

COMMONWEALTH of VIRGINIA

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 COMMISSIONER

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Dear Provider,

The Office of Licensing continues to conduct annual unannounced onsite inspections of providers licensed to provide Developmental Disability services. There are specific policies, procedures and documents which require significant time to review prior to conducting the onsite inspection. Please read this document carefully and provide those documents **via CONNECT by MONTH, DAY, 2024**. Refer to Appendix A-the highlighted rows to see what items must be submitted.

I will complete an unannounced onsite inspection and review implementation of any corrective action plans issued since the last annual unannounced inspection as well as a review of any remaining risk management, quality improvement and serious incident regulations, and other regulations.

To ensure that Office of Licensing is reviewing the correct documents we are asking providers to clearly name documents submitted by using the naming convention outlined in the chart below. It is also recommended that you upload a zip file with the requested documents since it is easier to upload a single file to CONNECT.

If you have any questions related to the content of this request, please do not hesitate to reach out directly to me.

Sincerely,

Office of Licensing

DBHDS

**APPENDIX A**

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| **Regulation Number** | **Documents Licensing Specialist (LS) will review to Determine Compliance**  | **Submit via CONNECT Portal****Or** **Review on-site** |
| 12VAC35-105-160.CMust be reviewed for all services **including** case management | Last two quarterly reviews of all serious incidents including Level I, Level II and Level III incidents.* 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.
 | Review on-site |
| 12VAC35-105-160.D.2Must be reviewed for all services **including** case management | 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.* Note: The Incident Management Unit (IMU) monitors reporting of serious incidents each business day. Please review [Guidance for Serious Incident Reporting](https://www.townhall.virginia.gov/L/ViewGDoc.cfm?gdid=6415%20) and the [Guidance on Incident Reporting Requirements](https://www.townhall.virginia.gov/L/ViewGDoc.cfm?gdid=6876)
* 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.
* 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.
 | Review on-site |
| 12VAC35-105-160.E.1.a-cMust be reviewed for all services **including** case management | 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. * 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.
* [Serious Incident Review and Root Cause Analysis Template (November 2023)](https://dbhds.virginia.gov/wp-content/uploads/2023/11/Serious-Incident-Review-and-Root-Cause-Analysis-Template-November-2023-1.pdf)
* [Updated Crosswalk of DBHDS Approved Risk Management Training](https://dbhds.virginia.gov/wp-content/uploads/2022/08/Updated-Crosswalk-of-DBHDS-Approved-Attestation-Trainings_August-2022.pdf)
 | Review on-site |
| 12VAC35-105-160.E.2.a-dMust be reviewed for all services **including** case management | Root cause analysis policy* 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.

A root cause analysis completed as a result of a threshold being met, if applicable* 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.
 | Review on-site |
| 12VAC35-105-160.JMust be reviewed for all services **including** case management | 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.
 |  Review on-site |
| 12VAC35-105-520.AMust be reviewed for all services **including** case management | * **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.** [**Updated Risk Management Attestation Form**](https://dbhds.virginia.gov/wp-content/uploads/2022/08/Updated-Risk-Management-Attestation-Form_August-2022.pdf)
* The Attestation should include the date the risk manager participated in a webinar or reviewed the presentation on the Office of Licensing webpage.
* Only training outlined in the DBHDS Crosswalk of Approved Training meets these requirements. [Updated Crosswalk of DBHDS Approved Risk Management Training](https://dbhds.virginia.gov/wp-content/uploads/2022/08/Updated-Crosswalk-of-DBHDS-Approved-Attestation-Trainings_August-2022.pdf)
 | **Submit via CONNECT Portal****Naming convention:****Risk Management** |
| 12VAC35-105-520.BMust be reviewed for all services **including** case management | **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****Naming convention:****Risk Management** |
| 12VAC35-105-520.C.1-5Must be reviewed for all services **including** case management | **Annual Systemic Risk Assessment**[Systemic Risk Assessment Template (April 2023)](https://dbhds.virginia.gov/wp-content/uploads/2023/05/Systemic-Risk-Assessment-Template_fillable-with-examples.pdf) * 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.
* 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.

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.If any components of the systemic risk assessment are not addressed the provider will be cited for that specific regulation.  | **Submit via CONNECT Portal****Naming convention:****Risk Management** |
| 12VAC35-105-520.DMust be reviewed for all services **including** case management | * **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.

Providers may access the *Provider Excel Individual Care Concern Threshold LSA notification*) to see a list of individuals who have met the Care Concern Thresholds. Case Managers can run the *Excel-CM report Care Concern Threshold LSA notification* to see a report of any individual served by them regardless of provider.The report is found in CHRIS under Individual Care Concern.* If the provider’s systemic risk assessment does not address care concerns the provider will be cited for non-compliance with 520.D.
* 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.
 | **Submit via CONNECT Portal****Naming convention:****Risk Management** |
| 12VAC35-105-520.EMust be reviewed for all services **including** case management | Evidence of annual safety inspection of all licensed locations for this service; andDocumentation of implementation of any annual safety inspection recommendations. | Review on-site |
| 12VAC35-105-620.AMust be reviewed for all services **including** case management | **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****Naming convention:****Quality Improvement** |
| 12VAC35-105-620.BMust be reviewed for all services **including** case management | **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.
* 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.
 | **Submit via CONNECT Portal****Naming convention:****Quality Improvement** |
| 12VAC35-105-620.C.1 -5Must be reviewed for all services **including** case management | **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. * 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, “[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](https://dbhds.virginia.gov/wp-content/uploads/2023/12/Expectations-regarding-provider-reporting-measures-and-risk-management-programs2.pdf) ,”
* 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?
* 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.

If specific components of the QI Plan are missing the provider will be cited for non-compliance specific to that regulation.  | **Submit via CONNECT Portal****Naming convention:****Quality Improvement**  |
| 12VAC35-105-620.D.1-3Must be reviewed for all services **including** case management | **QI Program/Policy responsive to the criteria outlined in these regulatory requirements** The provider’s QI Program/Policy must address 620.D.1, 620.D.2 and 620.D.3.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>* 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.
* 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.
* 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:

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.  | **Submit via CONNECT Portal****Naming convention:****Quality Improvement** |
| 12VAC35-105-620.EMust be reviewed for all services **including** case management | QI Plan; andProof that input was requested from individuals/AR and documentation of implemented improvements made as a result of analysis. | Review on site |