

ATTACHMENT A

Regulation Number	Regulation text	Documents Used to Determine Compliance Requiring Electronic Submission
12VAC35-105-160.C	The provider shall collect, maintain, and review at least quarterly all serious incidents, including Level I serious incidents, as part of the quality improvement program in accordance with 12VAC35-105-620 to include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.	<p>Last quarterly reviews of all serious incidents including Level I, Level II and Level III incidents.</p> <p>If provider did not have any level I, II, or III serious incidents to review during the last quarter, they will provide a copy from the previous quarter.</p>
12VAC35-105-160.D.2	The provider shall collect, maintain, and report or make available to the department the following information: Level II and Level III serious incidents shall be reported using the department's web- based reporting application and by telephone or email to anyone designated by the individual to receive such notice and to the individual's authorized representative within 24 hours of discovery. Reported information shall include the information specified by the department as required in its web-based reporting application, but at least the following: the date, place, and circumstances of the serious incident. For serious injuries and deaths, the reported information shall also include the nature of the individual's injuries or circumstances of the death and any treatment received. For all other Level II and Level III serious incidents, the reported information shall also include the consequences that resulted from the serious incident. Deaths that occur in a hospital as a result of illness or injury occurring when the individual was in a licensed service shall be reported.	<p>Provider does not need to submit level II or level III serious incidents. The specialist will review incidents within CHRIS.</p> <p>Note: The Incident Management Unit (IMU) monitors reporting of serious incidents each business day. Please review Serious Incident Report Guidance and the Guidance on Incident Reporting Requirements.</p> <p>In addition, if, during an annual inspection or an investigation, the licensing specialist identifies serious incidents that should have been reported, but were not reported at all, or that were not reported within 24 hours of their occurrence and for which a licensing report has not already been issued, then the Licensing Specialist will issue a licensing report for late reporting.</p>
12VAC35-105-160.E.	A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.	<p>Two most recent root cause analyses for Level II and Level III serious incidents that occurred during the provision of a service or on the provider's premises for the individuals being reviewed.</p> <p>If there are not any RCAs for the individuals being reviewed, provide the two most recent RCAs completed.</p>

12VAC35-105-160.E.1	<p>A root cause analysis shall be conducted by the provider within 30 days of discovery of Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.</p> <p>The root cause analysis shall include at least the following information: A detailed description of what happened; 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 Identified solutions to mitigate its reoccurrence and future risk of harm when applicable.</p>	<p>Two most recent root cause analyses for Level II and Level III serious incidents that occurred during the provision of a service or on the provider's premises.</p> <p>NOTE: In accordance with DOJ Settlement Agreement Indicator V.C.4.4: Providers that have been determined to be non-compliant with requirements of 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. Please refer to DBHDS Risk Management Attestation form and instructions posted on OL webpage.</p>
12VAC35-105-160.E.2	<p>The provider shall develop and implement a root cause analysis policy for determining when a more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors, should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when:</p> <p>A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location within a six-month period; Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six-month period; A threshold number, as specified in the provider's policy based on the provider's size, number of locations, service type, number of individuals served, and the unique needs of the individuals served by the provider, of similar Level II or Level III serious incidents occur across all of the provider's locations within a six-month period; or A death occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.</p>	<p>Root cause analysis policy; and</p> <p>A root cause analysis completed as a result of a threshold being met. If applicable</p>
12VAC35-105-160.J	<p>The provider shall develop and implement a serious incident management policy, which shall be consistent with this section and which shall describe the processes by which the provider will document,</p>	<p>Serious incident management policy.</p>

	analyze, and report to the department information related to serious incidents	
12VAC35-105-170.G	The provider shall implement their written corrective action plan for each violation cited by the date of completion identified in the plan.	Evidence that any CAPs from past year were implemented.
12VAC35-105-170.H	<p>The provider shall monitor implementation and effectiveness of approved corrective actions as part of its quality improvement program required by 12VAC35-105-620. If the provider determines that an approved corrective action was fully implemented, but did not prevent the recurrence of a regulatory violation or correct any systemic deficiencies, the provider shall:</p> <ol style="list-style-type: none"> 1. Continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies; or 2. Submit a revised corrective action plan to the department for approval. 	<p>Evidence that any CAPs from the past year were implemented in accordance with what is written in provider's QI Plan to monitor implementation and effectiveness of approved corrective action plans</p> <p>Proof that CAP(s) were updated in accordance with 170.H.1 if the CAP was not effective or</p> <p>Proof of submission of a revised corrective action plan submitted to OL specialist if the CAP was not effective.</p>
12VAC35-105-280.A-K	<ol style="list-style-type: none"> A. The physical environment, design, structure, furnishings, and lighting shall be appropriate to the individuals served and the services provided. B. The physical environment shall be accessible to individuals with physical and sensory disabilities, if applicable. C. The physical environment and furnishings shall be clean, dry, free of foul odors, safe, and well-maintained. D. Floor surfaces and floor coverings shall promote mobility in areas used by individuals and shall promote maintenance of sanitary conditions. E. The physical environment shall be well ventilated. Temperatures shall be maintained between 65°F and 80°F in all areas used by individuals. F. Adequate hot and cold running water of a safe and appropriate temperature shall be available. Hot water accessible to individuals being served shall be maintained within a range of 100-110°F. If temperatures cannot be maintained within the specified range, the provider shall make provisions for protecting individuals from injury due to scalding. 	<p>Virtual inspection of location will be conducted by specialist unless this service is for a home or non center-based service</p> <p>*providers must have thermometer and run water in several locations during inspection</p>

	<p>G. Lighting shall be sufficient for the activities being performed and all areas within buildings and outside entrances and parking areas shall be lighted for safety.</p> <p>H. Recycling, composting, and garbage disposal shall not create a nuisance, permit transmission of disease, or create a breeding place for insects or rodents.</p> <p>I. If smoking is permitted, the provider shall make provisions for alternate smoking areas that are separate from the service environment. This subsection does not apply to home-based services.</p> <p>J. For all program areas added after September 19, 2002, minimum room height shall be 7-1/2 feet.</p>	
12VAC35-105-440	<p>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"> 1. Objectives and philosophy of the provider; 2. Practices of confidentiality including access, duplication, and dissemination of any portion of an individual's record; 3. Practices that assure an individual's rights including orientation to human rights regulations; 4. Applicable personnel policies; 5. Emergency preparedness procedures; 6. Person-centeredness; 7. Infection control practices and measures; 8. Other policies and procedures that apply to specific positions and specific duties and responsibilities; and 9. 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 incident to the department in accordance with this chapter. 	Evidence of orientation for new employees, contractors, volunteers, and students with the completion date.
12VAC35-105-450	<p>The provider shall provide training and development opportunities for employees to enable them to support the individuals receiving services and to carry out their job responsibilities. The provider shall develop a training policy that addresses the frequency of retraining on serious incident reporting, medication administration, behavior intervention,</p>	<p>Training policy</p> <p>Training records</p>

	emergency preparedness, and infection control, to include flu epidemics. Employee participation in training and development opportunities shall be documented and accessible to the department.	
	12VAC35-105-520. Risk management.	
12VAC35-105-520.A	The provider shall designate a person responsible for the risk management function who has completed department approved training, which shall include training related to risk management, understanding of individual risk screening, conducting investigations, root cause analysis, and the use of data to identify risk patterns and trends.	<p>Name of the person responsible for the risk management function.</p> <p>Job description for this employee must reflect that all or part their responsibilities include those of the risk management function.</p> <p>A completed (signed and dated) DBHDS Risk Management Attestation.</p> <p>NOTE: In accordance with DOJ Settlement Agreement Indicator V.C.4.4: Providers that have been determined to be non-compliant with requirements of 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.</p>
12VAC35-105-520.B	The provider shall implement a written plan to identify, monitor, reduce, and minimize harms and risk of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability.	<p>Risk management plan.</p> <p>As required by 12VAC35-105-620, a provider's risk management plan may be a stand-alone risk management plan or it may be integrated into the provider's overall quality improvement plan. Risk management plans and overall risk management programs should reflect the size of the organization, the population served, and any unique risks associated with the provider's business model.</p>
12VAC35-105-520.C	<p>The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:</p> <ol style="list-style-type: none"> 1. The environment of care; 2. Clinical assessment or reassessment processes; 3. Staff competence and adequacy of staffing; 4. Use of high risk procedures, including seclusion and restraint; and 5. A review of serious incidents. 	<p>Annual Risk assessment review completed within the past 365 days.</p> <p>This review should include consideration of harms and risks identified and lessons learned from the provider's quarterly reviews of all serious incidents conducted pursuant to 12VAC35-105-160.C., including an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents.</p> <p>Any updates, as appropriate, made since the last review as a result of the provider identifying new risk areas that could result in the risk of harm to individuals receiving services. An example may be new risk areas identified as part of the quarterly review of serious incidents that were not already covered and how the provider plans to respond to serious incidents.</p>

12VAC35-105-520.D	The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department.	<p>Proof the systemic risk assessment process incorporates uniform risk triggers and thresholds as defined by the department.</p> <p>As presented during trainings and posted in in the QI-RM training (slide 37) DBHDS has defined risk triggers and thresholds as care concerns which are identified through the IMUs review of serious incident reporting.</p> <p>Therefore, systemic risk assessment shall include review of risk triggers that were met and how they were addressed.</p> <p>Providers are expected to have revised their annual systemic risk assessment based on Final regulations effective 11/1/2020.</p>
12VAC35-105-520.E	The provider shall conduct and document that a safety inspection has been performed at least annually of each service location owned, rented, or leased by the provider. Recommendations for safety improvement shall be documented and implemented by the provider.	Evidence of annual safety inspection of all licensed locations for this service; and Documentation of implementation of any annual safety inspection recommendations.
12VAC35-105-610	Individuals receiving residential and day support services shall be afforded opportunities to participate in community activities that are based on their personal interests or preferences. The provider shall have written documentation that such opportunities were made available to individuals served.	<p>Proof of participation in community activities in accordance with the individual's ISP.</p> <p>This applies to residential and day support services.</p> <p>If providers have not had the opportunity to participate in community activities due to COVID, there must be documentation of alternatives provided to individuals based on individuals preferences and identified needs.</p>
12VAC35-105-620.A	The provider shall develop and implement written policies and procedures for a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.	<p>Current QI polices and procedures (that demonstrate provider has a program).</p> <p>A quality improvement (QI) program is the structure used to implement quality improvement efforts. The structure of the program shall be documented in the provider's policies.</p>
12VAC35-105-620.B	The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan.	<p>Current QI policies and procedures (that demonstrate provider has a program).</p> <p>Evidence of the utilization of quality improvement tools, ex. Completed root cause analysis (RCA), Plan Do Check Act (PDCA).</p>
12VAC35-105-620.C	<p>The quality improvement plan shall:</p> <ol style="list-style-type: none"> 1. Be reviewed and updated at least annually; 2. Define measurable goals and objectives; 	Current quality improvement plan.

	<ol style="list-style-type: none"> 3. Include and report on statewide performance measures, if applicable, as required by DBHDS; 4. Monitor implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and 5. Include ongoing monitoring and evaluation of progress toward meeting established goals and objectives. 	**12VAC35-105-20 defines a quality improvement plan as “a detailed work plan developed by provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports, and health status of the individuals receiving services.”
12VAC35-105-620.D	<p>The provider's policies and procedures shall include the criteria the provider will use to</p> <ol style="list-style-type: none"> 1. Establish measurable goals and objectives ; 2. Update the provider's quality improvement plan; and 3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170. 	<p>QI policies and procedures responsive to regulatory requirements.</p>
12VAC35-105-620.E	<p>Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated.</p>	<p>QI Plan</p> <p>Proof that input was requested from individuals/AR and documentation of implemented improvements made as a result of analysis.</p>
12VAC35-105-645.B.1-5	<p>B. The provider shall maintain written documentation of an individual's initial contact and screening prior to his admission including the:</p> <ol style="list-style-type: none"> 1. Date of contact; 2. Name, age, and gender of the individual; 3. Address and telephone number of the individual, if applicable; 4. Reason why the individual is requesting services; and 5. Disposition of the individual including his referral to other services for further assessment, placement on a waiting list for service, or admission to the service. 	<p>Last two completed screening forms completed by providers regardless of whether or not the individuals were admitted.</p>
12VAC35-105-660.D (all of it)	<p>D. The initial ISP and the comprehensive ISP shall be developed based on the respective assessment with the participation and informed choice of the individual receiving services.</p>	<p>Informed choice form for annual ISP development</p> <p>ISP meeting notes with essential components discussed in D.1a-c</p>

	<ol style="list-style-type: none"> 1. To ensure the individual's participation and informed choice, the following shall be explained to the individual or the individual's authorized representative, as applicable, in a reasonable and comprehensible manner: <ol style="list-style-type: none"> a. The proposed services to be delivered; b. Any alternative services that might be advantageous for the individual; and c. Any accompanying risks or benefits of the proposed and alternative services. 2. If no alternative services are available to the individual, it shall be clearly documented within the ISP, or within documentation attached to the ISP, that alternative services were not available as well as any steps taken to identify if alternative services were available. 3. Whenever there is a change to an individual's ISP, it shall be clearly documented within the ISP, or within documentation attached to the ISP that: <ol style="list-style-type: none"> a. The individual participated in the development of or revision to the ISP; b. The proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative; and c. The reasons the individual or the individual's authorized representative chose the option included in the ISP. 	<p>For changes made to the ISP (part V) there should be documentation at the provider level that regulatory requirements for D.3 were met (notes, attached to ISP etc.)</p> <p>Signature sheet for ISP</p> <p>Informed Consent Form</p>
12VAC35-105-665.A.6	<p>A. The comprehensive ISP shall be based on the individual's needs, strengths, abilities, personal preferences, goals, and natural supports identified in the assessment. The ISP shall include:</p> <p>6. A safety plan that addresses identified risks to the individual or to others, including a fall risk plan;</p>	<p>Parts I-V of ISP including safety plan and falls risk plan</p>
12VAC35-105-665.A.7	<p>A. The comprehensive ISP shall be based on the individual's needs, strengths, abilities, personal preferences, goals, and natural supports identified in the assessment. The ISP shall include:</p> <p>7. crisis or relapse plan, if applicable;</p>	<p>If individual is open to REACH, provide a copy of the crisis, education and prevention plan, which should also be included in the ISP (part V)</p> <p>If CM service, than provide the most recent Crisis Risk Assessment with recommendation</p>

12VAC35-105-665.D	Employees or contractors who are responsible for implementing the ISP shall demonstrate a working knowledge of the objectives and strategies contained in the individual's current ISP, including an individual's detailed health and safety protocols.	Most recent proof of DD competency completed. Proof staff trained on individual's ISP, including health and safety protocols, for those individuals reviewed.
12VAC35-105-675.A	Reassessments shall be completed at least annually and any time there is a need based on changes in the medical, psychiatric, behavioral, or other status of the individual.	Last annual reassessment dated within past year; and Re-assessments completed as a result of changes in status.
12VAC35-105-675.B	Providers shall complete changes to the ISP as a result of the assessments.	Any changes to ISP as a result of assessments.
12VAC35-105-675.C	The provider shall update the ISP at least annually and any time assessments identify risks, injuries, needs, or a change in status of the individual.	Most recent ISP ISP updates within past year based on assessments or change in status.
12VAC35-105-675.D (all of it)	D. The provider shall review the ISP at least every three months from the date of the implementation of the ISP or whenever there is a revised assessment based upon the individual's changing needs or goals. <ol style="list-style-type: none"> 1. reviews shall evaluate the individual's progress toward meeting the ISP's goals and objectives and the continued relevance of the ISP's objectives and strategies. The provider shall update the goals, objectives, and strategies contained in the ISP, if indicated, and implement any updates made. 2. These reviews shall document evidence of progression toward or achievement of a specific targeted outcome for each goal and objective. 3. For goals and objectives that were not accomplished by the identified target date, the provider and any appropriate treatment team members shall meet to review the reasons for lack of progress and provide the individual an opportunity to make an informed choice of how to proceed. 	Last 2 quarterlies, signed or note that indicates that consent was given (due to COVID).
12VAC35-105-693.C	The provider shall make appropriate arrangements or referrals to all service providers identified in the discharge plan prior to the individual's scheduled discharge date.	Last discharge summary with official discharge date from service Proof of referrals made prior to discharge date.
12VAC35-105-780.5	The provider shall review medication errors at least quarterly as part of the quality assurance in 12VAC35-105-620.	Documentation that medication errors have been reviewed quarterly (last two quarters); If there are medication errors, provide QI Plan that demonstrates how this is being addressed.

		Data (meeting minutes) that shows provider is reviewing trends or looking at effectiveness of QI initiative if there is one.
12VAC35-105-810	A written behavioral treatment plan may be developed as part of the individualized services plan in response to behavioral needs identified through the assessment process. A behavioral treatment plan may include restrictions only if the plan has been developed according to procedures outlined in the human rights regulations. A behavioral treatment plan shall be developed, implemented, and monitored by employees or contractors trained in behavioral treatment.	Behavior plan; Assessment the plan was based on; Name/qualifications of person responsible for developing, implementing and monitoring plan Proof of OHR approval for any restrictions; Proof of monitoring of plan (data); and Documentation that shows who is monitoring; the plan and their qualifications
Case Management Regulations		
12VAC35-105-1240.1	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 1. Enhancing community integration through increased opportunities for community access and involvement and creating opportunities to enhance community living skills to promote community adjustment including, to the maximum extent possible, the use of local community resources available to the general public;	Community integration goals should be identified in ISP. Documentation of provision of the opportunities and individual's response.
12VAC35-105-1240.2	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 2. Making collateral contacts with the individual's significant others with properly authorized releases to promote implementation of the individual's individualized services plan and his community adjustment;	Last 3 months of case management notes Documentation of contacts made to significant others.
12VAC35-105-1240.4	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 4.. Linking the individual to those community supports that are most likely to promote the personal rehabilitative or rehabilitative and life goals of the individual as developed in the ISP	Last three months of case management notes; Documentation showing individual linked to supports consistent with the ISP; and Documentation that case manager located, developed, or obtained needed services.
12VAC35-105-1240.6	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP.	Documentation of coordination with other agencies and providers in accordance with ISP.

	6.. Assuring the coordination of services and service planning within a provider agency, with other providers, and with other human service agencies and systems, such as local health and social services departments;	
12VAC35-105-1240.7	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 7.. Monitoring service delivery through contacts with individuals receiving services and service providers and periodic site and home visits to assess the quality of care and satisfaction of the individual;	Last three months of case management notes; Proof that individual received case management every 90 days in person for TCM; or Proof individual received ECM every 30 days (10 day grace period) for ECM and every other month must be in the home. **due to pandemic will need documentation of how CM was provided and how it was determined this CM (phone or video) was sufficient to meet individual's needs and how it still make frequency requirement
12VAC35-105-1240.11	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 11.. Knowing and monitoring the individual's health status, any medical conditions, and his medications and potential side effects, and assisting the individual in accessing primary care and other medical services, as needed; and	Last three months of case management notes showing monitoring of individual's conditions and medication and accessing medical services.
12VAC35-105-1240.12	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 12.. Understanding the capabilities of services to meet the individual's identified needs and preferences and to serve the individual without placing the individual, other participants, or staff at risk of serious harm.	Submit the Virginia Informed Choice form, does it reflect that the services offered align with individual's needs and preferences
12VAC35-105-1245	Case managers shall meet with each individual face-to-face as dictated by the individual's needs. At face-to-face meetings, the case manager shall (i) observe and assess for any previously unidentified risks, injuries, needs, or other changes in status; (ii) assess the status of previously identified risks, injuries, or needs, or other changes in status; (iii) assess whether the individual's service plan is being implemented appropriately and remains appropriate for the individual; and (iv) assess whether supports and services are being implemented consistent with the individual's strengths and preferences and in the most integrated setting appropriate to the individual's needs.	Clear documentation that at each face to face meeting the CM is documenting that all expectations are being completed. Clear documentation of how this regulation is being met during COVID.

12VAC35-105-1255	The provider shall implement a written policy describing how individuals are assigned case managers and how they can request a change of their assigned case manager.	Written policy describing how individuals are assigned case managers and how they can request a change of their assigned case manager.
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