

## Key Regulatory Compliance Checklist for Provider Risk Management Processes

### ATTACHMENT A

Settlement Agreement Provision	Indicator	Indicator Text	Regulation Number
V.B.	3.a.ii	The provider has conducted at least quarterly review of all level I serious incidents, and a root cause analysis of all level II and level III serious incidents	12VAC35-105-160. C
V.B.	3.a.iii	The root cause analysis, when required by the Licensing Regulations, includes i) a detailed description of what happened; ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and iii) identified solutions to mitigate its reoccurrence.	12VAC35-105-160. E
V.C.1	1.a-c	<p>The Licensing Regulations require all licensed providers, including CSBs, to implement risk management processes, including:</p> <ul style="list-style-type: none"> <li>a. identification of a person responsible for the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis;</li> <li>b. implementation of a written plan to identify, monitor, reduce, and minimize harms and risks of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability; and</li> <li>c. conducting annual systemic risk assessment reviews, to identify and respond to practices, situations, and policies that could result in harm to individuals receiving services.</li> </ul> <p>Risk assessments reviews shall address: the environment of care; clinical assessment or reassessment processes; staff competence and adequacy of staffing; the use of high risk</p>	12VAC35-105-520 A - D

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		procedures, including seclusion and restraint; and a review of serious incidents. Risk assessments also incorporate uniform risk triggers and thresholds as defined by DBHDS. See 12 VAC 35-105- 520 found at <a href="http://register.dls.virginia.gov/details.aspx?id=6997">http://register.dls.virginia.gov/details.aspx?id=6997</a> .		
V.C.1	4	At least 86% of DBHDS-licensed providers of DD services have been assessed for their compliance with risk management requirements in the Licensing Regulations during their annual inspections. Inspections will include an assessment of whether providers use data at the individual and provider level, including at minimum data from incidents and investigations, to identify and address trends and patterns of harm and risk of harm in the events reported, as well as the associated findings and recommendations. This includes identifying year-over-year trends and patterns and the use of baseline data to assess the effectiveness of risk management systems. The licensing report will identify any identified areas of non-compliance with Licensing Regulations and associated recommendations.	12VAC35-105-520 A - D	See requested documentation for provision V.C.1 indicator 1.a-c.
V.C.4	3	Providers that have been determined to be non-compliant with risk management requirements (as outlined in V.C.1, indicator #4) for reasons that are related to a lack of knowledge, will be required to demonstrate that they complete training offered by the Commonwealth, or other training determined by the Commonwealth to be acceptable, as part of their corrective action plan.	12VAC35-105-520 A - D	<ul style="list-style-type: none"> <li>Evidence of completion of required training, if applicable.</li> </ul>
V.C.4	4	Providers that have been determined to be non-compliant with requirements about training and expertise for staff responsible for the risk management function (as outlined in V.C.1, indicator #1.a) and providers that have been determined to be non-compliant with requirements about conducting root cause analyses as required by 12 VAC 35-105-160(E) will be required to demonstrate that they complete training offered by the Commonwealth, or other training determined by the Commonwealth to be acceptable, as part of their corrective action plan process.	12VAC35-105-520 A – D 12 VAC 35-105-160 E	<ul style="list-style-type: none"> <li>Evidence of completion of required training, if applicable.</li> </ul>

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V.E.1	1	<p>DBHDS, through its regulations, requires DBHDS-licensed providers, including CSBs, to have a quality improvement (QI) program that:</p> <p>a. Is sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis;</p> <p>b. Uses standard QI tools, including root cause analysis;</p> <p>c. Includes a QI plan that:</p> <ul style="list-style-type: none"> <li>i. is reviewed and updated annually,</li> <li>ii. defines measurable goals and objectives;</li> <li>iii. includes and reports on statewide performance measures, if applicable, as required by DBHDS;</li> <li>iv. monitors implementation and effectiveness of approved corrective action plans; and</li> <li>v. includes ongoing monitoring and evaluation</li> </ul>	12VAC35-105-620	<ul style="list-style-type: none"> <li>• Current quality improvement program</li> <li>• Current quality improvement plan</li> <li>• Evidence of the utilization of quality improvement tools</li> <li>• Root cause analysis for all level II and level III serious incidents</li> <li>• Documented evidence of compliance of implementing a process to regularly evaluate the progress towards meeting those goals and objectives</li> <li>• Evidence of the incorporation of previously pledged corrective actions</li> <li>• Documented evidence of input from individuals and, if applicable, ARs.</li> <li>• Documented evidence of implementation of improvements indicated with the QIP</li> </ul>
V.E.1	3	On an annual basis at least 86% of DBHDS licensed providers of DD services have been assessed for their compliance with 12 VAC 35-105- 620 during their annual inspections.	12VAC35-105-620	See requested documentation for provision V.E.1 indicator 1.
V.E.1	4	On an annual basis, at least 86% of DBHDS-licensed providers of DD services are compliant with 12 VAC 35-105-620. Providers that are not compliant have implemented a Corrective Action Plan to address the violation.	12VAC35-105-620	See requested documentation for provision V.E.1 indicator 1.
V.G. 3	1-3	The DBHDS Office of Licensing (OL) develops a checklist to assess the adequacy of individualized supports and services (including supports and services for individuals with intensive medical and behavioral needs) in each of the domains listed in Section V.D.3 for which it has corresponding regulations. Data from this checklist will be augmented at least annually		<b>See Attachment B</b>

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		<p>by data from other sources that assess the adequacy of individual supports and services in those domains not covered by the OL checklist.</p> <p>2. The DBHDS Office of Licensing uses the checklist during all annual unannounced inspections of DBHDS-licensed DD service providers, and relevant items on the checklist are reviewed during investigations as appropriate. Reviews are conducted for providers at least annually pursuant to 12VAC35-105-70.</p> <p>3. DBHDS informs providers of how it assesses the adequacy of individualized supports and services by posting information on the review tool and how it is assessed on the DBHDS website or in guidance to providers. DBHDS has informed CSBs and providers of its expectations regarding individualized supports and services, as well as the sources of data that it utilizes to capture this information.</p>		
V.H.1	8	<p>Per DBHDS Licensing Regulations, DBHDS licensed providers, their new employees, contractors, volunteers, and students shall be oriented commensurate with their function or job-specific responsibilities within 15 business days. The provider shall document that the orientation covers each of the following policies, procedures, and practices:</p> <ol style="list-style-type: none"> <li>a. Objectives and philosophy of the provider;</li> <li>b. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual’s record;</li> <li>c. Practices that assure an individual’s rights including orientation to human rights regulations;</li> <li>d. Applicable personnel policies;</li> <li>e. Emergency preparedness procedures;</li> <li>f. Person-centeredness;</li> <li>g. Infection control practices and measures;</li> <li>h. Other policies and procedures that apply to specific positions and specific duties and responsibilities; and</li> <li>i. Serious incident reporting, including when, how, and under what circumstances a serious incident report must be submitted and the consequences of failing to report a serious</li> </ol>	12VAC35-105-440	<ul style="list-style-type: none"> <li>• Provider’s policy</li> <li>• Orientation records</li> <li>• Employee files</li> </ul>

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		incident to the department in accordance with the Licensing Regulations		
V.H.1	9	The Commonwealth requires through the DBHDS Licensing Regulations specific to DBHDS-licensed providers that all employees or contractors who are responsible for implementing an individual's ISP demonstrate a working knowledge of the objectives and strategies contained in each individual's current ISP, including an individual's detailed health and safety protocols.	12VAC35-105-665.D.	<ul style="list-style-type: none"> <li>• Individualized services plans</li> <li>• Individual progress notes</li> </ul>
V.H.1	12	At least 86% of DBHDS licensed providers receiving an annual inspection have a training policy meeting established DBHDS requirements for staff training, including development opportunities for employees to enable them to support the individuals receiving services and to carry out their job responsibilities. These required training policies will address the frequency of retraining on serious incident reporting, medication administration, behavior intervention, emergency preparedness, and infection control, to include flu epidemics. Employee participation in training and development opportunities shall be documented and accessible to the department. DBHDS will take appropriate in action in accordance with Licensing Regulations if providers fail to comply with training requirements required by regulation.	12VAC35-105-450	<ul style="list-style-type: none"> <li>• Training policy</li> <li>• Employee files</li> <li>• Training records</li> </ul>