



COMMONWEALTH of VIRGINIA

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MEMORANDUM

To: DBHDS Licensed Providers of Developmental Services
From: Jae Benz, Director, Office of Licensing
Cc: Veronica Davis, Associate Director for State Licensure Operations
Mackenzie Glassco, Associate Director of Quality & Compliance
Angelica Howard, Associate Director of Administrative & Specialized Units
Date: December 19, 2023, Revised January 2, 2024
Re: 2024 Annual Inspections for Providers of Developmental Services

Purpose: The purpose of this memo is to remind providers of developmental services that, as is customary, the annual unannounced inspections begin again at the start of each calendar year. In January 2020, the Office of Licensing began sharing a checklist (Attachment A) of the minimum requirements licensing specialists (LS) review during a provider's annual inspection as well as what document the LS will look at to determine compliance.

In accordance with V.G.3 of the Settlement Agreement, the Commonwealth is tasked with ensuring the licensing process assesses the adequacy of supports and services provided to individuals with developmental disabilities receiving services licensed by DBHDS. The Office of Licensing is also tasked with monitoring providers' compliance with the Rules and Regulations for Licensing Providers. This involves monitoring the adequacy of individualized supports delivered by each provider. The Office of Licensing developed a crosswalk that ties the eight domains outlined in the Settlement Agreement to specific Licensing Regulations. All of the regulations listed in the checklist are checked during the annual inspection. In addition, the licensing specialist will be reviewing any regulations cited since the last annual inspection to ensure implementation of the corrective action plans in accordance with 12VAC35-105-170.G, 12VAC35-105-170.H and 12VAC35-105-620.C.4.

At each annual inspection, the licensing specialist reviews a sample of individual records to ensure individuals being served are receiving services consistent with their assessed needs and their agreed upon service plan. If a review uncovers a provider is not meeting an individual's needs, the appropriate regulation is cited. A provider is required to submit and implement a corrective action plan for each violation cited including a detailed description of the corrective actions to be taken to correct the specific

deficiencies identified for individuals whose records were reviewed; that will minimize the possibility the violation will occur again and will correct any systemic deficiencies.

Included in this memo is a revised annual inspection chart for 2024 which incorporates feedback from providers as well as the Independent Reviewer. The chart outlines the minimum regulations that will be reviewed, the documents that will be viewed to determine compliance, and whether the documents will need to be submitted via the CONNECT provider portal or viewed onsite during the inspection. Please read this document carefully and provide all included information when requested by your licensing specialist. **CSB/BHA's participating in the Multi-Agency Review Team (MART) must ensure that the documents included in the Master Document List are uploaded to the repository prior to January 1, 2024.**

As part of the annual inspection process, the specialist will conduct a brief 30-minute exit meeting with the provider. This meeting time will be scheduled at the beginning of the inspection to allow the provider ample time to make arrangements. The exit meeting should be attended by the person responsible for oversight of the implementation of the pledged corrective action. The specialist will outline the preliminary findings from the inspection including areas of non-compliance. The provider will be given the opportunity to ask questions and provide additional information, as appropriate. A provider may choose to decline an exit meeting. If a provider does not respond to a request for an exit meeting or declines the opportunity to participate in the meeting, the specialist will note this and proceed with closing out the inspection or issuing citations for any regulatory violations, if indicated.

In order to support providers in achieving and maintaining compliance with the [Licensing Regulations](#), the Office of Licensing has offered training opportunities over the past few years as well as posted a significant number of power points, guidance documents and samples. Please take this opportunity to visit the [Office of Licensing Webpage](#) to review these materials if you have not already done so.

If you have any questions related to the content of this memorandum, please do not hesitate to reach out directly to your licensing specialist. For additional information related to the Settlement Agreement please visit the [DBHDS DOJ Settlement Agreement webpage](#).

Attachment A

Regulation Number	Regulatory Text	Documents Used to Determine Compliance	Submit via CONNECT OR Review on-site	Signature Required (Yes or No)
<p>*12VAC35-105-160.C Must be reviewed for all services including case management</p>	<p>The provider shall collect, maintain, and review at least quarterly <u>all serious incidents</u>, 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>	<p>Last two quarterly reviews of all serious incidents including Level I, Level II and Level III incidents.</p> <ul style="list-style-type: none"> • Must include an analysis of trends, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents. • If the provider does not have any Level I, II, or III serious incidents to review during the last two quarters, the provider must look back to 1/1/2023 to see if they had any serious incidents and provide the quarterly review for those. • If there were no serious incidents within the past year, the provider will be cited for non-compliance if there is no documentation to reflect why a quarterly review was not completed. • If there were no serious incidents within the past year, the provider will be cited for non-compliance if the provider does not have a form to show what the provider would use to document serious incidents if they were to occur. 	<p>Review on-site</p>	
<p>*12VAC35-105-160.D.2 Must be reviewed for all services including case management</p>	<p>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</p>	<p>Provider does not need to submit Level II or Level III serious incidents for review because the LS will review progress notes, quarterly reviews, medical information, and ISPs to ensure anything that meets the criteria for a serious incident was reported. The LS will use the Death and Serious Incident by Type and Status Query for a list of all reported incidents.</p> <ul style="list-style-type: none"> • Note: The Incident Management Unit (IMU) monitors reporting of serious incidents each business day. Please review <u>Guidance for Serious Incident Reporting</u> and the <u>Guidance on Incident Reporting Requirements</u> • 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>Review on-site</p>	

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	<p>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>	<ul style="list-style-type: none"> • If it is determined that a Level II or Level III serious incident occurred and the provider did not report it to the department, the provider will be cited for non-compliance with 160.D.2. 		
<p>*12VAC35-105-160.E.1.a-c Must be reviewed for all services including case management</p>	<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. The root cause analysis shall include at least the following information:</p> <ol style="list-style-type: none"> a. A detailed description of what happened; b. An analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the 	<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> <ul style="list-style-type: none"> • If a root cause analysis was not completed for a Level II or Level III serious incident or it was not completed within 30 days of discovery, the provider will be cited for non-compliance with 160.E.1.a, 160.E.1.b and 160.E.1.c. • <u>Serious Incident Review and Root Cause Analysis Template (November 2023)</u> • <u>Updated Crosswalk of DBHDS Approved Risk Management Training</u> 	<p>Review on-site</p>	

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	<p>control of the provider; and c. Identified solutions to mitigate its reoccurrence and future risk of harm when applicable.</p>			
<p>*12VAC35-105-160.E.2.a-d Must be reviewed for all services including case management</p>	<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> <ul style="list-style-type: none"> a. 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; b. Two or more of the same Level III serious incidents occur to the same individual or at the 	<p>Root cause analysis policy</p> <ul style="list-style-type: none"> • Root cause analysis policy with thresholds for each sub regulation. • Thresholds are already identified within the regulations for 160.E.2.b and 160.E.2.d. • Providers must determine their own threshold number for regulations 160.E.2.a and 160.E.2.c. • If the provider does not have a Root Cause Analysis policy, then the provider will be cited for non-compliance with 160.E.2.a, 160.E.2.b, 160.E.2.c and 160.E.2.d. <p>A root cause analysis completed as a result of a threshold being met, if applicable.</p> <ul style="list-style-type: none"> • If a more detailed Root Cause Analysis was not completed by the provider due to meeting a threshold, the provider will be cited for non-compliance with the specific regulation. 	<p>Review on-site</p>	

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	<p>same location within a six-month period;</p> <p>c. 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</p> <p>d. 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>12VAC35-105-160.J Must be reviewed for all services including case management</p>	<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, analyze, and report to the department information related to serious incidents.</p>	<p>Serious incident management policy. If any of the required components of the serious incident management policy are missing, the provider will be cited for non-compliance with 160.J.</p>	<p>Review on-site</p>	
<p>12VAC35-105-170.G Must be reviewed for</p>	<p>The provider shall implement their written corrective action plan for each violation cited by</p>	<p>The provider will be cited for 170.G if there is no evidence to show that all CAPs from the past year were implemented as stated and by the planned completion date.</p>	<p>Review on-site</p>	

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all services including case management	the date of completion identified in the plan.			
12VAC35-105-170.H Must be reviewed for all services including case management	<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. If a Corrective Action Plan (CAP) was implemented and effective in preventing the recurrence of the regulatory violation, the provider will be marked compliant for 170.H.1 and 170.H.2.</p> <p>If a Corrective Action Plan (CAP) was not effective and:</p> <ul style="list-style-type: none"> • There is no evidence that the CAP continued to be implemented and the provider put in to place additional measures to prevent the recurrence and address identified systemic deficiencies the provider will be cited for non-compliance with 170.H.1. <p>OR</p> <ul style="list-style-type: none"> • There is no evidence that a revised CAP was submitted to the licensing specialist for approval the provider will be cited for non-compliance with 170.H.2. 	Review on-site	
12VAC35-105-280.A-J	<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 	Review of physical environment requirements	Review on-site	

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	<p>with physical and sensory disabilities, if applicable.</p> <p>C. The physical environment and furnishings shall be clean, dry, free of foul odors, safe, and well-maintained.</p> <p>D. Floor surfaces and floor coverings shall promote mobility in areas used by individuals and shall promote maintenance of sanitary conditions.</p> <p>E. The physical environment shall be well ventilated. Temperatures shall be maintained between 65°F and 80°F in all areas used by individuals.</p> <p>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>			
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	<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> <p>K. This section does not apply to home and noncenter-based services. Sponsored residential services shall certify compliance of sponsored residential homes with this section.</p>			
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<p>12VAC35-105-410</p> <p>Must be reviewed for all services including case management</p>	<p>A. Each employee or contractor shall have a written job description that includes:</p> <ol style="list-style-type: none"> 1. Job title; 2. Duties and responsibilities required of the position; 3. Job title of the immediate supervisor; and 4. Minimum knowledge, skills, and abilities, experience or professional qualifications required for entry level as specified in 12VAC35-105-420. 	<p>Review of employee or contractor records who are responsible for providing the service.</p> <p>Review the job description for the employee or contractor responsible for the risk management function.</p> <p>If a job description is not in the record for the employee or contractor being reviewed then the provider will be cited for non-compliance with 410.A.1, 410.A.2, 410.A.3 and, 410.A.4.</p>	<p>Review on-site</p>	
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<p>12VAC35-105-420</p> <p>Must be reviewed for all services including case management</p>	<p>A. Any person who assumes the responsibilities of any position as an employee or a contractor shall meet the minimum qualifications of that position as determined by job descriptions.</p> <p>B. Employees and contractors shall comply, as required, with the regulations of the Department of Health Professions. The provider shall design, implement, and document the process used to verify professional credentials.</p> <p>C. Supervisors shall have experience in working with individuals being served and in providing the services outlined in the service description.</p>	<ul style="list-style-type: none"> • Proof of staff’s education, training, experience consistent with their job description (transcript, resume, etc.) • Proof of DHP qualifications for staff, as appropriate. 	<p>Review on-site</p>	
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	<p>D. Job descriptions shall include minimum knowledge, skills and abilities, professional qualifications and experience appropriate to the duties and responsibilities required of the position.</p> <p>E. All staff shall demonstrate a working knowledge of the policies and procedures that are applicable to his specific job or position.</p>			
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<p>12VAC35-105-430</p> <p>Must be reviewed for all services including case management</p>	<p>A. Employee or contractor personnel records, whether hard-copy or electronic, shall include:</p> <ol style="list-style-type: none"> 1. Individual identifying information; 2. Education and training history; 3. Employment history; 4. Results of any provider credentialing process including methods of verification of applicable professional licenses or certificates; 5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history; 6. Results of the required criminal background checks and searches of the registry of founded complaints of child abuse and neglect; 	<p>Review of employee or contractor records who are responsible for providing the service.</p> <p>If any components of 430.A.1-10, as applicable, are missing the provider will be cited for non-compliance with the specific regulation(s).</p>	<p>Review on-site</p>	
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	<p>7. Results of performance evaluations;</p> <p>8. A record of disciplinary action taken by the provider, if any;</p> <p>9. A record of adverse action by any licensing and oversight bodies or organizations, if any; and</p> <p>10. A record of participation in employee development activities, including orientation.</p>			
<p>12VAC35-105-440 Must be reviewed for all services including case management</p>	<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 	<p>Evidence of orientation for new employees, contractors, volunteers, and students with the completion date. If there is no evidence of the employee, contractor, volunteer or student being oriented or receiving orientation within 15 business days of hire then the provider will be cited for non-compliance with 440.1, 440.2, 440.3, 440.4, 440.5, 440.6, 440.7, 440.8 and 440.9.</p>	<p>Review on-site</p>	

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	<p>including orientation to human rights regulations;</p> <ol style="list-style-type: none"> 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. 			
<p>*12VAC35-105-450 Must be reviewed for all services including case management</p>	<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</p>	<p>For DSPs, the completed DMAS DSP Assurance form and a copy of the DSP orientation test. For supervisors, the completed DMAS Supervisor Assurance form and copy of the certificate of completion. Training policy; and Training records for employees being reviewed. If any component of the required training policy is missing, the provider will be cited for non-compliance with 450. If there is no documented evidence of training for the employee or contactor the provider will cited for non-compliance with 450.</p>	<p>Review on-site</p>	

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	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.			
12 VAC 35-105-460	There shall be at least one employee or contractor on duty at each location who holds a current certificate (i) issued by the American Red Cross, the American Heart Association, or comparable authority in standard first aid and cardiopulmonary resuscitation (CPR) or (ii) as an emergency medical technician. A licensed medical professional who holds a current professional license shall be deemed to hold a current certificate in first aid, but not in CPR. The certification process shall include a hands-on, in-person demonstration of first aid and CPR competency.	Proof of current CPR and First Aid for employees or contractors If an employee or contractor’s job description states that they are required to be CPR and First Aid certified, then there must be evidence of this certification in their record. If the certification process does not include a hands-on, in-person demonstration of first aid and CPR competency the provider will be cited for non-compliance with 460.	Review on-site	
	12VAC35-105-520. Risk management.			
12VAC35-105-520.A Must be reviewed for all services including case management	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,	Name of the person responsible for the risk management function. Job description for this employee must reflect that all or part their responsibilities include those of the risk management function. A completed (signed and dated) DBHDS Risk Management Attestation. <u>Updated Risk Management Attestation Form</u> The Attestation should include the date the risk manager participated in a webinar or reviewed the presentation on the Office of Licensing webpage.	Submit via CONNECT Portal	Yes signature of risk manager and supervisor. If no supervisor,

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	conducting investigations, root cause analysis, and the use of data to identify risk patterns and trends.	Only training outlined in the DBHDS Crosswalk of Approved Training meets these requirements. <u>Updated Crosswalk of DBHDS Approved Risk Management Training</u>		risk manager signature is sufficient.
12VAC35-105-520.B Must be reviewed for all services including case management	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.	Risk management plan. As required by 12VAC35-105-620, a provider’s risk management plan may be a standalone 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. If the risk management plan does not address all the required components as outlined in the regulation the provider will be cited for non-compliance with 520.B.	Submit via CONNECT Portal	No
12VAC35-105-520.C.1-5 Must be reviewed for all services including case management	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: <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. 	If a provider has not served any individuals, a Systemic Risk Assessment review would still need to be completed at least annually. Things to consider may be privacy (PHI), training for staff, emergency management protocols, etc. Systemic Risk Assessment Template (April 2023) Annual Risk assessment review completed within the past 365 days. 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. For 520.C.1-5: The Annual Systemic Risk Assessment requires the provider to identify and respond to practices, situations, and policies that could result in the risk of harm to individuals receiving services for at least the following: 520.C.1 – This review should address the environment of care. This is not the safety inspection but may include results of safety inspections. 520.C.2-This review should address clinical assessment or reassessment processes. 520.C.3-This review should include both staff competence and adequacy of staffing. 520.C.4-This review should include use of high risk procedures.	Submit via CONNECT Portal	

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		<p>520.C.5-Must address a review of serious incidents including 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, from incidents and investigations, potential systemic issues or causes, indicated remediation, and documentation of steps taken to mitigate the potential for future incidents. There must be documented evidence that data is being tracked in order to evaluate trends and patterns over time. After a year of tracking data, the provider should use this baseline data to assess the effectiveness of their Risk Management System.</p> <p>If a systemic risk assessment is not completed the provider will be cited for non-compliance with 520.C.1, 520.C.2, 520.C.3, 520.C.4 and 520.C.5.</p> <p>If any components of the systemic risk assessment are not addressed the provider will be cited for that specific regulation.</p>		
<p>12VAC35-105-520.D Must be reviewed for all services including case management</p>	<p>The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department.</p>	<p>Proof the systemic risk assessment process incorporates uniform risk triggers and thresholds as defined by the department As presented during trainings, DBHDS has defined risk triggers and thresholds as care concerns which are identified through the IMUs review of serious incident reporting. Therefore, if a provider has not had any care concerns, their systemic risk assessment review process would still need to outline how they would address care concerns if they were to occur. Providers will be able to generate CHRIS reports on incidents that have been identified as Care Concern Thresholds.</p> <p>Providers may access the <i>Provider Excel Individual Care Concern Threshold LSA notification</i> to see a list of individuals who have met the Care Concern Thresholds. Case Managers can run the <i>Excel-CM report Care Concern Threshold LSA notification</i> to see a report of any individual served by them regardless of provider.</p> <p style="text-align: center;"><u>The report is found in CHRIS under Individual Care Concern.</u></p> <p>If the provider’s systemic risk assessment does not address care concerns the provider will be cited for non-compliance with 520.D.</p>	<p>Submit via CONNECT Portal</p>	

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		If the provider has not had any care concerns and the systemic risk assessment does not include a section to address care concerns if they were to occur, the provider will be cited for 520.D.		
12VAC35-105-520.E Must be reviewed for all services including case management	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.	Review on-site	
*12VAC35-105-610	Individuals <u>receiving residential and day support services</u> 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.	Proof of participation in community activities in accordance with the individual's ISP. This applies to residential and day support services	Review on-site	
12VAC35-105-620.A Must be reviewed for all services including case management	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.	Current QI Program (policies and procedures) 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. If the quality improvement program/policy does not address all the required components as outlined in 620.A the provider will be cited for non-compliance. The QI Program/Policy must address the elements outlined in 620.A, 620.B, 620.C, 620.D.1, 620.D.2 and 620.D.3.	Submit via CONNECT Portal	
12VAC35-105-620.B Must be reviewed for all services including	The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan.	Current QI Program/Policy lists quality improvement tools used, including root cause analysis, and a current quality improvement plan. Examples of QI Tools include: process mapping, fishbone diagram, Failure Mod and Effects Analysis (FMEA), Plan Do Check Act (PDCA), Pareto chart, Plan Do Study Act (PDSA), and/or 5 Whys, etc.	Submit via CONNECT Portal	

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<p>case management</p>		<p>If the QI Program/Policy does not list the quality improvement tools used by the provider, including root cause analysis, the provider will be cited for non-compliance with 620.B. If there is no evidence of the utilization of the QI tools, the provider will be cited for non-compliance with 620.B. If the provider does not have a QI Plan, the provider will be cited for non-compliance with 620.B. Additionally, the provider will be cited for 620.C.1, 620.C.2, 620.C.3 (if applicable), 620.C.4 and 620.C.5.</p>		
<p>12VAC35-105-620.C.1-5 Must be reviewed for all services including case management</p>	<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; 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. 	<p>Current quality improvement plan. 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.” When assessing compliance, the licensing specialist will review the QI plan to ensure that it contains each of the elements specified in 620.C.1-C.5; and that the provider has evidence of implementing each element. This may include documentation of: 620.C.1: Is the QI Plan reviewed and updated at least annually? 620.C.2: Does the plan include measurable goals and objectives? 620.C.3: Does the QI plan include reporting on statewide performance measures, if applicable? If you are a DD provider of residential and/or day support services, please refer to the Office of Developmental Services Memo as it relates to 620.C.3, “<u>Expectations Regarding Provider Reporting Measures for Residential and Day Support Providers of Developmental Services and Expectations of Provider Risk Management Programs for All Providers of Developmental Services</u>,” 620.C.4: Does the QI Plan outline the process used to monitor the implementation and effectiveness of approved corrective actions (if applicable), and include the criteria for how long a CAP will require formal monitoring? A provider may develop a measurable goal/objective that is related to corrective actions, but a provider does not need to establish goals/objectives for each corrective action. A consideration may be made to develop a goal/objective for systemic corrective actions. 620.C.5: Does the QI Plan define the process the provider will use to review progress toward the goals and objectives of the plan and include actions that will be taken when goals/objectives have not been met?</p>	<p>Submit via CONNECT Portal</p>	

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		<p>If the provider does not have a QI Plan, the provider will be cited for non-compliance with 620.B and 620.C.1, 620.C.2, 620.C.3 (as applicable), 620.C.4 and 620.C.5.</p> <p>If specific components of the QI Plan are missing the provider will be cited for non-compliance specific to that regulation.</p>		
<p>12VAC35-105-620.D 1-3 Must be reviewed for all services including case management</p>	<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 Program/Policy responsive to the criteria outlined in these regulatory requirements.</p> <p>The provider's QI Program/Policy must address 620.D.1, 620.D.2 and 620.D.3.</p> <p>Please review December 2021 training https://dbhds.virginia.gov/assets/doc/QMD/OL/regulatory-compliance-with-qi-rm-rca-2021-12-16-21-presentation.pdf</p> <p>620.D.1: Providers need to explain (outline the criteria) when they will establish or update goals/objectives. For example, when a goal has been met, when the goal has been assessed as not effective to meet the needs, etc.</p> <p>620.D.2: Providers need to explain (outline the criteria) when they will update their quality improvement plan. For example, at least annually, when a new service is added, etc.</p> <p>620.D.3: In accordance with 170, 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 the provider needs to explain (include the criteria) for when:</p> <ol style="list-style-type: none"> 1. They will submit a revised CAP to the department for approval and 2. When they will continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation. 	<p>Submit via CONNECT Portal</p>	
<p>12VAC35-105-620.E Must be reviewed for all services</p>	<p>Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation</p>	<p>QI Plan; and Proof that input was requested from individuals/AR and documentation of implemented improvements made as a result of analysis.</p>	<p>Review on-site</p>	

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<p>including case management</p>	<p>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>*12VAC35-105-645.B.1-5 Must be reviewed for all services including case management</p>	<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>	<p>Review on-site</p>	
<p>*12VAC35-105-660.D (all of it) Must be reviewed for all services including case management</p>	<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> <ol style="list-style-type: none"> 1. To ensure the individual's participation and informed choice, the following shall be explained to the 	<p>660.D.1.a, 660.D.1.b, 660.D.1.c. and 660.D.2 will only be reviewed for case management services. 660.D.3 will be reviewed for Case Management and Non-Case Management Services. 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.) Signature sheet for ISP</p>	<p>Review on-site</p>	

	<p>individual or the individual's authorized representative, as applicable, in a reasonable and comprehensible manner:</p> <ul 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. <p>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.</p> <p>3. Whenever there is a change to an individual's ISP, it shall be clearly documented within the ISP, or within</p>			
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	<p>documentation attached to the ISP that:</p> <ul 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>*12VAC35-105-665.A.6 Must be reviewed for all services including case management</p>	<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> <ul style="list-style-type: none"> 6. A safety plan that addresses identified risks 	<p>Parts I-V of ISP including safety plan and falls risk plan</p>	<p>Review on-site</p>	

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	to the individual or to others, including a fall risk plan;			
*12VAC35-105-665.A.7 Must be reviewed for all services including case management	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: 7. crisis or relapse plan, if applicable;	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) If CM service, then provide the most recent Crisis Risk Assessment (CAT) with recommendation	Review on-site	
*12VAC35-105-665.D Must be reviewed for all services including case management	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.	Review on-site	
*12VAC35-105-675.A Must be reviewed for all services including case management	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.	Review on-site	
*12VAC35-105-675.B Must be reviewed for all services including	Providers shall complete changes to the ISP as a result of the assessments.	Any changes to ISP as a result of assessments.	Review on-site	

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*12VAC35-105-675.C Must be reviewed for all services including case management	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; and ISP updates within past year based on assessments or change in status.		
*12VAC35-105-675.D (all of it) Must be reviewed for all services including case management	D. The provider shall complete quarterly reviews of the ISP at least every three months from the date of the implementation of the comprehensive ISP. 1. These 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	Last 2 quarterlies signed	Review on-site	Yes

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	to proceed. Documentation of the quarterly review shall be added to the individual's record no later than 15 calendar days from the date the review was due to be completed, with the exception of case management services. Case management quarterly reviews shall be added to the individual's record no later than 30 calendar days from the date the review was due.			
12VAC35-105-680 Must be reviewed for all services including case management	The provider shall use signed and dated progress notes or other documentation to document the services provided and the implementation of the goals and objectives contained in the ISP.	Past three months of progress notes or other documentation for the individuals being reviewed.	Review on-site	
*12VAC35-105-693.C Must be reviewed for all services including case management	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; and Proof of referrals made prior to discharge date.	Review on-site	
*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); and 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.	Review on-site	
*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	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;	Review on-site	

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	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.	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 Must be reviewed for case management	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.	Review on-site	
12VAC35-105-1240.2 Must be reviewed for case management	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	Last 3 months of case management notes; and Documentation of contacts made to significant others.	Review on-site	

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	significant others with properly authorized releases to promote implementation of the individual's individualized services plan and his community adjustment;			
*12VAC35-105-1240.4 Must be reviewed for case management	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 habilitative 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 the case manager located, developed, or obtained needed services.	Review on-site	
*12VAC35-105-1240.5 Must be reviewed for case management	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 5. Assisting the individual directly to locate, develop, or obtain needed services, resources, and appropriate public benefits;	Last three months of case management notes; Documentation showing the individual was assisted directly to locate, develop or obtain needed services and resources, and appropriate public benefits consistent with the ISP; and Documentation that the case manager located, developed, or obtained needed services.	Review on-site	
*12VAC35-105-1240.6 Must be reviewed for case management	Providers of case management services shall document that the services below are performed consistent with the individual's assessment and ISP. 6. Assuring the coordination of services	Documentation of coordination with other agencies and providers in accordance with ISP.	Review on-site	

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	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 Must be reviewed for case management	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 Targeted Case Management; or Proof individual received Enhanced Case Management every 30 days (10 day grace period) for Enhanced Case Management and every other month must be in the home.	Review on-site	
*12VAC35-105-1240.11 Must be reviewed for case management	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.	Review on-site	
*12VAC35-105-1240.12	Providers of case management services shall document that the services below are performed	Review of the Virginia Informed Choice form, does it reflect that the services offered align with individual's needs and preferences	Review on-site	

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<p>Must be reviewed for case management</p>	<p>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.</p>			
<p>*12VAC35-105-1245 Must be reviewed for case management</p>	<p>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.</p>	<p>Documented use of the Onsite Visit Tool (OSVT) for face-to-face meetings. This form should be completed at least monthly for those individuals who receive Enhanced Case Management (ECM) or quarterly for individuals who receive Targeted Case Management (TCM). If the form is not present or it is incomplete, the provider will be cited for non-compliance.</p>	<p>Review on-site</p>	
<p>12VAC35-105-1255 Must be reviewed for</p>	<p>The provider shall implement a written policy describing how individuals are assigned case managers and how they can</p>	<p>Written policy describing how individuals are assigned case managers and how they can request a change of their assigned case manager.</p>	<p>Review on-site</p>	

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case management	request a change of their assigned case manager.			
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