06, the risk manager “take[s] steps necessary to assure the facility conducts the appropriate reviews.”

Review Methodology

During the FY2017 unannounced inspections, OSIG sought to conduct a review of significant events at DBHDS-operated facilities to include a review of the processes for reporting and responding to such events. To develop the inspection design, OSIG performed an extensive review of relevant laws, policies and procedures, regulations and guidelines concerning patient safety, healthcare risk management and event management. Additional resources included, but were not limited to:

- Federal, state and accrediting agency requirements;
- DBHDS documents:
 - DI401,
 - Training manual and other materials for risk managers,
 - Minutes of the CO Mortality Review Committee, and
 - Minutes of the CO Quality Improvement Committee;
- Communication between DBHDS and facilities, including memoranda, emails and letters;
- Facility documents:
 - Policies and procedures that supplement DI401,
 - Risk management and performance improvement plans,
 - Risk management reports,
 - Risk manager's event documentation,
 - Employee work profiles (EWPs),
 - DMH 158s,
 - Event database reports,
 - RCAs and other event analyses,
 - Facility census data,
 - Employee training/human resources files, and
 - Medical records.

On-site visits at the facilities were conducted by a team of OSIG staff between March and May 2017. During on-site visits, OSIG interviewed executive teams (typically including the facility director, risk and/or quality management director, fiscal director, medical director, psychosocial rehabilitation director and others). Individual interviews were also conducted with:

- Facility directors;
- Facility assistant directors for administration (when appropriate);
- Facility compliance staff; and
- Facility risk managers.

During the inspection period, there were 710 events reported in PAIRS. To identify a sample of those events, OSIG identified the top-three types of events at all facility types – behavioral health facilities, training centers, CCCA and VCBR – and used this as the basis for a sample. Further adjustments were made to account for the size of various facilities and severe injuries. Once completed, the sample contained 321 events. Two were eliminated as duplicate entries, and two were eliminated as medical

events where no injury occurred, leaving a final sample of 317 events. The PAIRS database categorizes significant events as follows:

- Accidents;
- Accidents by staff;
- Aggressive acts (AA) against objects;
- AA by peers;
- AA to staff;
- Choking;
- Deteriorating medical condition (DMC);
- Falls;
- Loss of consciousness;
- Physical altercations;
- Self-injurious behavior (SIB);
- SIB - accidental;
- SIB - intentional;
- SIB - recreational;
- Suicide attempts;
- Unexplained injuries; and
- Unspecified events that do not fall into one of the above categories.

OSIG developed a systematic process to review these events by capturing more than 60 discrete data points for all events, with an additional 30 discrete data points captured for deaths. These data points were obtained by reviewing many types of documents, including, but not limited to, DMH 158, PAIRS entries, risk management documentation, facility event database reports, event assessments and medical records. Additional documents reviewed relative to patient deaths included autopsies, facility death reviews and reports, medical staff meeting minutes and mortality review committee meeting minutes.

In using PAIRS as a primary data source for these inspections, OSIG discovered a number of issues with the utility and accessibility of PAIRS. The event definitions listed above are not fully mutually exclusive, which can lead to inconsistency in identifying events both within and between facilities. Additional potential challenges were identified when attempting to perform system-wide reviews of like-to-like events. OSIG also faced multiple challenges in obtaining and maintaining access to PAIRS in order to collect and analyze event data. A sample PAIRS report is included as Appendix III.

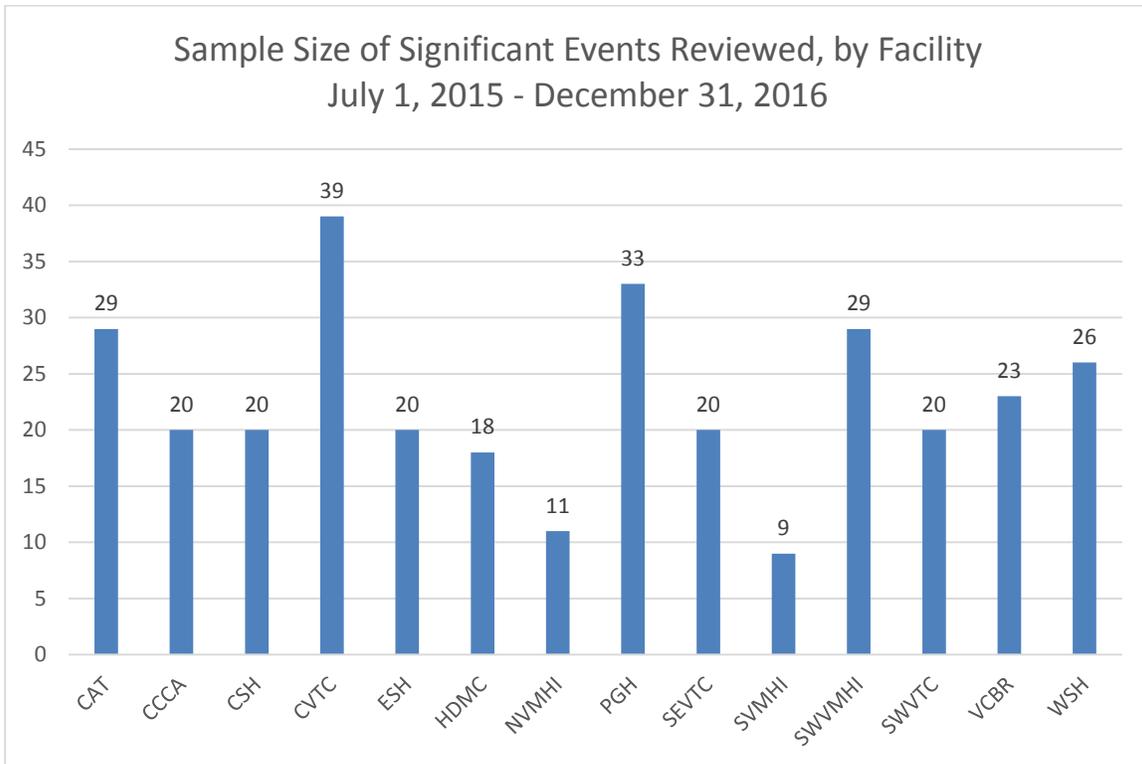
Review Results

OSIG found the current DBHDS event reporting and response system as defined in DI401 to be inadequate and in need of a comprehensive revision. DI401, last revised in 2012, is an outdated policy that contains areas of ambiguity and lacks definitions for key terms and criteria or specific requirements for key processes. The lack of clearly defined criteria or guidelines limits facilities' ability to take advantage of opportunities for quality reporting, analysis and performance improvement. Application of DI401 across the system does, or has the potential to, cause a variety of inefficiencies, waste and redundancies. The supporting infrastructure, including the age and utility of existing databases, results in data entry errors, redundancies and other inefficiencies. OSIG's review identified a number of recommendations with potential to improve the quality of risk management in the DBHDS-operated facilities, improve patient safety and minimize risks faced by DBHDS, facilities and individuals served.

Objective 1 – Conduct a quantitative analysis of significant events occurring in DBHDS-operated facilities to identify patterns and trends.

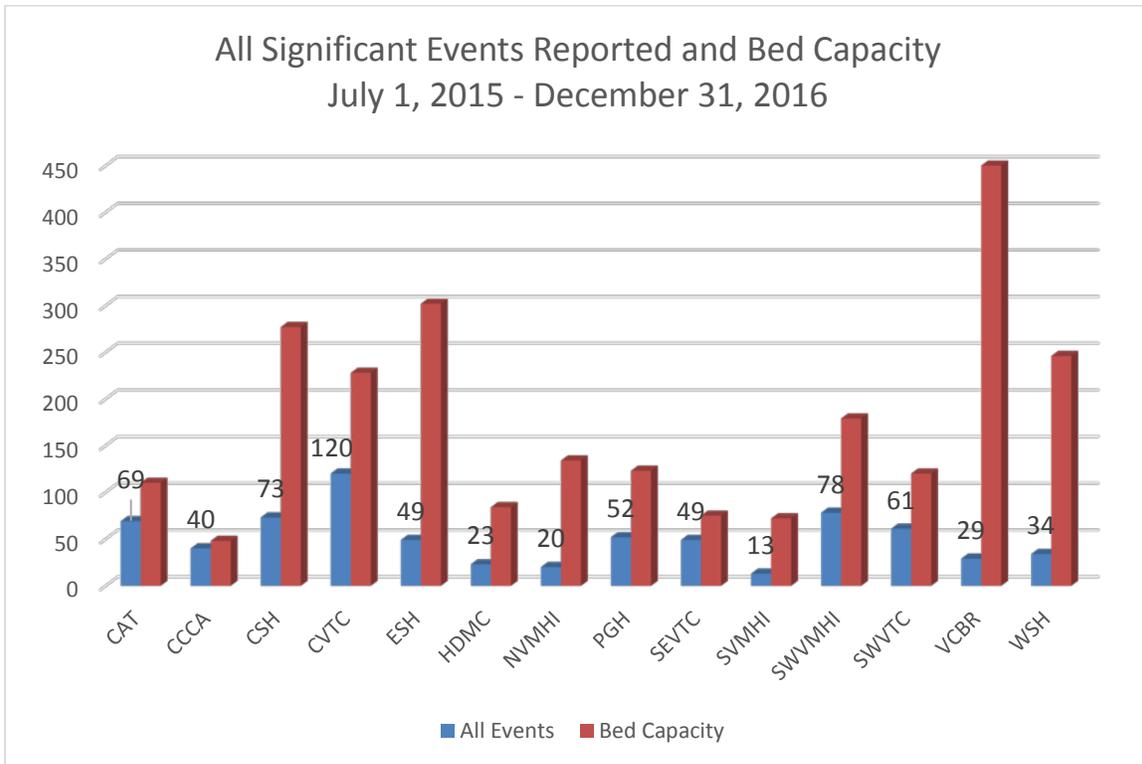
OBSERVATION NO. 1 - FALLS WERE THE LEADING SIGNIFICANT EVENT TYPE AT BEHAVIORAL HEALTH AND TRAINING FACILITIES; MORE THAN THREE-QUARTERS OF ALL EVENTS REVIEWED REQUIRED EVALUATION AT OR ADMISSION TO A HOSPITAL.

OSIG conducted an analysis of significant events using more than 60 discrete data points and other supplemental information on all 317 significant events identified in the sample. Of these 317 events, 53 were deaths. As described in the methodology section, an additional 30 discrete data points were collected relevant to deaths. The results of this analysis follow.

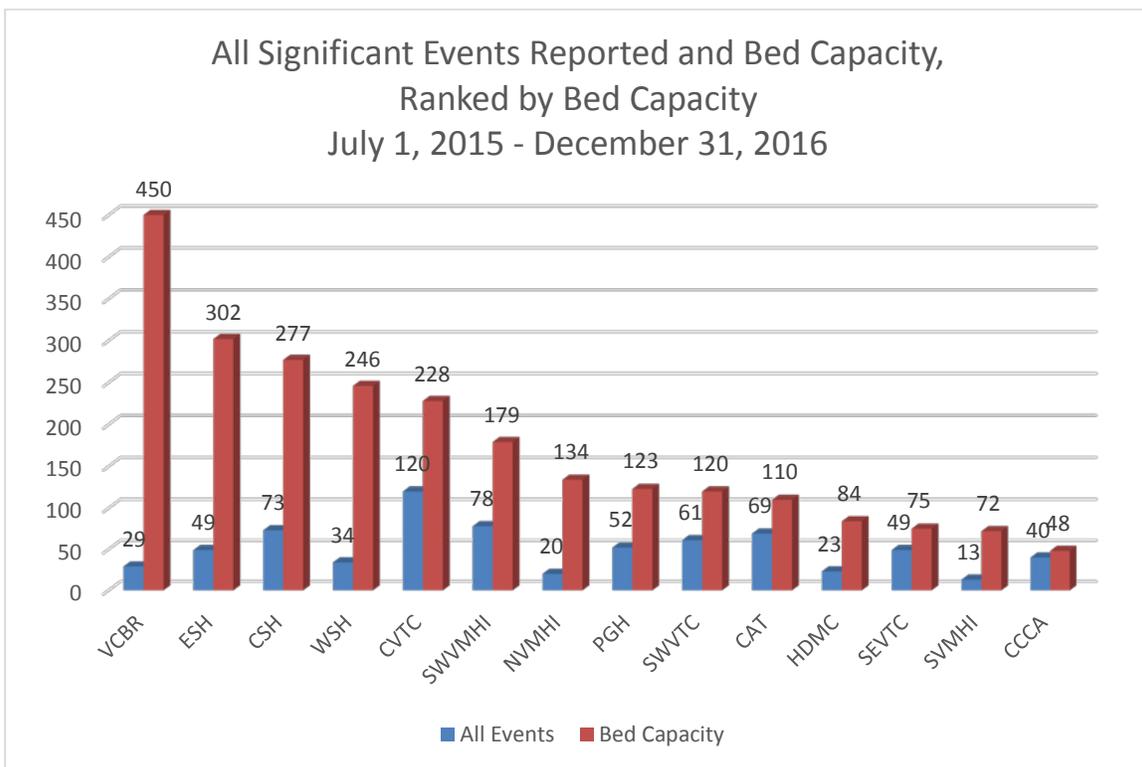


Females accounted for 40.1 percent of events reviewed, while males accounted for 59.9 percent. Unwitnessed events accounted for 55.5 percent of events reviewed. Adult behavioral centers averaged 22.1 events during the inspection period, while training centers averaged 26.3 events.

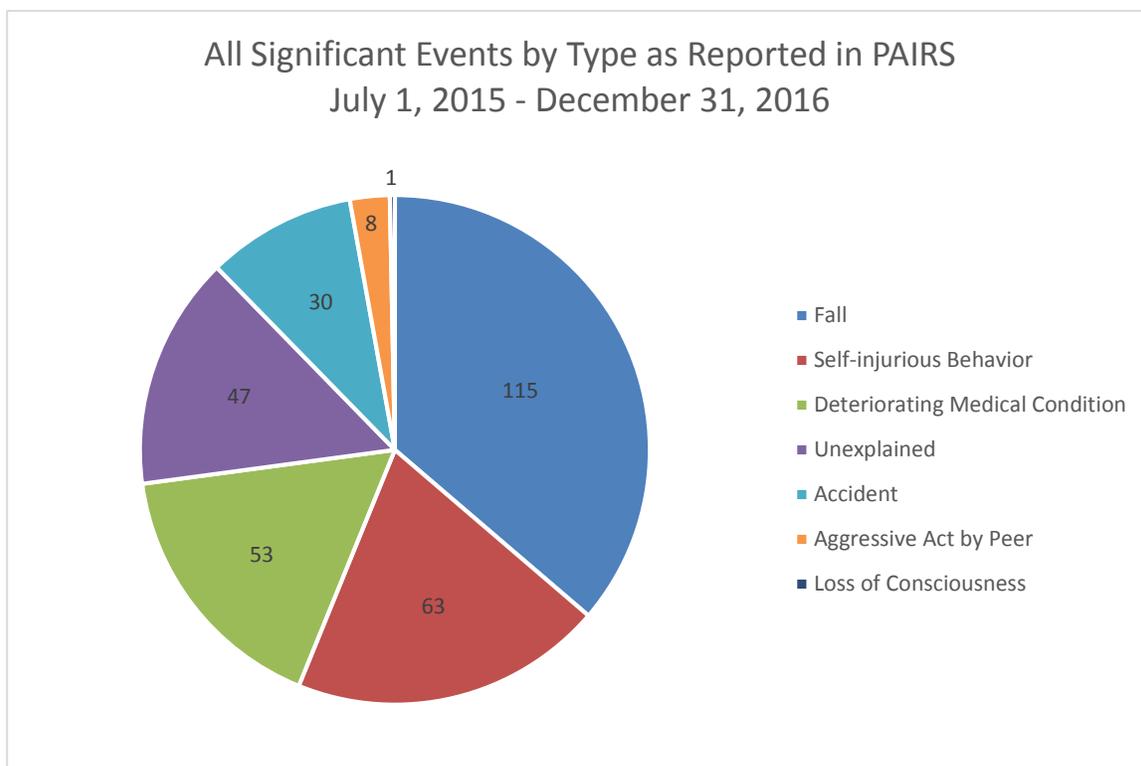
In an attempt to gauge overall facility event reporting prevalence, OSIG compared the total number of significant events at each facility during the inspection period to that facility's bed capacity. CVTC, the largest training center remaining, had the greatest number of significant events reported and reviewed during this series of inspections (39), while SVMHI, the smallest adult behavioral health facility, had the least (9).



Ranking results by bed capacity as presented in the chart below clarifies the data presented by this comparison.

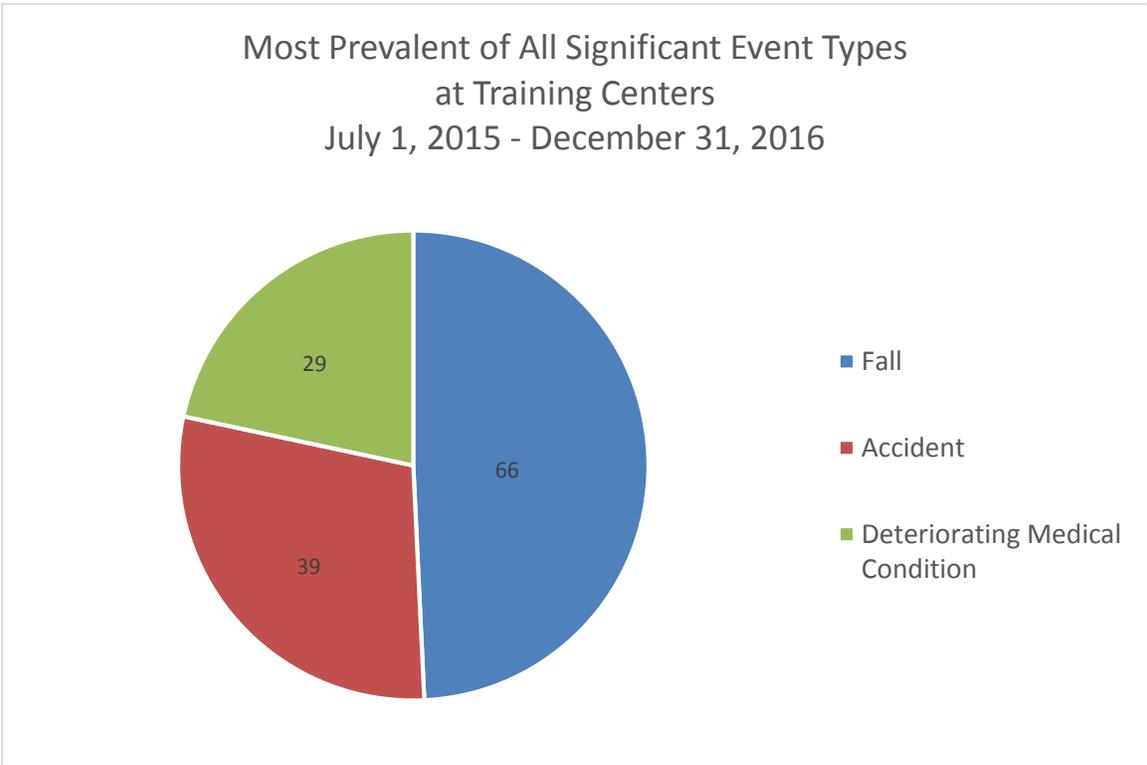
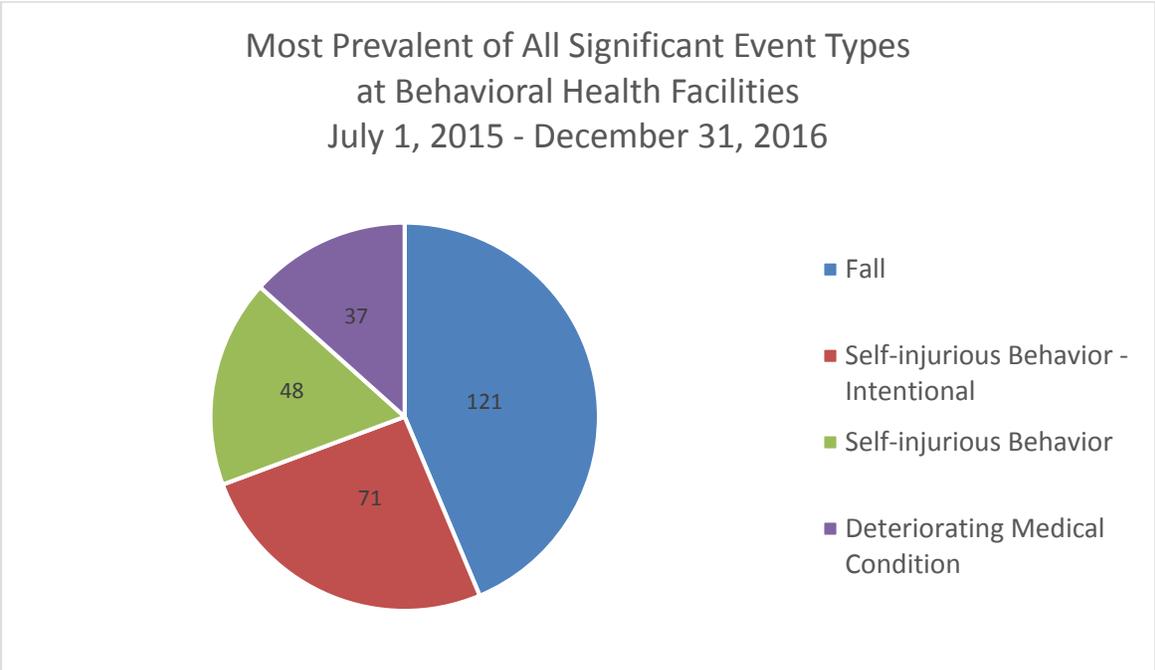


For the purpose of reviewing data, OSIG classified facilities as large (more than 200 beds), mid-sized (101 to 200 beds), or small (100 beds or less). It is important to keep in mind that individual facility accreditation and certification requirements, as well as populations served and census (e.g., while CVTC has a bed capacity over 200, daily census is approximately 135), must be taken into consideration when interpreting these figures. While the behavioral health facilities are operating at near capacity the majority of the time, the training centers, excluding SEVTC, are downsizing in anticipation of closure. Most large facilities have low numbers of reported significant events. VCBR, the largest facility DBHDS operates, has more events of all types but ranked tenth in significant event reports and serves a drastically different population than any other facility. CVTC, fifth in bed capacity, has the highest number of reported significant events and serves a potentially more fragile and complex population, even though the facility census is decreasing. Most mid-sized facilities have similar numbers of reported significant events, with the exception of NVMHI, which only had 20 reported significant events, the second lowest amount of any facility during the inspection period. Small facilities had varying levels of reporting. SEVTC and CCCA ranked eighth and ninth in significant event reporting despite being the third smallest and smallest facilities, respectively.

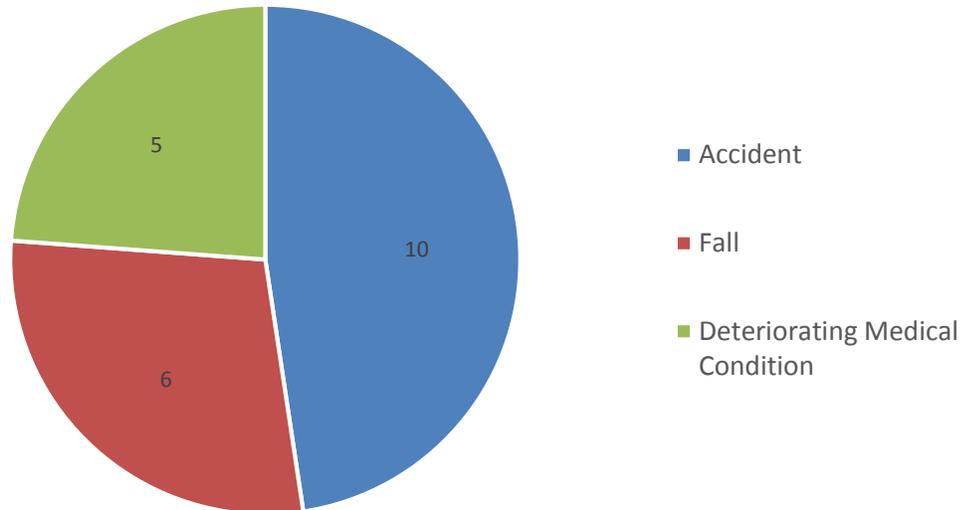


Falls with significant injury (defined as requiring medical intervention) were the most frequently reported event type, comprising 36.3 percent of all significant events reported in PAIRS, followed by SIB at 19.9 percent, and DMC at 16.7 percent. It is important to note there is no definition of DMC contained within DI401 or DMH 158 that a reporter may use as reference. There are 47

events (14.8 percent) categorized as “Unexplained” in PAIRS, but nearly half (48.9 percent) of those are the result of a limitation in PAIRS that is explained in more detail in Observation 2B.

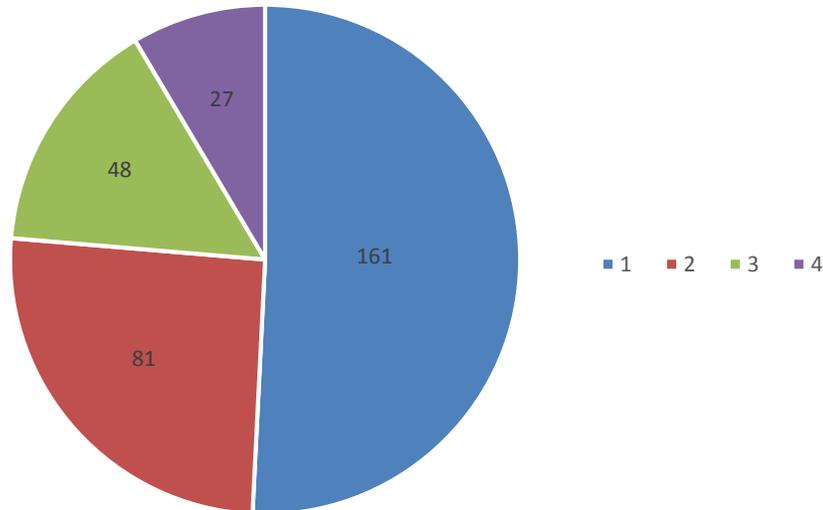


Most Prevalent of All Significant Event Types at VCBR
July 1, 2015 - December 31, 2016



While falls were the leading significant event type at both behavioral health facilities and training centers, SIB/SIB - Intentional were the second leading type of significant events at behavioral health facilities (including CCCA and HDMC), while accidents were the second leading type of event at training centers. Deteriorating medical condition was the third leading significant event type at both types of facilities. At VCBR, accidents were the leading significant event type, followed by falls and DMC.

Level of Care Required for Sampled Significant Events
July 1, 2015 - December 31, 2016



More than half of the events reviewed (50.8 percent) required transportation to a hospital emergency department for evaluation and, when warranted, treatment. Admission to a general hospital was required in 25.6 percent of events. Fifteen percent of events only required first aid and 27 events (8.5 percent) required no follow-up care. Twenty-two of those 27 events were deaths reported due to DMC, where the individual was found deceased. Of the remaining five, three events initially reported as requiring no follow-up care were later determined to be fractures, and two events were deaths within 21 days of discharge from a facility.

OBSERVATION NO. 1 - NO RECOMMENDATION

Objective 2 - Determine the consistency of application of DI401.

DI401 provides the standards by which risk managers oversee the process of reporting and responding to all events. Given its integral role in the process, OSIG performed a comprehensive review of DI401 prior to performing the inspections. The data collection process described above also provided OSIG with data to review the implementation of DI401 by facilities. These reviews identified issues with both DI401 and its implementation.

In reviewing the event reporting and review processes at facilities, OSIG identified a number of areas in which facilities are noncompliant with the standards set forth in DI401 concerning event reporting and response, document management and risk management processes.

OBSERVATION No. 2A - DI401 EVENT REPORTING REQUIREMENTS ARE NOT FOLLOWED CONSISTENTLY BY FACILITIES.

Below are specific facility examples of noncompliance with DI401.

CSH IS NOT USING DMH 158 AS REQUIRED

CSH no longer uses DMH 158 as the primary method for reporting events. At an unknown point in the past, it made the decision independently to utilize its 24-hour nursing and administrator-on-duty reports to identify events, which are then entered into PAIRS. According to facility risk management staff, in instances when CSH does complete DMH 158s, the form is not always completed by the witnessing staff member as required, but is completed after the event by unit staff using information gleaned from the 24-hour nursing and administrator-on-duty reports. The DMH 158s are then used to enter the event into the facility event reporting database. When asked whether the facility event database and PAIRS are cross-walked to ensure information on all relevant events is captured, OSIG received conflicting responses from different members of risk management staff. OSIG was able to determine that only data from the facility event database is used in reports submitted to the CSH Quality Council, suggesting information entered into PAIRS may not be reflected in these reports due to lack of a database crosswalk.

ESH USES AN ELECTRONIC VERSION OF DMH 158 NOT APPROVED BY DBHDS

Beginning in July 2016, approximately two-thirds through the inspection review period, ESH began the implementation of an electronic version of DMH 158 throughout the hospital. This occurred over a period of months, and as a result, a limited number of DMH 158s reviewed by OSIG were completed electronically. OSIG found the use of different forms led to inconsistencies in event data collected. In the units where the electronic version of the DMH 158 was used, more detailed information was collected than on units where the paper version was used. As of November 2017, the electronic version of DMH 158 has been fully implemented at ESH, and, per the facility risk manager, the electronic version of the form accounts for approximately 95 percent of event reports. This electronic version of DMH 158 was not approved for use by CO because, “there was no actual change in the form and it’s not a database. Its [sic] just a fillable form.” An electronic version of DMH 158 is being used at VCBR, but its use was reviewed and approved by CO. Additional related discussion follows.

COUNTER TO POLICY, STAFF WHO DO NOT WITNESS EVENTS COMPLETE DMH 158s

DI401 states any staff member, volunteer, contractor or student who witnesses an event “shall immediately complete, date and sign a DMH 158 and submit the report to his/her immediate supervisor or staff person in charge.” However, OSIG found that four facilities – **CAT, CSH, ESH and WSH** – have registered nurses or higher-level staff completing some DMH 158s in lieu of the event witness as required. At these four facilities, OSIG interviewed front-line staff to learn more about what training and guidance they received concerning event reporting.

The front-line staff reported receiving training consistent with DI401 that directed them to complete DMH 158s. However, the same staff reported they received supervisor guidance contradicting DBHDS and facility policy, requiring them to report a witnessed event to their supervisor verbally, who would complete the DMH 158. OSIG found evidence confirming this practice when reviewing DMH 158s completed at those facilities, which were signed by registered nurses or higher-ranking staff under “Signature of Person Completing Form.”

DMH 158s ARE NOT COMPLETED FOR ALL EVENTS AS REQUIRED

DI401 states that all events should be reported, regardless of whether the event occurred “in the facility or away from the facility; with or without staff present; or while the individual receiving services is on authorized leave, missing, or on special hospitalization.” Additionally, all known deaths within 21 days of discharge should be reported to dLCV via PAIRS. OSIG identified 54 events rated as severity level 03 or above by the risk manager for which a DMH 158 was not completed. There were 19 deaths for which no DMH 158 was completed, including five deaths that occurred within 21 days of discharge from various facilities. Furthermore, senior staff at HDMC stated they are not completing DMH 158s as required for “expected” deaths.

RISK MANAGERS DO NOT CONSISTENTLY RECEIVE DMH 158s WITHIN REQUIRED TIMEFRAMES

DI401 states that supervisors should, after reviewing the completed DMH 158 for clarity, legibility and completeness, “forward it to the Risk Manager as soon as possible, but no later than twenty-four business hours from occurrence or discovery of the event.” OSIG could only verify this standard being met in 60 (18.9 percent) of the DMH 158s reviewed for this inspection; 121 (38.2 percent) were not submitted within 24 hours; and 136 (42.9 percent) were not dated, prohibiting CO and OSIG from determining compliance with submission requirements.

FACILITIES ARE NONCOMPLIANT WITH PAIRS REPORTING REQUIREMENTS

According to DI401, only events with a severity level of 03-06 need to be entered into PAIRS. To calculate this metric, OSIG excluded events with lower severity levels, but included events that were scored incorrectly by risk managers and should have been scored level 03 or higher. With this consideration included, there were instances of late PAIRS entries identified at every facility, with 43.5 percent of events reviewed for these inspections entered more than 48 hours after the event occurred.

FACILITIES ARE INCONSISTENT IN DATA ENTRY BETWEEN DMH 158 AND PAIRS

PAIRS is the database used by facilities to report significant events to oversight agencies including dLCV and OSIG. As the DMH 158 is utilized to obtain event specifics entered into PAIRS, the quality of the documentation on the DMH 158 is crucial. When comparing DMH

158s and PAIRS entries for the same events, OSIG found a number of fields in which the data entered into PAIRS differed from the DMH 158, whether by providing a different level of detail or by providing different information altogether. One area where this occurs most often is the event description. OSIG found differences in description fields between the DMH 158 and PAIRS for same events at 13 of 14 facilities.

DI401 COMPLIANCE METRICS

As part of the quantitative analysis, OSIG collected a number of data points to determine the level to which facilities are compliant with certain key elements of DI401. A summary of this analysis follows.

Table 4: DMH 158 Compliance Metrics

Compliance Metric	Yes	No	Unknown	Not applicable
Was DMH 158 completed?	81.7%	18.3%	0.0%	0.0%
Was DMH 158 submitted to the risk manager within 24 hours?	18.9%	38.2%	42.9%*	0.0%
Was event entered into PAIRS within 48 hours?	56.5%	43.5%	0.0%	0.6%**
Was the PAIRS follow-up performed within 15 days?	79.5%	19.9%	0.6%	0.0%
For completed DMH 158s, were any fields not completed?	37.7%	62.3%	0.0%	0.0%
Did supervisor/administrator sign DMH 158?	72.2%	27.8%	0.0%	0.0%

* Dates required to make determination were not entered on DMH 158

** Two events were entered into PAIRS, but later determined to not meet criteria (database does not allow for entries to be deleted)

These compliance metrics represent an average compliance level of 57.5 percent. This figure includes the unknown percentage for the second metric, as a lack of dating the form is de facto noncompliance, preventing a determination of whether the 48-hour requirement was met.

OBSERVATION 2A- RECOMMENDATION

DBHDS should perform a comprehensive review and revision of DI401, including the DMH 158. This process should include input from relevant stakeholders, such as facility directors, facility risk managers and direct-care staff. The revision should focus on:

- Improving standardization of event reporting;
- Revising definitions for timeframes, severity levels and risk codes to include examples of “hard to classify” cases; and

- Revising DMH 158 to include standardization and revision of key terms that will meet the needs of all facilities.

The review and revision of reporting timeframes is noteworthy, as the current standards for submission may be outside certain reporting requirements for facilities that fall under Patient Protection and Affordable Care Act, and therefore should be considered for revision as soon as possible.

OBSERVATION NO. 2B - RISK MANAGEMENT STANDARDS AND PROCESSES ARE INCONSISTENT ACROSS THE SYSTEM.

FACILITY RISK MANAGEMENT PLANS AND REPORTS

DI401 requires facilities to develop and implement risk management plans that are reviewed and updated annually. OSIG determined 11 facilities had updated their plans in the 12 months preceding inspections, but three had not. According to its assistant director for administration, SVMHI has not updated its risk management plan since 2014, while both NVMHI and CCCA last updated their plans in 2015. When asked what information is used to perform annual updates and plan revisions, the most common responses were prior year event data (six responses), policies and procedures (six responses), regulatory guidelines and the previous plan (four responses each).

DI401 also requires facility directors to assure event data is aggregated, reviewed and analyzed, and that facility patterns and/or trends are identified and reported to the facility quality committee on a quarterly basis. OSIG reviewed minutes from all quality and risk management committee meetings that took place during the inspection period and facility quarterly and annual risk management reports, and found a lack of compliance with this requirement. Eight facilities aggregate data and present it to quarterly quality improvement or risk management committee meetings for review, but the minutes of those meetings do not indicate any analysis of the data being performed. OSIG found evidence of trend identification and analysis in annual risk management reports at three facilities and in minutes of quality improvement meetings at three facilities. For one facility, OSIG found no evidence of data aggregation for trend identification or analysis.

SEVERITY LEVELS AND RISK INDEX CODES

As part of the inspection protocol, OSIG assessed the severity levels and risk codes for all 317 events reviewed to ensure scoring was accurately performed. DI401 allows for delegation of this responsibility to another staff member, usually in risk management or quality management. This practice has been implemented at three facilities. At the other 11 facilities, risk managers perform the severity and risk scoring themselves.

OSIG found the majority of events had received a severity index of 03 and a risk code of M. Nearly eight percent of events were not assigned a severity index, and nearly 19 percent of events were deemed to pose no risk whatsoever.

Table 5: Severity Level and Risk Index Scoring

Severity Coding	Percentage	Risk Coding	Percentage
00	0.6%	L	24.1%
02	1.6%	M	45.8%
03	61.8%	H	9.4%
04	12.9%	N	18.9%
05	0.3%	Unknown	1.8%
06	14.8%		
None	7.9%		

The subjective nature of severity level and risk index scoring, along with a lack of relevant risk manager training, has led to significant errors in scoring. OSIG reviewed event descriptions and levels of care required and determined severity coding was inaccurate on 85 occasions, or 26.8 percent of DMH 158s reviewed. OSIG found examples of inaccurate coding at every facility.

At SVMHI and NVMHI, OSIG found severity level and risk index codes were not being assigned at all. At SVMHI, a staff member who had been on the job for less than a month was in charge of scoring events and was not assigning any risk codes. At a later inspection, OSIG found NVMHI had only started assigning severity codes within the last 60 days, implemented as a result of OSIG’s earlier inspection at another facility.

RCAs

DI401 states events with severity levels of 04 to 06 should be assessed by the risk manager to determine if an RCA should be performed. However, DI401 provides no criteria or guidance for how the risk manager should perform this assessment, nor criteria upon which a determination should be made. There is also no provision for external reviews of these assessments by peers or CO staff.

DI401 also requires risk managers monitor the status of RCA corrective action plans and provide ongoing updates to the facility director to ensure appropriate implementation. When asked about the process(es) used to track and evaluate corrective actions, risk managers reported the following:

- Two described a formalized process that includes documentation of actions and follow-ups;
- Four reported use of both formal and informal processes;

- Seven reported use of only informal processes, usually consisting of the risk manager going to the unit(s) where the corrective action was implemented and discussing its implementation with the unit supervisor. In these cases, no formal measurement or monitoring of corrective actions is performed; and
- One risk manager reported no involvement in the process of tracking implementation of corrective actions.

RISK MANAGER QUALIFICATIONS

DI401 lacks clear, standardized requirements for risk manager qualifications and training. DI401 does include requirements for training staff at the facility level, but does not speak to requirements for training risk managers other than to say risk managers should be “qualified by training or professional designation.”

During the FY2017 inspections, OSIG interviewed risk managers at all facilities. Twelve of these interviews were performed on site, while two were done via correspondence. The risk managers were asked a number of questions about their background, training, job duties and other related issues. Concurrently, OSIG reviewed EWPs for all facility risk managers to determine whether they reflected the breadth and depth of knowledge required to fulfill a risk manager’s responsibilities. OSIG then cross-walked elements of EWPs with the training current risk managers had received.

In reviewing the EWPs, OSIG focused on four sections:

- Knowledge, skills and abilities (KSAs);
- Education, experience, licensure and certification (EELCs);
- Core responsibilities; and
- Percentage of staff time dedicated to risk management.

In the KSA section, OSIG found the most common KSAs mentioned were experience with regulatory standards (85.7 percent), knowledge of principles of performance improvement/risk management (64.3 percent), and knowledge of, or familiarity with data analysis, analytical evaluations, and trend identification (57.1 percent). Only four facilities included experience with investigative techniques among the required KSAs.

In the EELC section, the most common requirement listed was training or experience in risk management (92.9 percent), a bachelor’s degree (64.3 percent), and certification (57.1 percent). Of those that included certification, the requirements varied:

- Five EWPs “preferred” the incumbent hold or be eligible for certification;
- Two required the incumbent hold or work toward the Certified Professional in Healthcare Risk Management (CPHRM) offered by the American Society for Healthcare Risk Management;

- Two required the incumbent be “formally certified in a DBHDS approved [sic] Healthcare Risk Management Program” (none of the other EWP’s mention this requirement);
- One required a certificate in healthcare risk management or equivalent professional risk management designation; and
- One required the incumbent be “certified as a risk manager in DI401.”

When asked what training the risk manager or designee had received, only three indicated they currently held a certification related to risk management – two hold the Certified Professional in Healthcare Risk Management (CPHRM) certification, while one holds the Registered Health Information Technician certification. Three others indicated they had taken CPHRM classwork, but either had let their certification lapse or never sat for the certification exam.

Six risk managers received training at the Virginia Risk Control Institute (VRCI), a certificate program offered by the Virginia Department of Human Resource Management’s Workers Compensation Services in partnership with the Virginia Commonwealth University School of Business and the Department of Treasury’s Division of Risk Management. The program offers five, three-semester credit undergraduate courses designed to assist state agencies better control workplace accidents, injuries and occupational health exposures. One of the six who attended VRCI courses currently holds the Risk Management Certificate.

Other sources of information cited most by risk managers were quarterly risk manager meetings sponsored by DBHDS (risk managers provided conflicting responses as to whether or not these meetings are currently taking place) and “on-the-job” training, usually from a predecessor.

When asked what training risk managers had received related to the DMH 158 and performing RCAs, three risk managers indicated they were part of the team that developed the current DI401. Five cited the quarterly risk manager meetings, four cited “on-the-job” training (usually from their predecessor), two cited training provided by DBHDS, and two indicated they had received no specific training. One risk manager stated that he or she is expected to do RCAs, but has not been trained in effective implementation of the process. That facility’s director added that the issues are not at the facility level, but at the DBHDS level. They commended their risk manager and medical staff for attempting to proactively address risk issues, but stated that the facility is not “getting affirmation or support from DBHDS to support these efforts to improve our facility and our system.”

None of the risk managers reported they received any specific training on performing RCAs or other types of analysis outside of individual courses from third-party trainers. Since the completion of these inspections, DBHDS held a two-day statewide training for facility

clinical, administrative, quality improvement and risk management leadership. This training provided an overview of the role of quality improvement and risk management principles on the first day, while the second day focused on best practices for conducting RCA processes (per a July 26, 2017, memo from Deputy Commissioner of Behavioral Health Services Daniel Herr).

When asked what specific training risk managers received concerning severity and risk coding, three cited being part of the DI401 development team; five cited “on the job” training; four cited DI401 itself; and five said they received no specific training on severity and risk coding.

Finally, OSIG asked facility risk managers what DBHDS and facilities could do to improve event reporting processes. The responses included:

- Implementation of electronic health records (eight responses);
- Revisions to DI401 (six responses);
- Changes to DBHDS facility event database (five responses);
- Revisions to PAIRS (five responses);
- Publishing guidance on severity and risk coding (two responses);
- Providing clear(er) definitions (two responses); and
- Modifying DMH 158 to allow for more space to describe events and account for near misses and events that were noteworthy even though they may not have caused an injury (one response).

Finally, one risk manager stated he or she made his or her own version of a risk management manual to use to supplement DI401 so it would be clearer and easier to operationalize.

OBSERVATION NO. 2B - RECOMMENDATION

DBHDS should perform a comprehensive review and revision of DI401 and DMH 158. This process should include input from relevant stakeholders, including facility directors, facility risk managers and direct-care staff. The revision should include a focus on:

- Revising guidelines for facility aggregation and analysis of event data to standardize identification of trends, including how often reviews should occur and who should perform said reviews;
- Defining standards for implementing and tracking corrective actions as well as criteria for RCA needs assessments;
- Requiring RCAs be performed if facility staff (including, but not limited to, risk management, medical and clinical staff) know or suspect that:
 - A death was caused or deemed by autopsy to be an accident, an injury or otherwise unexpected,

- The cause of a death determined by autopsy is not consistent with the individual's primary diagnosis(es),
- An event caused significant injuries, including dislocations, fractures, aspiration and loss of consciousness,
- An event was a near miss or a high-risk event led to no harm; and
- Ensuring that risk manager EWPs include all KSAs required for the responsibilities included.

Objective 3 - Assess the quality of DBHDS and facility reviews of significant events, data management and current quality management processes utilized to drive performance improvement and lessen risks of future events.

OBSERVATION NO. 3A - THE CURRENT RISK MANAGEMENT DOCUMENT STORAGE SYSTEM OPERATES ON OUTDATED INFRASTRUCTURE AND IS INCONSISTENT, DUE IN PART TO DEFINITIONS PROVIDED IN DI401.

RISK MANAGEMENT RECORDS ARE NOT ALWAYS KEPT CONFIDENTIAL AND SECURE

DI401 states risk managers are responsible for ensuring “all original facility event reports are maintained in a confidential and secured location,” and they must, “retain them in accordance with Commonwealth of Virginia record retention laws.” However, OSIG encountered one facility where this was not taking place.

On the first day of the inspection at CSH, OSIG requested copies of 20 significant event DMH 158s, consistent with the standard inspection protocol. After a significant wait time, CSH staff only provided six of the 20 DMH 158s requested and informed OSIG staff there were no DMH 158s for the other 14 significant events. Later in the day, CSH staff stated they did, in fact, have more of the DMH 158s requested, but were still working to locate them. At the end of the first inspection day, CSH had still only produced six of the 20 DMH 158s.

On the morning of the second day, OSIG requested access to the office where the DMH 158s were kept. CSH obliged the request and escorted OSIG staff to the office of one of CSH's risk management staff. There, OSIG was told the forms were in the office next door and that OSIG staff were welcome to enter that office unescorted, as the office was kept unlocked. Upon arriving at this office, OSIG found a note on the door that said “DO NOT LOCK” (See Appendix IV.) The door was unlocked, and upon entering there were no staff working in the office. Inside the office, in file cabinets as well as in plain view, were original DMH 158s, organized by month. Within 15 minutes, OSIG staff had found all DMH 158 forms CSH staff were not able to produce the day before.

RISK MANAGERS ARE INCONSISTENT IN THEIR FILE MAINTENANCE

DI401 dictates no requirements for document management at the facility level. Across the system, risk managers are inconsistent in the type or amount of documentation maintained for each event. At one facility, risk management documentation includes only copies of the PAIRS report and the DMH 158s. At the other end of the spectrum, there are facilities that maintain a more robust file on each event, including relevant interdisciplinary notes, consultation reports, special hospitalization discharge reports and other related information. Although each individual facility is responsible for decisions related to document storage systems, the variation and particularly sparse nature of some files may create risks for facilities when asked for proof of investigations and outcomes by oversight agencies and accrediting bodies.

THE DMH 158 FORM LACKS IMPORTANT DATA FIELDS

DI401 requires risk managers to assign severity and risk codes for events, as well as determine whether the event involves required reporting of suspected abuse or neglect. However, the DMH 158 does not have fields for risk managers to document those outcomes. As DMH 158 is an integral part of the event reporting and tracking process, adding the following fields to the DMH 158 would make documenting these outcomes clearer, more efficient and easier to ensure completion of:

- Severity and risk scoring;
- Date stamp received by risk management;
- Review for referral for abuse and neglect investigation; and
- Outcome or follow-up.

DBHDS NEEDS TO DEFINE KEY TERMS AND REVISE EXISTING DEFINITIONS IN DI401

The timeline for reporting events to facility risk managers in DI401 is 24 “business hours;” however, in a hospital or training center all hours are business hours. Additionally, due to the fact that PAIRS does not define “days” as working, business or calendar days, DI401 lacks clarity in its requirements for 15-day follow-up for PAIRS reports and 21-day reporting of post-discharge deaths.

The definitions of severity levels in DI401 include terms like moderate, minor, temporary and possible temporarily loss of bodily function. In the absence of clear definitions, risk managers are left to subjectively interpret these terms. Risk index code definitions raise the same concern. For instance, events receiving a risk coding of L have “**little** or no impact or requires [sic] **comparatively little** attention,” while events receiving a risk coding of M should have “**reasonably manageable** risks or requires [sic] **minimal** reduction/preventive efforts.” Emphasis has been added by OSIG to these definitions to illustrate the level of subjectivity involved in applying them to significant events occurring in facilities.

DI401 also states the facility risk manager shall assess the need to initiate an RCA and performance improvement plan for events with a severity level of 04 to 06 or a risk code of “H.” The latter includes:

- Incidents with actual or potential for high levels of public scrutiny;
- Incidents where claims are anticipated, threatened or initiated;
- Incidents involving criminal activity;
- Deaths with a clinical outcome severity level of 05;
- All suspicious unexplained injuries, regardless of clinical outcome severity level; or
- Incidents of any clinical outcome severity level where historical data on that individual indicates a trend suggesting a high-risk impact.

While some of these conditions are straightforward, others -- such as the potential for high levels of scrutiny, the anticipation of claims and unexplained, suspicious injuries -- require risk managers to make subjective determinations for which they may not have the knowledge base or prior training required.

FACILITY RISK MANAGEMENT DATABASES NEED TO BE REPLACED

To track the occurrence of significant events, 13 of 14 facilities use a database that was developed in Access 95, a software version more than 20 years old (VCBR uses a separate database developed by the facility itself). DBHDS developed the database for facility use, but has never provided infrastructure support, such as software updates or troubleshooting. Due to its age and the number of records it contains at each facility, the database is not user-friendly and requires significant time for start-up and running queries.

The age of the database presents security issues as well, which are manifest in various ways, including:

- A recent update removed recent entries staff made in database records, forcing the risk manager to enter data manually and causing what they called a “vast potential for compromising data;”
- One facility had to uninstall software updates because the updates caused systems to crash; and
- One facility continues to receive security warnings when opening the database because the Windows operating system identifies the database as a security risk.

Four risk managers use separate spreadsheets or databases to perform their own tracking and follow-up. These are redundant systems requiring manual entry of data that already exists in other databases. When asked the rationale for this, all four stated it was easier to maintain this information separately than to access it via the event database.

The VCBR event database, developed in 2013, is a web-based system that allows staff to enter event information on a form that captures the same information as DMH 158. Entry can be

done at terminals located on the units and is integrated with VCBR's EHR. Originally implemented on local servers, the database now runs on enterprise servers hosted by DBHDS and contains customizable reports by facility- and system-wide, supportive of efficient risk management operations, supervisor usage, and systemic performance improvement efforts. If the VCBR event database was installed at other facilities not currently slated for closure, it would create a cost-effective and system-wide platform presenting multiple efficiencies in data entry, aggregation, analysis and reporting.

Per DBHDS staff, every facility (except VCBR) has requested the facility event database be replaced.

THE PAIRS DATABASE IS OUTDATED

Much like the event tracking database, PAIRS has a number of limitations due to age and structure. As of July 2017, PAIRS had more than 9,500 entries and is still running on version 1.0. As a result, the database suffers from similar issues as the facility event databases – slow record searches, report queries and even start-up time. Additionally, definitions and event categories have not been clearly defined in order to accurately capture the number and complexity of events occurring in facilities. For instance, PAIRS currently allows users to choose from three different types of categories for SIB; SIB, SIB-intentional and SIB-accidental. However, there is already an “accident” category that can be used for accidental events. Furthermore, it seems illogical for there to be an accidental subgroup of SIB, an action that by definition indicates intentionality. Similarly, aggressive acts have four categorizations: against objects, by peers, to peers, and to staff. It should be noted that PAIRS is utilized to “feed” data to the DBHDS data warehouse, raising question as to the accuracy and reliability of warehouse reports.

PAIRS has additional issues that present greater challenges. PAIRS entries are made in two stages – an initial report is required within 48 hours of the event having occurred or being discovered, and a follow-up report must be entered within 15 days of the event. The 15-day report expands on the initial 48-hour entry and provides more detailed information. However, no changes are allowed to the initial 48-hour report, which causes issues with the integrity of the data that PAIRS collects. For instance, one risk manager reported he is not always able to identify the specific injury type within the first 48 hours, which forces him to identify the event type as “Unexplained.” Eventually, the event type may be identified, but initial PAIRS reports are not modifiable once entered, so the event type never gets modified to include the known information. Additionally, two risk managers reported that PAIRS includes character limits on certain data fields, sometimes prohibiting entry of all relevant information. One risk manager stated that many entries get bounced back, meaning the database does not accept the entry, forcing staff to reenter that information.

OBSERVATION 3A - RECOMMENDATION

DBHDS should perform a comprehensive review and revision of DI401 and DMH 158. This process should include input from relevant stakeholders, including facility directors, facility risk managers and direct-care staff. The revision should include a focus on:

- Standardizing requirements for risk management documentation and storage;
- Updating DMH 158 to add important data fields; and
- Updating definitions in DI401.

Once all revisions are complete, a standardized training curriculum should be developed. Facilities should have the option to customize the document to suit their needs.

DBHDS should implement the VCBR event database (including event reporting form) at all facilities not currently slated for closure. This database, developed specifically for facility use, is hosted on DBHDS enterprise servers and could be customized for use at other facilities with minimum effort. This represents a solution to a system-wide problem that could be implemented with relatively few resources and little effort, and would greatly improve the efficiency of event data management at facilities.

As part of this process, OSIG recommends DBHDS study the possibility of updating facility event databases to include the capability of reporting events as required in Code § [37.2-709](#) (48-hour requirement) and § [37.2-304.7](#) (15 working-day requirement). These code sections only mandate the timeframes for reporting, not the method of reporting. By doing so DBHDS could simplify the event reporting process and significantly improve efficiency by alleviating the need for PAIRS altogether.

OBSERVATION No. 3B – THE QUALITY OF SIGNIFICANT EVENT REVIEWS PERFORMED BY DBHDS-OPERATED FACILITIES DOES NOT MEET GUIDELINES AND BEST PRACTICES SET FORTH BY REGULATORY STANDARDS

OSIG evaluated a sample of facility significant event reviews to determine the quality of those reviews in identifying causative factors, developing corrective action plans and verifying whether corrective action plans include due dates for completion and identification of responsible parties. Very few of the significant events included in the sample had significant event reviews completed. Therefore, OSIG obtained copies of all reviews (22) performed during the inspection period, including 10 RCAs, four Baseline Analysis and Reviews (BAR), four Severe Event Causal Analyses (SECAs, a review process developed by an individual facility), and four Mortality Committee Death Reviews (MCDRs). These reviews were performed on a variety of events, including a number of deaths due to DMC, one death due to injury, one unexpected death, one accidental death, and a number of significant injuries. OSIG reviewed the quality of corrective action plans (including the amount and type),

measures used to track completion of corrective actions, the identification of individuals responsible for implementing corrective action steps and due dates for completion.

Table 6: Significant Event Review Compliance Metrics

Analysis Type	Total Analyses	Total Corrective Actions	Strong Action	Intermediate Action	Weak Action	Identify Parties Responsible	Indicate Due Dates
RCA	10	36	10	7	19	6	6
BAR	4	2	0	1	1	0	0
SECA	4	0	0	0	0	0	0
MCDR	4	21	2	3	16	0	0
Total	22	59	12 (20.3%)	11 (18.6%)	36 (61.0%)	6	6

The significant event reviews OSIG evaluated included 59 corrective action items. In terms of corrective actions, seven of the significant event reviews included 12 action items that rose to the level of “Stronger,” including architectural changes, engineering controls and the involvement of leadership. Eight reviews included 11 “Intermediate” action items, including checklists, enhanced documentation and/or communication and efforts to increase staffing. Ten event reviews included 36 “Weaker” actions, including training, policy changes, memos and reminders, and double checks.

In summary, only nine of the 22 significant event reviews (40.9 percent) followed TJC guidelines by including “Stronger” or “Intermediate” corrective action items. Only six (27.3 percent) identified individuals responsible for implementing corrective actions and due dates for completion. None of the significant event reviews included measurements that could be used to determine the completion and effectiveness of the action plan. Finally, 10 of the reviews (45.5 percent) included no corrective action plan whatsoever. These figures confirm that facility significant event reviews are not consistently recommending, implementing, tracking and evaluating corrective actions as described in NPSF or TJC standards, therefore failing to optimize opportunities for performance improvement and prevention of future events.

OBSERVATION NO. 3B - RECOMMENDATION

DBHDS should develop and require a standardized significant event review process. Upon development, DBHDS should train facility risk management staff on its use (including annual refreshers) and monitor implementation to determine fidelity and evaluate quality of reviews and outcomes.

Objective 4 - Conduct case reviews of individuals who experienced significant events to identify potential risk points and opportunities for improvement.

OBSERVATION NO. 4 - IN-DEPTH CASE REVIEWS REVEAL A PATTERN OF CONCERNS, INCLUDING LACK OF STANDARDIZED PROCESSES, POOR QUALITY AND RELIABILITY OF DOCUMENTATION, NONCOMPLIANCE WITH EXISTING POLICIES AND LACK OF TIMELY, ACTIVE TREATMENT.

After reviewing more than 300 significant events, OSIG identified five cases presented below to illustrate how the variations and limitations of the current system for reporting and responding to significant events creates different risk points for DBHDS and the individuals it serves.

CASE STUDY ONE

Patient A was a male under the age of 10, transported to CCCA on October 8, 2015, at 5:58 p.m., under a temporary detention order for treatment of increased aggression, self-harm and mood swings. According to documentation provided by CCCA, Patient A had no prior psychiatric hospitalizations. He reportedly had a history of prematurity, trauma, and may have suffered a traumatic brain injury secondary to a near drowning (required resuscitation) in 2014. A Virginia Preadmission Screening Report (VPSR) completed by a preadmission screener from Rappahannock-Rapidan Community Services Board (CSB) documented the following medications:

1. Adderall, 10 mg at 8 a.m. and 12:30 p.m.;
2. Risperdal, 1 mg at 6 a.m. and 0.5 mg at 2 p.m.; and
3. Clonidine, “.5” every night at bedtime.

The same medications and dosages were indicated on the CCCA Initial Referral Information form.

The CCCA Medication Reconciliation Form for current medications prior to admission or transfer was completed October 8, 2015, at 4 p.m., by a Registered Nurse (RN, signature illegible) and included the following:

1. Adderall, 10 mg at 8 a.m. and 12:30 p.m., per father;
2. Risperdal, 1 mg at 6 a.m., per father;
3. Risperdal, 0.5 mg at 2 p.m., per father;
4. Clonidine, “.5” _____ “Do Not Order _____ ERROR;”
5. Clonidine, 0.1 mg, per father;
6. BLANK; and
7. “spoke [with] father at 0105 10-9-15 [signature illegible].”

The “per father” notations on lines one, two and three and the entirety of lines five and seven appear to have been written by a different registered nurse (signature illegible). Both the Adderall and clonidine 0.5 mgs every night at bedtime have boxes checked indicating they should not be ordered, but it is unclear who or when these boxes were checked. The “Do Not Order _____ ERROR,” an accompanying strikethrough of the “Order” checkbox, and a check added to the “Do Not Order” checkbox appear to have been made by a third individual who did not sign the form. The nurse practitioner who was on call the night of the event, signed as the form reviewer on October 9, 2015, the day after admission. No boxes are checked to identify the information source(s), add comments or indicate allergies. The completed form is attached as Appendix IV.

When OSIG inquired about the medication reconciliation processes at CCCA, a senior staff member stated there are redundancies in place to avoid medication variances (errors), but they are only active during business hours; during off hours (inclusive of evenings, nights, holidays and weekends), the onus rests solely on the nurse to ensure those protections.

Below is a summary of the NP’s recollection of events on October 8, provided at the request of the risk manager. CCCA did not provide any such account compiled by the unit nurse (UN).

After Patient A arrived, the NP, who was serving as the on-call medical provider that evening, received a call from the UN requesting admission orders. Adderall and Risperdal verbal orders were given without conflict, but considerable confusion arose related to the clonidine order. The NP, who was not physically on site at the facility, did not review admission paperwork or assess Patient A prior to giving verbal admission orders. The NP reported questioning the clonidine dose reported by the UN, but stated the UN insisted the dose on the admission paperwork was “.5 mg.” The NP reported the conversation as follows:

UN: “He’s on clonidine .5 mg at bedtime.”

NP: “No. That should be 0.05 mg, not 0.5 mg.”

UN: “Nope. It’s .5 mg.”

NP: “No. That’s not right. That might be guanfacine at 0.5 mg but not clonidine. Clonidine should be 0.05 mg.”

UN: “It’s supposed to be .5 mg.”

NP: “Did you confirm that dose?”

UN: “Yes.”

NP: “How? With who?”

UN: “The IRI says he’s taking .5 mg.”

NP: “[UN], the IRI is rarely ever correct. It should be 0.05 mg.”

UN: “So you want him to have the Risperdal and clonidine and no Adderall?”

NP: “Let’s go with the Risperdal and clonidine and no Adderall.”

A nursing note completed by the UN at 9 p.m. documented administration of Risperdal and clonidine per the NP order (Adderall was held per facility policy). No confirmation of a “read back” of the verbal order as written exists on the order page and the NP signed the verbal order as written the following day. In her transcript, the NP indicated she, “felt uneasy and just had this instinct or feeling that [she] should call him back just to make sure [they] were clear.” Per her recollection, she called back 60-90 minutes later, and had the following conversation:

NP: “Just checking in with you about the clonidine dose for the new admission.”
UN: “Yes, I gave him .5 mg.”
NP: “Are you saying you gave him 0.5 mg of clonidine?”
UN: “No. I gave him .5 mg.”
NP: “What? Are you saying you gave him 0.5 mg?”
UN: “No. I gave him .5 mg.”
NP: “That’s the same thing. 0.5 mg and .5 mg is the same thing!”
UN: “Right, yes, I gave him 0.5 mg. I had to give him five tablets. You confirmed it.”
NP: “No! It’s supposed to be 0.05 mg not 0.5 mg!”

A nursing note written by the UN October 8, 2015, at 6 p.m., states medication orders were obtained from the NP, and were “relayed to the [NP] from this narrator including an order for clonidine 0.5mg. The practitioner questioned this order as well as myself (sic). I reread the order back to her from the prescreen [IRI] exactly as it was written.” The UN states that the NP “gave a verbal order for medications including the one we had questioned...the practitioner called back about 1.5 hours later further clarifying the order, and requesting a STAT BP.”

From this point forward, reports of the NP and UN match. Patient A’s blood pressure was taken and read 80/60. The NP told the UN to have the patient sit up immediately and call the medical doctor on duty (MOD). The MOD directed the UN to call poison control who advised the patient be sent to the ED, which was so ordered by the MOD. After being evaluated at the ED, the patient was transferred to the University of Virginia pediatric intensive care unit for observation. He was discharged back to CCCA the following morning with instructions to continue to monitor for sedation.

MEDICATION MANAGEMENT

CCCA is accredited by TJC under the Behavioral Health (BH) standards. As such, they are required to comply with the National Patient Safety Goals (NPSG) and all relevant standards and elements of participation. NPSG 3 for facilities accredited under the BH standards require facilities to, “Improve the safety of using medications.” Additional standards under the Care, Treatment, and Services chapter require coordinating information during transitions in care

inside and outside of organizations and communicating with other providers - both of which failed during this event.

When reviewing this event, OSIG requested a copy of the DMH 158 completed following the event, as well as a copy of the facility medication variance report required by facility policy. OSIG was informed a DMH 158 was never completed and OSIG was never provided a copy of a medication variance report.

CLONIDINE

Clonidine is a medication used to treat hypertension (HTN), attention deficit hyperactivity disorder (ADHD) in children and adolescents and several other conditions. In a child weighing 73 pounds (33.1 kg) such as Patient A, the maximum dose should be 0.05 mg up to 0.2 mg daily. It was determined that the dosage for clonidine listed on the intake paperwork and the dose given October 8, 2015, was incorrect, and should have been 0.05 mg instead of .5 mg, although documentation in a progress note and on the Medication Reconciliation form stated the dose as 0.5 mg and 0.1 mg. Prescribing information for clonidine indicates that dosages as small as 0.1mg can produce signs of toxicity in children.

Clonidine toxicity has become an increasing concern in children and young adults in recent years. In 2002, a [review of trends and toxic effects](#) from pediatric clonidine exposures from 1993 to 1999 was published in the Archives of Pediatrics and Adolescent Medicine, which found that “the trend towards increasing the number of exposures in children, especially with the evidence of toxic effects in children receiving clonidine therapeutically, is cause for concern.” A similar conclusion was reached in a November 2013 newsletter published by the Department of Pediatrics at the University of Virginia School of Medicine, which noted that the rise in pediatric clonidine use has been accompanied by a significant increase in the number of unintentional clonidine exposures.

POLICY ANALYSIS

CCCA Nursing Policy and Procedure No. 9-C, Report of Medication Variances (March 2015), defines the required steps CCCA staff must take in response to a medication variance. These steps include the completion of a DMH 158 and a Medication Variance Report, which are to be shared with the nurse involved, the Chief Nurse Executive and the Nursing Continuous Quality Improvement (CQI) staff. As stated earlier, OSIG requested copies of these and CCCA was unable to produce them.

A monthly Medication Variance Report is to be made available to the Pharmacy and Therapeutics Committee. OSIG requested and received minutes of the Pharmacy and Therapeutics Committee that covered the time period during which this medication variance occurred and found no evidence the event was discussed. The Nursing CQI Committee did

review aggregate medication error data for three errors in October 2015, but described them all as, “No adverse effect; no serious harm, risk was low.”

CCCA EVENT REVIEW

CCCA did not complete an RCA despite the significance of this event, a decision made by the facility director who opted instead to convene a group to review the event including the medical director, the chief nurse executive and the director of community services. Factors identified as “contributing” to the event included incorrect medication information on the CSB prescreening form, “miscommunication” between the NP and UN and failure of the UN to seek supervision despite, “some uncertainty about proceeding as ordered.” Steps identified by the facility director, in a communication with DBHDS, to “decrease the likelihood of recurrence” include:

1. Communication with CSB emergency services directors regarding errors in medication lists and requesting that “they” include a statement regarding whether information has been verified;
2. Reminders to physicians and nurses about using lead zeros (0.5 versus .5) and read-back process for verbal orders; and
3. Reminders to RNs to immediately contact the charge nurse when they have questions about medication orders.

No root causes, issues with after-hours admissions, issues related to high-risk or look-a-like, sound-a-like medications, medication variance reporting, responsibility of CCCA to make efforts to verify medication lists (especially involving abnormal dosages) or documentation issues were discussed. Additionally, CCCA has no defined process in place for following up on the completion or effectiveness of corrective actions identified by significant event reviews. The risk manager at CCCA indicated this process is done informally, usually including “check-ins” with the appropriate supervisory staff. Therefore, CCCA was unable to provide documentation confirming the implementation of corrective actions or any measure of success thereof.

AREAS OF CONCERN

Areas of concern regarding this case study include:

1. Lack of standardized medication reconciliation process for “off hours”
A [Sentinel Event Alert](#) released by TJC in January 2006, emphasized the importance of medication reconciliation to reduce medication variances in healthcare settings. CCCA senior staff indicated that CCCA has a system in place for medication reconciliation, but because this admission occurred after business hours, the system was not available to review the medications and dosages listed for Patient A on the VPRS, the IRI or the initial medication orders provided by the NP. In the absence of this system, nurses were responsible for performing the medication reconciliation independently and without safety checks to protect them or patients.

2. Lack of compliance with medication management and event reporting policies
 CCCA was unable to produce a DMH 158 or a Medication Variance Report concerning this event, both of which are required either by facility or departmental policy. These policies are intended to provide facilities the opportunity to review events and medication variances to utilize for the improvement of patient safety and quality of care.

3. Lack of RCA and strong/intermediate corrective actions
 OSIG determined that, based on definitions in DI401, the severity level and risk index scoring for this event should have been 04 and H, respectively, which should have led to the assessment of need for an RCA. However, despite DI401 identifying the risk manager as the professional responsible for determining when or whether an RCA is completed, the facility director determined that a less formal review of the event would be conducted.

By not completing documentation or performing an RCA, CCCA did not take advantage of opportunities to identify and address the root causes of this event. Doing so should have led to the facility identifying stronger corrective actions that could be implemented and measured, helping to improve the quality of CCCA’s services, the safety of CCCA’s patients and reducing the likelihood of similar events in the future.

CASE STUDY TWO

Resident A was a 22-year-old male admitted to VCBR August 11, 2015. Initial physician and nursing assessments were completed. The Comprehensive Psychological Assessment documented previous treatment for asthma and HTN, as well as obesity and head injury sustained in a motor vehicle accident. Resident A was 67 inches tall and weighed 236 pounds. It was also documented that his father died secondary to a cerebrovascular accident, more commonly known as a stroke, and his mother died of a cerebral (brain) hemorrhage.

CHRONOLOGY OF PATIENT EVENTS

Date	Time	Event
8/19/15	Not indicated	Chest X-ray subsequent to a positive tuberculin skin test. Results - Enlarged cardiac silhouette, no evidence of tuberculosis.
10/2/15	Not indicated	Seen after hours in VCBR clinic by on-call physician for complaints of abdominal pain, nausea, headache, body aches and constipation. Echocardiogram (ECG) ordered and completed.
10/4/15	Not indicated	Seen in VCBR clinic for similar complaints. Vital signs normal. Resident released.
10/5/15	Not indicated	Seen in VCBR clinic for similar complaints. Vital signs normal. Resident released.
10/7/15	Not indicated	ECG reviewed, results included “left ventricular atrophy by voltage criteria, and ST-T change, Abnormal ECG.” Ordered to follow-up with clinic in one to two weeks.

		No cardiology referral ordered or scheduled.
10/15/15	12:15 p.m.	Routine observation, in room, in no acute distress.
10/15/15	12:30 p.m.	Routine observation, found unconscious and without pulse. Facility emergency system activated; cardiopulmonary resuscitation initiated; automatic external defibrillator applied, indicated shock not advised. EMS transported to ED.
10/15/15	1:35 p.m.	Pronounced dead by ED physician.

The official autopsy report obtained by OSIG (November 29, 2015), identifies the cause of death as cardiac tamponade due to aortic dissection. Other pathological diagnoses include cardiac enlargement with left ventricular hypertrophy and coronary artery atherosclerosis, severe.

VCBR EVENT REVIEWS

VCBR completed several reviews of this death and the care Resident A received, including an Independent Death Review (IDR), a Death Summary (DS) completed by the attending physician and an RCA.

The IDR, which was undated, was performed by a physician employed by another DBHDS facility, PGH, located next door to VCBR. The IDR was the only post-mortem death review that mentioned the resident had visited the clinic a total of three times between October 2- 5, 2015, complaining of the same symptoms, but no mention was made of the past medical history of asthma, HTN or obesity. The physician found the death to be, “unexpected and unavoidable.” The IDR also stated the physician, “...did not find anything unusual at this time...” No mention was made of the cardiac presentations found on X-ray and ECG, nor of the unusual nature of a 22-year-old dying a sudden death.

The DS, also undated, was performed by the VCBR medical director. It made no mention about the second or third clinic visit, the history of asthma, hypertension and obesity, nor the five-day lag time for reading the abnormal ECG, which is noteworthy given the enlarged cardiac silhouette found on the chest X-ray two months prior.

An RCA was completed October 15, 2015, and a meeting was held to discuss the RCA on October 22, 2015. The meeting was attended by the facility director, medical director (also the attending physician who completed the DS), the assistant director of administration, the director of nursing, the resident services director, and assorted representatives from medical and nursing staff, residential and security staff. No minutes or other documentation concerning items discussed at this meeting were provided by VCBR. The only documentation for the meeting is a meeting sign-in sheet, which shows that the risk manager was not in attendance.

The RCA documented a summary of Resident A’s admission, excluding the second and third clinic visits, as well as the history of asthma, HTN and obesity. Despite the absence of follow-up after the abnormal chest X-ray, the five-day lag time between obtaining and reading the

abnormal ECG and the unexpected death of a 22-year-old in the facility, the RCA focused on staff observation checks, the medical emergency response system and the poor quality of medical information VCBR receives for residents on admission. The RCA produced no action items.

An RCA follow-up meeting was held on November 2, 2015, which was attended by the facility director, the medical director, the assistant director of administration, the clinical director, the director of nursing, the residential services director and the training coordinator. No minutes or other documentation concerning items discussed at this meeting were provided by VCBR. The only documentation for the meeting is a meeting sign-in sheet, which shows the risk manager was not in attendance.

AREAS OF CONCERN

Areas of concern regarding this case study include:

1. ECG Availability

Numerous documents provided by VCBR indicate there was no prior ECG available to serve as a baseline for comparison to the ECG performed October 2, 2015. However, documentation provided to OSIG by the facility includes results of an ECG performed at Keen Mountain Correctional Center on July 10, 2012. The summary of the test was “Abnormal ECG,” with findings of sinus rhythm and first degree A-V block.

2. Lack of Referral

Available documentation provides no evidence that Resident A ever visited a cardiologist for a consultation while at VCBR. Given the results of the ECGs performed July 10, 2012, and October 2, 2015, both of which were available to VCBR, such a consultation appears warranted.

3. RCA Implementation

An RCA was performed on this event using the TJC template, which identified two findings, one of which focused on systemic issues. No corrective actions were identified to improve system performance in order to reduce the likelihood of similar events in the future.

CASE STUDY THREE

Patient B was a 64-year-old male admitted to HDMC from CAT on February 19, 2015, for total care due to acute medical needs. His diagnoses included chronic undifferentiated schizophrenia with catatonic features, dysphagia, colostomy secondary to colon cancer, peripheral vascular disease, anemia and gastroesophageal reflux disease. He had a durable do not resuscitate (DDNR) order in place. At the time of this event, Patient B’s medications

included clonazepam, lorazepam, trazodone, fluphenazine (as needed), and acetaminophen (as needed for pain or temperature of 100.6 or greater).

CHRONOLOGY OF PATIENT EVENTS

Date	Time	Event
11/12/16	12:30 a.m.	Vomited large amount of brown-colored emesis
	1:00 a.m.	Vomited twice, coffee ground emesis, gastroculture positive for blood
	3:30 a.m.	Fever of 101.2
	10:15 a.m.	Fever of 101.6
	5:30 p.m.	Fever of 100.7. Vomited yellow emesis
	8:30 p.m.	Vomited moderate yellow and coffee ground emesis
11/13/16	6:15 a.m.	Fever of 100.7
	8:30 a.m.	Fever of 100.1
	10:15 a.m.	Fever of 100.6
	6:00 p.m.	Fever of 100.2
11/14/16	1:10 a.m.	Fever of 101.6
	1:10 a.m.	Orders entered: Begin Cipro 500mg every 12 hours for ten days Begin Levaquin 750mg daily for ten days Modify Duoneb to inhalation every eight hours for four days Modify albuterol to 0.083 percent every two hours for four days for wheezing
	6:15 a.m.	Fever of 101.7
	8:00 a.m.	Fever of 101.0
	2:00 p.m.	Fever of 99.7
	4:00 p.m.	Fever of 101.0
11/15/16	6:45 a.m.	Vomited coffee ground emesis
	8:00 a.m.	Temperature of 98.2
	10:00 p.m.	Fever of 99.1
11/16/16	12:00 a.m.	Fever of 99.0
	6:00 p.m.	Temperature of 98.6
11/17/16	6:00 p.m.	Fever of 102.1
11/18/16	8:00 a.m.	Temperature of 98.1
	3:00 p.m.	Fever of 102.1
	4:00 p.m.	Fever of 102.1 Vomited immediately after receiving medications
	4:30 p.m.	Vomited Fever of 100.0
	6:00 p.m.	Fever of 102.1
	6:15 p.m.	Orders entered: Discontinue Levaquin and Cipro Begin meropenem 1gm IV every eight hours for 10 days Begin azithromycin 500mg IV every 24 hours for five days Begin Zofran 1mg intravenously (IV) every eight hours as needed for nausea Modify albuterol 0.083 percent to every six hours for four days Perform comprehensive metabolic panel and complete blood count with differential on morning of 11/19 Immediately begin saline IV at 120ml per hour continuously Immediately prohibit oral intake Contact attending physician at 9 a.m. on 11/19
	7:30 p.m.	Vomited moderate amount of greenish substance Fever of 101.7
	8:30 p.m.	Orders entered: Modify acetaminophen to 650mg per rectum every six hours as needed for fever of 100.6 or higher

		Modify Zofran from 1mg to 4mg IV every eight hours as needed for nausea and vomiting for the next three days
	9:25 p.m.	Vomited minimal amount of greenish fluid
	9:15 p.m.	Acetaminophen administered as ordered
	11:50 p.m.	Fever of 102.2
11/19/16	12:00 a.m.	Fever of 101.3 O2Sat 84 percent on room air Supplemental oxygen given (2L), O2Sat increased to 95 percent
	12:30 a.m.	Vomited small amount of dark brown emesis
	1:00 a.m.	MOD Notified No new orders issued
	3:00 a.m.	Fever of 104.4 O2Sat 92 percent on 2L supplemental oxygen Acetaminophen administered Cold compresses applied MOD notified No new orders issued
	4:00 a.m.	Fever of 104.0 Cold compresses reapplied
	5:45 a.m.	Patient B found unresponsive, cyanotic, and diaphoretic O2Sat between 70-75 percent on 2L supplemental oxygen Rebreather applied, O2Sat increased to 82-84 percent MOD notified. Order entered to transport to ED
	5:46 a.m.	911 called
	5:55 a.m.	EMS arrived
	6:15 a.m.	EMS leaves HDMC to transport Patient B to Southside Regional Medical Center (SRMC)
	7:00 a.m.	HDMC staff notified by SRMC staff Patient B pronounced dead

HDMC REVIEW

The attending physician prepared an internal Death Report to the facility Mortality Committee concerning Patient B's death on November 19, 2016 (no such report was made to CO). This report provides information concerning Patient B's death. In it, the attending physician states:

- "...since [11/14/16] the patient did not have a fever until November 18, 2016."
- "RN called on November 18, 2016 around 18[:]00 due to patient had [sic] temperature of 104 and vomiting."
- "RN called again on November 19, 2016 at 05[:]45 to report that the patient was unresponsive, ashy facial color and unable to obtain vital signs."

No mortality review or root cause analysis of this death was performed by HDMC.

AREAS OF CONCERN

Areas of concern regarding this case study include:

1. Quality of medical record documentation

Patient B's medical record lacked relevant and important documentation. For example, a Vital Sign Flow Sheet indicates he had a fever of 102.1 at 6 p.m. on November 17, 2015. The only documentation in the chart dated November 17, 2015,

is a 60-day Physician Progress Note, which states there were no changes to be made to the plan of care, medications or treatments, nor any change in Patient B's response to the aforementioned. It is important to note that at the time of this inspection, HDMC's policy was to chart by exception. The Nurses Service Organization (the nation's largest provider of nurses' professional liability insurance coverage), states that while there are numerous variations to charting by exception, the general rule is that "only unusual or unexpected findings, or those outside the norm, are recorded...this form of documentation should also call for notes concerning any significant indicator of the patient's condition or change in status."

A physician's interdisciplinary progress note dated November 14, 2015, documented, "a/p aspiration/pneumonia 2nd vomit." A documented fever of 102.1 on November 17, 2015, confirms a change in condition for Patient B, which requires documentation in the medical record to address symptoms and treatment planning. Per 42 CFR 483.70.i.1, facilities must maintain medical records in accordance with accepted professional standards and practices to include addressing clinical changes and reflecting active treatment. Medical records must be complete, accurately documented, readily available and systematically organized.

Given these criteria, Patient B's chart should have included ID notes and/or physician notes identifying and actively addressing his symptoms.

2. Timeliness of response to changes in symptoms

OSIG found a lack of evidence of timely responses to multiple episodes of vomiting beginning November 12, 2015. Despite eight episodes of vomiting between November 12 and November 18, including three with coffee ground emesis, OSIG found no evidence of medications for nausea or vomiting being ordered until 6:15 p.m., November 18, 2015.

OSIG found a similar lack of timely response to elevated temperatures. The Vital Signs Flow Sheet records a fever of 102.1 on November 17, at 6 p.m. However, the medication administration record (MAR) does not indicate any acetaminophen being administered on the 17th. Patient B did not receive a dose of acetaminophen until 24 hours later, at 6 p.m. on November 18.

3. Inconsistencies between the patient chart and the Death Report

OSIG found the following inconsistencies between these two documents:

- The Death Report stated Patient B did not have a fever between November 14 and November 18. This contradicts information provided in the timeline above.
- The Death Report indicates a temperature of 104 around 6 p.m. on November 18. The ID note for November 18, at 6 p.m. indicates a temperature of 102.1.

- The Death Report indicates that the attending physician received calls from nursing staff at 6 p.m. on November 18, and 5:45 a.m. on November 19. However, ID notes in the chart indicate nursing staff informed the attending physician of Patient B’s status changes on November 18, at 6 p.m., 8 p.m. and 9:30 p.m., and on November 19, at 1 a.m., 4 a.m. and 5:45 a.m.

CASE STUDY FOUR

Patient C was a 60-year-old woman admitted to HDMC June 26, 2009. Her medical history included a traumatic brain injury suffered as a result of a motor vehicle accident in 1990 that left her wheelchair-bound with right-side hemiplegic and diagnosed with a mental disorder, not otherwise specified. She was described as having difficulty completing activities of daily living and exhibiting disruptive behaviors.

CHRONOLOGY OF PATIENT EVENTS

Date	Time	Event
5/12/16	8:45 a.m.	Patient C complained of right leg pain, right thigh and knee found to be swollen and warm to touch. Right leg X-rays ordered and completed, negative for fracture in right leg.
	10:30 a.m.	Venous Doppler of right leg ordered and completed, negative for deep vein thrombosis (DVT).
5/13/16	6:00 a.m.	Right leg still swollen and warm to touch.
	1:50 p.m.	Order entered: Right knee X-ray. Begin Bactrim DS every 12 hours for ten days.
	3:01 p.m.	X-ray completed and reviewed by radiologist, finding positive for intra-articular fracture of lateral tibial plateau, age indeterminate.
	4:50 p.m.	Orders entered: Discontinue Bactrim. Brace to immobilize knee worn at all times (except patient care) for 30 days. Ibuprofen 600mg every six hours for two days, then every eight hours for three days, then as needed for 30 days. Aspirin 81mg every day for 30 days. Prilosec 20mg twice a day for five days, then daily for 30 days. Consultation with (orthopedist).*
5/16/16	2:30 p.m.	Orders entered: Discontinue aspirin. Begin Lovenox 30mg daily for 21 days. “Consult ortho (not in our clinic).”
5/18/16	Unknown	Consult with orthopedist, report stated: Fracture was acute. Recommended using a hinged knee brace to relieve soreness caused by immobilizing brace. “[I]f patient is chronically wheelchair bound no role of DVT prophylaxis.”
5/25/16	Unknown	Follow-up with orthopedist, brace discontinued
5/27/16	12:45 p.m.	Orders entered: Discontinue Lovenox. Begin ibuprofen 600mg every six hours for eight days, then every six hours with food for 30 days. Begin propranolol 60mg every eight hours for 60 days for agitation and impulsivity. Right leg should be kept elevated in bed.

6/9/16	5:25 p.m.	Patient C moving around unit in wheelchair, when noticed to be having trouble breathing. Staff attempted to transport to room for breathing treatment; became unresponsive and cyanotic. Code called, CPR started, EMS arrived and transported Patient C to local hospital.
6/9/16	9:07 p.m.	Pronounced dead.

** HDMC was unable to provide a Patient Referral for Consultation form, a consultation report or other documentation to verify that this consultation with the orthopedist occurred.*

HDMC REVIEW

In the Death Report, the attending physician states, “There were suspicions of pulmonary embolism due to DVT v.s. [sic] acute coronary syndrome,” and lists acute respiratory failure as the cause of death. Probable acute pulmonary embolism, probable DVT, and right knee intra-articular fracture are listed as the “Immediate Cause (Final Disease or condition resulting in death)” of death.

HDMC did not perform an RCA of either the fracture or death. The medical staff did meet to discuss the death on July 19, 2016, and the minutes from that meeting stated:

- “It is the belief of the [HDMC] physicians that the patient died from a pulmonary embolism, possibly from DVT.”
- “An autopsy was requested from the medical examiner’s office in Richmond.”
- In the absence of an autopsy, HDMC staff “still believed that the cause of death was a pulmonary embolism.”

The Medical Examiner’s Report of Investigation ruled the death to be natural, caused by hypertensive cardiovascular disorder. OSIG consulted the state administrator for the Office of the Chief Medical Examiner concerning the denial of HDMC’s request for a full autopsy. While unable to speak specifically to this case, the state administrator stated that full autopsies are only performed when an external examination does not conclusively determine the cause and manner of death.

AREAS OF CONCERN

The area of concern regarding this case study is the quality of documentation.

OSIG found a lack of consistent documentation between the HDMC medical record, the Death Report and the minutes of the HDMC Medical Staff Meeting for the Unanticipated Death Review meeting held on July 19, 2016.

Regarding the discontinuation of Lovenox, the physician’s orders state that Lovenox was discontinued May 27, 2016. This is supported by the MAR. However, both the Death Report and the Medical Staff Meeting minutes report that the full 21-day regimen of Lovenox was administered.

OSIG found additional inconsistencies between the Medical Staff Meeting minutes for the Unanticipated Death Review meeting (July 19, 2016), and medical record documentation. In item three, the Medical Staff Meeting minutes note:

1. The consulting orthopedic surgeon ordered a knee brace, Lovenox, and pain medications. On the Patient Referral for Consultation form, the orthopedist only recommended the use of a knee brace. The orthopedist did not reference pain medications and the form clearly states that there was no role for DVT prophylaxis in this case (Lovenox).
2. “The 21-day DVT prophylaxis (Lovenox) was completed on June 6, 2016.” As shown above, the last dose of Lovenox was administered May 26, 2016.

CASE STUDY FIVE

Patient D was an 80-year-old male admitted to CAT on April 9, 2016, on a temporary detention order from Lynchburg General Hospital. His medical history included hyperlipidemia, chronic constipation, hypothyroidism, hypertension, chronic anemia and Parkinson’s Disease. While at CAT, he was diagnosed with major neurocognitive disorder secondary to Parkinson’s Disease with behavioral disturbances. Upon admission, he was prescribed Depakote, Seroquel, Zoloft and other medications to treat his medical conditions.

CHRONOLOGY OF PATIENT EVENTS

Date	Time	Event
4/12/16	No time indicated	Admission dysphagia screening completed. No swallowing difficulties were observed.
5/24/16	No time indicated	Dysphagia screening starts. HDMC was unable to provide documentation specifying why the screening was repeated, or instructions within CAT Policy 06.035, Dysphagia/Choking Risk Reduction Program that dictate the need for recurring/follow-up dysphagia screenings.
5/25/16	9:45 a.m.	Patient D “...Put himself on floor,” observed vomiting and experiencing seizure-like activity. Vital signs indicated low O2Sat. Transported to ED for respiratory failure and admitted to Carilion Roanoke Memorial Hospital (CRMH).
5/31/16	3:30 p.m.	Returns to CAT after discharge from special hospitalization at CRMH. Discharge Summary indicated acute respiratory failure (likely secondary to aspiration pneumonia) with hypoxia, hypothyroidism and neurocognitive disorder as active problems.
6/13/16	10:00 a.m.	Repeat dysphagia screening ordered, found instances of delayed swallowing on 6/15 and 6/17, comment on report stated Patient D was “packing [his] mouth full of food and not chewing and/or swallowing in [a] timely fashion.”
6/22/16	10:30 a.m.	Occupational Therapy (OT) consult performed, found occasional pocketing of small amounts of food in cheeks, but that pocketing of food was “not causing any overt problems with eating,” was able to eat bread and meat with no difficulty. No dietary modifications were recommended.
7/27/16	5:15 p.m.	Choked on piece of biscuit during dinner. Food dislodged by patting on back.
7/28/16	9:50 a.m.	Physician order entered to “try to remind patient to eat slowly, chew well and take drinks of fluids often.”
7/29/16	3:50 p.m.	Follow-up OT consult documented continued pocketing of food, no swallowing difficulties. Recommendation made for diet change to finger foods, discontinuation of OT services.
8/1/16	12:00 p.m.	Choked on sweet potato during lunch. Heimlich Maneuver required.

8/1/16	1:00 p.m.	Physician's progress note states "...will discuss OT evaluation and any other recommendation."
8/2/16	9:40 a.m.	Order entered for diet change; "finger foods only and only give him small pieces/amounts at a time at meals (will have to <u>not</u> give him his tray for ad lib feeding" [emphasis in original].
8/4/16	7:26 p.m.	Weekly nurse's note states "a few" choking episodes during the week.
8/9/16	5:00 p.m. (approx.)	Choked on unknown "ball of food" during supper, Heimlich Maneuver required, Patient D later told staff "I almost died."
8/10/16	3:00 p.m.	ID note written by RN states that doctor and OT were informed, per nurse OT "will see him again to eval. Per OT – suggests that we feed pt."
9/3/16	1:35 p.m.	Quietly eating lunch, staff noticed he was pocketing food but displaying no swallowing difficulties. Then, per ID notes: "...all sudden pt got choked while eating and was unable to talk. Pt kept his mouth closed and was making choking gesture. Heimlich done by two staff, was not successful, pt started turning blue. Medic alert called. Pt was given oxygen via mask 15 L/minute. PT was turned on his side. [Oxygen saturation] 89% then came up to 99%." Emergency medical services then arrived to provide care... pt has had swallowing problem for about a month and was evaluated by OT too."
	1:54 p.m.	Admitted to CRMH.
9/4/16	2:50 p.m.	A Speech Language Pathologist (SLP) at CRMH performed a swallowing assessment, the results of which recommended a barium swallow study be performed. This study found that Patient D was at high risk for aspiration regardless of diet modifications. The family decided to continue oral nutrition with the acceptance of aspiration risk, informing CRMH staff that CB "never wanted tube-feeding." The discharge instructions from CRMH include: <ul style="list-style-type: none"> • Recommendation for a dysphagia 1/puree consistency diet with nectar thick liquids with thin liquids in between meals by teaspoon only; • Patient D only to eat with one to one supervision, taking small bites and sips, with attempts to elicit dry swallows between bites and sips and throat clearings during meals; • Long-term SLP follow up for education and clinical correlation; and • Trials of small bites of very soft, fork mashable, chopped soft solids for potential advancement of food texture.
9/4/16	11:06 p.m.	Returns to CAT after special hospitalization at CRMH.
9/5/16	9:55 p.m.	Weekly nurses note states continued swallowing difficulties, "taking only small sips of liquid and taking about 30-45 seconds to swallow each sip."
9/5/16	10:00 a.m.	Became weak and congested, O2Sat dropped, became irritable when staff attempted to administer supplemental oxygen. Became unable to walk, required assistance with ADLs, noted to have coarse rhonchi and delirium. X-ray indicated patchy right upper lobe infiltrate. Transported and admitted to CRMH. Family decided to place on palliative care.
9/11/16	8:18 a.m.	Patient D died. Autopsy identified complications of aspiration pneumonia as the cause of death.

POLICY ANALYSIS

OSIG requested, received and reviewed CAT's dietary policies and manuals to determine compliance and if policies are in line with best practices and national guidelines. CAT Hospital Policy and Procedure 09.10, Nutritional Guidelines, indicates that the CAT Diet Manual (CDM) serves to guide practitioners when ordering regular or therapeutic diets based on their nutritional needs. The CDM draws from the National Dysphagia Diet (NDD), "a multi-level diet for patients experiencing dysphagia, [including] sample diets, preparation

methods and practice applications,” which was developed in 2002 by the American Dietetic Association (now known as the Academy of Nutrition and Dietetics).

The CDM includes a specific diet called “Finger Food Mechanical Soft,” which provides foods that are easy to eat with fingers and/or a spoon and are easy to chew. The manual states that “All food items are in compliance with the Level 2: Dysphagia Mechanically Altered Diet,” which is described as foods that are moist, soft-textured and easily formed into a bolus [or a small rounded mass of substance]. Meats are ground or are minced no larger than one-half inch pieces. The sample menus for both these diets include broccoli – chopped broccoli for the Mechanically Altered diet and steamed broccoli for the Finger Food Diet.

The NDD specifically indicates that broccoli should not be included in Level 2 diets. The vegetables section of the NDD Level 2: Mechanically Altered Nutrition Therapy Diet recommends that “All soft, well-cooked vegetables, should be less than ½ inch[and] [s]hould be easily mashed with a fork.” The vegetables that should be avoided include “soups with large chunks, rice, corn, or peas; cooked corn and peas; and fibrous, nontender [sic], or rubbery cooked vegetables **including broccoli**, cabbage, brussels [sic] sprouts or asparagus” (emphasis added).

CAT Policy 06.035, Dysphagia/Choking Risk Reduction Program, delineates guidelines for staff based on the individual’s patient care role. Licensed Independent Practitioners (LIPs) are responsible for discussing referrals to an SLP for incorporation of recommendations into treatment plans as well as reviewing all recommendations made by referrals and/or consultations and ensuring they are documented in the medical record. Under the LIP section, the policy also states “...additional tests and/or procedures are ordered as clinically indicated,” and “Collaboration with the treatment team regarding choking risk will be documented in the physician progress notes.” Registered dietitians (RDs) are to assess patients at risk for choking and make recommendations to the LIP regarding nutritional status and needs.

EVENT ANALYSIS

CAT performed a mortality review and an internal risk management inquiry/review, but did not perform an RCA of this death. In the Death Summary provided to DBHDS, none of the choking episodes that took place in August 2016, were mentioned.

AREAS OF CONCERN

Areas of concern for OSIG regarding this case study are:

1. Dietary Standards

OSIG discovered inconsistencies between CAT’s Diet Manual and the standards identified in the NDD. While both the Level 2: Mechanically Altered Soft and Finger

Food Mechanical Soft diets in the CAT Diet Manual include broccoli in their sample meal plans, the NDD Level 2: Mechanically Altered Diet specifically includes broccoli in the list of vegetables that should be **avoided**. Furthermore, while the Level 2: Mechanically Altered Soft Diet in CAT's Diet Manual indicates broccoli should be chopped, the Finger Food Mechanical Soft diet only indicates broccoli should be steamed; it does not indicate the method or degree to which it should be mechanically altered.

2. Policy Compliance

CAT was unable to produce evidence in the medical record documenting compliance with the following elements of CAT Policy 06.035:

- Discussion of referral to SLP;
- Discussion of dysphagia in treatment planning;
- Documentation of treatment team collaboration regarding choking risk in physician progress notes; and
- Assessment of Patient D by RD (last reassessment note in chart dated July 18, 2016).

3. Lack of Speech Language Pathologist (SLP) Consultation at CAT

Patient D experienced at least four choking episodes in the last 42 days of his life. In spite of this, no consultation with an SLP was ordered for him while he was at CAT. The American Speech-Language-Hearing Association (the national professional, scientific and credentialing association for audiologist, speech language pathologists and speech/language/hearing scientists), [states](#) SLPs are involved in the diagnosis and management of oral and pharyngeal dysphagia and are integral members of any inter-professional team. OSIG verified with the facility director that CAT does have an SLP on contract to perform consultations, but no order for consultation was made for Patient D. Patient D did see an SLP at Carillion Roanoke Memorial Hospital on September 4, the day after his last choking episode, and seven days before his death.

4. Lack of any consult addressing dysphagia at CAT after July 29

Despite at least two choking events in August, CAT was unable to provide any evidence that Patient D received any follow-up consultation addressing dysphagia concerns. The last consult Patient D had with the OT at CAT occurred on July 29. The report from that consultation "recommend[ed] finger foods," but noted "continued OT not needed at this time for this problem." OSIG's review of chart documentation for August discovered two notes and one order relative to OT consultation for Patient D's choking issues:

- A physician's progress note on August 1, at 1 p.m., stated, "Will discuss OT evaluation and any recommendations."

- An order on August 2, at 9:40 a.m., ordered a diet change to finger foods in response to the July 29 consult.
- In an ID noted on August 10, at 3 p.m., an RN noted “Spoke [with OT] regarding concerns related to pt’s swallowing and choking episodes. [OT] will see him again to eval.”

These notes suggest a follow-up consult may or should have occurred, but there are no physicians’ orders or consult reports in the chart to confirm that such a follow-up took place.

OBSERVATION NO. 4 - RECOMMENDATION

As a part of its quality improvement process, DBHDS should develop a system of performing case reviews – following a specified number or percentage of significant events – to evaluate policy compliance, quality of documentation, quality of reviews and outcomes.

Appendix I: Departmental Instruction 401

Issued: 01/06/03
Revised: 05/20/03
Revised: 1/10/12
Reissued: 2/15/13

Departmental Instruction 401(RM)03 Risk and Liability Management

401 - 1 Background

This Instruction recognizes the need for the Department of Behavioral Health and Developmental Services (the Department) to provide high quality services in a recovery oriented/skill development environment that respects and promotes the dignity, rights, and full participation of individuals receiving service and the staff. Risk Management is an integrated system-wide program to ensure the safety of individuals receiving services, employees, visitors, volunteers, contractors and students through prevention, monitoring, early detection, evaluation and control of risks. It is the intent of the Department, through its Risk Management program, to enhance safety and to minimize the potential liability exposure and financial loss to the Department and the Commonwealth of Virginia.

401 - 2 Purpose

The purpose of this Instruction is to establish requirements and guidance for a comprehensive and uniform system-wide risk management program, aimed at achieving the optimum degree of risk reduction, elimination, and control through the identification, analysis, and treatment of those exposures that may result in harm to individuals receiving services, employees, visitors, volunteers, students and contractors, or a loss.

401 - 3 Definitions

The following definitions shall apply to this Instruction:

Claim This means a demand for restitution made against a facility or its agents. It is usually precipitated by an incident occurring within the facility. A claim may be asserted either orally or in writing. Tort claims pursuant to Virginia statute must be made in writing.

Event This means any occurrence, accidents or experience and situations that either do or could alter or change the status or condition of an individual receiving service, employee, volunteer, visitor, contractor or student, or the routine operations of the organization.

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Facility Event Report	This refers to a Departmental form (DMH 158, Attachment 1) used by employees to notify their supervisors, facility Risk Managers, and other appropriate management of an event that presents either actual or potential risk/liabilities.
Liability	This means an obligation incurred as a result of an inappropriate or wrongful act, or the failure to act, as required within the scope of one's duty.
Risk	This means the possibility of, or exposure to one or both of the following: (i) physical or emotional harm/injury to individuals, family members, employees, visitors, volunteers, contractors, students, or the community; (ii) the loss of financial assets and/or damage to the reputation of the Department or the Commonwealth.
Risk Manager	This means the designated person responsible for coordinating, managing and implementing the facility's risk management program and activities.
Sentinel event	This means any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to an individual receiving services, not related to the natural course of an individual's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome
Suspicious injury	This means an injury to an individual receiving services that, due to its: shape; type; location; pattern; severity; frequency; or other circumstances leads to an inference of abuse or neglect.
Unexplained injury	This means an injury to an individual receiving services that is discovered after an un-witnessed event where, upon initial discovery, the surrounding facts and circumstances provide no apparent reasonable or logical explanation sufficient to determine its cause.

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401 - 4 Responsible Authorities

- Central Office** The Central Office Director of Clinical Quality and Risk Management is responsible for:
- Interpreting this Instruction;
 - Developing and maintaining Departmental risk management procedures and guidelines;
 - Overseeing and monitoring the implementation of facility risk management programs, which include reviewing facility policies developed pursuant to this Instruction; and
 - Reporting system-wide trend data.

Assistant Commissioners who are responsible for state hospital and training center operations, in collaboration with the Director of Clinical Quality and Risk Management, are responsible for ensuring facility compliance with recommended operational risk reduction strategies.

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- Facilities** Each Facility Director is responsible for:
- Assuring that policies and procedures are developed to provide for establishment of a committee designated to address safety issues, pursuant to § 8.01-581.17 of the *Code of Virginia*;
 - Implementing a comprehensive and integrated risk management program managed by a facility Risk Manager who is qualified by training or professional designation;
 - Taking immediate, expedient and appropriate actions to identify and minimize or eliminate the adverse impact of liability exposures;
 - Assuring that all incident reports are aggregated, reviewed and analyzed and facility patterns and/or trends are identified and reported to the facility Quality Committee on a quarterly basis;
 - Developing and implementing risk reduction plans based on event/incident analyses;
 - Routinely reviewing and analyzing facility claims and losses;
 - Assuring that the facility Risk Manager is actively involved in the assessment of all facility liability exposures;
 - Addressing and implementing as deemed appropriate all corrective actions plans and risk reduction strategies recommended by the facility Risk Manager or the Committee, or both; and

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- Facilities**
(continued)
- Incorporating the requirements of this Instruction into the Risk Manager's employee work profile.
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- Facility Risk Managers**
- The facility Risk Manager is responsible for:
- Developing, coordinating, and administering an interdisciplinary facility-wide risk management program;
 - Assuring all events are reviewed which are reported via the Facility Event Report Form, DMH 158, assigning appropriate clinical severity levels and risk index codes, and taking steps necessary to assure appropriate investigations and follow-up reviews are conducted;
 - Ensuring that all original facility event reports are maintained in a confidential and secured location and retain them in accordance with Commonwealth of Virginia record retention laws;
 - Providing information to the committees designated to address safety issues on reported/reportable events and other risk-related issues and recommending and monitoring the implementation of risk reduction strategies;
 - Communicating on an ongoing basis with the human rights advocate and abuse/neglect investigator on abuse/neglect matters to identify and manage systemic risk/liability issues;
 - Developing and implementing a facility-wide staff education program for loss prevention and loss control, which includes comprehensive orientation to inform employees, volunteers, students, and contract employees who will be assigned direct care responsibilities of their obligations, responsibilities, protections and role in the facility's risk management program;
 - Monitoring the status of corrective action plans for identified risks and risk reduction strategies and providing ongoing updates to the Facility Director to ensure appropriate implementation; and
 - Serving as a member of facility committee(s) to protect privileged risk management activities and communications.
-

401 - 5 Specific Guidance

- Privileged committee activities & communication**
- Each facility shall establish an appropriate committee or committees to protect privileged risk management activities and communications
- Each facility Risk Manager shall serve as an ex officio member of any facility committee established to focus on facility risk and liability issues and function
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- Privileged committees activities & communications**
(continued)
- primarily to review, evaluate, or make recommendations on issues such as the following:
- the duration of patient stays;
 - the necessity of medical, dental, psychological, podiatric, chiropractic or optometric or other professional services that are furnished to individuals receiving services;
 - the most efficient use of available facilities and services;
 - the adequacy or quality of professional services;
 - the competency and qualifications for professional staff privileges;
 - the reasonableness or appropriateness of charges made on behalf of the facilities; and
 - the safety of individuals receiving services and others.
- As a member of any such committee, the facility Risk Manager shall take all appropriate steps to maintain the privileged character of information in accordance with § 8.01-581.17 of the *Code of Virginia*.
 - The Commissioner, Assistant Commissioners responsible for state hospital and training center operations, Director of Clinical Quality and Risk Management, and Central Office Medical Director shall serve as ex-officio members of the above-referenced facility committees.

Program coordination

The facility risk management program shall maintain interrelationships with key facility departments and functions including, but not limited to: senior management, financial and contracting services, medical and clinical services (including privileging and credentialing), abuse investigations, quality management, human rights, safety and security, medical records, infection control and human resources.

The facility risk management program must have in place processes that provide for coordination with internal facility departments and offices as well as external agencies and organizations (e.g., OSHA, Board of Health Professions, state and local police).

-
- Claims management**
- The role of the Division of Risk Management in the Department of Treasury is to provide management services for potential and actual professional liability and malpractice claims.
 - The role of the Office of the Attorney General is to monitor claims filed against the Department or its staff under the medical malpractice self-insurance program and defends medical malpractice claims or suits against the Commonwealth and its employees.

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- Claims management**
(continued)
- The facility Risk Manager shall:
 - Work collaboratively with Division of Risk Management in the Department of the Treasury and the Office of the Attorney General in the management of claims and litigation;
 - Develop summaries of liability issues raised during claims settlement and litigation; and
 - Develop strategies to prevent/minimize recurrences of the same or similar claims.

401 - 6 Procedures -- General

Mandatory requirements for all personnel to report

Any employee, volunteer, contractor, or student who witnesses or discovers any event that causes or has the potential to cause harm or injury to any individual or an event that poses risks or liability to the organization facility, shall immediately complete, date and sign a Facility Event Report Form, DMH 158 and submit the report to his/her immediate supervisor or staff person in charge.

A facility may use a form other than DMH 158 to facilitate the capture of certain, high frequency events, when that form is approved by the facility Risk Manager. However the Facility Event Report Form, DMH 158 shall remain the primary form for reporting events that present actual or potential risk/liabilities.

-
- RM plan and review**
- Each facility shall develop a written risk management plan consistent with the Department's *Risk Management Plan* that outlines:
- The facility's comprehensive risk management program, its goals and objectives;
 - Essential program components, activities, and responsibilities;
 - Processes for developing/implementing plans of correction for identified risks; and
 - Integration of the risk management program with key departments and functions.

The risk management plan will be reviewed and updated annually by the facility staff and senior management. The Office of Clinical Quality and Risk Management shall be informed of any changes to such plan.

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- RM operations documents** The facility Risk Manager shall maintain in paper or electronic format or have electronic access to the following information:
- Commonwealth of Virginia *Risk Management Plan*;
 - Reference list of risk management-related Departmental Instructions, memoranda, and guidelines;
 - Facility risk management-related policies, procedures, and protocols;
 - Facility risk management plan;
 - Facility annual risk management evaluations;
 - Risk Manager's EWP consistent with this Instruction;
 - Other information, as appropriate (e.g., laws relevant to the care of individuals receiving services, operations, employment, current literature on risk management topics); and
 - Incident management procedures in the absence of the Risk Manager.

-
- Risk identification and assessment system** Each facility's risk management program, as described in the facility risk management plan, shall include the following:
- An event/incident management protocol to provide for:
 - Reporting all deaths and critical events, as required by Code, regulation and accreditation requirements;
 - Responses to and review of all events; **AND**
 - A proactive risk identification and assessment process to reduce the likelihood of or mitigate the impact of events that have the potential to result in injury, accident, or other loss to individuals receiving services, employees, visitors, volunteers, students, contractors, or assets. This shall include:
 - A proactive process to evaluate the potential adverse impact of direct and indirect care processes, the physical plant, equipment, and other systems on health and safety; and
 - Routine assessments of the physical environment and high-risk areas, as well as periodic reviews of facility policies and procedures for risk identification purposes.

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401 - 7 Procedures – Assignment of Event Outcome Severity and Risk Indices

**Clinical
outcome/
severity level**

The facility Risk Manager or designee shall assign one of the following clinical outcome severity levels to each event:

- 00 = No injury occurred;
- 01 = Minor injury occurred; no specific area of the body required any special attention; no medical treatment by a physician or physician extender required; possibly first aid administered, but no increased monitoring of the individual is required;
- 02 = Moderate injury occurred involving a relatively small and/or minor area of the body; no medical treatment beyond first aid by a physician or physician extender required; possibly first aid administered; increased monitoring warranted, no ultimate harm or loss of bodily function(s).
Injuries in this category are distinguished from those in category 01 in that all injuries here require some increased monitoring, but no medical treatment as described below;
- 03 = Injury requiring medical treatment beyond first aid (no hospitalization) by a physician or physician extender; possible temporary loss of bodily function(s); includes loss of consciousness
The injury received requires treatment of the individual by a licensed physician, podiatrist or dentist or physician extender (e.g., physician's assistant or nurse practitioner), but the treatment required is not serious enough to warrant or require hospitalization. The treatment may be provided within the facility or provided outside the facility where it may range from treatment at a doctor's private office through treatment at the emergency room of a general acute care hospital;
- 04 = Injury or loss of consciousness requiring hospitalization; possible temporary loss of bodily function; possible major/permanent loss of bodily function(s).
The injury received requires medical treatment as well as care of the injured individual at a general acute care hospital. Regardless of the length of stay, this severity level requires the injured individual be formally admitted as an inpatient to the hospital and assigned to a bed on a unit outside of the emergency room;

Continued on next page

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Clinical outcome/severity level
(continued)

05 = Injury received was so severe it resulted in death, or complications from the injury led to death of the individual;
06 = Deaths involving no injury.

Risk index

The facility Risk Manager shall assess the risk/liability associated with each event and assign it one of the following index codes:

N = No risk or liability identified.

L = Low/minor risk or liability. The event has little or no impact or requires comparatively little attention or concern.

M = Moderate/some risk or liability. The event has reasonably manageable risks or requires minimal reduction/preventive efforts.

H = High/significant risk or liability. These events include:

- incidents with actual, or the potential for high levels of public scrutiny;
 - incidents where claims are anticipated, threatened or initiated;
 - incidents involving criminal activity;
 - deaths with a clinical outcome severity level of 05;
 - all suspicious unexplained injuries, regardless of clinical outcome severity level; or
 - incidents of any clinical outcome severity level where historical data on that individual indicates a trend suggesting a high-risk impact.
-

401 - 8 Procedures – Event Reporting and Initial Review

The following procedures shall be used to review and report all events:

Step #1 initial report

Any employee, volunteer, student or contractor who is involved in, witnesses or receives a report of an event that causes or has the potential to cause harm or injury to any individual or an event that poses risks and/or liabilities to the organization, shall complete, date and sign a Facility Event Report Form, DMH 158 or its equivalent, and submit the report to his/her immediate supervisor or staff person in charge.

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Step #1
initial report
(continued)

- The content of the original event report, as submitted by the originating employee, volunteer, student or contractor shall not be altered or edited in any manner, except by the Risk Manager, who may write an addendum on the form to clarify or update the event. Any such addendum must be signed and dated by the Risk Manager.
- All events shall be reported, regardless of whether they occurred
 - In the facility or away from the facility;
 - With or without staff present; or
 - While the individual receiving services is on authorized leave, missing, or on special hospitalization.
- Event reports shall include only factual information, such as when the event took place, what was observed, who was involved, and other relevant facts. Assumptions, conclusions and irrelevant facts shall not be included in the report.
- No copies and/or distribution shall be made of the original event report unless otherwise permitted by this Instruction.
- Event Report Form, DMH 158 or its equivalent shall not be filed in the Clinical Record.

Step #2
review of events
by supervisor

Review of Events.

- The employees shall submit the event report to his or her immediate supervisor or the designated staff person in charge.
- The supervisor or designated staff person in charge who receives the event report shall review the report for clarity, legibility and completeness and forward it to the Risk Manager as soon as possible, but no later than twenty-four business hours from occurrence or discovery of the event.
- Documentation that is not to be included in the event report should be recorded separately and maintained appropriately, to assist with individual treatment needs, and/or related investigations.
- When an injury is involved and no cause of injury is immediately evident, the supervisor or staff person in charge shall attempt to ascertain the event associated with the injury, so note, and then sign and date this note on the supervisor's line of the report.

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Step #2 Review of Unexplained Injuries. If no event can be associated with the injury, the review of events the supervisor or person in charge shall note that the injury is unexplained and by supervisor shall immediately:

- Report the injury to the Facility Director, per facility policy and external agencies, as required by law or regulation.
- Determine and assure documentation of the following:
 - the type of injury;
 - the shape of the injury;
 - the location of the injury;
 - the apparent clinical outcome of the injury;
 - the ability/probability of the individual self-inflicting the injury; and
 - the frequency or apparent pattern or patterns associated with the injury, including any pattern of injuries suffered by one or more individuals on the same shift or living unit over a period of time.

Step #3
review by
Risk Manager

- All events – the facility Risk Manager shall assure:
 - A clinical outcome severity level and risk index code is assigned to the event; and
 - The event data, including clinical outcome severity level and risk index code is entered into the facility database.
- If the injury appears to meet the definition of a suspicious injury, the Risk Managers shall ensure that the injury is reported to the Facility Director;
- Events with clinical outcome severity levels 03 through 06 – the facility Risk Manager shall report the event to Virginia Office of Protection and Advocacy (VOPA) within 48 hours of discovery.
 - Events with clinical outcome severity levels 05 and 06 – the facility Risk Manager shall take steps necessary to assure the facility conducts the appropriate reviews. All deaths shall be reported to the appropriate medical examiner. Additionally, deaths related to the use of restraint and seclusion shall be reported to CMS, as required by regulations.
 - Events with clinical outcome severity levels 04 through 06 and any other event with an assigned a risk index of “H,” – the facility Risk Manager shall assess the need to initiate a Root Cause Analysis (RCA) and performance improvement plan. The RCA should be conducted by soliciting, and

Continued on next page

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Review by Risk Manager
(continued) including feedback from staff who have input into the treatment of individuals receiving services and/or operational system issues impacting or impacted by the event.

- Events not reported to VOPA that have a risk index of “H.” – the facility Risk Manager shall notify the Office of Clinical Quality and Risk Management and other designated positions within the Central Office.

Additional reviews The Risk Manager shall initiate or confirm that appropriate staff have taken steps to implement additional reviews/reporting for all events, when necessary, including but not limited to:

- Medical consultation or peer review;
- Medication review;
- Safety committee review; and
- Reporting pursuant to Joint Commission Sentinel Event Policy; OSHA and/or Safe Medical Devices Act Guidelines, and other applicable laws and regulations.

Refer to Attachment 2, “Algorithm for Review and Follow-up of Death and Injuries in DBHDS Facilities,” which describes the process that is explained in this section.

401 - 9 **Procedures – VOPA Reporting**

Requirement Pursuant to §§ 51.5-37.1, 37.1-42.1(7) and 37.1-42.2 of the *Code of Virginia*, certain events involving individual receiving services shall be reported to VOPA within 48 hours of occurrence or, if the time of occurrence is unknown, within 48 hours of discovery of the event.

Additionally, any known deaths within 21 days of discharge shall be reported to VOPA within 48 hours of their discovery.

Reporting to VOPA

- The Risk Manager, through the Facility Director, shall report an incident to VOPA when:
 - There has been an injury to an individual receiving services with an outcome severity level of 03 and 04 associated with or reasonably believed to be associated with the incident **AND** an assessment has been made by a physician or physician extender; **AND** a physician or physician

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- Reporting to VOPA**
(continued)
- extender took action or gave an order in response to the injury that was more than first aid treatment and intended to affect a cure or provide therapy for the injury.
- o There has been an allegation of sexual abuse or sexual assault/rape;
 - o All events involving a loss of consciousness; and
 - o All deaths (05 and 06)
- When there is no action or order by a physician or physician extender following an initial assessment of the individual who received an injury with an outcome severity level of 03 or 04, but at a later time an action is taken or an order given in response to the same incident or occurrence, the Risk Manager, through the Facility Director, shall report the injury to VOPA within 48 hours of the action or order.

This report should provide a chronology of good faith efforts the facility has taken to address the complaint or observation of the injury prior to the discovery date indicated on the report.

Reporting via PAIRS The Risk Manager, on behalf of the Facility Director, shall report incidents meeting the above criteria via the PAIRS on-line system within 48 hours of the incident or discovery of the incident and shall provide a 15 day follow-up report.

Should access to the PAIRS system be unavailable, a report must be faxed to VOPA and emails sent to the others on the email distribution list. Reports faxed to VOPA must be entered into the PAIRS system as soon as possible after the system becomes available (see Attachment 3).

Notification of incidents reported to VOPA When medical treatment for an injury rises to a level beyond first aid, the authorized representative, if applicable, shall be notified of any incident reported to VOPA as soon as practical following the incident.

401 - 10 Procedures – Receipt and Handling of Legal Documents

- Legal documents**
- The following documents require immediate attention. Whenever any Department employee receives one of the following documents that involves the Department, Commonwealth or an employee acting in an official capacity or in the scope of his or her employment, the employee shall immediately

Continued on next page

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Legal documents
(continued)

notify the facility Risk Manager or Central Office Director of Clinical Quality and Risk Management in person or by telephone:

- Letters of attorney representation and letters from attorneys;
 - Subpoenas for documents or witnesses (summons and interrogatories);
 - Notices of Claim or Suit;
 - Motions for Judgment, complaints, Bills of Complaint; and
 - Other case-related or court documents.
- Upon receipt of any of the above documents, the facility Risk Manager shall notify the Facility Director or designee.
 - Upon receipt of a Notice of Claim or Suit the facility Risk Manager shall notify the following by telephone or email:
 - Appropriate State Division of Risk Management personnel;
 - Office of the Attorney General; and
 - Central Office Director of Clinical Quality and Risk Management.
 - When notified by the facility Risk Manager of receipt of a Notice of Claim or Suit, the Central Office Director of Clinical Quality and Risk Management shall notify the Commissioners, the Medical Director and the appropriate Assistant Commissioners.
 - All procedures for handling legal documents shall adhere to Departmental Instruction 405(RM)95 *Requests for Legal Assistance*.
 - Legal documents shall be maintained as prescribed in Departmental Instruction 403(RM)86 *Coordination of Investigations and Security of Patient/Resident Records Associated with Potential or Actual Litigation or Professional Liability Claims*.

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References

Code of Virginia §§ 8.01-581.16 and 8.01-581.17

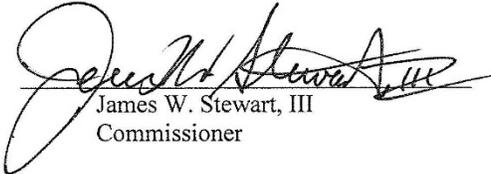
- Code of Virginia, Chapter 21, Virginia Freedom of Information Act, § 2.2-3704, et seq
- Code of Virginia, Virginia Tort Claims Act, § 8.01-195.1
- Commonwealth of Virginia *Risk Management Plan*

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References
(continued)

- Departmental Instruction 403(RM)86 *Coordination of Investigations and Security of Patient/Resident Records Associated with Potential or Actual Litigation or Professional Liability Claims*
- Departmental Instruction 405(RM)95 *Requests for Legal Assistance*
- Departmental Instruction 201(RTS)03 *Reporting and Investigating Abuse and Neglect of Clients*
- Virginia Worker's Compensation Act


James W. Stewart, III
Commissioner

Effective Date: February 15, 2013

Attachments

Attachment 1

FACILITY EVENT REPORT*

Client Register #:	Client Name	Age	Living Area/Ward:
Situation: <input type="checkbox"/> 1:1 <input type="checkbox"/> Dir. Obs. <input type="checkbox"/> Protective Device <input type="checkbox"/> Restraint <input type="checkbox"/> Seclusion <input type="checkbox"/> Time Out <input type="checkbox"/> Q15 <input type="checkbox"/> Q30 <input type="checkbox"/> Q60			
<input type="checkbox"/> Visitor	<input type="checkbox"/> Volunteer/Other	Event Date	Event Time <input type="checkbox"/> AM <input type="checkbox"/> PM
Check One Event Type (Shaded Area) and One Sub-Category Listed Below Event			
<input type="checkbox"/> Accidental	<input type="checkbox"/> Medical	<input type="checkbox"/> Missing	<input type="checkbox"/> SIB
<input type="checkbox"/> By Another Client <input type="checkbox"/> By Other <input type="checkbox"/> By Staff <input type="checkbox"/> Swallowing Inedible <input type="checkbox"/> Other	<input type="checkbox"/> Aspiration <input type="checkbox"/> Choking <input type="checkbox"/> Cluster Seizure <input type="checkbox"/> Deterioration In Condition <input type="checkbox"/> Seizure Related Injury <input type="checkbox"/> Status Epilepticus <input type="checkbox"/> Swallowing Problem	<input type="checkbox"/> Attempted Escape <input type="checkbox"/> Escape <input type="checkbox"/> Off Campus <input type="checkbox"/> On Campus	<input type="checkbox"/> Intentional <input type="checkbox"/> Unintentional <input type="checkbox"/> Suicide <input type="checkbox"/> Suicide Attempt <input type="checkbox"/> Suicide Gesture <input type="checkbox"/> Pica
<input type="checkbox"/> Aggressive Act	<input type="checkbox"/> Medications	<input type="checkbox"/> Other	<input type="checkbox"/> Treatment/Habilitative
<input type="checkbox"/> Against Client <input type="checkbox"/> Against Staff <input type="checkbox"/> Against Object <input type="checkbox"/> By Another Client Reg.# _____ <input type="checkbox"/> Sexual Assault <input type="checkbox"/> Retaliative/Act/Self Defense	<input type="checkbox"/> Wrong Route <input type="checkbox"/> Wrong Medication <input type="checkbox"/> Time Variance <input type="checkbox"/> Wrong Dosage <input type="checkbox"/> Wrong Client <input type="checkbox"/> Omitted <input type="checkbox"/> Refused <input type="checkbox"/> Transcription Error <input type="checkbox"/> Adverse Drug Reaction <input type="checkbox"/> Dispensing Error <input type="checkbox"/> Missing Medication <input type="checkbox"/> Improper Storage <input type="checkbox"/> Improper Order <input type="checkbox"/> Given, Not Charted <input type="checkbox"/> Medication Error - Other	<input type="checkbox"/> Client/Family Complaint <input type="checkbox"/> Contraband <input type="checkbox"/> Environmental Problem <input type="checkbox"/> Exposure to Elements <input type="checkbox"/> Fire <input type="checkbox"/> Insect Bite <input type="checkbox"/> Sexual Encounter <input type="checkbox"/> Substantiated Abuse <input type="checkbox"/> Other	<input type="checkbox"/> Delayed <input type="checkbox"/> Consent Problem <input type="checkbox"/> Deviation Policy & Procedure <input type="checkbox"/> Dietary Problem <input type="checkbox"/> Injection Site <input type="checkbox"/> Meal Refusal <input type="checkbox"/> Monitoring <input type="checkbox"/> Omitted <input type="checkbox"/> Positioning <input type="checkbox"/> Refusal <input type="checkbox"/> Test Results <input type="checkbox"/> Other
<input type="checkbox"/> Fall		<input type="checkbox"/> Property/Equipment	<input type="checkbox"/> UNEXPLAINED
<input type="checkbox"/> Balance/Coordination <input type="checkbox"/> Client Reported Fall <input type="checkbox"/> Footwear <input type="checkbox"/> Found on Floor <input type="checkbox"/> Obstacle <input type="checkbox"/> Reclining/Sitting <input type="checkbox"/> Running <input type="checkbox"/> Seizure Related <input type="checkbox"/> Slippery Surface <input type="checkbox"/> Transfer		<input type="checkbox"/> Damaged <input type="checkbox"/> Failure/Malfunction <input type="checkbox"/> Missing <input type="checkbox"/> Tampered With <input type="checkbox"/> User Error	
Location: Check One			
<input type="checkbox"/> Bathroom	<input type="checkbox"/> Bedroom	<input type="checkbox"/> Dining Room	<input type="checkbox"/> Hall
<input type="checkbox"/> Grounds	<input type="checkbox"/> Program Area/OWT	<input type="checkbox"/> Sidewalk	<input type="checkbox"/> Vehicle
			<input type="checkbox"/> Living Room <input type="checkbox"/> Off Grounds
			<input type="checkbox"/> Unknown <input type="checkbox"/> Other
<input type="checkbox"/> Abrasion/Scratch	<input type="checkbox"/> Allergic/Adverse Reaction	<input type="checkbox"/> Aspiration	<input type="checkbox"/> Bite
<input type="checkbox"/> C/O Pain	<input type="checkbox"/> Cardiac/Resp. Arrest	<input type="checkbox"/> Death *	<input type="checkbox"/> Dislocation
<input type="checkbox"/> Laceration	<input type="checkbox"/> None Apparent	<input type="checkbox"/> Other	<input type="checkbox"/> Reddened Area/Swelling
			<input type="checkbox"/> Contusion/Hematoma/Bruise <input type="checkbox"/> Fracture <input type="checkbox"/> Wound Disruption
* Check One: <input type="checkbox"/> medical sequela/ geriatric <input type="checkbox"/> medical sequela/non-geriatric <input type="checkbox"/> unforeseen/cause determined <input type="checkbox"/> unforeseen/cause undetermined			
<input type="checkbox"/> suicide <input type="checkbox"/> homicide Describe Event:			
Treatment/Interventions:			
Notified: <input type="checkbox"/> MD <input type="checkbox"/> RN <input type="checkbox"/> Supervisor		Client Seen by: <input type="checkbox"/> MD <input type="checkbox"/> RN Date/Time Seen:	
Family Notified: <input type="checkbox"/> Yes <input type="checkbox"/> No		Notified by: Date/Time:	
<input type="checkbox"/> Med Attn Needed	<input type="checkbox"/> Infirmity Admission	<input type="checkbox"/> Emergency Center	
<input type="checkbox"/> Trans Via Rescue Squad	<input type="checkbox"/> Hospitalization Required		
Signature of Person Completing Form:		Date:	
Signature of Nurse/Supervisor:		Date:	
Signature of Risk Manager or Designee:		Date:	
<input type="checkbox"/> Litigation Anticipated	Reason:		

* Facilities have the option to alter or amend Form #158 provided all information on form #158 is included in the altered or amended form

Attachment 2

**ALGORITHM FOR REVIEW AND FOLLOW UP
 OF DEATHS AND INJURIES IN DBHDS FACILITIES**



Attachment 3

VOPA 48 Hour Faxed Report

This report is to be used only when the PAIRS system or the internet are unavailable. Email the report to VOPA and others on the distribution list when the PAIRS system is down. If the PARS system is down and the internet is unavailable, fax the report to VOPA and others on the distribution list. Reports faxed or emailed to VOPA must be entered into the PAIRS system as soon as possible after the system becomes available.

Type of Incident/Event

Narrative

Plan for Follow-up Review

Summary Information:

- Full Name of Individual receiving services
- Date and time of incident/event
- Date and time of discovery
- Place (facility, building and unit) where death or incident occurred

Appendix II: The Joint Commission Sentinel Event Policy

Sentinel Events (SE)

I. Sentinel Events

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help behavioral health care organizations that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of patient safety events,* as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent harm to individuals served. The Sentinel Event Policy explains how The Joint Commission partners with organizations that have experienced a serious patient safety event to protect the individual served, improve systems, and prevent further harm.

Definition of Sentinel Event

A sentinel event is a patient safety event (not primarily related to the natural course of an illness or underlying condition of an individual served) that reaches an individual served and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm[†]

An event is also considered sentinel if it is one of the following:

- Suicide of any individual served receiving care, treatment, or services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the organization's emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family

* In the term *patient safety event*, the word "patient" corresponds to "individuals served" in the Behavioral Health Care setting.

[†] *Severe temporary harm* is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. Adapted from: Throop C, Stockmeier C. *The HPI SEC & SSER Patient Safety Measurement System for Healthcare*. 2011 May. Accessed Aug 12, 2014. <http://hpiresults.com/publications/HPI%20White%20Paper%20-%20SEC%20SSER%20Measurement%20System%20REV%202%20MAY%202010.pdf>.

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- Abduction of any individual served receiving care, treatment, or services
- Any elopement (that is, unauthorized departure) of an individual served from a staffed around-the-clock care setting (including the ED) leading to the death, permanent harm or severe temporary harm of the individual served
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any individual served receiving care, treatment, or services while on site at the organization[‡]
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure[§]
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery^{||}
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)

[‡]Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving an individual served and another individual served, staff member, or other perpetrator while being treated or on the premises of the organization, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:

- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the organization to support allegations of unconsented sexual contact

[§]Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

^{||}"After surgery" is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

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Sentinel Events ▾

- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of care[#]
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity (not primarily related to the condition of an individual served) when it reaches an individual served and results in permanent harm or severe temporary harm ^{**}

The above list is consistent across all Joint Commission accreditation programs, though some of these events may be unlikely to occur in certain settings. In cases in which the organization is uncertain that a patient safety event is a sentinel event as defined by The Joint Commission, the event will be presumed to be a patient safety event and not a sentinel event unless determined otherwise through further investigation or the presentation of relevant information. Patient safety events require analysis and should be shared with the Office of Quality and Patient Safety through an organization response.

All sentinel events must be reviewed by the organization and are subject to review by The Joint Commission. Accredited organizations are expected to identify and respond appropriately to all sentinel events (as defined by The Joint Commission) occurring in the organization or associated with services that the organization provides. An appropriate response includes all of the following:

[#]Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association. *NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data*. Quincy, MA: NFPA, 2011.

^{**}Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of 4 or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk—and timely implementation of clinical interventions consistent with evidence-based guidelines—are important steps in the ongoing provision of safe and reliable care. Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings. For additional details, see “Update: Revised Definition of Severe Maternal Morbidity in Sentinel Event Policy,” June 2015 *Perspectives*.

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- A formalized team response that stabilizes the individual served, discloses the event to the individual served and family, and provides support for the family as well as staff involved in the event
- Notification of organization leadership
- Immediate investigation
- Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
- Strong corrective actions derived from the identified causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvement over time
- Time line for implementation of corrective actions
- Systemic improvement

Sentinel events are one category of patient safety events. A *patient safety event* is an event, incident, or condition that could have resulted or did result in harm to an individual served. A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error. Patient safety events also include adverse events, no-harm events, close calls, and hazardous conditions, which are defined as follows:

- An *adverse event* is a patient safety event that resulted in harm to an individual served.
- A *no-harm event* is a patient safety event that reaches the individual served but does not cause harm.
- A *close call* (or “good catch”) is a patient safety event that did not reach the individual served.
- A *hazardous* (or “unsafe”) *condition(s)* is a circumstance (other than an individual’s own disease, process, or condition) that increases the probability of an adverse event.

The organization determines how it will respond to patient safety events that do not meet the Joint Commission’s definition of sentinel event. Adverse events shall prompt notification of organization leaders, investigation, and corrective actions, in accordance with the organization’s process for responding to patient safety events that do not meet the definition of sentinel event. An adverse event may or may not result from an error.

No-harm events, close calls, and hazardous conditions are tracked and used as opportunities to prevent harm, in accordance with the organization’s process for responding to patient safety events that do not meet the definition of sentinel event. (*See*

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also Leadership [LD] Standard **LD.04.04.05**, element of performance [EP] 3, which states: The scope of the safety program includes the full range of safety issues, from potential or no-harm errors [sometimes referred to as near misses, close calls, or good catches] to hazardous conditions and sentinel events.)

II. Goals of the Sentinel Event Policy

The policy has the following four goals:

1. To have a positive impact in improving care, treatment, or services and in preventing unintended harm
2. To focus the attention of an organization that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or organization culture), and on changing the organization's culture, systems, and processes to reduce the probability of such an event in the future
3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention
4. To maintain the confidence of the public, clinicians, and organizations that the safety of individuals served is a priority in accredited organizations

III. Responding to Sentinel Events

Standards

Each Joint Commission accreditation manual contains standards that relate specifically to the management of sentinel events. (See the Appendix to this chapter for related standards.)

LD.04.04.05, EP 7, requires each accredited organization to define *patient safety event* for its own purposes and to communicate this definition throughout the organization. This definition must encompass sentinel events as defined by The Joint Commission. An accredited organization is encouraged to include in its definition events, incidents, and conditions in which no or only minor harm occurred to an individual served. The organization determines how it will respond to patient safety events that do not meet the definition of sentinel event.

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In addition, Rights and Responsibilities of the Individual (RI) Standard **RI.01.02.01**, EP 21, requires accredited organizations to inform the individual served or surrogate decision-maker about unanticipated outcomes of the care, treatment, or services that relate to sentinel events as defined by The Joint Commission.

Comprehensive Systematic Analysis

As indicated above, appropriate response to a sentinel event includes the completion of a comprehensive systematic analysis for identifying the causal and contributory factors. Root cause analysis, which focuses on systems and processes, is the most common form of comprehensive systematic analysis used for identifying the factors that underlie a sentinel event.

An organization may use other tools and methodologies to conduct its comprehensive systematic analysis. The Joint Commission encourages the organization to contact the patient safety specialist assigned to the organization's event or to call the Office of Quality and Patient Safety at 630-792-3700 if it has questions regarding using the tools discussed above or other tools it is considering. (See the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for further discussion of acceptability.)

Corrective Action Plan

The product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the organization intends to implement in order to reduce the risk of similar events occurring in the future. The identified actions should eliminate or control system hazards or vulnerabilities that have been identified by the comprehensive systematic analysis. Analysis teams should identify at least one stronger or intermediate strength action when possible (see Figure 3 on page 17 of the National Patient Safety Foundation [NPSF] *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm* report at http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/PDF/RCA2_v2-online-pub_010816.pdf for more information on strength of action). The plan must address the following:

- Identification of corrective actions to eliminate or control system hazards or vulnerabilities directly related to causal and contributory factors
- Responsibility for implementation
- Time lines for completion

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- Strategies for evaluating the effectiveness of the actions
- Strategies for sustaining the change

Reporting a Sentinel Event to The Joint Commission

Each organization is strongly encouraged, but not required, to report to The Joint Commission any patient safety event that meets the Joint Commission definition of sentinel event. An organization benefits from self-reporting in the following ways:

- The Joint Commission can provide support and expertise to the organization during the review of a sentinel event.
- A review with the Office of Quality and Patient Safety provides the opportunity for the organization to collaborate with a patient safety specialist who is likely to have reviewed similar events.
- Reporting raises the level of transparency in the organization and helps promote a culture of safety.
- Reporting conveys the organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future.

Further, reporting the event enables the addition of the "lessons learned" from the event to be added to The Joint Commission's Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events in many other organizations.

The value of this review is reflected by the fact that more than 75% of sentinel events reported to The Joint Commission are self-reported by the organizations that experienced the events. Alternatively, The Joint Commission may become aware of a sentinel event by some other means such as communication from an individual served, a family member, an employee of the organization, a surveyor, or through the media.

Self-reporting a sentinel event is not required and there is no difference in the expected response, time frames, or review procedures, whether the organization voluntarily reports the event or The Joint Commission becomes aware of the event by some other means. If an organization wishes to report to The Joint Commission an occurrence of a sentinel event, the organization will be asked to complete a form accessible through its

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Joint Commission Connect[™] extranet site. From this site, place the cursor over “Continuous Compliance Tools.” A dropdown list will appear. From this list, select “Self Report Sentinel Event.”

If The Joint Commission becomes aware of a sentinel event that was not reported by the organization to The Joint Commission, the organization’s CEO (or designee) is contacted, and a preliminary assessment of the sentinel event is made. An event that occurred more than one year before the date The Joint Commission became aware of the event will not, in most cases, be reviewed under the Sentinel Event Policy. In such a case, a written response will be requested from the organization, including a summary of the processes that were designed to prevent similar occurrences.

Required Response to a Sentinel Event

All sentinel events must be reviewed by the organization, whether or not they are reported to The Joint Commission. In addition, if The Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the criteria of this policy and the event has occurred in an accredited organization, the organization is expected to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and corrective action plan within 45 business days of the event or of becoming aware of the event.
- Submit to The Joint Commission its comprehensive systematic analysis and corrective action plan, or otherwise provide for Joint Commission evaluation its response to the sentinel event using an approved methodology within 45 business days of the known occurrence of the event. The Joint Commission will determine whether the comprehensive systematic analysis and corrective action plan are acceptable.

The fact that an organization has experienced a sentinel event will not impact its accreditation decision. However, willful failure to respond appropriately to the sentinel event could have such an impact. For instance, if the organization fails to submit a comprehensive systematic analysis within an additional 45 days following its due date, its accreditation decision may be impacted. In these instances, patient safety specialists in the Office of Quality and Patient Safety, along with the medical director and patient safety officer, would recommend the chief medical officer and the executive leadership of The Joint Commission change the organization’s accreditation status.

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Submission of Comprehensive Systematic Analyses and Corrective Action Plans

An organization that reports a sentinel event must submit the comprehensive systematic analysis, including the resulting corrective action plan that describes the organization's risk reduction strategies as well as how the effectiveness of those strategies will be evaluated. This information is submitted electronically and will be reviewed in a conference call involving Joint Commission staff and organization staff (Alternative-0). Documents shall not include the names of caregivers and individuals served involved in the sentinel event.

If the organization has concerns about waiving confidentiality protections as a result of sending the comprehensive systematic analysis documents to The Joint Commission, the following four optional alternative approaches to a review of the organization's response to the sentinel event are acceptable:

1. A review of the comprehensive systematic analysis and corrective action plan documents brought to Joint Commission headquarters by organization staff, then taken back to the organization on the same day (Alternative-1). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative). When the web-based video conference is used, the organization's participants remain at the organization.
2. An on-site meeting at the organization with a Joint Commission patient safety specialist to review the comprehensive systematic analysis and corrective action plan (Alternative-2). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).
3. An on-site review with a Joint Commission patient safety specialist to review the corrective action plan and relevant documentation (Alternative-3). The patient safety specialist may ask questions regarding the comprehensive systematic analysis, but will not review that document itself. For purposes of this review activity, *relevant documentation* includes, at a minimum, any documentation relevant to the organization's process for responding to sentinel events and the corrective action plan resulting from the analysis of the sentinel event. The corrective action plan serves as the basis for determining appropriate follow-up activity. This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).
4. An on-site visit by a specially trained surveyor arranged to conduct the following (Alternative-4):

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- a. Interview and review of relevant documentation, including, if applicable, the medical record of the individual served, to evaluate the following:
 - The process the organization uses in responding to sentinel events
 - The relevant policies and procedures preceding and following the organization's review of the specific event, and the implementation thereof, sufficient to permit inferences about the adequacy of the organization's response to the sentinel event
- b. A standards-based survey that traces care, treatment, or services received by an individual served and the organization management functions relevant to the sentinel event under review

Each of these options will result in a fee to the organization to cover the average direct costs of the option. Inquiries about the fee should be directed to the Joint Commission's Pricing Unit at 630-792-5115.

The Joint Commission must receive a request for review of an organization's response to a sentinel event using any of these options within five business days of the self-report of a sentinel event or of the initial communication by The Joint Commission to the organization that it has become aware of a sentinel event.

Review of Comprehensive Systematic Analyses and Corrective Action Plans

A comprehensive systematic analysis will be reviewed for thoroughness, credibility, and acceptability. A behavioral health care organization's comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. The analysis should not focus on individual health care worker performance, but should seek out underlying systems-level causations that were manifest in personnel-related performance issues. ^{††} To help adhere to these characteristics it is recommended but not required that the following guidelines be considered when developing causative factor statements: ^{‡‡}

- Clearly show the cause-and-effect relationship.

^{††}National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston: National Patient Safety Foundation, 2015.

^{‡‡}Department of Veterans Affairs. *Veterans Health Administration Patient Safety Handbook 1050.01*. Mar 4, 2011. Accessed Feb 11, 2015. http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389.

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- Use specific and accurate descriptors for what occurred, rather than negative and vague words.
- Human errors must have a preceding cause.
- Violations of procedure are not root causes, but must have a preceding cause.
- Failure to act is only causal when there is a preexisting duty to act.

To be **thorough**, the comprehensive systematic analysis must include the following:

- The analysis repeatedly asks a series of “Why” questions, until it identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event
- The analysis focuses on systems and processes, not solely on individual performance
- A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence
- The analysis of the underlying systems and processes through the series of “Why” questions determines where redesign might reduce risk
- An inquiry into all areas appropriate to the specific type of event
- An identification of risk points and their potential contributions to this type of event
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

To be **credible**, the comprehensive systematic analysis must do the following:

- Include participation by a process owner, who is not a member of the response team; typically this is a senior leader of the organization or a designee^{§§}
- Each action recommended by a review team should be approved or disapproved, preferably by the CEO or alternatively by another relevant member of top management. If an action is disapproved the reason for its disapproval should be shared with the comprehensive systematic analysis and action team so that the constraint can be understood and another developed by the team to replace it if the system vulnerability is not otherwise effectively addressed in the **corrective** action plan.^{|||}

^{§§}A senior leader is not necessarily required to be actively involved in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and he or she should be involved in deciding or approving the actions the organization will take as a result of the comprehensive systematic analysis.

^{|||}National Patient Safety Foundation. *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston: National Patient Safety Foundation, 2015.

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- Include individuals served, family, or representatives of individuals served when appropriate to ensure a thorough understanding of the facts
- Include individuals most closely involved in the processes and systems under review
- Be internally consistent (that is, not contradict itself or leave obvious questions unanswered)
- Provide an explanation for all findings of “not applicable” or “no problem”
- Include a bibliography of any relevant literature

A corrective action plan will be considered **acceptable** if it does the following:

- Identifies and implements actions to eliminate or control systems hazards or vulnerabilities
- It is recommended but not required that review teams should attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur.
- It is recommended that the review team use a tool that will assist in identifying stronger actions that provide effective and sustained system improvement. A tool such as the Action Hierarchy can help organizations evaluate the strength of the corrective actions identified in their comprehensive systematic analysis. The US Department of Veterans Affairs National Center for Patient Safety developed this tool in 2001.**
- Identifies, in situations in which improvement actions are planned, who is responsible for implementation, when the action will be implemented, how the effectiveness of the actions will be evaluated, and how the actions will be sustained
- Identifies at least one stronger or intermediate strength action for each comprehensive systematic analysis

All comprehensive systematic analyses and corrective action plans will be considered and treated as confidential by The Joint Commission.

Follow-up Activities

After The Joint Commission has determined that an organization has conducted an acceptable comprehensive systematic analysis (for example, root cause analysis) and developed an acceptable corrective action plan, The Joint Commission will notify the organization that the comprehensive systematic analysis and corrective action plan are

** An example of the Action Hierarchy tool is available at http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf, page 28.

acceptable and will assign an appropriate follow-up activity. This will be a mutually agreed-upon documentation of sustained improvement and reduction of risk, which may include one or more Sentinel Event Measure(s) of Success (SE MOS).

IV. The Sentinel Event Database

The third goal of the Sentinel Event Policy is to increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention. To achieve this, The Joint Commission collects and analyzes data from the review of sentinel events, and their comprehensive systematic analyses, corrective action plans, and follow-up activities. These data and information form the content of the Joint Commission's Sentinel Event Database.

The Sentinel Event Database is also a major component of the evidence base for developing and maintaining the Joint Commission's National Patient Safety Goals. The database also informs the development prevention advice to organizations through *Sentinel Event Alert* or other media. For these purposes, The Joint Commission uses de-identified aggregate data relating to root causes, contributing factors, and risk-reduction strategies. The Joint Commission is committed to developing and maintaining this Sentinel Event Database in a fashion that will protect the confidentiality of the organization, the caregiver, and the individual served.

V. Determination That a Sentinel Event Is Subject to Review

Based on available information received about the event, a patient safety specialist from the Office of Quality and Patient Safety (OQPS) will determine whether an event meets the definition in Section I, and is therefore a sentinel event. Challenges to a determination that an event is a sentinel event will be resolved through discussions between senior Joint Commission staff and senior organization leaders.

VI. Optional On-Site Review of a Sentinel Event

An initial on-site review of a sentinel event will usually not be conducted unless it is determined that a potential ongoing Immediate Threat to Health or Safety exists. An *Immediate Threat to Health or Safety* is a threat that represents the most immediate risk and has or may potentially have serious adverse effects on the health or safety of

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individuals served. All potential Immediate Threats to Health or Safety are referred to Joint Commission executive leadership for authorization to conduct an unannounced on-site for-cause survey. If an on-site survey is conducted, the organization will be billed a sufficient charge, based on an established fee schedule, to cover the costs of conducting such a survey.

VII. Disclosable Information

If The Joint Commission receives an inquiry about the accreditation decision of an organization that has experienced a sentinel event, the organization's current accreditation status will be reported in the usual manner without making reference to the sentinel event. If the inquirer specifically references the particular sentinel event, The Joint Commission will acknowledge that it is aware of the event and currently is working or has worked with the organization through the sentinel event review process.

VIII. The Joint Commission's Response

Patient safety specialists from The Joint Commission assess the acceptability of the organization's response to the sentinel event, including the thoroughness and credibility of any comprehensive systematic analysis information reviewed and the organization's corrective action plan. (Root cause analysis is the most commonly used method of comprehensive systematic analysis.) If the comprehensive systematic analysis and corrective action plan are found to be thorough and credible, patient safety specialists from The Joint Commission will notify the organization and assign one or more or other mutually agreed-upon documentation of sustained improvement and reduction of risk, such as SE MOS. (*See* the "Sentinel Event Measures of Success [SE MOS]" section below for more details.)

A patient safety specialist from The Joint Commission will provide consultation to the organization if the response is unacceptable, and will allow an additional 15 business days beyond the original submission period for the organization to resubmit its response. If the response is still unacceptable, the organization's accreditation decision may be impacted.

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IX. Sentinel Event Measures of Success (SE MOS)

The organization's follow-up activity may be conducted through the SE MOS process. An SE MOS is a numerical or quantifiable measure, ideally with a numerator and denominator, that indicates whether a planned action was effective and sustained. The SE MOS is due on a mutually agreed-upon date.

If an SE MOS is used, the following information would apply:

- If an SE MOS is submitted on time but does not meet pre-established levels of compliance, the patient safety specialist from The Joint Commission will request an additional four months of data. If the second set of data does not meet pre-established levels of compliance, the organization's accreditation decision may be impacted.
- If submission of an SE MOS is 90 or more days late, the organization's accreditation status may be impacted.

X. Handling Sentinel Event–Related Documents

Handling of any submitted comprehensive systematic analysis and corrective action plan is restricted to specially trained staff in accordance with procedures designed to protect the confidentiality of the documents.

At the time the review of the de-identified comprehensive systematic analysis is entered into the Sentinel Events Database, the original documents will be destroyed, as well as any copies. However, upon request the original documents may be returned to the organization. The information contained in any electronically submitted comprehensive systematic analysis tool will be de-identified after the review is completed.

The corrective action plan resulting from the analysis of the sentinel event will initially be retained long enough to serve as the basis for appropriate follow-up activities, such as the SE MOS or other mutually agreed-upon documentation of sustained improvement. After the corrective action plan has been implemented and meets the established levels of compliance, The Joint Commission will destroy and delete the corrective action plan. If the SE MOS was submitted electronically, the information will likewise be de-identified upon completion of the review.

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XI. Oversight of the Sentinel Event Policy

The executive leadership of The Joint Commission is responsible for approval of this policy and overseeing its implementation. In addition to reviewing and deciding individual cases involving changes in an organization's accreditation decision, Joint Commission staff will periodically audit the comprehensive systematic analysis and documentation of follow-up activities. For the purposes of these audits, The Joint Commission temporarily retains random de-identified samples of these documents. Upon completion of the audit, these documents are also destroyed.

For more information about the Joint Commission's Sentinel Event Policy, visit the Joint Commission's website at <http://www.jointcommission.org> or call the Office of Quality and Patient Safety at 630-792-3700.

XII. Survey Process

When conducting an accreditation survey, The Joint Commission seeks to evaluate the organization's compliance with the applicable standards, National Patient Safety Goals, and Accreditation Participation Requirements, and to assess the organization's performance based on those requirements. Surveyors are instructed not to search for or investigate sentinel events during an accreditation survey or to inquire about sentinel events that have been reported to The Joint Commission. However, surveyors may assess an organization's performance improvement practices, such as its processes for responding to a sentinel event.

If, during the course of conducting any survey activities, a potential serious patient safety event is newly identified, the surveyor will take the following steps:

- Inform the organization CEO that the event has been identified
- Inform the CEO the event will be reported to The Joint Commission for further review and follow-up under the provisions of the Sentinel Event Policy

Surveyors are not authorized to review the comprehensive systematic analysis documents and determine credibility, thoroughness, or acceptability. Surveyors can only apply the related standards and elements of performance to assess performance improvement practices, such as processes for responding to safety events, adverse events, hazardous unsafe conditions, close calls, and sentinel events.

The surveyor makes no determination of whether or not the event is a sentinel event and does not focus on or explore the event further, but rather will hand off further discussion to a patient safety specialist in the Office of Quality and Patient Safety. Surveyors are

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not authorized to investigate sentinel events. The patient safety specialist will contact the organization after all survey activity is entirely completed to explore the event and determine whether or not submission of a comprehensive systematic analysis is required. If so, the organization will proceed with the steps described after an event is determined to be a sentinel event. (See the “Required Response to a Sentinel Event” section in this chapter.)

During the on-site survey, the surveyor(s) will assess the organization’s compliance with sentinel event–related standards in the following ways (see Standards LD.04.04.05 and RI.01.02.01 in the Appendix):

- Review the organization’s process for responding to a sentinel event
- Interview the organization’s leaders and staff about their expectations and responsibilities for identifying, reporting on, and responding to sentinel events

Appendix. Accreditation Requirements Related to Sentinel Events

The following standards and associated elements of performance (EPs) are related to sentinel events:

Leadership (LD)

Standard LD.04.04.05

The organization has an organizationwide, integrated safety program for individuals served.

Elements of Performance for LD.04.04.05

1. The leaders implement an organizationwide safety program for individuals served.
2. One or more qualified persons manage the safety program.
3. The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as close calls [“near misses”] or good catches) to hazardous conditions and sentinel events.

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4. All programs and services within the organization participate in the safety program.
5. As part of the safety program, the leaders create procedures for responding to system or process failures.

Note 1: *Responses might include continuing to provide care, treatment, or services to those affected, containing the risk to others, and preserving factual information for subsequent analysis.*

Note 2: For opioid treatment programs: *Examples of reportable patient deaths include the following:*

- *Drug-related deaths*
- *Methadone or buprenorphine deaths*
- *Unexpected or suspicious deaths*
- *Treatment-context deaths that raise individual, family, community, or public concern*

6. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.01.01, EP 8; LD.03.04.01, EP 5; LD.04.04.03, EP 3)

Note: *This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.*

7. The leaders define patient safety event and communicate this definition throughout the organization.

Note: *At a minimum, the organization's definition includes those events subject to review in the "Sentinel Events" (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of resulting in a serious adverse outcome or an adverse event, often referred to as a close call or near miss.*

8. The organization conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual.

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9. The leaders make support systems available for staff who have been involved in an adverse or sentinel event.

Note: Support systems recognize that conscientious health care workers who are involved in sentinel events are themselves victims of the event and require support. Support systems provide staff with additional help and support as well as additional resources through the human resources function or an employee assistance program. Support systems also focus on the process rather than blaming the involved persons.

11. To improve safety, the organization analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. (See also LD.04.04.03, EP 3)

12. The leaders disseminate lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation. (See also LD.03.04.01, EP 5)

13. ④ At least once a year, the leaders provide governance with written reports on the following:
- All system or process failures
 - The number and type of sentinel events
 - Whether the individuals served and the families were informed of the event
 - All actions taken to improve safety, both proactively and in response to actual occurrences

14. The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs.

Note: Examples of voluntary programs include The Joint Commission Sentinel Event Database and the US Food and Drug Administration (FDA) MedWatch. Mandatory programs are often state initiated.

Rights and Responsibilities of the Individual (RI)

Standard RI.01.02.01

The organization respects the right of the individual served to collaborate in decisions about his or her care, treatment, or services.

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Elements of Performance for RI.01.02.01

21. The organization informs the individual served or surrogate decision-maker about unanticipated events that relate to sentinel events as defined by The Joint Commission. (Refer to the Glossary for a definition of sentinel event.)

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Appendix III: Sample PAIRS Report

Fac	IncidentNum	State_Id	Discovery_TimeDate	Client_First_Name	Client_Last_Name	Date	Precipitating Event
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	01-Sep-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-Jul-15	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	30-Jul-15	Unexplained
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	03-Mar-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	04-Feb-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	31-May-16	Accident
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	02-Oct-15	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	17-Aug-15	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	15-Aug-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	14-Oct-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-Jul-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	14-Jul-15	Suicide Attempt
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-Nov-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	28-Nov-16	Accident
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	26-Oct-16	Unexplained
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	21-Jan-16	Unexplained
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	23-Mar-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	21-Mar-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	05-Aug-15	Aggressive Act - By Peer
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	04-Nov-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	04-Jan-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	12-Feb-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	15-Apr-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	29-Apr-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	02-May-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-May-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-Jun-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	25-Oct-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	22-Feb-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	30-Mar-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	27-Jun-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	26-Feb-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	21-Sep-15	Self-Injurious Behavior
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	29-Jul-16	Other - Specify
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	26-Sep-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	13-Oct-15	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	16-Oct-15	Aggressive Act - Against Object
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	12-Jul-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	15-Dec-15	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	09-Feb-16	Choking
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	17-Jul-15	Self-Injurious Behavior
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-May-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	30-Jun-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	09-Feb-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	20-Apr-16	Aggressive Act - By Peer
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	28-Mar-16	Sexual Allegation
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	22-Dec-15	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-May-16	Unexplained
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	20-Dec-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	19-Dec-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	13-Jun-16	Aggressive Act - By Peer
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	08-Aug-16	SIB - Intentional

XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	08-Aug-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-Feb-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-Nov-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	25-Apr-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	27-Apr-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	22-Aug-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	10-Nov-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-Mar-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	19-May-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	16-Jun-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	15-Jul-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	04-Oct-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	14-Oct-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	06-Jul-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	17-Jul-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	31-Jul-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	25-Sep-15	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	31-Mar-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	26-Jul-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	15-Aug-16	SIB - Intentional
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	28-Sep-15	Sexual Allegation
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	28-Sep-15	Sexual Allegation
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	17-Aug-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	18-May-16	Fall
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	05-Oct-16	Deteriorating Medical Condition
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	22-Aug-16	Aggressive Act - By Peer

Appendix IV: CSH Office Photo



Appendix VI: Dictionary of Medications and Medical Terminology

Medications

Acetaminophen – Pain reliever and fever reducer.

Adderall – Combination of amphetamine and dextroamphetamine, central nervous system stimulants that affect chemicals in the brain and nerves that contribute to hyperactivity and impulse control.

Albuterol – Bronchodilator that relaxes muscles in the airways and increases airflow to the lungs.

Aspirin – Salicylate that works by reducing substances in the body that cause pain, fever and inflammation; sometimes used to treat or prevent heart attacks, strokes and chest pain.

Bactrim – Contains a combination of sulfamethoxazole and trimethoprim, antibiotics that treat different types of bacterial infections.

Cipro – Antibiotic used to treat different types of bacterial infections.

Clonazepam – Benzodiazepine that affects chemicals in the brain that may be unbalanced, also known as an anti-epileptic drug used as a seizure medication.

Clonidine – Medication used to treat high blood pressure; also used to treat attention deficit hyperactivity disorder and anxiety.

Depakote – Medication used to treat various types of seizure disorders; also used to treat manic episodes related to bipolar disorder.

Duoneb – Inhalation that contains albuterol and ipratropium, bronchodilators that relax muscles in the airways and increase airflow to the lungs.

Ibuprofen – Nonsteroidal anti-inflammatory drug that reduces hormones that cause inflammation and pain in the body.

Fluphenazine – Antipsychotic medicine that works by changing the actions of chemicals in the brain; used to treat psychotic disorders such as schizophrenia.

Guanfacine – Used to treat high blood pressure; works by reducing nerve impulses in your heart and blood vessels to relax the vessels and lower blood pressure.

Levaquin – Antibiotic that fights bacteria in the body; used to treat infections of the skin, sinuses, kidneys, bladder or prostate.

Lorazepam – Benzodiazepine that affects chemicals in the brain that may be unbalanced in people with anxiety; used to treat anxiety disorders.

Lovenox – Anticoagulant that helps prevent the formation of blood clots; used to treat a type of blood clot called deep vein thrombosis.

Meropenem – Antibiotic used to treat severe infections of the skin or stomach as well as bacterial meningitis.

Prilosec – Proton pump inhibitor that decreases the amount of acid produced in the stomach; used to treat symptoms of gastroesophageal reflux disease and other conditions caused by excess stomach acid.

Propranolol – Beta-blocker that affects heart and circulation; used to treat tremors, chest pain, hypertension, heart-rhythm disorders and other heart or circulatory conditions.

Risperdal – Antipsychotic medicine that works by changing the effects of chemicals in the brain; used to treat schizophrenia in adults and children 13 and older. Also used to treat symptoms of bipolar disorder in adults and children 10 and older.

Seroquel – Antipsychotic medication that works by changing the actions of chemicals in the brain; used to treat schizophrenia in adults and children 13 and older. Also used to treat bipolar disorder in adults and children 10 and older.

Trazodone – Antidepressant that affects chemicals in the brain that may be unbalanced in people with depression; used to treat major depressive disorder.

Zoloft – Antidepressant; part of a group of medications called selective serotonin reuptake inhibitors. Affects chemicals in the brain that may be unbalanced in people with depression, panic, anxiety or obsessive-compulsive symptoms. Used to treat depression, obsessive-compulsive disorder, panic disorder, anxiety disorder, post-traumatic stress disorder and premenstrual dysphoric disorder.

Terminology

Activities of Daily Living (ADLs) – Term used in healthcare to refer to an individual's daily self-care activities.

Aortic Dissection – A tear in the inner muscle wall lining of the aorta in the heart, allowing blood to split apart the muscle layers of the aortic wall.

Atherosclerosis – A process of progressive thickening and hardening of the walls of medium- and large-sized arteries as a result of fat deposits on their inner lining.

Benzodiazepines – Class of medications that work on the central nervous system by actively selecting specific receptors in the brain. Used to treat anxiety, panic and sleep disorders as well as seizures.

Emesis – Vomit.

Cardiac Silhouette – Refers to the outline of the heart as seen on chest X-rays; the size and shape of the silhouette proves useful clues for underlying diseases.

Catatonia – State of psychogenic motor immobility and behavioral abnormality manifested by stupor.

Coffee Ground Emesis – Vomit that is or contains a substance that resembles coffee grounds. Occurs when blood has been exposed to gastric acid and becomes oxidized.

Deep Vein Thrombosis – A blood clot within a deep vein, typically in the thigh or leg. The clot can break off as an embolus and make its way to the lung, where it can cause lung problems.

Dysphagia – Difficulty swallowing due to abnormal nerve or muscle control.

Echocardiogram – A diagnostic test where sound waves of ultrasound are used to produce images of the heart at rest and at the peak of exercise.

Hypertension – High blood pressure, defined as repeatedly elevated systolic pressure above 140 or a diastolic pressure above 90.

Hypertensive Cardiovascular Disease – A number of complications of high blood pressure that affect the heart, including heart failure and other cardiac complications of hypertension.

Hypothyroidism – Deficiency of thyroid hormone, causing poor ability to tolerate cold, fatigue, constipation and depression.

Intra-articular fracture – A type of fracture where the break crosses into the surface of a joint, always resulting in some degree of cartilage damage.

Left Ventricular Hypertrophy – Enlargement and thickening of the walls of the heart’s main pumping chamber that causes the ventricle to work harder. As the workload increases, the muscle tissue thickens and the chamber increases in size. The enlarged muscle loses elasticity and eventually may fail to pump with as much force as needed.

Major Neurocognitive Disorder – Previously known as dementia, an acquired cognitive decline in one or more cognitive domains – complex attention, executive function, learning, memory, language, motor or social cognition.

Oxygen Saturation – The level of oxygen in the blood, 95-100 percent saturation on room air considered normal.

Rebreather – Breathing apparatus that includes a soft plastic reservoir bag that saves approximately one-third of exhaled air. Rebreathing carbon dioxide can act to stimulate breathing.

Schizophrenia – Chronic, severe, debilitating mental illness with no known cause. Factors leading to diagnosis include genetic, biologic and environmental factors. Symptoms may include delusions, hallucinations, catatonia and disorganized speech or behavior.

ST-T Change – Wave change readings on EKGs that may represent cardiac pathology or be normal variations.

Supplemental Oxygen – Oxygen provided by a storage tank or compressor when the lungs alone are unable to provide adequate oxygen.

Tamponade – A life-threatening situation where there is so much fluid (usually blood) inside the pericardial sac around the heart that it interferes with the performance of the heart.

Tibial Plateau Fracture – A break of the upper part of the tibia that involves the knee joint.

Venous Doppler – Uses soundwaves to produce images of the veins in the body, commonly used to search for blood clots, especially in the veins of the leg.