

Regulation #	Existing Text	New Text
50.A.2.	2. A provisional license may be issued to a provider for a service that has demonstrated an inability to maintain compliance with Human Rights Regulations (12VAC35- 115) or this chapter, has violations of human rights or licensing regulations that pose a threat to the health or safety of individuals receiving services, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan.	2. A provisional license may be issued to a provider for a service that has demonstrated an inability to maintain compliance with all applicable regulations, including this chapter and 12VAC35-115, has violations of human rights or licensing regulations that pose a threat to the health or safety of individuals receiving services, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan.
150.3.c.	For home and community-based services waiver settings subject to this chapter, 42 CFR 441.301(c)(1) through (4), Contents of request for a waiver;	For home and community-based services waiver settings subject to this chapter, 42 CFR 441.301(c)(1) through (4)
160.C.	C. The provider shall collect, maintain, and review at least quarterly all 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.	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.
160.D.2.	Level II and Level III serious incidents shall be reported using the department's web-based reporting application and by telephone 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 or risk of harm 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.	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.
160.E.	E. A root cause analysis shall be conducted by the provider within 30 days of discovery of	E. A root cause analysis shall be conducted by the provider within 30 days of discovery of

	Level II and Level III serious incidents. The root cause analysis shall include at least the following information: (i) a detailed description of what happened; (ii) an analysis of why it happened, including identification of all identifiable underlying causes of the incident that were under the control of the provider; and (iii) identified solutions to mitigate its reoccurrence.	Level II serious incidents and any Level III serious incidents that occur during the provision of a service or on the provider's premises.
160.E.1.	N/A	1. The root cause analysis shall include at least the following information:
160.E.1.a.	N/A	a. A detailed description of what happened;
160.E.1.b.	N/A	b. 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
160.E.1.c.	N/A	c. Identified solutions to mitigate its reoccurrence and future risk of harm when applicable. A more detailed root cause analysis, including convening a team, collecting and analyzing data, mapping processes, and charting causal factors should be considered based upon the circumstances of the incident.
160.E.2.	N/A	2. 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:
160.E.2.a.	N/A	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;
160.E.2.b.	N/A	b. 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;
160.E.2.c.	N/A	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
160.E.2.d.	N/A	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.
160.F.	The provider shall submit, or make available, reports and information that the department requires to establish compliance with these regulations and applicable statutes.	The provider shall make available and, when requested, submit reports and information that the department requires to establish compliance with these regulations and applicable statutes.
160.J.	N/A	J. 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.
170.B.	B. The provider shall submit to the department and implement a written corrective action plan for each violation cited.	B. The provider shall submit to the department a written corrective action plan for each violation cited.
170.C.3.	3. Signature of the person responsible for the service.	3. Signature of the person responsible for oversight of the implementation of the pledged corrective action.
170.E.	E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that the department has not approved the revised plan. If the submitted revised corrective action plan is still unacceptable, the provider shall follow the dispute resolution process identified in this section.	E. Upon receipt of the corrective action plan, the department shall review the plan and determine whether the plan is approved or not approved. The provider has an additional 10 business days to submit a revised corrective action plan after receiving a notice that the department has not approved the revised plan. If the submitted revised corrective action plan is, the provider shall follow the dispute resolution process identified in this section.
170.F.	F. When the provider disagrees with a citation of a violation or the disapproval of the revised corrective action plans, the provider shall discuss this disagreement with the licensing specialist initially. If the disagreement is not resolved, the provider may ask for a meeting with the licensing specialist's supervisor, in consultation with the director of licensing, to challenge a finding of noncompliance. The determination of the director is final.	F. When the provider disagrees with a citation of a violation or the disapproval of a revised corrective action plan, the provider shall discuss this disagreement with the licensing specialist initially. If the disagreement is not resolved, the provider may ask for a meeting with the licensing specialist's supervisor, in consultation with the director of licensing, to challenge a finding of noncompliance. The determination of the director is final.
170.G.	G. The provider shall implement and monitor the approved corrective action plan. The provider shall incorporate corrective actions in its quality improvement program specified in 12VAC30-105-620.	G. The provider shall implement their written corrective action plan for each violation cited by the date of completion identified in the plan.

170.H.	N/A	H. 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:
170.H.1.	N/A	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
170.H.2.	N/A	2. Submit a revised corrective action plan to the department for approval.
320	The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.	The provider shall document at the time of its original application and annually thereafter that buildings and equipment in residential service locations serving more than eight individuals are maintained in accordance with the Virginia Statewide Fire Prevention Code (13VAC5-51). This section does not apply to correctional facilities or home and noncenter-based or sponsored residential home services.
400.D.2	2. Documentation that the provider submitted all information required by the department to complete the criminal history background checks and registry searches, memoranda from the department transmitting the results to the provider, and the results from the Child Protective Registry search.	2. Documentation that the provider submitted all information required by the department to complete the criminal history background checks and registry checks searches, memoranda from the department transmitting the results to the provider, if applicable, and the results from the Child Protective Registry check search.
500.B.	B. The provider shall not rely on students or volunteers for the provision of direct care services. The provider staffing plan shall not include volunteers or students.	B. The provider shall not rely on students or volunteers for the provision of direct care services to supplant direct care positions. The provider staffing plan shall not include volunteers or students.
520.A.	A. The provider shall designate a person responsible for the risk management function who has training and expertise in conducting investigations, root cause analysis, and data analysis.	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.
520. B.	B. The provider shall implement a written plan to identify, monitor, reduce, and minimize harms and risk of harm, including personal injury,	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.	infectious disease, property damage or loss, and other sources of potential liability.
520.C.	C. 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 (i) the environment of care; (ii) clinical assessment or reassessment processes; (iii) staff competence and adequacy of staffing; (iv) use of high risk procedures, including seclusion and restraint; and (v) a review of serious incidents. This process shall incorporate uniform risk triggers and thresholds as defined by the department.	C. 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:
520.C.1.	N/A	1. The environment of care;
520.C.2.	N/A	2. Clinical assessment or reassessment processes;
520.C.3.	N/A	3. Staff competence and adequacy of staffing;
520.C.4.	N/A	4. Use of high risk procedures, including seclusion and restraint; and
520.C.5.	N/A	5. A review of serious incidents.
520.D.	D. 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.	D. The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department.
520.E.	E. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.	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.
520.F.	N/A	F. The provider shall document serious injuries to employees, contractors, students, volunteers, and visitors that occur during the provision of a service or on the provider's property. Documentation shall be kept on file

		for three years. The provider shall evaluate serious injuries at least annually. Recommendations for improvement shall be documented and implemented by the provider.
530.A.5.e	Conducting evacuations to emergency shelters or alternative sites and accounting for all individuals receiving services;	e. Evacuation procedures, including for individuals who need evacuation assistance;
530.A.5.f	Relocating individuals receiving residential or inpatient services, if necessary;	f. Conducting evacuations to emergency shelters or alternative sites and accounting for all individuals receiving services;
530.A.5.g	Notifying family members or authorized representatives;	g. Relocating individuals receiving residential or inpatient services, if necessary;
530.A.5.h	Alerting emergency personnel and sounding alarms;	h. Notifying family members or authorized representatives;
530.A.5.i	Locating and shutting off utilities when necessary; and	i. Alerting emergency personnel and sounding alarms;
530.A.5.j	Maintaining a 24 hour telephone answering capability to respond to emergencies for individuals receiving services.	j Locating and shutting off utilities when necessary; and
530.A.5.k	n/a	k. Maintaining a 24 hour telephone answering capability to respond to emergencies for individuals receiving services.
530.A.9.	Schedule for testing the implementation of the plan and conducting emergency preparedness drills.	a. Schedule for testing the implementation of the plan and conducting emergency preparedness drills. Fire and evacuation drills shall be conducted at least monthly.
530.B.	The provider shall implement annual emergency preparedness and response training for all employees, contractors, students, and volunteers. This training shall also be provided as part of orientation for new employees and cover responsibilities for:	The provider shall evaluate each individual and, based on that evaluation, shall provide appropriate environmental supports and adequate staff to safely evacuate all individuals during an emergency.
530.B.1.	1. Alerting emergency personnel and sounding alarms;	REMOVED
530.B.2.	2. Implementing evacuation procedures, including evacuation of individuals with special needs (i.e., deaf, blind, nonambulatory);	REMOVED
530.B.3.	3. Using, maintaining, and operating emergency equipment;	REMOVED
530.B.4.	4. Accessing emergency medical information for individuals receiving services; and	REMOVED
530.B.5.	5. Utilizing community support services.	REMOVED
530.C.	C. The provider shall review the emergency preparedness plan annually and make necessary revisions. Such revisions shall be communicated to employees, contractors, students, volunteers, and individuals receiving services and incorporated into training for employees,	C. The provider shall implement annual emergency preparedness and response training for all employees, contractors, students, and volunteers. This training shall also be provided as part of orientation for new employees and cover responsibilities for:

	contractors, students, and volunteers and into the orientation of individuals to services.	
530.C.1.	N/A	1. Alerting emergency personnel and sounding alarms;
530.C.2.	N/A	2. Implementing evacuation procedures, including evacuation of individuals with special needs (i.e., deaf, blind, nonambulatory);
530.C.3.	N/A	3. Using, maintaining, and operating emergency equipment;
530.C.4.	N/A	4. Accessing emergency medical information for individuals receiving services; and
530.C.5.	N/A	5. Utilizing community support services.
530.D.	D. In the event of a disaster, fire, emergency or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider shall take appropriate action to protect the health, safety, and welfare of individuals receiving services and take appropriate actions to remedy the conditions as soon as possible.	D. The provider shall review the emergency preparedness plan annually and make necessary revisions. Such revisions shall be communicated to employees, contractors, students, volunteers, and individuals receiving services and incorporated into training for employees, contractors, students, and volunteers and into the orientation of individuals to services.
530.E.	E. Employees, contractors, students, and volunteers shall be knowledgeable in and prepared to implement the emergency preparedness plan in the event of an emergency. The plan shall include a policy regarding regularly scheduled emergency preparedness training for all employees, contractors, students, and volunteers.	E. In the event of a disaster, fire, emergency or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider shall take appropriate action to protect the health, safety, and welfare of individuals receiving services and take appropriate actions to remedy the conditions as soon as possible.
530.F.	F. In the event of a disaster, fire, emergency, or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider should first respond and stabilize the disaster or emergency. After the disaster or emergency is stabilized, the provider should report the disaster or emergency to the department, but no later than 24 hours after the incident occurs.	F. Employees, contractors, students, and volunteers shall be knowledgeable in and prepared to implement the emergency preparedness plan in the event of an emergency. The plan shall include a policy regarding regularly scheduled emergency preparedness training for all employees, contractors, students, and volunteers.
530.G.	G. Providers of residential services shall have at all times a three-day supply of emergency food and water for all residents and staff. Emergency food supplies should include foods that do not require cooking. Water supplies shall include one gallon of water per person per day.	G. In the event of a disaster, fire, emergency, or any other condition that may jeopardize the health, safety, or welfare of individuals, the provider should first respond and stabilize the disaster or emergency. After the disaster or emergency is stabilized, the provider should report the disaster or emergency to the department, but no later than 24 hours after the incident occurs.
530.H.	H. This section does not apply to home and noncenter-based services.	H. Providers of residential services shall have at all times a three-day supply of emergency

		food and water for all residents and staff. Emergency food supplies should include foods that do not require cooking. Water supplies shall include one gallon of water per person per day.
530.I	N/A	I. All provider locations shall be equipped with at least one approved type ABC portable fire extinguisher with a minimum rating of 2A10BC installed in each kitchen.
530.J.	N/A	J. All provider locations shall have an appropriate number of properly installed smoke detectors based on the size of the location, which shall include at a minimum:
530.J.1.	N/A	1. At least one smoke detector on each level of multi-level buildings, including the basement;
530.J.2.	N/A	2. At least one smoke detector in each bedroom in locations with bedrooms;
530.J.3.	N/A	3. At least one smoke detector in any area adjacent to any bedroom in locations with bedrooms; and
530.J.4.	N/A	4. Any additional smoke detectors necessary to comply with all applicable federal and state laws and regulations and local ordinances.
530.K.	N/A	K. Smoke detectors shall be tested monthly for proper operation.
530.L.	N/A	L. All provider locations shall maintain a floor plan identifying locations of:
530.L.1.	N/A	1. Exits;
530.L.2.	N/A	2. Primary and secondary evacuation routes;
530.L.3	N/A	3. Accessible egress routes;
530.L.4	N/A	4. Portable fire extinguishers; and
530.L.5	N/A	5. Flashlights.
530.M.	N/A	M. This section does not apply to home and noncenter-based services.
590.F.	F. Direct care staff who provide brain injury services shall have at least a high school diploma and two years of experience working with individuals with disabilities or shall have successfully completed an approved training curriculum on brain injuries within six months of employment.	F. Staff in direct care positions providing brain injury services shall have at least a high school diploma and two years of experience working with individuals with disabilities or shall have successfully completed an approved training curriculum on brain injuries within six months of employment.
620	The provider shall develop and implement a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis. The program shall (i) include a quality improvement plan that is reviewed and updated at least annually; (ii) establish measurable goals and objectives; (iii) include	REMOVED



	and report on statewide performance measures, if applicable, as required by DBHDS; (iv) utilize standard quality improvement tools, including root cause analysis; (v) implement a process to regularly evaluate progress toward meeting established goals and objectives; and (vi) incorporate any corrective action plans pursuant to 12VAC35-105-170. 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.	
620.A.	N/A	A. The provider shall develop and implement written policies and procedures to for a quality improvement program sufficient to identify, monitor, and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis.
620.B.	N/A	B. The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan.
620.C.	N/A	C. The quality improvement plan shall:
620.C.1.	N/A	1. Be reviewed and updated at least annually;
620.C.2.	N/A	2. Define measurable goals and objectives;
620.C.3.	N/A	3. Include and report on statewide performance measures, if applicable, as required by DBHDS;
620.C.4.	N/A	4. Monitor implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170; and
620.C.5.	N/A	5. Include ongoing monitoring and evaluation of progress toward meeting established goals and objectives.
620.D.	N/A	D. The provider's policies and procedures shall include the criteria the provider will use to
620.D.1.	N/A	1. Establish measurable goals and objectives;
620.D.2.	N/A	2. Update the provider's quality improvement plan; and
620.D.3.	N/A	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.
620.E.	N/A	E. 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 assurance system improvement plan. The provider shall implement improvements, when indicated.
660.D.	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. To ensure the individual's participation and informed choice, the provider shall explain to the individual or his authorized representative, as applicable, in a reasonable and comprehensible manner, the proposed services to be delivered, alternative services that might be advantageous for the individual, and accompanying risks or benefits. The provider shall clearly document that this information was explained to the individual or his authorized representative and the reasons the individual or his authorized representative chose the option included in the ISP.	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.
660.D.1	N/A	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:
660.D.1.a	N/A	a. The proposed services to be delivered;
660.D.1.b	N/A	b. Any alternative services that might be advantageous for the individual;
660.D.1.c	N/A	c. Any accompanying risks or benefits of the proposed and alternative services.
660.D.2.	N/A	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.

660.D.3.	N/A	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:
660.D.3.a.	N/A	a. The individual participated in the development of or revision to the ISP
660.D.3.b.	N/A	b. The proposed and alternative services and their respective risks and benefits were explained to the individual or the individual's authorized representative, and;
660.D.3.c.	N/A	c. The reasons the individual or the individual's authorized representative chose the option included in the ISP.
665.D.	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.	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.