OFFICE OF THE STATE INSPECTOR GENERAL

Department of Behavioral Health and Developmental Services: Review of Serious Injuries Reported by Licensed Providers of Developmental Services

December 2018

Michael C. Westfall, CPA
State Inspector General

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COMMONWEALTH OF VIRGINIA
Office of the State Inspector General

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December 28, 2018

Governor Ralph Northam
P.O. Box 1475
Richmond, VA 23219

Dear Governor Northam:

Pursuant to *Code of Virginia (Code)* § 2.2-309.1, the Office of the State Inspector General (OSIG) conducted a review of serious injuries reported by licensed providers (providers) serving individuals with developmental disabilities between July 1, 2016, and December 31, 2017. In addition, OSIG reviewed the efficiency and effectiveness of the Virginia Department of Behavioral Health and Developmental Services' (DBHDS) Quality Improvement Committee (QIC) and Regional Quality Councils' (RQCs) review and response to those injuries, identified actual and potential risk points, and made recommendations to improve the overall effectiveness of the process and individuals' safety and freedom from harm.

On behalf of OSIG, I would like to express our appreciation for the assistance provided by DBHDS during the review. 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,

Michael C. Westfall, CPA
State Inspector General

CC: Clark Mercer, Chief of Staff to Governor Northam
Suzette Denslow, Deputy Chief of Staff to Governor Northam
The Honorable Rosalyn R. Dance, Chair, Joint Commission on Health Care
The Honorable T. Scott Garrett, Vice Chair, Joint Commission on Health Care

The Honorable R. Creigh Deeds, Chair, Joint Subcommittee to Study Mental Health Services in the 21st Century
The Honorable Robert B. Bell, Vice Chair, Joint Subcommittee to Study Mental Health Services in the 21st Century
Daniel Carey, M.D., Secretary of Health and Human Resources
S. Hughes Melton, M.D., M.B.A., F.A.A.F.P., F.A.B.A.M., Commissioner, DBHDS
Connie Cochran, Acting Deputy Commissioner for Administrative Services, DBHDS
Heather Norton, Acting Deputy Commissioner of Developmental Services, DBHDS
Dev Nair, Assistant Commissioner for Licensing and Compliance, DBHDS
Kathy Brown, Acting Internal Audit Director, DBHDS

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Executive Summary

Pursuant to *Code of Virginia (Code)* § 2.2-309.1, the Office of the State Inspector General (OSIG) conducted a review of serious injuries reported by licensed providers (providers) serving individuals with developmental disabilities between July 1, 2016, and December 31, 2017, and the Virginia Department of Behavioral Health and Developmental Services' (DBHDS) Quality Improvement Committee (QIC) and Region Quality Councils' (RQC) review and response to those injuries.

OSIG has identified several recommendations that, if implemented, may improve the overall effectiveness of the process of reviewing and responding to serious injuries as well as improve individuals' safety and freedom from harm. OSIG found the quality, consistency and reliability of reports used by DBHDS relevant to serious injuries to be insufficient. DBHDS offers no definitions to providers relevant to serious injuries or guidance to support consistent and reliable reporting. The lack of clearly defined terms and guidelines limits the QIC and RQCs' abilities to analyze serious injury data, identify patterns and trends or prioritize the highest risk injuries for performance improvement initiatives. When reports are provided to QIC and RQCs relevant to individuals' serious injuries, they are inconsistent, not directly related to serious injuries and of limited utility.

To improve DBHDS' reporting and response to serious injuries impacting individuals with developmental disabilities in provider settings, OSIG recommends DBHDS commit to the following action items:

1. DBHDS should develop a clear and consistent list of serious injuries, prioritized as having significant impact on individuals served by providers. The list should rank serious injuries that a) have potential for the greatest negative impact on individuals' health and safety; b) occur with the most frequency; and c) impact the highest number of individuals. All serious injuries (or changes in medical condition) should have one set of clear, specific and accurate definitions and include exclusionary criteria for reporting serious injuries as "other." Following development of this list, the Computerized Human Rights Information System (CHRIS) and OneSource reports should be updated to reflect the changes and a guidance document should be developed to reflect the same.
2. DBHDS should implement appropriate internal controls, safeguards and data validation processes to ensure CHRIS and OneSource produce reliable and consistent reports.
3. DBHDS should develop targeted performance improvement efforts related to falls and urinary tract infections (UTIs) as a starting point for its Quality Management (QM) efforts.
4. In order to review and respond to serious injuries reported by providers, the DBHDS QIC should utilize QM principles to identify consistent injury types upon which to develop QIC reports that will efficiently and effectively support analysis and development of performance improvement initiatives. Additionally, QIC members, including committee leadership, should be trained in QM principles, meeting facilitation, risk management and

performance improvement. New members should receive the same training prior to meeting attendance.

5. Regional Quality Councils (RQCs) should be provided with consistent, region-specific data, reports and presentations related to specific serious injuries. Reports should support quarterly and annual analysis, trending and development of performance improvement plans related to significant injuries and comparisons to other regions. RQC members, including committee leadership, should be trained in QM principles, facilitation, risk management and performance improvement. New members should receive the same training prior to meeting attendance.

Purpose and Scope

OSIG conducted a review of serious injuries reported by providers serving individuals with developmental disabilities and evaluated the efficiency and effectiveness of the DBHDS QIC and RQCs, identified actual and potential risk points, made recommendations to increase the overall effectiveness of the process and improve individuals' safety and freedom from harm. It was not designed to be a comprehensive review of DBHDS' or providers' quality or risk management systems or duplicate efforts of the Department of Justice (DOJ) Independent Reviewer (IR) in assessing compliance with the United States Department of Justice (DOJ) Settlement Agreement (SA).

The review was performed pursuant to *Code of Virginia (Code) §* 2.2-309.1, 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… 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… of providers… 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…
>
> 5. Review, comment on, and make recommendations about, as appropriate, any reports prepared by the Department of Behavioral Health and Developmental Services and the critical incident data collected by the Department of Behavioral Health and Developmental Services in accordance with regulations adopted under § 37.2-400 to identify issues related to quality of care, seclusion and restraint, medication usage, abuse and neglect, staff recruitment and training, and other systemic issues[.]"

The scope of this review was selected after OSIG encountered significant challenges obtaining consistent, valid and reliable serious injury data, as well as concerns identified with reports and operations of the DBHDS quality management committees.

Review objectives included:

1. Conduct a review of serious injuries reported by providers serving individuals with developmental disabilities between July 1, 2016, and December 31, 2017.
2. Review the efficiency and effectiveness of DBHDS' QIC and RQCs relevant to serious injuries reported by providers serving individuals with developmental disabilities to identify actual and potential risk points and make recommendations to improve the process and individuals' overall safety and freedom from harm.

Background

Principles of Quality Management (QM)

The Institute of Medicine (IOM) defines health care quality as, "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." In developing a quality system, efforts should focus on the most critical processes. This approach allows entities to prioritize data collection, standardize reporting formats to support decision-making and ensure the Quality Management (QM) structure is designed to support desired outcomes. QM teams must have an understanding of QM principles, performance improvement (PI) and facilitation of committees and performance improvement activities. Principles of risk management must also be understood not just as something that begins following risk events, but as a proactive and organized effort to identify, assess and reduce risks to individuals, staff and organizations as a whole.

In today's world there are enormous amounts of data collected and administrative requirements impacting the healthcare system. In order to improve outcomes, a consistent way to coordinate efforts and focus on the highest risk areas is required to achieve positive results. If an organization can focus on a select few high-risk, high-impact areas, problems may be discovered and addressed faster and with less wasted time and energy than if attention is spread too widely.

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services (CMS), a division of the United States Department of Health and Human Services (HHS), is the administrator of Medicare and Medicaid programs. Medicare is a federal health insurance program designed for adults aged 65 or older and certain individuals with disabilities. Medicaid is a joint federal and state insurance program for low-income adults, children, pregnant women, elderly adults and disabled people.

Section 2176 of the Omnibus Budget Reconciliation Act of 1981 created § 1915(c) of the Social Security Act, which established Medicaid Home and Community-Based Waivers (HCBS Waivers) that allow states to waive certain Medicaid requirements for specific populations in order to provide care to individuals in their homes and communities versus institutions.

The Commonwealth of Virginia (Commonwealth) has participated in CMS HCBS Waivers since 1984. Currently, the Commonwealth is approved for six 1915(c) HCBS Waivers, of which three (i.e., Community Living Waiver, Family and Individual Support Waiver and Building Independence Waiver) are specifically designed to address services to individuals diagnosed with developmental disabilities.

Virginia Department of Medical Assistance Services (DMAS)

In addition to administering the state Medicaid program, the Virginia Department of Medical Assistance Services (DMAS) is the operating agency for the Commonwealth's HCBS Waivers and is responsible for submitting waiver applications and ensuring compliance. In December 2009,

DBHDS and DMAS entered into an agreement (amended June 2015) outlining DBHDS' responsibility for daily operation of the HCBS Waivers.

At the time of waiver application, CMS requires states develop a quality assurance system to continuously monitor key performance measures and outline their quality assurance system. The quality assurance system must include how states will develop and monitor performance measures, such as health and welfare of waiver participants, levels of care utilized, provider qualifications and service planning and delivery. Appendix H (Quality Improvement Strategy) of the application focuses primarily on protection of participants' health and welfare:

> "In Appendix H of the application, a State describes (1) the *system improvement* activities followed in response to aggregated, analyzed discovery and remediation information collected on each of the assurances; (2) the correspondent *roles/responsibilities* of those conducting [,] assessing and prioritizing improving system corrections and improvements; and (3) the processes the state will follow to continuously *assess the effectiveness of the [Q]IS* and revise it as necessary and appropriate."

The July 1, 2016, renewal application for the 1915(c) Community Living Waiver outlined the Commonwealth's quality improvement strategy and DBHDS' responsibilities including the following:

- Collect quarterly data regarding individuals' health and well-being;
- Review relevant DBHDS Division of Quality and Risk Management and Division of Developmental Services reports;
- DBHDS committees will review relevant data, identify trends and recommend responsive action; and
- DBHDS shall establish a provider-reporting framework to assess providers in terms of quality of service and outcomes.

DBHDS Quality Management and Development (QMD)

Prior to August 2018, the DBHDS Quality Management and Development (QMD) division reported to the Chief Deputy Commissioner and was responsible for,

> "…improving the quality of care to individuals including standardizing, improving, and monitoring the quality of services in state facilities and community programs. The division serves as one focal point of these efforts, ensuring that quality improvement activities, including best practices and evidence-based outcomes, are coordinated and integrated into the primary functions of the organization."

During the time period of this review, the QMD consisted of the following offices and areas of responsibility:

- Office of Community Quality Improvement and Risk Management (CQIRM);
- Office of Data Quality and Visualization (DQV);

- Office of Facility Quality Improvement and Risk Management (FQIRM);
- Office of Human Rights (OHR);
- Office of Licensing (OL); and
- Regulations of the DBHDS State Board.

On August 24, 2018, DBHDS announced a reorganization of its structure with risk management, quality assurance, OHR and OL being placed under a new position, the Assistant Commissioner for Licensing and Compliance. Quality improvement for both community operations and DBHDS-operated facilities, mortality review and DQV were placed under another new position, the Chief Clinical Officer.

The guidance document for DBHDS' quality management system is its Quality Management Plan (QMP), last updated October 20, 2016. According to the QMP, the QM System, "… is driven by a constant process of integrating data and information across programs and systems; evaluating system performance and identifying opportunities for improvement; recommending and directing QI projects and initiatives; measuring the impact of interventions; and identifying and implementing further activities as necessary."

QM program goals are stated as follows:

- "To implement quantitative and qualitative measurement to assess key processes and outcomes related to important aspects of services and supports;
- To bring clinicians, administrators, and key stakeholders together to review quantitative and qualitative data as well as major clinical adverse occurrences to identify problems;
- To carefully prioritize actions to address identified problems and set goals for their resolution;
- To achieve measurable improvement in the highest priority areas; and
- To develop or adopt necessary tools to support quality assurance and quality improvement, such as practice guidelines, consumer surveys and quality indicators."

QM system components are stated to include:

- Risk management through the operations of the Office of Clinical, Quality, and Risk Management (not found on the current or previous DBHDS organizational chart), which coordinates quality and safety initiatives. This office is also responsible for operation of the Mortality Review Committee (MRC) and the Risk Management Review Committee (RMRC).
- Quality assurance through the OLC and OHR licensing and monitoring providers, ensuring compliance with the human rights regulations.
- Quality improvement through monitoring and analysis of data and the development and implementation of quality improvement initiatives utilizing the Plan-Do-Study-Act (PDSA) model.

According to the QMP, DBHDS, "has worked with a team of stakeholders to develop guidance for enhanced risk management processes that include uniform risk triggers and thresholds related to individual deaths (including suicide and homicide), use of restraint, medication errors, falls, fractures, choking, aspiration pneumonia, constipation, self-injurious behavior, decubitus ulcers, protective services referrals, and incidents or accidents requiring medical treatment beyond first aid." While some of these triggers are events, such as falls, others would be considered medical diagnoses or changes in medical condition, and others, such as fractures, could be considered injuries. No thresholds are found relevant to the triggers listed. In determining which performance indicators DBHDS uses to measure system performance, the QMP further states that DBHDS considers importance, relevance, measurability and feasibility (of improvement) in selecting measures. An associated QMP work plan is to be reviewed annually and a report submitted back to the QIC. No requirements for reviewing or revising the QMP based on improvements or changes are defined.

Offices of Licensing (OL) and Human Rights (OHR)

Pursuant to §37.2-405, the Office of Licensing,

> "… DBHDS licenses public and private providers of community services throughout Virginia. DBHDS licenses services that provide treatment, training, support and habilitation to individuals who have mental illness, developmental disabilities or substance abuse disorders, to individuals receiving services under the Medicaid DD Waiver, or to individuals receiving services in residential facilities for individuals with brain injuries."

Licensing regulations define the requirements by which OL conducts provider inspections, investigations, visits and reviews. Recent emergency regulations were developed in order to support DBHDS in better meeting SA requirements. Guidance documents developed by DBHDS contain clarification for providers regarding the definition of a serious incident, which includes death and serious injuries.

According to the DBHDS website, "The mission of the Office of Human Rights is to monitor compliance with the human rights regulations by promoting the basic precepts of human dignity, advocating for the rights of persons with disabilities in our service delivery systems, and managing the DBHDS Human Rights dispute resolution program." OHR additionally offers guidance and training to new and existing providers on human rights regulations and abuse and neglect investigations.

According to the QMP, OL and OHR are responsible for quality assurance and reviewing serious injuries reported by providers. OL issues licenses to providers and monitors their compliance with DBHDS' Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services (12VAC35-105) by conducting announced and unannounced inspections, reviewing complaints, conducting investigations and issuing corrective action plans to violators. OHR monitors providers' compliance with the Regulations to Assure the Rights of

Individuals Receiving Services from Providers Licensed, Funded, or Operated by the Department of Behavioral Health and Developmental Services (12VAC35-115) by reviewing complaints and investigating allegations of abuse, neglect and exploitation.

Quality Improvement Committee (QIC)

As the designated oversight body for the DBHDS Quality Management Program, the QIC

- "Reviews reports and analyses focused on systemic quality improvement issues and makes recommendations for actions to improve the quality of services received by individuals;
- Reviews information on the implementation and effectiveness of provider quality improvement programs; identifies opportunities for improvement; and recommends and oversees activities to ensure that all providers (state hospitals, training centers, community service boards (CSBs), and other providers licensed by DBHDS) operate a quality improvement program consistent with the requirements of the DBHDS Licensing Regulations and external credentialing bodies, as applicable; and
- Addresses significant provider service quality issues."

The QMP states QIC meets "quarterly or as often as necessary" and membership includes:

- DBHDS Commissioner (chair)
- Deputy Commissioner (now known as Chief Deputy for Community Behavioral Health Services);
- Assistant Commissioner for Developmental Services (now known as Deputy Commissioner for Developmental Services);
- Assistant Commissioner for Behavioral Health Services (now known as Deputy Commissioner for Facility Services);
- Assistant Commissioner for Quality Management and Development (now known as Assistant Commissioner for Licensing and Compliance);
- Director of the Office of Licensing;
- Director of the Office of Human Rights;
- Director of the Office of Clinical, Quality, and Risk Management;
- DBHDS Medical Director (now known as Chief Clinical Officer);
- Representatives of the RQCs; and
- Up to three, at-large members appointed by the Commissioner who represent the community provider network, individuals and families, and other stakeholders.

Regular reporting to QIC is said to focus on licensing, human rights, QM, RM, mortality, DOJ timelines, RQCs, crisis services, Quality Service Reviews (QSR) and Office of the State Inspector General (OSIG) reports.

Regional Quality Councils (RQC)

According to the QMP:

> "The Commissioner has established five Regional Quality Councils for Developmental Disabilities to identify issues of concern at the regional level, review data, analyze trends, and develop and continuously monitor regional improvement initiatives."

RQC activities are directed by the QIC. RQC operations include the review and assessment of regional data; identification of trends; and recommendations of regional quality improvement initiatives to QIC. RQCs meet quarterly and are open to the public.

The chair of all five RQCs during the review period was the Assistant Commissioner of QMD. Other, nonspecified DBHDS staff serve on the councils and are permanent members. Three-year terms are held by community members of the councils, to include residential providers, day support providers, employment providers, case management providers, CSB quality assurance/improvement staff, individuals receiving services, family members of individuals receiving services and other relevant stakeholders.

Risk Management Review Committee (RMRC)

The Risk Management Review Committee (RMRC) reviews and analyzes data collected from providers relevant to triggers and thresholds and makes recommendations to QIC.

According to the RMRC overview document provided by DBHDS, RMRC's goal is to "improve quality and safety by learning from *past* (emphasis added) performance, errors, and near misses, and to gain awareness of areas of vulnerability in practice and to improve these areas…" Furthermore:

> "All information reviewed by the RMRC is factual information. The Committee does not assess the quality or adequacy of care provided. The sole purpose of the committee is to identify individuals and providers who have experienced trigger events or met thresholds and determine if follow-up beyond continued monitoring is required, the nature of that follow-up and who should provide follow-up."

The RMRC overview document also states that RMRC meets monthly to, "review data and discuss cases." Data elements to be utilized are listed and include facility and community risk data, risk triggers and threshold data produced by the OneSource database (explained on page 9), hospital risk measures, abuse and neglect data and "other relevant risk data." Findings and recommendations are to be reported to QIC. Membership includes representatives from:

- Quality and Risk Management;
- Integrated Health Services;
- Case Management;
- Community Integration;
- OL;
- OHR; and

- Others as recommended by the Office of Quality and Risk Management.

Quality Review Panel (QRP)

According the Quality Review Panel (QRP) charter (December 2016), QRP was established as a result of:

> "…questions about the validity, reliability, and usefulness of the report in decision-making. Reporting that is accurate, easily understood, and presented in a user-friendly format will assist with informing stakeholders generally and the QIC in making informed decisions for systems improvements."

The charter also states the QRP is to, "… develop and implement a standardized process for review and feedback on reports, leading to recommendations for precise reporting, prior to submission of reports to the QIC and its related committees" and that data for reports is extracted from multiple sources of varying degrees of development. Further limiting the benefit of its work is the fact that QRP only makes recommendations and division heads decide whether or not to utilize them. Membership includes representatives from CQIRM, DQV, DBHDS' executive team, Division of Developmental Services, Division of Behavioral Health Services and data analytics staff.

DBHDS Information Systems

SERIOUS INJURY REPORTING:

Pursuant to 12VAC35-105-160[C](2) Reviews by the Department; Requests for Information:

> "Each instance of death or serious injury shall be reported in writing to the department's assigned licensing specialist within 24 hours of discovery… and include the following: the date and place of the individual's death or serious injury; the nature of the individual's injuries and the treatment received; and the circumstances of the death or serious injury."

Serious injury, as defined in 12VAC35-105-20, is: "[A]ny injury resulting in bodily damage, harm, or loss that requires medical attention by a licensed physician, doctor of osteopathic medicine, physician assistant, or nurse practitioner while the individual is supervised by or involved in services, such as attempted suicides, medication overdoses, or reactions from medications administered or prescribed by the service." To the lay person, a serious injury usually implies harm or damage inflicted on a person's body by an external force rather than a consequence of a medical diagnosis.

COMPUTERIZED HUMAN RIGHTS INFORMATION SYSTEM (CHRIS)

Licensed providers report serious injuries (to include serious incidents) and death; human rights complaints; and allegations of abuse, neglect and exploitation to DBHDS via CHRIS, a Web-based event reporting system developed and maintained by DBHDS. According to Navigating CHRIS V5.1, a document available on the DBHDS website, CHRIS is divided into three sections entitled

"Abuse Information," "Complaint Information," and "Death/Injury." Providers must select the appropriate section within which to report injuries and events.

According to the Office of Licensing Online Resource Guide (June 2017), also available on the DBHDS website, providers are advised, "there could be serious incidents [versus serious injuries] which [providers] must report **BOTH** on the Human Rights side of the CHRIS system and the SIR[serious injury report]/Death side of the CHRIS system." Licensing specialists are "automatically" notified by email when a serious injury report is entered into CHRIS.

ONESOURCE DATA WAREHOUSE

DBHDS' OneSource Date Warehouse (OneSource) is a reporting service utilized by DBHDS to create and customize various reports. According to DBHDS' FY 17 Annual Report, OneSource implementation,

> "…provides a reliable and sustainable platform for creating, managing, and leveraging information across its entire scope of strategic and operational domains… [and serves as a] new integrated system, which houses information about all aspects of care, serves as the system of record for statistical and pattern analysis, internal management reporting, and external reporting."

The OneSource Data Warehouse Product Overview (September 2017) states the intent of OneSource is to, "…support decision making processes by integrating data from a variety of operational data sources." These data sources include:

- CHRIS;
- Community Consumer Submission 3 (CCS 3): An extract specification used by DBHDS and CSBs to comply with federal and state reporting requirements;
- Protection and Advocacy Incident Reporting System (PAIRS): DBHDS event management system used to report critical incidents (events requiring medical attention beyond first aid), versus serious incidents or injuries, or deaths to the disAbility Law Center of Virginia, as required by §37.2-709;
- Office of Licensing Information System: DBHDS' OL licensing application and case management system;
- Seclusion/Restraint Database: A database used by DBHDS to store seclusion and restraint data submitted as required by §37.2-400[D], which requires DBHDS-operated, funded and licensed providers to submit seclusion and restraint data to DBHDS;
- Virginia Waiver Management System (WaMS): An electronic system used to manage waivers and the waiver waiting list; and
- Regional Education, Assessment, Crisis Services, and Habilitation (REACH) database: A DBHDS databased used to store REACH information submitted by regional REACH programs.

According to the OneSource Data Warehouse Product Overview presentation given to OSIG by

DBHDS staff, when DBHDS receives data it is “cleansed, standardized, de-normalized, and moved to the data warehouse.” The data is exposed in a “business-friendly format” that allows users, DBHDS subject matter experts or division heads, to customize and create reports. All reports are located in the OneSource Enterprise folder, which contains 26 reports in five subfolders. Each subfolder contains user-specific reports. OneSource reports are submitted to QIC, RQCs, RMRC, MRC and others.

Review Methodology

During this review, OSIG performed extensive research into relevant laws, policies and procedures, regulations and guidelines concerning quality management, risk management and event management systems. Additional resources included, but were not limited to:

- Federal, state and accrediting agency requirements:
    - Social Security Act §1915 (i)(1)(H)(i) Quality Assurance of Home and Community-Based Services Waiver;
    - §1915(c) Home and Community-Based Services Waiver requirements;
    - CMS, HHS §441.745(b)(1) Quality Improvement Strategy;
    - Blueprint for the CMS Measures Management System (May 2017);
    - Quality in Home and Community- Based -Services Authorities Part 1 (January 2017)
    - HCBS Quality Measures Summit (June 17, 2014);
    - Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Services Waivers (March 12, 2014);
    - Risk Management and Quality in HCBS: Individual Risk Planning and Prevention, System-Wide Quality Improvement (February 15, 2005);
    - United States Department of Justice (DOJ) Settlement Agreement. United States of America v. Commonwealth of Virginia (August 23, 2012);
    - Report of the Independent Reviewer on Compliance with the Settlement Agreement: United States v. Commonwealth of Virginia (June 6, 2015);
    - Report of the Independent Reviewer on Compliance with the Settlement Agreement: United States v. Commonwealth of Virginia (December 23, 2016);
    - Report of the Independent Reviewer on Compliance with the Settlement Agreement: United States v. Commonwealth of Virginia. (December 13, 2017); and
    - Report of the Independent Reviewer on Compliance with the Settlement Agreement: United States v. Commonwealth of Virginia. (June 13, 2018).

- DBHDS documents:
    - Quality Management Plan (updated October 20, 2016);
    - FY2017 Quality Management Work Plan Update (Undated);
    - Draft Quality Management Program (July 2018);
    - Draft Quality Improvement Committee Operating Procedures (July 2018);
    - Draft Quality Improvement and Risk Management Framework System Level (revised November 17, 2017);
    - Provider Quality Improvement and Risk Management Framework (Undated);
    - QIC operating procedures, minutes, reports and data utilized (July 2016 — December 2017);
    - RQC guidelines document, minutes, reports and data utilized (July 2016 — December 2017);
    - RMRC overview document, minutes, reports and data utilized (July 2016 — December 2017);

- QRP charter, minutes, reports and data utilized (July 2016 — December 2017);
- DBHDS Office of Licensing Guidance for Serious Incident Reporting (August 6, 2018); and
- DBHDS Office of Licensing Guidance for a Quality Improvement Program (August 6, 2018).

OSIG staff attended QICs, RQCs and RMRC between November 2017 and March 2018. Interviews were also conducted with the following DBHDS staff:

- Acting Commissioner;
- Chief Deputy Commissioner;
- Deputy Commissioner of Developmental Services;
- Assistant Commissioner of Quality Management and Development;
- Director of the Office of Quality and Risk Management;
- Director of Data Analytics and Data Analytics staff;
- Director of the Office of Human Rights and Acting Director of the Office of Licensing; and
- DMAS Office of Long Term Services and Supports senior leadership.

Review Results

OSIG found the current DBHDS system for provider serious injury reporting and the efficiency and effectiveness of the QIC and RQCs to be inefficient, ineffective and in need of comprehensive revision. OSIG identified a number of recommendations that, if implemented, may minimize actual and potential risk points, increase overall effectiveness of the process and improve individuals' safety and freedom from harm. It must be noted that confusion related to variation in definitions, reporting by providers and reports produced and utilized by DBHDS complicated this review. The organization and operations of this system evidenced a lack of clarity in various processes and stalled progress in achieving positive outcomes and improving the safety of individuals served.

Objective 1 – Conduct a review of serious injuries reported by providers serving individuals with developmental disabilities between July 1, 2016, and December 31, 2017.

Observation No. 1A – Serious injuries reported by providers do not correspond with those identified as important by DBHDS

According to the "Risk Management Triggers and Thresholds" section of DBHDS' QMP:

"[DBHDS] has worked with a team of stakeholders to develop guidance for enhanced risk management processes that include uniform risk triggers and thresholds related to individual deaths (including suicide and homicide), use of restraint, medication errors, falls, fractures, choking, aspiration pneumonia, constipation, self-injurious behavior, decubitus ulcers, protective services referrals, and incidents or accidents requiring medical treatment beyond first aid."

In reviewing data and reports in the CHRIS reporting system used by providers to report serious injuries, OSIG identified that the same concerns reported in the 7th Report of the Independent Reviewer on Compliance with the Settlement Agreement (December 6, 2015) remain:

> "The CHRIS reporting form has not been improved since it was created in 2012. It is inadequately designed, inconsistently completed and does not produce reliable incident data. Although widely adopted throughout the licensed provider system, there are several shortcomings with the CHRIS report form... The check boxes are for both incidents (i.e. falls) and for harms (i.e. sprain). The filers, however, rarely check more than one box. The most frequently checked box is "other" and many reports do not have any box checked. These deficiencies, which are well known, contribute to data that are not complete or reliable."

OSIG confirmed with the former OL director that the CHRIS reporting form remains unchanged since the 2012 independent reviewer's (IR's) observation.

According to the Office of Licensing Online Resource Guide (June 2017) (Licensing Online Resources Guide), 32 serious injuries shall be reported by providers in CHRIS. The Licensing

Online Resource Guide contains a link to the DBHDS Serious Injury Guidance (May 2013) (Serious Injury Guidance), which identifies 22 serious injury types. Although it is stated that this is not an exhaustive list, this variation has the potential to be confusing to reporters who may omit reporting of 10 serious injury types not listed.

Serious injuries reported in CHRIS are uploaded into OneSource and integrated into several different reports. Three OneSource reports provide summary or aggregated data regarding serious injuries that could be utilized for system-wide review. Two of the three reports provide aggregate data on 14 serious injury types. Of the 32 serious injury types providers must report in CHRIS, only six are available in OneSource reports that may be used to analyze and support performance improvement.

In an effort to reconcile the variation in reporting requirements, OSIG obtained a copy of a DBHDS document entitled, "Event-based Triggers and Thresholds: Individuals with an Intellectual Disability." The document is undated and remains in draft form. It's stated purpose is, "…to allow the DBHDS to identify patterns and trends in the types of serious events and to identify the accumulated risk of an individual from any single type of event." The triggers and thresholds are to be utilized by the RMRC to review events and patterns of events requiring follow-up action and make appropriate recommendations on an annual basis. The document contains a list of 19 risk domains.

Complicating OSIG's efforts to determine the number of serious injuries DBHDS has identified as triggers requiring reporting, measurement and analysis, the DBHDS Mortality Review Committee (MRC) has identified an additional list of eight "conditions" contributing to the deaths of DD individuals they have reviewed. Of the eight injuries (conditions) identified, four (Urinary Tract Infection (UTI), sepsis, seizures and dehydration) are not included in the list of injuries the QMP states QIC monitors; two (sepsis and dehydration) are not included in the list of serious injuries able to be reported in CHRIS; and three (sepsis, seizure, and dehydration) are not included in the Event-based Triggers and Thresholds: Individuals with an Intellectual Disability. No single document was able to be obtained reconciling these various lists or the various terms utilized by DBHDS to identify serious injuries DBHDS has identified as triggers for reporting and review. OSIG provides the following table as an illustration of variations between databases when presenting conditions identified as high risk by the MRC and DBHDS guidance documents.

Databases		Committee Risk Triggers	Guidance Documents	
CHRIS	**OneSource *(Triggers and Thresholds Report)***	**MRC**	**QMP**	**Event-based Triggers and Thresholds: Individuals with an Intellectual Disability**
Adverse Reaction	Adverse Medication Reaction			Adverse medication event with injury
Aspiration Pneumonia/ Pneumonia	Aspiration Pneumonia	Aspiration pneumonia	Aspiration Pneumonia	Aspiration pneumonia with medical attention
Assault by Client	Founded peer-to-peer aggression			Peer-to peer founded as neglect
	Reported peer-to-peer aggression			Peer-to-peer reported as neglect
Choking	Choking		Choking	Choking with medical attention
Constipation/Bowel Obstruction	Bowel Issues	Constipation/Bowel obstruction	Constipation	Constipation or bowel obstruction with medical attention
Decubitus Ulcer	Decubitus Ulcer	Decubitus ulcers	Decubitus ulcer	Decubitus ulcer with medical attention
Dislocation/Fracture			Fractures	-----
Falls	Fall with fracture/dislocation	Fall injury or fracture	Falls	Fall with fracture or dislocation
	Fall with loss of consciousness			Fall with loss of consciousness
	Fall with injury			Fall with injury
Medication Error			Medication errors	
Seizure/Convulsion		Seizure disorder		
Suicidal Attempt	Self-injurious behavior			
Urinary Tract Infection	UTI	UTI		UTI with medical attention
Other		Dehydration	Self-injurious behavior	Self-injurious behavior
		Sepsis	Death (suicide and homicide)	Unplanned emergency medical visits
			Protective services referrals	Unplanned emergency medical visits for some condition
			Incidents/Accidents requiring medical treatment beyond first aid	Unplanned psychiatric hospitalizations

Variation in reporting language, reporting options and the lack of guidance to providers (and DBHDS), brings into question the accuracy, consistency and reliability of serious injury data and reports utilized by DBHDS to support their QM efforts.

OSIG attempted over the course of this review to obtain access to serious injury data and clarify DBHDS serious injury and reporting definitions, practices and CHRIS/OneSource reports. DBHDS data analytic staff was able to clarify that when providers report serious injuries in CHRIS a notation requests they "check all (emphasis added) that apply." As a result, some OneSource reports may combine two or more serious injury options simultaneously reported for a single injury (condition). For example, reporting a fall with fracture/dislocation is not an option in CHRIS, but the OneSource measure is determined when providers check both fall and fracture/dislocation. As OneSource reports depend on providers selecting all serious injury options that apply in CHRIS, if done in error the risk of inaccuracies increases, as well as the risk of QM performance improvement actions being developed based on reporting errors or focusing on lesser injuries or events. As an example, if an individual has an open wound, a provider may report the injury as any or all of the following:

- Abrasion/cut/scratch;
- Assault by a peer;
- Assault by a staff member;
- Bleeding;
- Contusion/hematoma;
- Fall;
- Fracture;
- Laceration;
- Seizure; or
- Suicide attempt.

Given this, it would be difficult to determine where to focus QM efforts.

OBSERVATION NO. 1A – RECOMMENDATION

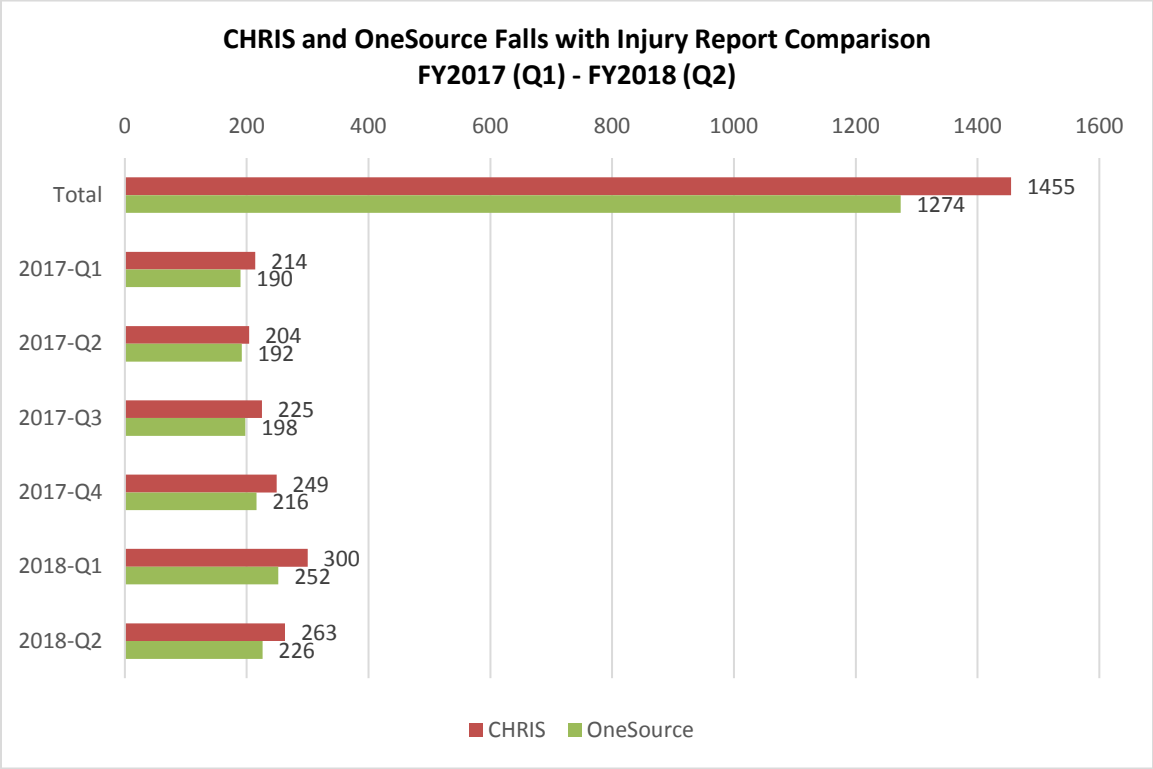
DBHDS should develop a clear and consistent list of serious injuries, prioritized as having significant impact on individuals served by providers. The list should rank serious injuries that 1) have potential for the greatest negative impact on individuals' health and safety; 2) occur with the most frequency; and 3) impact the highest number of individuals. All serious injuries (or changes in medical condition) should have one set of clear, specific and accurate definitions and include exclusionary criteria for reporting serious injuries as "other." Following creation of this list, CHRIS and OneSource reports should be updated to reflect the changes and a guidance document should be developed to reflect the same.

OBSERVATION NO. 1B – CHRIS AND ONESOURCE DATA ARE INCONSISTENT

As serious injuries reported in CHRIS are uploaded into OneSource, the two should be able to consistently and reliably produce reports with the same results for the same parameters. In an effort to test this, OSIG compared CHRIS and OneSource reports on the same serious injuries. The CHRIS *Summary Report of Serious Injuries by Date of Injury* (SI-01Summary) used

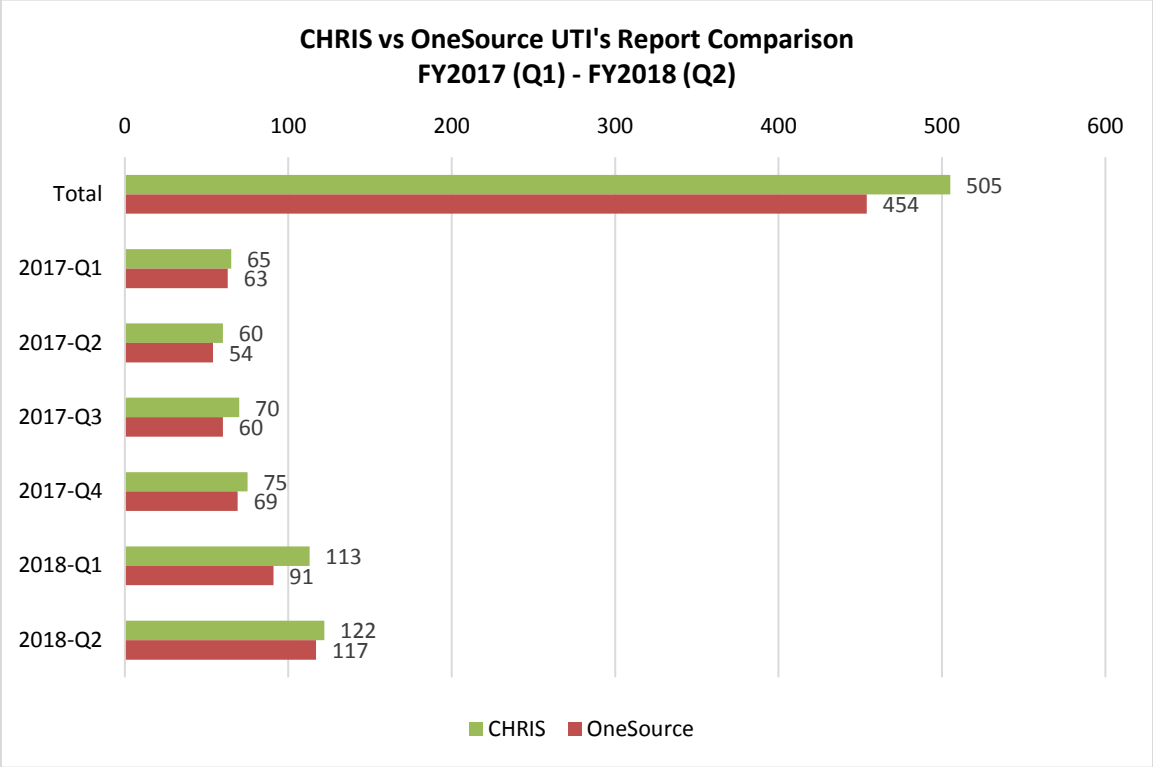
previously, was tested against the OneSource reports entitled, *Provider Injury Rate Report* (DW-0007) and *Triggers and Thresholds Report (DW-0009).*

Of the seven most frequently reported serious injuries in CHRIS, falls and UTIs are the only two listed as options for inclusion in both reports. According to DBHDS data analytic staff, when providers choose the "falls" reporting option in CHRIS, it is uploaded into OneSource as "fall with injury." OSIG utilized these reports to examine falls (with injury) and UTI's quarterly between FY2017 (Q1) and FY2018 (Q2). The results follow.



**Source: CHRIS:* Summary Report of Serious Injuries by Date of Injury (Accessed April 17, 2018). OneSource: *Provider Injury Rate Report (Accessed May 9, 2018); Triggers and Thresholds Report (Accessed May 9, 2018, and May 16, 2018).*

The total number of falls reported in OneSource (1,274) did not match that reported in CHRIS (1,455), a 12.4 percent difference.



**Source: CHRIS:* Summary Report of Serious Injuries by Date of Injury (Accessed April 17, 2018). OneSource: *Provider Injury Rate Report (Accessed May 9, 2018); Triggers and Thresholds Report (Accessed May 9, 2018, and May 16, 2018).*

A similar discrepancy was found in the UTI reports. The OneSource reports identified 454 individuals with a reported UTI during the review period. CHRIS reports identified 505 individuals with a reported UTI in the same period, a 10.1 percent difference.

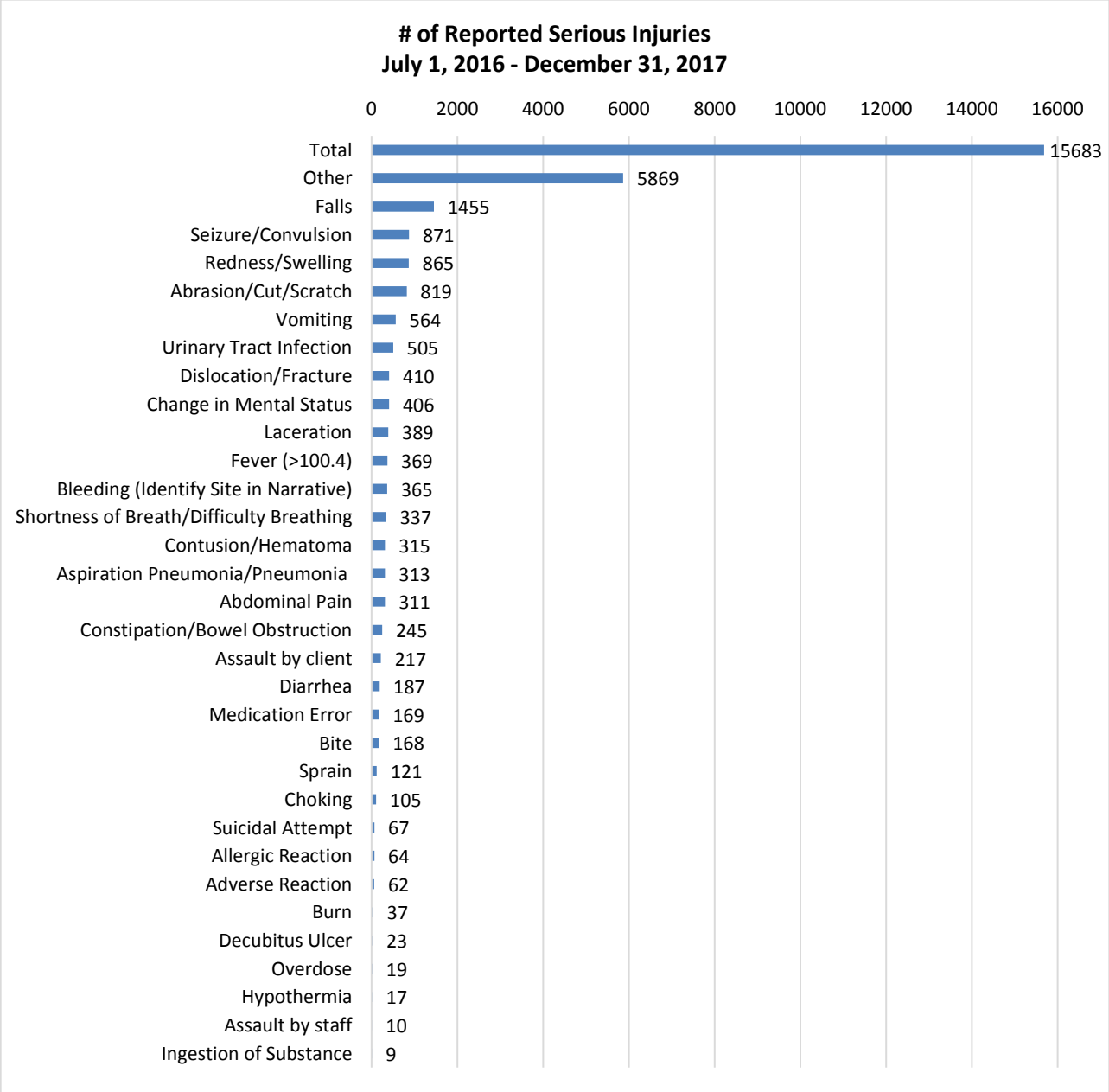
Observation No. 1B – Recommendation

DBHDS should implement appropriate internal controls, safeguards and data validation processes to ensure CHRIS and OneSource produce reliable and consistent reports.

Observation No. 1C – Excluding serious injuries reported as "other," the seven most frequently reported serious injuries provide opportunity for use in developing targeted Performance Improvement Efforts

Summary Report of Serious Injuries by Date of Injury

In an effort to conduct a review of serious injuries and determine patterns and trends, OSIG determined the most relevant report is a CHRIS report entitled, *Summary Report of Serious Injuries by Date of Injury* (SI-01Summary), as no appropriate OneSource report exists. The following is a summary of data from that report.



*Accessed April 17, 2018.

"Other," although undefined, was the most frequently serious injury reported by providers, accounting for 37.4 percent of the total, followed by falls, seizures/convulsions, redness/swelling and abrasion/cut/scratch, vomiting, UTIs and dislocations/fractures. As "Other" is an undefined injury, targeting efforts in this area would prove of little value or impact at the individual level. At a minimum, falls are identified as an event-based trigger by the DBHDS document entitled, "Events-based Triggers and Thresholds: Individuals with an Intellectual Disability," and both falls and UTIs are identified by the MRC as one of eight conditions leading to the death of DD individuals. Excluding "Other," the total number of serious injuries reported equals 9,814. Reported falls and UTIs account for 1,960, or approximately 20 percent of serious injuries

reported. If DBHDS were to develop performance improvement efforts related to these as a start, the potential exists for significant impact.

OBSERVATION 1C- RECOMMENDATION

DBHDS should develop targeted performance improvement efforts related to falls and UTIs as a starting point for its QM efforts.

Objective 2 - Review the efficiency and effectiveness of DBHDS' QIC and RQCs relevant to serious injuries reported by providers serving individuals with developmental disabilities to identify actual and potential risk points and make recommendations to improve the process and individuals' overall safety and freedom from harm.

OBSERVATION NO. 2A –THE DBHDS QIC DOES NOT EFFICIENTLY OR EFFECTIVELY REVIEW OR RESPOND TO SERIOUS INJURIES REPORTED BY PROVIDERS

In order to succeed, a QM system must have an interest and tolerance for exploring negative events and an understanding that performance improvement is largely based upon improving processes. QM systems must have participants well versed in QM principles, although DBHDS leadership reported to OSIG that neither QIC, RQC, RMRC nor other participants in DBHDS QM committees are offered any QM training. As stated previously, the DBHDS QIC is responsible to provide, "…a systemic, coordinated and continuous approach to measure, assess, and improve the processes, structure and outcomes of the statewide system of services and supports," and is the oversight body for the DBHDS system of services and supports.

To the exclusion of the behavioral health segment of the population served, the QIC focused solely on the DOJ population. In an effort to support the DOJ SA and IR recommendations and requirements, DBHDS utilizes the QIC and RQCs as the committees responsible for supporting its QM efforts. Both have been operational since 2012. QIC and the RQCs have scheduled meetings and a schedule of reports upon which they are to build their QM system and improve quality of care and outcomes.

According to QIC's current Operating Procedures (updated April 16, 2015), among other tasks, QIC performs the following "functions:"

- "Review the reports and recommendations of the Mortality Review Committee…
- Review the reports and recommendations of Regional Quality Councils and prepare recommendations for the Commissioner for actions to improve safety and quality improvement of services."

According to DBHDS leadership, long-standing, existing OneSource reports are utilized as QM reports to the QIC and RQCs rather than reports based upon identified requirements, triggers, thresholds and measures relevant to the domains discussed below. DBHDS leadership was specifically asked why reports have not been revised over time to better serve their purposes; it was reported that no expectation exists for subject matter experts/division heads to improve reports based on QRP recommendations, updated knowledge or QM functioning. It was also reported that division directors are responsible for developing reports and DBHDS does not require changes to reports be made upon the suggestion of the QRP.

In response to the DOJ SA, DBHDS focused its QM efforts on quarterly monitoring of the eight domains identified in the DOJ SA. In January 2017, DBHDS revised its existing system, combining and dividing the eight domains into four Key Performance Areas (KPAs). The KPAs, associated domains and QIC (RQC) reports are listed below.

Key Performance Areas and Domains from QIC Reports Schedule (January 2017)

Key Performance Area	Domain	Reports Submitted to QIC
Health & Well-being	1. Safety/Freedom from Harm	Licensing Report
		Human Rights Report
		Risk Management Committee
		Mortality Review Committee
	2. Health and Well-being	Post-Move Monitoring Report
		Enhanced Case Management
	3. Avoiding Crisis	REACH Crisis Reports
Integrated Setting	4. Stability	Housing Report
		Training Center Discharges Report
		Regional Support Team Report
	7. Access to Services	Provider Networks
	8. Provider Capacity	Provider Capacity
Person-Centered Services	5. Choice and Self-Determination	Delmarva Quality Service Reviews
		National Core Indicators
		Quality Improvement Plan
		Regional Quality Council Reports
		DMAS/DBHDS Quality Review Team
Community Inclusion	6. Community Inclusion	Employment Report
		Case Management Employment Report/CE
Source: QIC Report Calendar (January 26, 2017)		

Within the eight domains, safety and serious injuries are monitored under "Safety/Freedom from Harm." According to the QIC report schedule provided to OSIG, this domain is included in the QIC report schedule as follows, and at most, reports from each originating committee or division are submitted twice annually:

KPA	Domain	Report (origin)	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
Health & Well-being	1. Safety/ freedom from harm	Office of Licensing				X						X		
		Office of Human Rights				X						X		
		RMRC	X						X					
		MRC	X						X					

OSIG attended QIC meetings and collected and reviewed reports submitted between July 1, 2016, to December 31, 2017. A review of QIC minutes and the above list of reports submitted to QIC follows.

OFFICE OF LICENSING (OL) REPORTS

During the review period, OL submitted written reports and/or provided verbal presentations at five of the 10 QIC meetings. Of the four OL reports submitted, only one is relevant to serious injuries, the *Serious Injury Reporting Time Summary Report*, which addresses time from injury discovery to a provider's notification in CHRIS. It does not address serious injuries themselves. The *Serious Injury Reporting Time Summary Report*, submitted in four of the 10 meetings, each covering a different time period, provides data relevant to the percentage of serious injuries reported in CHRIS "within 24-48 hours" of incident discovery. This "24-48 hours" timeframe does not allow QIC to ensure providers report serious injuries "in writing to the department's assigned licensing specialist within 24 hours of discovery," as required by 12VAC35-105-160[C](2) and the DOJ SA. Neither does it include any data relevant to the incidence, prevalence or type of serious injury discovered. As a result, this report does not support any review of serious injuries impacting individuals, their occurrence, root cause(s) or development of targeted performance improvement.

On multiple occasions both OSIG and a member of DBHDS leadership inquired about the fact that the report's use of the "24-48 hours" timeframe does not comply with 12VAC35-105-160[C](2), nor does the DOJ SA 24-hour reporting requirement. In response, senior DBHDS staff stated that CHRIS captures the date and time serious injuries occurred; the date (not time) providers discover serious injuries, and the date and time providers report serious injuries in CHRIS. As a result of failing to capture the time of serious injury discovery, DBHDS is unable to prove providers are reporting them as required. DBHDS leadership facilitated no discussion of possible solutions to address this deficiency.

In an effort to validate data presented, OSIG attempted to replicate data provided to QIC by running Death and Serious Incident Reporting Time Summary Report (DW-0026), the OneSource basis for the *Serious Injury Reporting Time Summary Report* for the appropriate

period. Each report contains a count of "total incidents" for each region and the state. Statewide data follows.

Death and Serious Incident Reporting Time Summary Report (OneSource Report- DW-0026) Serious Injury Totals					
Date Report Run by OSIG:	**1/30/2018**	**2/1/2018**	**2/2/2018**	**2/8/2018**	**3/14/2018**
All	8682	8689	8693	8690	8681
DOJ Only	3660	3660	3661	3676	3696
DOJ + CHRIS Waiver Support	3859	3859	4023	3874	3895

Of the five separate occasions OSIG ran the report, none replicated the 3,746 injuries reported in the November 2017, QIC. On only two occasions did reports with the same parameters produce the same data (January 1, 2018, and February 1, 2018). When an explanation was requested, DBHDS staff stated,

> "The date that drives inclusion in the report is the incident date. The data load assesses the source data for the prior two years. If there was an update of the incident date, data on the warehouse is update appropriately."

When asked for possible explanations as to what would precipitate a significant number of providers to revise incident reports 31 weeks following an actual event, no explanation was provided. Once again, the accuracy and reliability of data and reports used to support QM functions of the QIC is called into question.

Office of Human Rights (OHR) Reports

OHR presented reports at five of the 10 QIC meetings held during the review period. Reports submitted include:

- *Retrospective Review of Human Rights Investigations;*
- *Retrospective Review of Abuse/Neglect Investigations;*
- *Retrospective Review of Sexual Abuse Allegation/Investigations;* and
- *FY2017: Abuse/Neglect Allegations for Waiver Services.*

The *Retrospective Review of Human Rights Investigations* and *Retrospective Review of Abuse/Neglect Investigations* appear to be the same report, and were described in QIC meeting minutes as:

> "[A] new 'look-behind' process intended to ensure community provider investigations are being conducted in compliance with Human Rights Regulations and expectations. OHR anticipates that this retrospective review process will identify areas where training or follow-up assistance is warranted in order to improve investigative results and outcomes reported."

The third report, a *Retrospective Review of Sexual Abuse Allegation/Investigations was* reported to be, "…an internal review of sexual abuse allegations" completed following

concerns expressed by the DOJ IR. The report states the review, "consisted of 37 cases reported between July 1, 2016 and December 31, 2016." OHR reported they expanded the population reviewed to include more recent allegations, including allegations reported between April 1, 2017, and June 30, 2017. The report findings section states that, "total of 37 provider investigations were reviewed." No discussion regarding the actual number of allegations occurred in the QIC, so the total number of allegations reviewed is unknown. This is further complicated by the fact that in a later report, the FY2017: Abuse/Neglect Allegations for Waiver Services report, 32 allegations of sexual abuse were reportedly made in FY2017, rather than 37 reported above. Four of the allegations were substantiated. None of these four substantiated cases were analyzed, explained or reviewed by OHR or QIC. OSIG questioned whether any variables relevant to sexual abuse allegations were reviewed by OHR, such as the nature of founded allegations or other variables such as injuries, provider, region, outcomes, etc., in order to assess patterns, root causes or trends and develop targeted performance improvement activities to lessen potential risks to those served. No response or agreement to develop such a report or process was provided by DBHDS.

In addition, neither the QIC chair nor key system leaders on the committee facilitated any discussion of the need to question report discrepancies, the quality or usefulness of reports or substantiated sexual assault allegations impacting individuals served by providers.

Risk Management Review Committee (RMRC) Reports

According to the Risk Management Review Committee Overview provided to OSIG, RMRC's goal is, "to improve quality and safety… and to gain awareness of areas of vulnerability in practice and to improve these areas…" RMRC is tasked with reviewing data from providers and DBHDS-operated facilities, to include risk triggers and thresholds, OHR abuse and neglect data and "other relevant risk data." RMRC's review of triggers and thresholds and related recommendations are to be reported to QIC.

RMRC provided reports at two of 10 QIC meetings held during the review period. The *Report to the DBHDS Quality Improvement Committee (RMRC Report)* contains a summary of triggers and thresholds data by quarter. The report includes data on:

- Restraint use with injury (non-specified);
- Restraint use reported as abuse/neglect;
- Self-injurious behavior (non-specified);
- Peer-to-peer aggression reported as neglect; and
- Peer-to-peer aggression founded for neglect.

No reports were submitted relevant to serious injuries as defined.

In July 2016, RMRC reported to QIC a list of revisions to its review process, to include:

- "Establish reports to allow daily review of Triggers and Thresholds data[.]

- Establish a protocol for the dissemination and immediate follow-up on Triggers and Thresholds[.]
- Develop a tracking mechanism to ensure that all follow-ups are conducted and their outcomes recorded[.]
- Report follow-up action on each event at RMRC meetings[.]
- RMRC meetings will address risk trends and system-wide and provider specific quality improvement efforts.
- Conduct updated research on Triggers and Thresholds and use the data collected thus far to revise Triggers and Thresholds, as needed.
- Update data warehouse reports to allow for daily reviews by Triggers and Thresholds, by individual and by provider[.]
- Review the new processes six months after implementation to assess improvements in process and follow-up."

As RMRC members believed that providers should monitor their own risks, it recommended allowing providers access to their own CHRIS data and alerts to be sent when triggers or threshold are met. Once this process was designed, RMRC would be responsible for monitoring "trends and patterns by providers and possibly individuals who have met Triggers and Thresholds repeatedly over time."

For the remaining 14 months of the review period OSIG was provided no additional RMRC reports submitted to QIC. As RMRC is the only committee specifically charged with reviewing serious injury data, this lack of reporting further negates QIC's ability to effectively monitor and review risks and triggers and develop meaningful plans to improve health and safety.

OBSERVATION 2A- RECOMMENDATION

In order to review and respond to serious injuries reported by providers, the DBHDS QIC should utilize QM principles to identify consistent injury types upon which to develop QIC reports that will efficiently and effectively support analysis and development of performance improvement initiatives. Additionally, QIC members, including committee leadership, should be trained in QM principles, meeting facilitation, risk management and performance improvement. New members should receive the same training prior to meeting attendance.

OBSERVATION NO. 2B – RQCS DO NOT EFFICIENTLY OR EFFECTIVELY RESPOND TO REGIONAL SERIOUS INJURIES REPORTED BY PROVIDERS

According to the DBHDS' QMP, RQCs were established "to identify issues of concern at the regional level, review data, analyze trends, and develop and continuously monitor regional improvement initiatives. An RQC has been established in each of the five Primary DBHDS Regions (as opposed to the Developmental Services Regions or the Health Planning District

Regions) in Virginia." DBHDS' Guidelines for the Operation of Regional Quality Councils states RQCs, "shall focus on improvement of the quality of services for individuals with intellectual or developmental disabilities." No work of the RQCs is related to any other segment of the DBHDS system. Accordingly, RQCs functions are:

"1. To systematically review regional data generated from quality management reports…
2. To assess the data as it relates to the specific region.
3. To identify trends in the region.
4. To monitor quality improvement efforts.
5. To plan and recommend regional quality improvement initiatives or responsive actions in the region for submission to the DBHDS Quality Improvement Committee."

Between November 2017, and February 2018, OSIG attended all five RQCs either in-person or via teleconference. Meeting minutes, reports and presentations from the RQCs between July 1, 2016, and December 17, 2017, were also reviewed. During the first RQC attended by OSIG, a community provider stated she did not understand what the committee was supposed to be doing. When OSIG asked about an RQC charter or training, it was confirmed that despite their multiple-year committee tenure and the committee's years in existence, members had not received any training in quality management, performance improvement, etc., much like QIC members. Additionally, committee members were unaware of the existence of a committee charter, although DBHDS staff referenced operational guidelines but could not recall their content. In all five meetings, the same data, reports and presentations to QIC were submitted to the RQCs in their entirety. As a result, RQCs were also unable to track, trend or identify serious-injury patterns in their specific regions, make comparisons of serious injuries by quarter or develop targeted performance improvement plans to benefit those served in their regions. While some reports contained data by region, the data presented was not connected to serious injuries, leaving RQCs unable to, "plan and recommend regional quality improvement initiatives or responsive actions" to QIC as set forth in RQC guidelines. RQC FY2017 (Q1) meeting minutes contained 45 total "recommendations," all in reference to OL reports and taken from committee discussions and requests for improved reports, rather than the actual reports utilized and any analysis, review of root causes or RQC recommendations for action to the QIC. The following are examples of what were reported to be recommendations made from RQCs to QIC:

- "Provide ongoing guidance on what should be reported;"
- "Recommend unduplicated counts and ratios for SIR reports;"
- "Review requirement for 24 hour reporting if no one is looking at the data until the next business day (weekends/holidays);"
- "Provide guidance:
  - What should be reported -- lack of consistency across the region on this - CHRIS report says Serious Injury not Serious Incident and CHRIS report only has boxes for injuries;
  - Review medication error reporting -- currently reported as neglect, which has staff ramifications;

    - Work with DMAS on the new requirement from Magellan, which requires duplicate reporting of adverse events and outcomes (add to CHRIS report if this person is Magellan so that a report could be generated and faxed to Magellan);"
- "For Serious Injury and deaths [reports], recommend breaking out by provider and location;"
- "The SIR report says serious injury but the report indicates the report is serious incident. Recommend clarification on what is included and what needs to be reported;" and
- "Recommend more clarity on what should be reported injury vs incidents."

Despite a rising number of serious injuries reported by providers, none of these recommendations resulted in the requested change.

OBSERVATION 2B- RECOMMENDATION

RQCs should be provided with consistent, region-specific data, reports and presentations related to specific serious injuries. Reports should support quarterly and annual analysis, trending and development of performance improvement plans related to significant injuries and support comparison to other regions. RQC members, including committee leadership, should be trained in QM principles, facilitation, risk management and performance improvement. New members should receive the same training prior to meeting attendance.

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January 30, 2019

Michael C. Westfall, CPA
State Inspector General
Office of the State Inspector General
101 North 14th Street, 7th Floor
Richmond, Virginia 23219

Dear Mr. Westfall:

I am writing to respond to the recommendations contained in OSIG Report 2019-BHDS-002 Review of Serious Injuries Reported by Licensed Providers of Developmental Services. DBHDS is in agreement with many of the recommendations that you have suggested and we have been taking steps over the past year to address these issues. Since the end of the review period, DBHDS has amended its licensing regulations to improve the reporting of serious injuries and incidents and has made organizational changes which have included moving the quality improvement functions under our chief clinical officer. Please see below for a summary of actions related to your recommendations that we have either already initiated or are planning to implement.

Observation No. 1A – Serious injuries reported by providers do not correspond with those identified as important by DBHDS.
Observation No. 1A – Recommendation: DBHDS should develop a clear and consistent list of serious injuries, prioritized as having significant impact on individuals served by providers... All serious injuries (or changes in medical condition) should have one set of clear, specific and accurate definitions and include exclusionary criteria for reporting serious injuries as "other."

DBHDS concurs with this observation and recommendation. The CHRIS reporting system was originally designed as a system to report single events to alert human rights advocates to individual concerns that needed follow-up. The initial goal was to shift the reporting of human rights complaints from a paper based form that was faxed in, to an electronic one. Over time DBHDS added the reporting of serious injuries to this system and most recently, has attempted to use this data for statistical reporting purposes. However; as noted in the report, the lack of clear definitions of terms, as well confusing interface that is not designed for collecting aggregate statistical data, makes it impossible to collect valid and reliable data regarding system-wide events.

DBHDS has already begun work to address this issue. On September 1, 2018, DBHDS promulgated emergency amendments to its licensing regulations, which expanded and better defined the types of serious incidents that are required to be reported. On August 6, 2018, DBHDS requested public comment on a guidance document on reporting serious incidents, based upon the resulting comments, final guidance on reporting serious incidents was published on December 28, 2018

(http://townhall.virginia.gov/L/GetFile.cfm?File=GuidanceDocs\720\GDoc_DBHDS_6415_v1.pdf). DBHDS is currently in the process of re-designing the CHRIS reporting form to align with the new licensing reporting requirements and guidance and to better capture valid statistical data. Planned enhancements include a clear definition of reportable items; separation of harms from the incident or event that led to the harm; and better organization of the form to reduce the frequency of reporting "other." We will provide the proposed changes to DBHDS IT developers before January 31, with expected implementation of the revised form by May 31, 2019. A guidance document will be developed to educate providers on the use of the new reporting form.

Once the new reporting form has been developed, OneSource reports will be updated to accurately capture these changes.

Observation No. 1B – CHRIS and OneSource data are inconsistent

Observation No. 1B Recommendation: DBHDS should implement appropriate internal controls, safeguards and data validation processes to ensure CHRIS and OneSource produce reliable and consistent reports.

DBHDS acknowledges the need for improvement in some of the data warehouse reports. Several of the reports cited in 2019- BHDS-002 were in the process of being retired at the time of the review due to changes in business processes and requirements; they have since been removed from the reporting platform. Once the new CHRIS reporting form and underlying data tables have been developed; the OneSource team will develop and document updated reports to capture serious incidents and injuries based upon the new requirements. Validation will be assure that the OneSource reports are consistent with the underlying CHRIS data and a process will be set-up for routine, ongoing validation to assure the reliability and validity of ongoing reporting.

Observation No. 1C - Excluding serious injuries reported as "other," the seven most frequently reported serious injuries provide opportunity for use in developing targeted performance Improvement efforts.

Observation No. 1C Recommendation: DBHDS should develop targeted performance improvement efforts related to falls and UTIs as a starting point for its QM efforts.

As noted above, and in the report, the data collected through CHRIS is not statistically valid or reliable; is limited by the lack of definition of terms, and the high rate of "other" responses. With "other" representing over 1/3 of all reported serious injuries and being four times greater than the next highest category, it is difficult to know what the resulting ranking of injuries would look like if "other" was disaggregated into reportable categories. However; despite that caveat, the OSIG correctly notes that both falls and urinary tract infections have been separately identified as areas of concern related to mortality of individuals with developmental disabilities.

DBHDS, through the Quality Improvement Division, will review data related to reported serious injuries along with other data, such as mortality review data to recommend the development of targeted performance improvement efforts. This will occur by June 30, 2019.

Observation No. 2A –The DBHDS QIC does not efficiently or effectively review or respond to serious injuries reported by providers.

Observation No. 2A Recommendation: The DBHDS QIC should utilize QM principles to identify consistent injury types upon which to develop QIC reports that will efficiently and effectively support analysis and development of performance improvement initiatives. Additionally, QIC members, including committee leadership, should be trained in QM principles, meeting facilitation, risk management and performance improvement. New members should receive the same training prior to meeting attendance.

As noted in the response to recommendation No. 1A, DBHDS has revised provider reporting requirements in its licensing regulations and is currently in the process of redesigning the CHRIS reporting form to better identify incidents and injuries that will support quality improvement initiatives. DBHDS is also in the process of developing a centralized triage process to review all serious incidents at the time they are reported (currently the review of individual incidents is distributed across all licensing specialists resulting in variable response). The triage team will review each reported incident, make a determination as to which require further review or investigation, and track to ensure appropriate follow-up. The team will also track data over time to identify and ensure follow-up on patterns or trends within specific providers, and across the larger system.

Beginning in January 2018, DBHDS purchased a subscription to the Institute for Healthcare Improvement's *Passport to IHI Training.* The subscription provided access to all DBHDS central office staff to the full range of IHI quality improvement webinars and other on-line training activities. In 2018 a total of 44 DBHDS staff participated in nine different offerings, including *Root Cause Analyses and Actions, Quality Improvement Essentials, Leading Quality Improvement, Strategies for Running Successful Improvement Projects,* and others. DBHDS will continue this subscription in 2019 and will identify specific offerings that may be useful for QIC members.

In addition, DBHDS is in the process of updating the Quality Management Plan. This includes, but is not limited to a restatement of agency commitment of a culture of quality, quality improvement principles, DBHDS organizational chart, DBHDS committee structures and charters, website for applicable regulations, and a list of regularly used acronyms. All quality committees, including the Quality Improvement Committee (QIC) and Regional Quality Council (RQC) charters and membership will be updated. Upon completion, the members of the respective committees will receive a copy of the updated charter(s) which will include their roles and responsibilities.

In addition to the above recommendation, the OSIG report cites concerns with existing DBHDS reports that have been presented to the QIC:

- *The Office of Licensing report on timeliness of serious injury reports calculates the percentage of providers reporting incidents within 24-48 hours, not the 24 hours that is required by regulation.*

As noted in the OSIG report, the current CHRIS form captures only the day, but not the time that the provider was notified of the reportable injury. Therefore it has not been possible to calculate the percentage of providers that report injuries within 24 hours. This is being addressed in the revised CHRIS reporting form, which will now capture both the date and time that a provider was notified or made aware of a reportable injury or incident. Future reports will assess the percentage of providers reporting within the required 24 hour time period.

Observation No. 2B – RQCs do not efficiently or effectively review or respond to serious injuries reported by providers.

Observation No. 2B Recommendation: RQCs should be provided with consistent, region-specific data, reports and presentations related to specific serious injuries. Reports should support quarterly and annual analysis, trending and development of performance improvement plans related to significant injuries and support comparison to other regions. RQC members, including committee leadership, should be trained in QM principles, facilitation, risk management and performance improvement. New members should receive the same training prior to meeting attendance.

Revisions to licensing reporting requirements and the CHRIS reporting form will result in the ability for DBHDS to capture more reliable data on serious incidents and injuries. New reports will be created by the OneSource data warehouse, which will include region specific data that will be made available to RQCs. New regional reporting should be available by the end of the 2nd quarter of FY2020.

DBHDS has been working with RQCs to increase participation, data reporting and the development of quality improvement initiatives for improved efficiency and effective response to serious injuries. Oversight of the activities of the RQC will be directed by the Quality Improvement Committee to monitor progress and improvement.

Should you have any questions regarding actions, please feel free to contact Dev Nair, PhD., Assistant Commissioner, Compliance, Legislative, and Regulatory Affairs at 804-225-3857, or by email at dev.nair@dbhds.virginia.gov.

Sincerely,

S. Hughes Melton, MD, MBA

c: The Honorable Ralph Northam, MD, Governor
Clark Mercer, Chief of Staff to Governor Northam
Suzette Denslow, Deputy Chief of Staff to Governor Northam
The Honorable Rosalyn R. Dance, Chair, Joint Commission on Health Care
The Honorable T. Scott Garrett, Vice Chair, Join Commission on Health Care
The Honorable R. Creigh Deeds, Chair, Join Subcommittee to Study Mental Health Services in the 21st Century
The Honorable Robert B. Bell, Vice Chair, Joint Subcommittee to Study Mental Health Services in the 21st Century
Daniel Carey, MD, Secretary of Health and Human Resources
Alexis Aplasca, MD, Chief Clinical Officer, DBHDS
Heidi Dix, Deputy Commissioner, Compliance, Legislative and Regulatory Affairs, DBHDS
Dev Nair, PhD, Assistant Commissioner (Licensing), DBHDS
Heather Norton, Acting Deputy Commissioner of Developmental Services, DBHDS
Alvie Edwards, Director, Internal Audit, DBHDS