OFFICE OF THE STATE INSPECTOR GENERAL

Report to DBHDS Interim Commissioner Jack Barber, MD

FY 2015 Unannounced Inspections of the State-Operated Training Centers

September 2016

June W. Jennings, CPA
State Inspector General

Report No. 2015-BHDS-005

COMMONWEALTH OF VIRGINIA

Office of the State Inspector General

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September 16, 2016

Jack Barber, MD, 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) conducted unannounced inspections of the state-operated training centers pursuant to the *Code of Virginia (Code)* § 2.2-309.1[B](1) and respectfully submits this report as required by *Code* § 2.2-309.1[B](4). The primary purpose of unannounced inspections is to review the quality of services and make policy and operational recommendations to state facilities in order to prevent problems, abuses, and deficiencies and improve the effectiveness of programs and services.

The focus for these inspections was to utilize select elements of Section V: Quality and Risk Management of the U.S. Department of Justice (DOJ) Settlement Agreement as measures by which to evaluate quality and risk management systems at the DBHDS-operated training centers. Those measures are as follows:

1. C. Risk Management.
    a. Uniform risk triggers and thresholds (Section V.C.1)
    b. Web-based incident reporting system (Section V.C.2)
2. D. Data to Assess and Improve Quality
    a. Regional Quality Councils (Section V.D.5)
3. H. Training
    a. Competency-based training (Section V.H.1)
4. I. Quality Service Reviews
    a. Elements of Quality Service Reviews (Section V.I.1)

These elements were selected due to the importance of ensuring that individuals served in training centers are afforded the benefits of the same quality and risk management standards required by the Settlement Agreement for those served in the community.

Although the quality and risk management systems at DBHDS-operated training centers meet some of the selected elements of Section V of the Settlement Agreement, OSIG concludes that DBHDS has not been fully successful in applying them to those served in training centers.

On behalf of OSIG, I would like to express our appreciation for the assistance DBHDS and the training centers' leadership and staff provided during and following our inspections. If you have any questions, please call me at (804) 625-3255 or email me at june.jennings@osig.virginia.gov. I am also available to meet with you in person to discuss this report.

Respectfully,

Digitally signed by
June W Jennings
Date: 2016.09.16
13:27:45 -04'00'

June Jennings, CPA
State Inspector General

CC: Paul Reagan, Chief of Staff to the Governor
Suzette Denslow, Deputy Chief of Staff to the Governor
Delegate John M. O'Bannon, III, Chair of the Joint Commission on Health Care
Senator L. Louise Lucas, Vice Chair of the Joint Commission on Health Care
Dr. William A. Hazel Jr., Secretary of Health and Human Resources
Connie Cochran, DBHDS Assistant Commissioner of Developmental Services

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Executive Summary

The Office of the State Inspector General (OSIG) performed the FY 2015 unannounced inspections at the training centers operated by the Department of Behavioral Health and Developmental Services (DBHDS) as required by *Code* § 2.2-309.1[B](1)(4). The primary purpose of unannounced inspections is to review the quality of services and make policy and operational recommendations to state facilities in order to prevent problems, abuses, and deficiencies and to improve the effectiveness of programs and services.

The focus for these inspections was to utilize select elements of Section V: Quality and Risk Management of the U.S. Department of Justice (DOJ) Settlement Agreement[1] as measures by which to evaluate quality and risk management systems at the DBHDS-operated training centers. Those measures are as follows:

1. C. Risk Management (RM)
    a. Uniform risk triggers and thresholds (Section V.C.1)
    b. Web-based incident reporting system (Section V.C.2)
2. D. Data to Assess and Improve Quality
    a. Regional Quality Councils (Section V.D.5)
3. H. Training
    a. Competency-based training (Section V.H.1)
4. I. Quality Service Reviews
    a. Elements of Quality Service Reviews (Section V.I.1)

These elements were selected due to the importance of ensuring that individuals served in training centers are afforded the benefits of the same quality and risk management standards required by the Settlement Agreement for those served in the community.

Although the quality and risk management systems at DBHDS-operated training centers meet some of the selected elements of Section V of the Settlement Agreement, OSIG concludes that DBHDS has not been fully successful in applying them to those served in training centers.

OSIG reached this conclusion after:

- Unannounced on-site inspections of DBHDS-operated training centers,
- Interviews with DBHDS Assistant Commissioner for Quality Management and Development, DBHDS Director for the Office of Community Integration, members of training center senior management, programming, and direct care staff,
- Reviews of relevant documents including but not limited to:
    - Facility Risk Management (RM) Plans;

[1] Department of Justice Settlement Agreement. United States of America. vs. Commonwealth of Virginia. U.S. District Court for the Eastern District of Virginia. January 2012. http://www.justice.gov/sites/default/files/crt/legacy/2012/01/26/va-ada_settlement_1-26-12.pdf.

- Facility Quality Management (QM) Plans;
- Facility Restraint Reduction Plans;
- Human Rights complaint data;
- Facility Falls Prevention Plans;
- Third Quarter FY 2015 facility-based event data reports;
- 20 randomly selected abuse and neglect investigation reports;
- 60 randomly selected resident services and supports records;
- Training records for 60 randomly selected programming and/or direct care staff;
- Facility new-employee orientation and annual mandatory training curriculums; and
- Policies and procedures related to, but not limited to, performance improvement and RM.

In order to advance quality management and risk management systems in the DBHDS-operated training centers, OSIG recommends:

1. DBHDS' Office of Quality Management and Development, subject-matter experts, and facility-based quality and risk managers should revise Departmental Instruction 301(QM)99 Quality Management Program (issued July 13, 1999) and Departmental Instruction 401(RM)03 Risk and Liability Management (reissued February 15, 2013) to reflect quality and risk management standards defined in the Settlement Agreement, current facility operations, and current quality and risk management standards.
2. DBHDS should ensure facility event reporting is streamlined, accurate, consistent, thorough, and timely. This should be accomplished by engaging facility-based quality and risk managers and subject-matter experts in revising the facility event reporting process to ensure accuracy, timeliness, consistency, and quality, reduced redundancies, and collection of event data relevant to identified risk triggers and thresholds. DBHDS should then develop and implement a system-wide training program on the revised event reporting process to ensure quality and consistency in reporting and data.
3. DBHDS should develop statewide core competency-based training for all direct care positions including those in training centers that aligns with the requirements of Section V: Quality and Risk Management in the Settlement Agreement.

Purpose and Scope of the Review

OSIG performed unannounced inspections at the DBHDS-operated training centers, pursuant to *Code* § 2.2-309.1[B](1)(4), whereby the State Inspector General shall have the power and duty to:

> "1. Provide inspections of and make policy and operational recommendations for state facilities and for providers, including licensed mental health treatment units in state correctional 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 of providers, including licensed mental health treatment units in state correctional facilities, on an ongoing basis in response to specific complaints of abuse, neglect, or inadequate care and as a result of monitoring serious incident reports and reports of abuse, neglect, or inadequate care or other information received. The State Inspector General shall conduct unannounced inspections at each state facility at least once annually;"
>
> "4. Keep the General Assembly and the Joint Commission on Health Care fully and currently informed by means of reports required by *Code* § 2.2-313 concerning significant problems, abuses, and deficiencies relating to the administration of the programs and services of state facilities and of providers, including licensed mental health treatment units in state correctional facilities, to recommend corrective actions concerning the problems, abuses, and deficiencies, and report on the progress made in implementing the corrective actions …"

The focus for these inspections was to utilize select elements of Section V: Quality and Risk Management of the U.S. Department of Justice (DOJ) Settlement Agreement[2] as measures by which to evaluate quality and risk management systems at the DBHDS-operated training centers. Those measures are as follows:

1. C. Risk Management
   a. Uniform risk triggers and thresholds (Section V.C.1)
   b. Web-based incident reporting system (Section V.C.2)
2. D. Data to Assess and Improve Quality
   a. Regional Quality Councils (Section V.D.5)
3. H. Training
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4. I. Quality Service Reviews
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These elements were selected due to the importance of ensuring that individuals served in training centers are afforded the benefits of the same quality and risk management standards required by the Settlement Agreement for those served in the community.

All elements of Section V were not included in these investigations due to focus on community requirements and prioritization of current and future investigations.

[2] Ibid. http://www.justice.gov/sites/default/files/crt/legacy/2012/01/26/va-ada_settlement_1-26-12.pdf.

Background

In August 2008, DOJ initiated an investigation of the Central Virginia Training Center (CVTC), pursuant to the Civil Rights of Institutionalized Persons Act[3] (CRIPA). The DOJ expanded its investigation in April 2010 to the entire Virginia developmental services system to determine Virginia's compliance with the Americans with Disabilities Act[4] (ADA) and the US Supreme Court 1999 Olmstead ruling.[5]

A February 2011 DOJ letter,[6] sent to then-Governor Robert McDonnell, provided notice of the state's failure to comply with the ADA and Olmstead, and the steps Virginia needed to take in order to meet the requirements. On August 23, 2012, the U.S. District Court for the Eastern District of Virginia formally approved a Settlement Agreement between the United States and the Commonwealth of Virginia defining the agreed-upon actions Virginia would take in order to meet the requirements of the ADA and Olmstead and entered it as a court order. Following the approval of the Settlement Agreement, an Independent Reviewer was selected to conduct investigations into Virginia's progress and report to the court through the issuance of reports every six months.

In September 2015, the DOJ filed a motion requesting the court establish an enforceable schedule for implementation of the Settlement Agreement due to their concerns over lack of progress in complying with the Settlement Agreement. A hearing was held October 23, 2015. While the court did not rule out a future enforcement action, it delayed a decision until a January 12, 2016, court date following receipt of the December 6, 2015, Report by the Independent Reviewer.[7] On January 8, 2016, the Department of Justice withdrew its motion for a court-ordered schedule for implementation.

Quality and Risk Management System

Section V of the Settlement Agreement requires the Commonwealth to develop and implement a quality and risk management system that will "identify and address risks of harm; ensure the sufficiency, accessibility, and quality of services to meet individuals' needs in integrated settings; and collect and evaluate data to identify and respond to trends to ensure continuous quality assurance."

In the December 2015 report, the Independent Reviewer noted progress has been made in several areas, but has been impeded by state regulations in others. For example, DBHDS cannot currently require community-based providers to report risk triggers under Rules and Regulations for Licensing

[3] Civil Rights of Institutionalized Person Act. 42. U.S.C. §1997 ET SEQ. http://www.justice.gov/crt/civil-rights-institutionalized-persons.
[4] Americans with Disabilities Act. 2008 Amendments. P.L. 110-325. January 1, 2009. http://www.ada.gov/pubs/adastatute08.htm.
[5] Supreme Court of the United States; Olmstead (98-536) 527 U.S. 581 (1999). Commissioner, Georgia Department Of Human Resources, Et Al. *V.* L. C., CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT. June 22, 1999. https://www.law.cornell.edu/supct/html/98-536.ZS.html.
[6] U.S. Department of Justice, Civil Rights Division/Letter to Governor Robert McDonnell. Investigation of the Commonwealth of Virginia' Compliance with the American with Disabilities Act and of the Central Virginia Training Center. February 10, 2011. http://www.ada.gov/olmstead/documents/virginia_findings.pdf.
[7] Report of the Independent Reviewer on Compliance with the Settlement Agreement/United States vs. Commonwealth of Virginia. United States District Court for the Eastern District of Virginia. Civil Action No. 3:12 CV 059. April 7, 2015-October 6, 2015. http://www.dbhds.virginia.gov/library/developmental%20services/7th%20report%20to%20the%20court.pdf.

Providers by the Department of Behavioral Health and Developmental Services. The Independent Reviewer's summary regarding the Commonwealth's compliance maintains, "The (Settlement) Agreement requires quality improvement programs for all services and of all service providers ... It is the Independent Reviewer's considered opinion that it is possible to achieve quality standards only after identifying the quality standards and employing a quality improvement mechanism to provide information about whether a program is accessible, available and effectively meeting individuals' needs."

DBHDS' Division of Quality Management and Development

According to the DBHDS website, the Division of Quality Management and Development identifies its value as stemming from improving the quality of care to clients, "including standardizing, improving, and monitoring the quality of services in state facilities … (and) ensuring that quality improvement activities, including best practices and evidence-based outcomes, are coordinated and integrated into the primary functions of the organization." Departmental Instructions (DIs) have been utilized as departmental policy for many years to direct and ensure consistency in policies and procedures for the 15 facilities it operates, including the four remaining training centers. Two DIs that address quality management and risk management programs in all DBHDS-operated facilities are Departmental Instruction 301(QM) 99 Quality Management Program, July 1, 1999 (DI 301) and Departmental Instruction 401(RM) 03 Risk and Liability Management, February 15, 2013 (DI 401).

Event Reporting Requirements

According to DI 401, DBHDS-operated facilities utilize a Facility Event Report (DMH 158) form to inform supervisors, facility risk managers, and others of events that pose actual or potential risks. Training centers also have internal event databases, many of which have been customized, where information from the Facility Event Report is input by hand. Facility risk managers are responsible for collecting and aggregating data, assigning clinical severity scales and risk index codes, analyzing risk events for trends and patterns, and ensuring those trends and patterns are reported to a Quality Committee at least quarterly.

Code § 37.2-709 requires the disAbility Law Center of Virginia (dLCV) be notified of critical incidents, defined as serious bodily injury or loss of consciousness requiring medical treatment or deaths of individuals receiving services in state facilities within 48 hours. In section 401-8 Step #3 of DI 301, it states that events with severity levels of 03 to 06 are to be reported to the dLCV within 48 hours of *discovery*. In a later section of DI 301, 401-9 VOPA (now dLCV) Reporting it states that reporting to dLCV is required at the time of occurrence or, if the time of occurrence is unknown, within 48 hours of discovery and includes several other reporting requirements. The program utilized for reporting such events to dLCV is known as the Protection and Advocacy Incident Reporting System (PAIRS). According to DBHDS, the PAIRS application was created specifically to report events requiring medical attention beyond first aid to dLCV. As facility risk managers generally do not work weekends or holidays, this reporting does not always occur within DI or Code-required timeframes.

A third application that all training centers must utilize to report events is the Computerized Human Rights Information System (CHRIS). Serious injuries, deaths, abuse, or neglect allegations, complaints, and peer-to-peer events, are required to be entered into CHRIS. Section V of the Settlement Agreement requires Virginia have and implement a real-time (i.e. within 24 hours), web-based incident reporting system and protocol, and that the system shall require any staff of a training center aware of any suspected or alleged abuse or neglect, serious injury, or death and any remedial steps taken directly report to the DBHDS Assistant Commissioner for Quality Management and Development or designee. CHRIS has been identified as the web-based incident reporting system DBHDS has elected to utilize to meet the Settlement Agreement requirements. The December 2015 Report of the Independent Reviewer found several areas of concern related to CHRIS' use by community providers. OSIG, who also has access to CHRIS, has had similar experiences with the program in reviewing training center reports and data:

- Event reports are not consistently entered into CHRIS in "real time" i.e. within 24 hours, as required by the Settlement Agreement;
- The original CHRIS form has not been improved since its 2012 creation;
- CHRIS is not consistently completed by providers; and
- CHRIS does not provide reliable data.

The Independent Reviewer also stated that DBHDS should add to the community triggers and thresholds for harm and risks of harm that have been developed to include those relevant to the population covered by the Settlement Agreement such as: urinary tract infections, constipation/bowel obstruction, aspiration pneumonia, pressure ulcers, sepsis, seizures, falls, and dehydration. With the exception of falls, the other conditions identified are not currently included in the DBHDS-operated Facility Event Report unless reported as a general change in medical condition, an infrequently reported event, or captured in PAIRS or CHRIS unless the condition rises to the level of serious injury or death.

DBHDS Training Centers

When the Settlement Agreement was reached in 2012, there were five training centers in Virginia. Southside Virginia Training Center (SVTC) in Petersburg closed in 2014. Northern Virginia Training Center (NVTC) in Fairfax, originally scheduled to close by March 2015, discharged its last resident January 21, 2016. Currently there are plans to close two of the three remaining training centers by 2020. Southwestern Virginia Training Center (SWVTC) in Hillsville has a scheduling closure date of June 30, 2018, and CVTC has a scheduled closure date of June 30, 2020. Southeastern Virginia Training Center (SEVTC) in Chesapeake is the only training center scheduled to remain open. In 2012, SEVTC opened 15 newly constructed homes that support five individuals each for a total bed capacity of 75. According to the Director of DBHDS' Office of Community Integration, the November 6, 2015, census in the training centers was 443 residents, a reduction from 931 on June 30, 2010. CVTC had the largest number of residents (217 or nearly 50 percent of the statewide total) and NVTC, the smallest (44 or roughly 10 percent of the statewide total).

DI 301 states that training center facility directors are responsible for ensuring the establishment and execution of a comprehensive facility-specific QM program. The QM plan is to be "data-driven and has as its goal the improvement of clinical processes and/or physical, mental and behavioral health outcomes." Although position title and the name of the quality oversight council vary across training centers, each has an individual designated QM coordinator and a quality committee, which provides oversight to the QM Plan and activities. Also required in DI 301, all DBHDS-operated facilities must develop Risk Management Plans to be reviewed and updated annually and any changes to plans are required to be reported to the DBHDS Office of Quality Management and Development.

Methodology

This series of inspections was conducted in keeping with the Association of Inspectors General Principles and Standards for Offices of Inspector General Quality Standards for Inspections, Evaluations, and Reviews (May 2014). The design for the inspections was created after a review of the following:

1. Documents relevant to the DOJ investigation and Settlement Agreement, such as, but not limited to:
   a. DOJ Investigation Findings Letter (February 10, 2011);
   b. DOJ Settlement Agreement (January 26, 2012);
   c. Seven reports by the court-appointed Independent Reviewer on Virginia's compliance with the Settlement Agreement. (The most recent report was issued December 6, 2015);
   d. United States' Statement of Issues and Motion for Court-Ordered Schedule (September 23, 2015);
   e. Defendant's (Commonwealth) Response to the U.S. and Interveners' Statements of Issues and in Opposition to the U.S. Motion for Court-Ordered Schedule (October 13, 2015); and
   f. Interveners' Statement of Issues (October 5, 2015).
2. DOJ Settlement Agreement Stakeholder Group's written materials and presentations – August 2014 through December 2015.
3. 2014 Assessment of Disability Services in Virginia, Volume 2 (reprinted October 2014) by the Virginia Board for People with Disabilities.
4. DBHDS Comprehensive State Plan 2014-2020 (December 2013).
5. Training Center Closure Plan Quarterly Update (June 2015).
6. DBHDS DI 301 (July 1, 1999).
7. DBHDS DI 401 (February 15, 2013).
8. National Association for Healthcare Quality's Call to Action: Safeguarding the Integrity of Healthcare Quality and Safety Systems (October 2012).

Following the completion of background activities, OSIG prepared a work plan to guide the inspections. Inspection procedures included:

- Interviews with DBHDS Assistant Commissioner for Quality Management and Development, DBHDS Director for the Office of Community Integration, and members of training center senior management, clinical, and direct care staff, including:
  - Facility Directors;
  - Facility Directors of Training;
  - Facility Risk Managers;
  - Facility Quality Management Directors; and
  - Fifty-seven training center staff members, including those providing programming, direct care, and administrative services.
- Document reviews including:
  - Facility Risk Management Plans;

- Facility Quality Management Plans;
- Facility Restraint Reduction Plans;
- Human Rights complaint data;
- Facility Falls Prevention Plans;
- Third Quarter FY 2015 Facility Event Data Reports;
- 20 randomly selected abuse and neglect investigation reports;
- 60 randomly selected resident services and supports records;
- Training records for 60 randomly selected programming and/or direct care staff;
- Facility new employee orientation and annual mandatory training curriculums; and
- Facility Policies and procedures related to, performance improvement, risk management, etc.

Review Results

DOJ Settlement Agreement Compliance

Although DBHDS has made progress, OSIG concludes that DBHDS has not been fully successful in applying selected elements of Section V of the Settlement Agreement to those served in training centers.

OBSERVATION NO. 1:

The current Quality and Risk Management systems in DBHDS-operated training centers vary significantly and are not in keeping with Section V: Quality and Risk Management standards selected for review, DBHDS departmental instruction requirements, or current standards. According to the Assistant Commissioner for Quality Management and Development, three of the four training center Quality Management Plans and none of the training centers Risk Management Plans were reviewed during FY 2015 as required by Departmental Instructions. In a statement to OSIG, the Assistant Commissioner for Quality Management and Development reported, "There is no requirement for the CO (DBHDS Central Office) review and approval of a risk management plan. If a facility makes a major revision to their risk management plan, they are to notify the Office of Clinical Quality and Risk Management. There is a requirement that the CO review annual quality management reports and we have identified this policy as one that must be rescinded. This is an old policy and since that time the CO has implemented centralized monitoring of key facilities quality measures through the PAIRS data and, for hospitals, through the Core Measures." As annual revisions to Risk Management Plans should be based upon the prior year's data, changes in event occurrences, successes, failures, and changes in departmental priorities all would necessarily contain changes that should be reviewed by DBHDS.

DI 301 was written in 1999 and has not been revised since. As it is the DI that governs requirements both for DBHDS Central Office and facility quality management programs, an updated Departmental Instruction would guide DBHDS-operated facilities in meeting the standards set forth in the Settlement Agreement, creating a system-wide QM program, and advancing that program to current standards. DI 401 was re-issued in 2013 but requires revision to ensure compliance with the Settlement Agreement, current facility operations, and current quality and risk management standards.

OBSERVATION NO. 1 RECOMMENDATION:

DBHDS' Office of Quality Management and Development, subject matter experts, and facility-based quality and risk managers should revise Departmental Instruction 301(QM)99 Quality Management Program (issued July 13, 1999) and Departmental Instruction 401(RM)03 Risk and Liability Management (reissued February 15, 2013) to reflect quality and risk management standards defined in the Settlement Agreement, current facility operations, and current quality and risk management standards.

Management Response

DBHDS agrees that DI 301 should be reviewed and revised to reflect current national practices in quality

management, Joint Commission standards and CMS regulations as they relate to quality, as well as the requirements broadly outlined in the DOJ settlement agreement. Consideration will be given to assure that adequate flexibility exist within the DI given the broad based settings that individuals live beyond institutional settings. DBHDS will review DI 401 and update as needed language to reflect quality and risk management system components defined in the Settlement Agreement.

OBSERVATION NO. 2:

Facility Event Reporting is cumbersome and inconsistent, complicated by multiple data entry systems limiting quality and outcomes of the quality management and risk management systems. Facility event reporting requires data collection and entry in multiple steps and systems, each with its own reporting requirements and outputs. Facility staff initiate event reporting with handwritten forms that have not been updated in many years or customized by setting and are not able to capture facility-defined risk triggers. Risk management staff of varied backgrounds and training then score events and enter the data into a facility-event database. Depending upon the nature and scoring of the event, data entry may also be required into PAIRS, CHRIS, or another database. As risk management staff generally do not work weekends and holidays, data entry is not consistently completed within required timeframes of *Code*, DBHDS Departmental Instructions, or Settlement Agreement requirements (24 hours).

Interviews with risk management staff at the training centers revealed difficulties guaranteeing events are reported and entered into the appropriate application(s) in a timely manner. Documentation reviews and interviews with risk management staff that enter data into CHRIS revealed that not all staff reporters are adequately trained or supervised in completing handwritten Facility Event Reports. Risk management staff are frequently required to seek out clarification of the information reported on Facility Event Reports due to difficulties reading handwriting, inaccurate or incomplete reporting, or other concerns, resulting in data entry delays and inefficiency.

The PAIRS database is used by all DBHDS-operated facilities, including the training centers, to report serious injuries and deaths to dLCV. OSIG utilizes the database to collect data on significant events or injuries. A reportable injury is one that requires physician or physician-extender intervention(s) above first aid. Facility reporting into this database is also inconsistent and limited in scope. Definitions of event types allow for a single event to be entered as several different event types, or not entered at all depending upon the judgement of the individual risk manager or their staff, making review and analysis unreliable. Training on the use of PAIRS, evaluating and scoring events, and supervision of data entry also varies. PAIRS report options are also limited and must be run by individual facility name or provider and hand tallied. Custom reports are not available. Utilizing only PAIRS data limits DBHDS' ability to identify potential problems and effect corrective actions. This information alone does not provide for a reliable or comprehensive system for monitoring quality or risk points.

OBSERVATION NO. 2 RECOMMENDATION:

DBHDS should ensure facility event reporting is streamlined, accurate, consistent, thorough, and timely. This should be accomplished by engaging facility-based quality and risk managers and subject matter experts in revising the facility event reporting process to ensure accuracy, timeliness, consistency and quality, reduced redundancies and waste, and collection of event data relevant to identified risk triggers and thresholds. DBHDS should then develop and implement a system-wide training program on the revised event reporting process to ensure quality and consistency in data and reporting.

Management Response

DBHDS has not yet implemented a centralized event reporting system for facilities; however, all facilities are required by Departmental Instruction 401(RM)03 to use the standardized event reporting form #(DMH)158. This reporting form addresses a wide range of risk events, including events associated with the physical plant, personnel events that may result in a risk to the facility, legal notices, and other events. Facilities may elect to capture event data in additional areas as required for the population served. This flexibility ensures that a facility meets basic reporting and review requirements but is also free to address concerns more specific to that facility. DBHDS has initiated planning for a centralized event reporting system for both community and facility programs to address a variety of reporting needs. This system will include facility event reporting, which will further standardize the reporting process and ensure centralized review of systems risk issues. Furthermore, we envision common data elements for both community and facility event reports as appropriate to the setting. This is a major IT&S project that will prominently involve facility risk and quality staff as well as central office staff. Funding and specific timeframes for the development of this project are still in process. In the meantime, DBHDS will review the Training Centers' current processes, timeliness and accuracy within the current system to identify where improvements can be made. Staff at the training centers will receive training on any changes in the system wide reporting processes when implemented.

OBSERVATION NO. 3:

A system to ensure core competency-based training for training center direct care staff is absent. According to the University of Minnesota's Institute of Community Integration, "Competency-based training is an avenue to achieve a highly knowledgeable and skilled workforce … Clear and detailed outcomes or competency statements are used to develop the training curriculum and measure learners' competence. Competency statements are derived from a thorough job analysis of the learner's duties, which contributes to the training goal of meeting individual learner needs as they master various skill levels."[8] Competency-based training is most effective when it mirrors the duties and responsibilities staff deal with in their day-to-day responsibilities. Training that is task driven and frequently tested by supervisory coaches is more effective than training that is primarily classroom based at the time of hire, which is the primary training system for training center new employees.[9]

[8] Larson, S.A., Hewitt, A., McCulloh, N., LaLiberte, T. & Gaylord, V. (Eds.). (Fall/Winter 2007/08). *Impact: Feature Issue on Direct Support Workforce Development, 20*(2). [Minneapolis: University of Minnesota, Institute on Community Integration (http://ici.umn.edu/products/impact/202/default.html).

[9] Ibid.

In addition to new employee orientation, training centers provide direct care staff opportunities to participate in the College of Direct Support, a national online curriculum for direct support professionals and front-line supervisors that includes topics such as person-centered planning and supports, community inclusion, positive behavioral supports, and home and community living. While training centers' staffs have had the benefit of increased training activities since the Settlement Agreement was finalized in 2012, the training has not been based on uniformly defined processes and procedures as required for all providers in the Settlement Agreement.

Core competency- based training described in the Settlement Agreement includes, but is not limited, to the following:

- Person-centered planning;
- Community integration and self-determination;
- Proactively identifying and addressing risks of harm; and
- Conducting root-cause analysis and addressing corrective action.

DBHDS' training curriculum for training centers and other providers under the Settlement Agreement has not been finalized at this time.

OBSERVATION NO. 3 RECOMMENDATION:

DBHDS should develop statewide core competency-based training for all direct care positions including those in training centers that aligns with the requirements of section v: quality and risk management in the settlement agreement.

Management Response

DBHDS will review the training curriculums for the three remaining training centers as to core competency training to validate that training is being provided on person-centered practices, community integration and self-determination for each training center. Within the text of Observation No. 3, it should be noted and clarified that there is not a requirement in the Settlement Agreement for uniformly defined processes and procedures.

Appendix 1 — Departmental Instruction 301(QM)99

Issued 07/01/99

Departmental Instruction 301(QM)99
Quality Management Program

301- 1 Background

The Department of Mental Health, Mental Retardation and Substance Abuse Services is committed to the delivery of quality care in its facilities. The facilities' missions, values, operational systems, and human resources should demonstrate a commitment to organizational quality and service excellence. Previous efforts to ensure comprehensive and integrated programs for quality combined quality management and risk management in a single Departmental Instruction. The Instructions for quality management and risk management are now being separated to more fully address the specific requirements of each.

301- 2 Purpose

To establish baseline requirements for quality management programs for all facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

301- 3 Definitions

The following definitions are applicable to this instruction:

Analysis The systematic use of appropriate statistical quality control techniques to answer questions about important processes and outcomes.

Assess To assess is to transform data into information by analyzing it.

Data Data refers to uninterpreted material, facts, or clinical observations.

Improve Improve means to take actions that result in the desired measurable change.

Continued on next page

Departmental Instruction 301(QM)99
July 1, 1999

Information	Information refers to interpreted set(s) of data that can assist in decision making.
Measure	To measure means to collect quantifiable data about a function or process.
Measurement	Measurement is the systematic process of data collection, repeated over time or at a single point in time.
Outcome	An outcome is the result of the performance (or nonperformance) of a function or process(es).
Performance indicators	Performance indicators are assessment tools used to measure and evaluate the quality of important governance, management, clinical and support functions that affect patient/resident outcomes. Indicator categories may include: volume and flow; risk management/safety indicators; process and output measures; education and competency measures; cost and efficiency measures; customer satisfaction; and outcome measures.
Plan	Plan means to formulate or describe an approach to achieve goals related to improving the performance of an organization.
Process	A process is a goal-directed, interrelated series of actions, events, mechanisms, or steps.
Quality management	Quality management refers to an organization's strategies, structures, functions, and processes intended to plan, design, measure, assess and improve the quality of its performance, services and products.

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Reference database An organized collection of similar data from many organizations that can be used to compare the organization's performance to that of others.

System A system is a group of interrelated processes.

301- 4 Responsible Authority

Facilities The facility director will ensure the establishment and implementation of a comprehensive facility-specific quality management program, which effectively improves care through improvement of the quality of performance, services and products.

DMHMRSAS The Commissioner or his designee is responsible for communicating the agency's priorities to facilities for incorporation in the facility quality management plan.

The Quality Manager is responsible for the interpretation of this instruction and monitoring its implementation.

301- 5 Specific Guidance

Basic requirements Each facility will have a Quality Management Program that is data-driven and has as its goal the improvement of clinical processes and/or physical, mental and behavioral health outcomes. The Quality Management Program is a tool that promotes the use of quality management constructs to enhance system effectiveness and client outcomes.

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Departmental Instruction 301(QM)99
July 1, 1999

Role of leadership

In order for the quality management program to be effective, the Facility Director and his management team must:

- define the organization's vision, mission and values upon which quality management initiatives will be based
- ensure the availability of resources for education and training on all relevant aspects of quality management
- ensure the availability of necessary resources for the implementation of the quality management plan
- ensure that quality management principles are pervasive within the organization's culture
- participate in or support the function of the Quality Council
- evaluate the effectiveness of quality program oversight and performance; and
- ensure that sound quality management principles are utilized in designing new or changing existing processes within the facility.

Role of Quality Council

Within each organization, the Quality Council will:

- prioritize the opportunities for improvement in accordance with the plan, vision and mission of the organization
- ensure the formulation of a written quality management plan and update/revise the plan annually, as indicated
- ensure an annual comprehensive appraisal of the quality management program is completed and reported
- oversee the implementation of quality management processes (planning, process design, measurement, assessment and improvement)
- promote quality culture throughout all levels of the organization
- establish facility-wide quality initiatives and ensure their completion;
- ensure that performance indicators address needs of the individual facility and requirements of relevant external regulatory agencies;
- ensure that appropriate disciplines/departments/staff receive feedback on quality management findings; and
- monitor implementation and effectiveness of improvement efforts developed in response to quality management findings.

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Role of QM Coordinator

Each facility must have a designated Quality Management Coordinator who will:

- coordinate and monitor the implementation of the quality management program
- coordinate and integrate the quality management and risk management functions
- oversee day-to-day operations of quality management activities
- oversee the annual review/appraisal of the quality management program
- ensure and/or provide training in quality management to the facility executive leadership, the Quality Council, and others as appropriate
- provide consultative services on application of quality management processes
- oversee the development/implementation of quality management training initiatives
- prepare the annual quality management report
- obtain and disseminate resource material to administrative and clinical staff; and
- coordinate the activities of the Quality Council.

Role of Central Office

The Department will:

- communicate the agency's priorities to the facilities
- identify systemic quality or specific performance issues for inclusion in facility quality management plans
- review annual quality management reports and updates and provide feedback to facilities; and
- evaluate the effectiveness of facility quality management programs.

Privileged communication

Virginia Code § 8.01-581.17 provides that the proceedings, minutes, records and reports of any committee created under § 8.01-581.16 to review the adequacy or quality of professional services are privileged and may not be disclosed or obtained by legal discovery proceedings unless ordered by a court to be produced following a hearing and for good cause arising from extraordinary circumstances.

This privilege does not apply to hospital medical records kept with respect to any patient in the ordinary course of hospitalization of the patient.

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Essential processes of QM programs

Facility quality management programs will include the following essential processes:

PLANNING: Organization wide, systematic, collaborative planning is necessary to the effective design (or redesign) of processes and performance measurement, assessment and improvement.

PROCESS DESIGN: Facilities are called upon frequently to design more effective processes, functions and systems. Processes that are designed well:

- are consistent with mission, vision, values, and plans
- meet the needs and expectations of key constituents
- are clinically sound and current; and
- establish baseline performance expectations by defining expected outcomes before designing/redesigning functions, systems or processes and by developing a measurement method to track movement toward the expected outcome.

MEASUREMENT/DATA COLLECTION: Measurement provides the underpinning for all improvement activities. Through performance measurement the facility can identify opportunities for improvement, appraise process stability, determine what processes should be redesigned and decide if redesigned processes have been successful.

- To measure performance, data collection should be systematic and should include
  - processes and outcomes
  - comprehensive set of performance measures (indicators); and
  - high risk, high volume, and problem prone processes.

- The collected data should then be used to
  - establish baseline for process implementation/redesign
  - describe process performance or stability
  - identify areas for improvement; and/or
  - determine whether changes in a process have met objectives.

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Essential process of QA programs *(continued)*

- Data sources may include, but are not limited to:
  - peer review
  - medical record review
  - pharmacy and therapeutics review
  - mortality and morbidity review
  - infection control studies
  - risk management activities
  - Inspection of Care (IOC) review (MR-specific)
  - client satisfaction surveys; and
  - employee satisfaction surveys.

ASSESSMENT: The facility must use a systematic process of assessing or analyzing collected data to answer questions about important processes and outcomes throughout the facility. These questions are related to:

- level of performance
- stability of current processes
- areas that could be improved, and
- effectiveness of improvement efforts and process redesign.

The assessment/analysis requires the use of appropriate statistical quality control techniques, including statistical process control and common-cause and special-cause variation. It also compares data internally over time, with up-to-date information sources and with reference databases.

IMPROVEMENT: Facilities improve performance and outcomes by:

- redesigning current processes (making incremental improvements); or
- designing new processes.

To systematically improve performance, facilities take the following steps:

1. Set performance goals and establish performance indicators, against which results can be judged.
2. Implement action and collect data about change's performance.
3. Compare actual performance to desired performance.
4. If goals are not achieved, plan and test new actions.
5. If actions prove effective, incorporate as standard operating procedure.
6. Verify through ongoing measurement and assessment that improvement is sustained.

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301- 6 Procedures

The following procedures are to be used for this Instruction:

Structure

Each facility will have a designated quality management coordinator appointed by the facility director and will establish a Quality Council.

Membership of the Quality Council must include, but is not limited to:
- the facility director
- representatives of the medical staff
- representatives of the nursing staff, and
- representatives of a combination of clinical and nonclinical program staff.

QM plan

Through the authority of the Quality Council, the quality management Coordinator will draft the organization's quality management plan, following the format delineated in Attachment I.

The quality management plan will be finalized and:
- approved by the Quality Council
- reviewed, approved, and signed by the facility director; and
- reviewed, approved, and signed by the Commissioner of DMHMRSAS.

This review and approval process will be repeated only when changes are made to the contents of the plan.

The Quality Council will provide oversight and direction for the implementation of the plan.

The facility quality management coordinator will coordinate and facilitate implementation of the plan and support the council.

Annual report

- At the end of each fiscal year, a thorough review of the year's quality management program and its activities will be performed.

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Annual report

- The coordinator will draft an annual quality management report which:
  - summarizes the review of the previous year's program and
  - outlines the updated program for the coming year following the format delineated in Attachment II.

  If any changes to the organization's quality management plan are required, they will be completed at this time.

- The annual report will be finalized and approved by the council and reviewed, approved and signed by the facility director and the Commissioner of DMHMRSAS.

301- 7 References

- *Code of Virginia,* § 8.01-581.16 and § 8.01-581.17.
- *Joint Commission on Accreditation of Healthcare Organizations 1998 Comprehensive Accreditation Manual for Hospitals.*

Richard E. Kellogg
Commissioner

Attachment

Effective Date: July 1, 1999

ATTACHMENT I

QUALITY MANAGEMENT PLAN

I. INTRODUCTIONS

Includes a brief summary of services provided by the facility

II. PLAN OBJECTIVES

Includes the Quality Management Plan's mission, goals, and purpose.

III. QUALITY MANAGEMENT ACTIVITIES

Includes a description of the activities performed within the framework of planning, process design, measurement/data collection, assessment and improvement, as well as the:

- relationship of the activities to the facility's mission;
- process for the establishment and revision of quality management priorities; and
- process for routine monitoring, evaluation, improvement, and performance measurement of high-risk, high-volume, and problem prone areas.

IV. QUALITY MANAGEMENT STRUCTURE AND RESPONSIBILITY

A. Overview of the Facility's Quality Management Structure (Includes an organizational chart.)

B. Quality Management Responsibilities

Includes a description of the QM-related responsibilities of the following:

- Leadership
- Quality Council
- Quality Management Coordinator
- Facility managers/supervisors
- Facility staff
- Quality management teams
- Central Office

Quality Management Plan
Page Two

C. QM Committees

1. Description of committee structure utilized to support QM functions
2. For each committee, a description of:
   - frequency of meetings;
   - minimum information to be submitted by committee to Quality Council (minutes, reports, data);
   - activities;
   - authority; and
   - responsibility.

D. Quality Management Model

Includes a brief description of the model used (10 step, PDSA, etc)

E. Information and Analysis

Describes the process and resources for collecting and analyzing data. Outlines sources of information, how the information is to be collected and analyzed and who is responsible for doing so.

F. Evaluation of Competence and Training Needs

Includes a comprehensive description of the mechanism for utilization of quality management assessment findings in the credentialing and individual performance evaluation processes of the facility. Describes a process wherein training needs identified through quality management findings are addressed in a timely and effective manner.

V. CONFIDENTIALITY GUIDELINES

VI. ANNUAL APPRAISAL

Includes requirements for an annual review of the facility's quality management program, stipulating content and reporting mechanism.

ATTACHMENT II

ANNUAL QUALITY MANAGEMENT REPORT

I. QUALITY MANAGEMENT PLAN REVIEW

Includes a review of the organization's quality management plan to determine continued appropriateness and relevance of content and focus. Describes any identified changes or updates to be made to the plan with rationale.

II. REVIEW OF PREVIOUS YEAR'S ANNUAL QM REPORT

Briefly iterates the priorities and major quality management goals identified and planned for in the previous year's annual quality management report.

III. SUMMARY OF ACTIVITIES AND APPRAISAL OF EFFECTIVENESS

Includes a summary of the year's major quality management activities, including findings and improvements resulting from the activities. Describes goals of the activities, progress toward goals and significant obstacles encountered. Evaluates improvements in performance relative to the priorities and goals identified in previous year's annual report.

IV. ANNUAL UPDATE

Includes the updated priorities and quality management goals for the coming year. Lists changes in performance indicators and data collection sources/methods. Updates goals for existing quality management teams and identifies need for establishment of additional teams.

Appendix 2 — Departmental Instruction 401(RM)03

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.

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

Continued on next page

Facilities *(continued)*

- Incorporating the requirements of this Instruction into the Risk Manager's employee work profile.

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

Continued on next page

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

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.

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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.

Continued on next page

Step #2 review of events by supervisor

Review of Unexplained Injuries. If no event can be associated with the injury, the the supervisor or person in charge shall note that the injury is unexplained and 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

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

Continued on next page

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.

- There has been an allegation of sexual abuse or sexual assault/rape;
- All events involving a loss of consciousness; and
- 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.

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401 - 10 Procedures – Receipt and Handling of Legal Documents

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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

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Continued on next page

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.*

401 - 11 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*

Continued on next page

Departmental Instruction 401(RM)03
February 15, 2013

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

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Attachment 1

FACILITY EVENT REPORT*

Client Register #:	Client Name	Age	Living Area/Ward:

Situation: ❑ 1:1 ❑ Dir. Obs. ❑ Protective Device ❑ Restraint ❑ Seclusion ❑ Time Out
❑ Q15 ❑ Q30 ❑ Q60

❑ Visitor	❑ Volunteer/Other	Event Date	Event Time	❑ AM	❑ PM

Check One Event Type (Shaded Area) and One Sub-Category Listed Below Event

❑ Accidental
- ❑ By Another Client
- ❑ By Other
- ❑ By Staff
- ❑ Swallowing Inedible
- ❑ Other

❑ Aggressive Act
- ❑ Against Client
- ❑ Against Staff
- ❑ Against Object
- ❑ By Another Client
- Reg.# _____
- ❑ Sexual Assault
- ❑ Retaliative/Act/Self Defense

❑ Fall
- ❑ Balance/Coordination
- ❑ Client Reported Fall
- ❑ Footwear
- ❑ Found on Floor
- ❑ Obstacle
- ❑ Reclining/Sitting
- ❑ Running
- ❑ Seizure Related
- ❑ Slippery Surface
- ❑ Transfer

❑ Medical
- ❑ Aspiration
- ❑ Choking
- ❑ Cluster Seizure
- ❑ Deterioration In Condition
- ❑ Seizure Related Injury
- ❑ Status Epilepticus
- ❑ Swallowing Problem

❑ Medications
- ❑ Wrong Route
- ❑ Wrong Medication
- ❑ Time Variance
- ❑ Wrong Dosage
- ❑ Wrong Client
- ❑ Omitted
- ❑ Refused
- ❑ Transcription Error
- ❑ Adverse Drug Reaction
- ❑ Dispensing Error
- ❑ Missing Medication
- ❑ Improper Storage
- ❑ Improper Order
- ❑ Given, Not Charted
- ❑ Medication Error - Other

❑ Missing
- ❑ Attempted Escape
- ❑ Escape
- ❑ Off Campus
- ❑ On Campus

❑ Other
- ❑ Client/Family Complaint
- ❑ Contraband
- ❑ Environmental Problem
- ❑ Exposure to Elements
- ❑ Fire
- ❑ Insect Bite
- ❑ Sexual Encounter
- ❑ Substantiated Abuse
- ❑ Other

❑ Property/Equipment
- ❑ Damaged
- ❑ Failure/Malfunction
- ❑ Missing
- ❑ Tampered With
- ❑ User Error

❑ SIB
- ❑ Intentional
- ❑ Unintentional
- ❑ Suicide
- ❑ Suicide Attempt
- ❑ Suicide Gesture
- ❑ Pica

❑ Treatment/Habilitative
- ❑ Delayed
- ❑ Consent Problem
- ❑ Deviation Policy & Procedure
- ❑ Dietary Problem
- ❑ Injection Site
- ❑ Meal Refusal
- ❑ Monitoring
- ❑ Omitted
- ❑ Positioning
- ❑ Refusal
- ❑ Test Results
- ❑ Other

❑ UNEXPLAINED

Location: Check One

❑ Bathroom ❑ Bedroom ❑ Dining Room ❑ Hall ❑ Living Room ❑ Off Grounds
❑ Grounds ❑ Program Area/OWT ❑ Sidewalk ❑ Vehicle ❑ Unknown ❑ Other

❑ Abrasion/Scratch ❑ Allergic/Adverse Reaction ❑ Aspiration ❑ Bite ❑ Contusion/Hematoma/Bruise
❑ C/O Pain ❑ Cardiac/Resp. Arrest ❑ Death * ❑ Dislocation ❑ Fracture
❑ Laceration ❑ None Apparent ❑ Other ❑ Reddened Area/Swelling ❑ Wound Disruption

* Check One: ☐ medical sequela/ geriatric ☐ medical sequela/non-geriatric ☐ unforeseen/cause determined ☐ unforeseen/cause undetermined

☐suicide ☐ homicide **Describe Event:**

Treatment/Interventions:

Notified: ❑ MD ❑ RN ❑ Supervisor	Client Seen by: ❑ MD ❑ RN	Date/Time Seen:
Family Notified: ❑ Yes ❑ No	Notified by:	Date/Time:

❑ Med Attn Needed ❑ Infirmary Admission ❑ Emergency Center
❑ Trans Via Rescue Squad ❑ Hospitalization Required

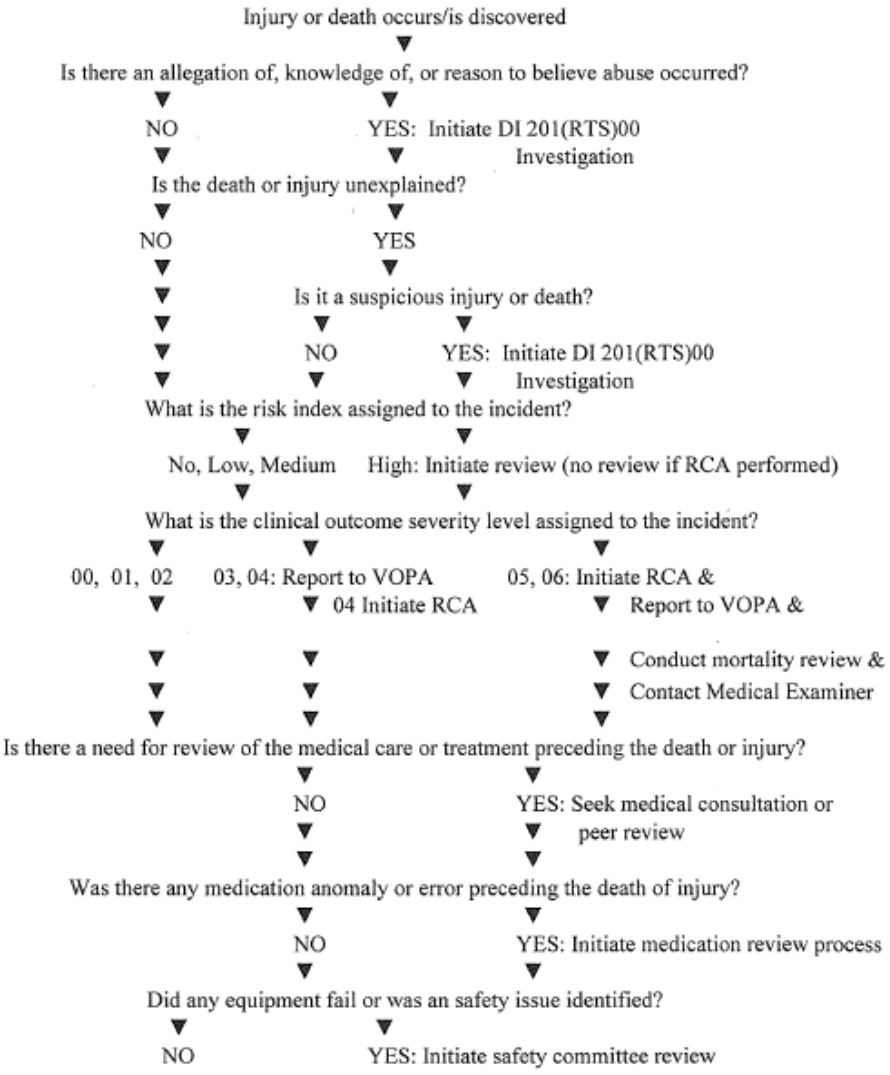
Signature of Person Completing Form: **Date:**
Signature of Nurse/Supervisor: **Date:**
Signature of Risk Manager or Designee: **Date:**

❑ 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