General Overview:

The purpose of this protocol is to define the processes and procedures that govern investigations conducted by the Office of Licensing in accordance with the following state laws and regulations:

Code of Virginia § 37.2-411 states that the commissioner must promptly investigate all complaints.

In addition, the *Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services* ("Licensing Regulations"), regulation **12VAC35-105-80**, states that the department shall investigate all complaints regarding potential violations of licensing regulations. Complaint investigations may be based on onsite reviews, a review of records, a review of provider reports or telephone interviews.

Regulation **12VAC35-105-20** defines an **investigation** as "a detailed inquiry or systematic examination of the operations of a provider or its services regarding an alleged violation of regulations or law. An investigation may be undertaken as a result of a complaint, an incident report, or other information that comes to the attention of the department." The regulation also defines a **complaint** as "an allegation of a violation of this chapter or a provider's policies and procedures related to this chapter."

Lastly, the *Standards for the Regulation of Children's Residential Facilities* ("Children's Residential Regulations"), **regulation12VAC35-46-160,** define a complaint as an accusation against a licensed facility regarding an alleged violation of regulation or law. In addition, the Children's Residential Regulations state that the department is responsible for complete and prompt investigation of all complaints and allegations made against providers, and for notification of the appropriate persons or agencies when removal of residents may be necessary. Suspected criminal violations shall be reported to the appropriate law-enforcement authority.

If it is determined during an investigation that the provider failed to comply with any applicable regulation(s), the Office of Licensing shall issue a licensing report describing the noncompliance and requesting the provider to submit a Corrective Action Plan for each violation cited. All approved Corrective Action Plans resulting from investigations will be posted on the DBHDS website and available for public viewing.

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SIU Trained 12/3/19; Effective 1/1/20; Formal OL Training 1/7/20 & 1/8/20
Revised Dec 2020; March 2021; Sept 2021; Revised for CONNECT Nov 2022

COMPUTERIZED HUMAN RIGHTS INFORMATION SYSTEM "CHRIS"

Providers enter reportable incidents, including death notifications, via the CHRIS system. According to regulation **12VAC35-105-160.D.2.** D. The provider shall collect, maintain, and report or make available to the department the following information: 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 and, 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.

TRIAGING CHRIS INCIDENTS

The Incident Management Unit "IMU" staff reviews and triages serious incident reports ("SIRS") and, if the incident meets criteria for a referral of an investigation refers the incident via Connect to either the assigned licensing specialist and/or SIU shared queue.

- The LS/Investigator is then responsible for reviewing the SIR and making a determination of whether an investigation is warranted based on protocol. If an investigation is conducted the LS/Investigator is responsible for initiating the investigation **within three business days for incidents involving DD services and within seven business days for incidents involving MH/SA services.**

- Please refer to specific investigation appendix *(B-Complaints, C-DD Deaths, D-SIRs) for further information regarding how to initiate investigations in Connect.

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Specialized Investigation Unit "SIU"

The Specialized Investigation Unit was developed to supplement the efforts of current Office of Licensing Specialists in conducting investigations to protect the health and safety of Individuals with Developmental Disabilities; and to ultimately improve the overall quality of services and supports. The SIU will review and investigate serious reportable incidents in a timely manner as established in this protocol. The SIU will be implemented in three phases in an effort to determine the feasibility of SIU staff completing all investigations for all regions. Phase One consists of completion of all death investigations for individuals with developmental disabilities; Phase Two consists of completion of complaint investigations for individuals with developmental disabilities. The overall goal of the SIU is to improve processes relating to investigations, promote consistency, allow for specialized training of investigators, and to ensure the overall safety of all individuals served throughout the Commonwealth.

DETERMINING METHODS OF INVESTIGATION

An investigation can occur because of a complaint, CHRIS report (report of death or serious incident), or an allegation of abuse or neglect. The result and method of an investigation **MUST** be entered under the "Investigations" folder within the Office of Licensing Information Management System "CONNECT". Refer to appendixes A, B, C, D, and E regarding how to enter information into CONNECT for respective investigations.

An **on-site inspection** must be conducted in any of the following situations:

1. A death of an individual with developmental disabilities that occurs during the provision of a provider's services. *For example, a death of an individual with developmental disabilities that occurs at a group home, 911 was called to intervene, and rescue attempts were unsuccessful resulting in death of the individual.*
2. Serious Incidents involving an individual with developmental disabilities resulting in significant injuries/risks and/or a repeated pattern of similar serious incidents within 30 days for the same individual.
3. The continuing operation of the service may present an immediate risk to the health, safety, or welfare of current individuals receiving services.
4. The provider has a history of failing to address and resolve serious issues affecting care and treatment of individuals served.
5. The provider's internal investigation fails to identify and resolve issues of noncompliance.

Please be advised that there are additional circumstances in which an onsite inspection may be required. This includes situations in which a LS/Investigator has concerns that there are potential violations of the Licensing Regulations due to staff actions associated with an incident or complaint.

An **in-office review** may be conducted for all other incidents such as:

1. Case management death investigations.
2. Any other incidents that did not occur during the provision of services and OL can determine compliance during documentation review.

DETERMINING PRIORITY OF INVESTIGATIONS THAT OCCUR DURING PROVISION OF SERVICES

- **Any Level III Serious Incidents.**
- **All deaths of individuals with developmental disabilities.**
    - *Per DOJ indicator **V.C.5.7c**, the Office of Licensing SIU unit will investigate all unreported deaths of individuals with developmental disabilities from **DBHDS licensed providers** that were not reported via the incident reporting system and take appropriate action in accordance with DBHDS licensing regulations and protocols.*
    - SIU will investigate unreported deaths where it was identified that the individual was receiving a DBHDS licensed service at the time of death.
    - Please refer to **Appendix-C DD Death Investigations**-for further detail information
- **SIRs that require investigations are as follows:**
    - Similar Level II SIRs for the same Individual within 30days.
        - *For example, Individual who has repeated falls with serious injuries.*
    - Level II SIRs for a diagnosis of a decubitus ulcer or an increase in severity of level of previously diagnosed decubitus ulcer; a bowel obstruction; or Aspiration pneumonia (when Multiple, 2 or more, ER visit or unplanned hospital admissions).
    - RMRC (Risk Management Review Committee: Departmental Initiative): Urinary Tract Infections (UTIs):
        - If there is a UTI related care concern, or it's found that a provider is not doing what they are supposed to do, that report would be sent to a Licensing Specialist to determine if an investigation is needed. If investigation is not required, staff should enter a DSI action detailing why an investigation is not warranted before closing out the DSI and case.
        - If it is suspected that a UTI is a result of neglect, this will be referred to OHR to review and for determination.
        - If the UTI was as a result of staff not following an ISP, or the ISP not reflecting the person's changing needs, OL will cite the provider accordingly.
        - For all Care Concerns involving UTI, IMU refers to OIH who does provide the provider with resources regarding UTIs.
    - All Level III SIRs; with exception of a death of natural causes (except DD deaths)
- All reported allegations of suspected abuse, neglect, with injury in which it is reasonable to assume that the individual's safety may be at ongoing risk should receive priority.
- Reported deaths and serious incidents in which it reasonably can be determined that the safety of the individuals remaining within the service are not at on-going risk shall receive the next degree of investigative priority.
- All suicides that occur during service delivery will be investigated.
- All other allegations of violations of regulations shall receive the lowest degree of investigative priority.

TIMELINE FOR INITIATING AN INVESTIGATION AND ISSUING A CITATION

- All investigations must be initiated in Connect **within three business days** of the incident/complaint in question for **DD services** and for **MH/SA services** investigations should be initiated **within seven business days** of the incident/complaint in question.
    - Initiating an investigation refers to opening the investigation in CONNECT, entering an investigation action detailing the course of action for the investigation, scheduling the onsite visit if applicable, requesting documents, and/or completion of onsite investigation.
    - **It is key for data collection purposes to ensure that the correct investigation type is selected in CONNECT on the investigation screen**
        - (ex, DD Death Investigation, DD Complaint Investigation, DD SIR Investigation, MH Death Investigation, MH Complaint Investigation, MH SIR Investigation, SA Death Investigation, SA Complaint Investigation, SA SIR Investigation)
- Investigations are required to be **completed within 45 business days** of the notification of the complaint, SIR, or death. Completed means that the LS/Investigator has **completed** their process regarding the investigation.
    - An investigation is deemed **complete** if the following steps have occurred:
        - All investigation actions are entered into CONNECT
        - The findings report is completed and entered in CONNECT; and
        - If applicable, the licensing report has been issued to the provider.
    - Although the LS/Investigator may have completed their investigation as required above, the investigation may not be **closed** yet because the LS/Investigator is waiting for the provider to submit an approved Corrective Action Plan (CAP).
- If a regulatory violation is revealed during the investigation, the LS/Investigator should issue the provider a citation **within 3 business days** of completing their review.
- Investigations are required to be **closed within 60 business days** from receipt of the complaint, SIR, or death.
    - Not until after the provider reviews the citation, submits their plan of action in response, and has their response accepted by the LS/Investigator, is the investigation considered **closed**.
- If a CAP is labeled as a **"Health and Safety CAP"** then the investigation remains open until the LS/Investigator completes the **required 30 business day follow up** inspection to ensure that the provider has successfully implemented their CAP.
    - **Per Settlement Agreement Provision Indicator V.C.6a:**
      Specialists must follow up on the implementation of approved corrective action plans related to serious incidents or substantiated abuse or neglect as

detailed in SA Indicator **V.C.6a** which states "For serious injuries and deaths that result from substantiated abuse, neglect, or health and safety violations, the OL **verifies that corrective action plans have been implemented within 45 days of their start date**." (This is 30 business day for the OL).

Please note: In cases of substantiated abuse or neglect that do not involve serious injury or death, the Office of Human Rights verifies that corrective action plans have been implemented within 90 days of their start date.

- If, for any reason, the investigation is not complete or remains open outside of the above-mentioned timelines, the LS/Investigator should clearly document the reasons why in CONNECT on the investigation screen section labeled ***Investigation Past Due Reason.***
    - For example, if the LS/Investigator is waiting for the Office of Human Rights (OHR) to enter their citations of the Human Rights Regulations for the Licensing Report or for OHR to accept the CAP response for OHR citations, that should be noted as reason past due.
        - Ex: *"Investigation remains open as LS/Investigator is waiting for OHR to review and accept providers responses to OHR citations for the licensing report"*
    - Another example, if a CAP is labeled as "Health and Safety" the LS/Investigator would document in the Investigation Past Due Reason:
        - *"CAP issued was deemed a Health & Safety CAP, therefore investigation remains open until completion of 30 business day follow up visit."*

Potential violations of the Office of Human Rights (OHR) regulations (V.C.5.6b)

- ***V.C.5.6b:*** *Any deaths that appear to be related to abuse or neglect or that pose an imminent and substantial threat to the health, safety, or welfare of other individuals served by that provider have an investigation initiated by the DBHDS Licensing Investigation Team immediately, with actions taken, as appropriate in accordance with licensing protocols.*
- IMU will notify OHR whenever an incident reported via CHRIS may have potential human rights concerns.
- If the LS/Investigator discovers **during** the course of an investigation that there may be potential abuse/neglect concerns, they are to **immediately** notify the assigned OHR regional manager via telephone **and** e-mail. The LS/Investigator should provide the OHR manager with all the details available regarding the possible human rights concerns, including a completed HIPAA form, when applicable.

- The OHR regional manager will review the case, refer the case to OHR advocate if applicable and make a determination as to whether any OHR violations exist.
- When it is determined that a violation of the Human Rights Regulations exists, the OHR manager/advocate will send the human rights citation to the LS/Investigator within five business days of their notification of a substantiated finding/violation.
    - The OHR manager/advocate will utilize the agreed upon template to submit the human rights citation(s) to the LS/Investigator.
    - OHR will ensure their citations match up with HIPAA form LS/Investigator enters in CONNECT and includes any additional individuals or provider staff if applicable.
    - LS/Investigator will follow applicable steps in CONNECT process guide to allow OHR to enter their OHR citations directly into CONNECT.
- The LS/Investigator must document OHR's communication referring OHR citations within CONNECT as investigation actions.
- If an investigation is approaching the 45-business day deadline for completion, and the OHR citation has not been received, the LS/Investigator will contact the OHR advocate to follow up and note this follow up in as an investigation action in CONNECT.
- If the OHR citation is not received prior to the 45-business day deadline to complete the investigation, the LS/Investigator will proceed with completing the investigation. The LS/Investigator should issue any applicable OL licensing report and note that if OHR submits a HR citation, the licensing report will be issued under an inspection not associated with the investigation, as investigations must be closed within 60 business days. When OHR issues their citation outside of the related investigation, a notation will be made as an investigation action referencing the OHR citation is related to an investigation.
    - (ex . Please note OHR issued a related OHR citation for the investigation under inspection 123- 01-001 Inspection #4; please refer to that inspection for further details if needed).
- Communication between LS/Investigator and OHR advocate is key when deciding best course of action for investigations.

INVESTIGATION FINDINGS

The LS/Investigator may determine the following:

- **A provider has not violated any regulation.** The investigation may be closed at this point.
- **A provider is in violation of regulation.** The LS/Investigator sends the Licensing Report to the provider via steps in CONNECT. The LS/Investigator would follow protocol for issuing a Licensing Report.
- **If the provider's response is not acceptable**, then the CAP is returned to the provider requesting additional information. Follow applicable steps in CONNECT for reissuing the licensing report to the provider.
- **The investigation remains open until an acceptable plan of correction is received**.
- **When an acceptable corrective action plan is received**, the LS/Investigator enters the their accepted response into CONNECT, completes finding section, and closes the investigation.
- The LS/Investigator must enter the close date in CONNECT for the investigation and must enter the close date on the case in CONNECT.
- Staff should enter their closed date for the investigation in CONNECT **within 5 business days** of receiving an acceptable response to a provider licensing report.
- The LS/Investigator shall consult with their regional manager and/or SIU manager if there are any unusual circumstances.
- Please refer to **Appendix E-Investigation Templates** for examples of how to organize findings reports based on investigation type.

EVALUATING RISK MANAGEMENT (520) AND SERVICE QUALITY (620) FOR INVESTIGATIONS

Under the following conditions, a LS/Investigator may want to request a provider's risk management plan and quality improvement plan:

1. If the incident being investigated and the evidence that is being collected indicates that the incident could have been prevented.
2. If the provider has had previous investigations involving the same circumstances.
3. If the provider has been cited previously for similar violations regarding similar incidents that were investigated.

- LS/Investigator should then request the provider's Risk Management Plan (520) and the provider's Quality Improvement Plan (620) to review.
    - As noted in the Guidance for Risk Management, the plan may be a stand-alone plan or it may be integrated into the provider's quality improvement plan. The provider's quality improvement program and risk management efforts may include other documents such as policies, procedures, or systemic risk assessment reviews.

- LS/Investigator should request a copy of the provider's Root Cause Analysis (160E) to review for any investigation that involves a Level II, or Level III incident that occurs during provision of the provider's services or on the provider premises.
    - When a RCA is received, LS/Investigator should be reviewing the RCA for compliance with all of 160E; 160E.1 (a,b,c) requirements.
    - If a provider is found to be non-complaint with any sections of 160E; E.1 (a,b,c) then LS/Investigator should pull either the **DOJ Key Licensing Regulatory Compliance Report** or the **Progressive Citation Search Query** from CONNECT to determine if provider has been cited previously and if this repeat citation is due to a failure to implement a previous CAP. If this is the case, the LS/Investigator should refer to 170G and cite accordingly.
    - If this is a repeat citation, the LS/Investigator should label the citation as NS (Non-Compliant Systemic).
        - If concerns are noted with 160.E. then LS/Investigator should also review 160.E.2 (a-d). Please note that 160.E.2 is checked at a minimum during annual inspections.
    - The only exception to requesting a RCA would be if the investigation were complete and ready to be closed before the 30 days a provider has to complete a RCA.
- The purpose of the review of the provider's Risk Management Plan and Quality Improvement Plan is to determine if the provider has taken responsibility for incorporating previously identified issues into their Risk Management and Quality Improvement plans, etc. The provider may also have included previously identified issues in their annual risk assessment review.
- For example, if an LS/Investigator has investigated falls several times for a provider in which the provider was cited, then in review of the provider's Quality Improvement plan, the LS/Investigator should review to see if the provider has developed a goal/objective to reduce falls. Another example could be that the provider has included in their risk management plan how they are monitoring risks related to falls.
- The LS/Investigator can use either the **DOJ Key Licensing Regulatory Compliance Report** or the **Progressive Citation Search Query** from CONNECT data to search for previous violations issued to a provider. In addition, an Investigator should consult with the primary licensing specialist regarding a provider's history of compliance as needed.

EVALUATING CORRECTIVE ACTIONS PLANS FOR INVESTIGATIONS (REG 170G, 170H 1 AND 2)

G. The provider shall implement their written corrective action plan for each violation cited by the date of completion identified in the plan.
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:
    a. 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
    b. Submit a revised corrective action plan to the department for approval.

The following section below is specific to any investigations involving individuals with **developmental disabilities**, however, can also be used for investigations in other populations. Staff should ensure they are:

1. **Use CONNECT Report-DOJ Indicators-Key Licensing Regulatory Compliance Report or Progressive Citation Search Query:**
    a. Check to see if a provider has been previously cited for a regulation over the past rolling year from when issuing a violation.
2. **Pull CAP (s) to Review:**
    a. Pull the previous CAP or CAP(s) to review to first see if what was cited before is the same/similar to the citations you are issuing.
3. **Cite Accordingly 170G, 170H1 or 170H2:**
    a. If the provider failed to implement a previously approved corrective action plan for the same regulation being cited for your investigation, then staff would cite the regulation as Non-Compliance Systemic, indicating at the end of the citation.
        i. **Please note provider was previously cited for this regulation on CAPs dated xx-xx-xxxx and xx-xx-xxxx. Therefore the provider failed to implement their previous approved corrective action plans.*
    b. 170G: If the provider failed to implement their written corrective action plan for each violation cited by the date of completion identified in the plan.
    c. 170H: If the provider failed to monitor implementation and effectiveness of approved corrective actions as part of its quality improvement program required by 12VAC35-105-620.
    d. 170H1: If the provider failed to put in additional measures to prevent the reoccurrence of the cited violation.
    e. 170H2: If the provider failed to submit a revised corrective action plan to the department.

TOOLS FOR EVALUATING RISKS AND FOR INVESTIGATION RESPONSE

Incidents that rank as top priority include in no particular order:

- Death suicide
- Death unexpected
- Abuse /neglect with injury
- Lack of supervision
- Serious injury
- Restraint with injury
- Overdoses
- Multiple Health & Safety violations
- Multiple medication errors and/or errors that require medical attention
- Peer to peer assaults
- Individuals who are or were missing or residents who have runaway
- Lack of financial resources that affect service delivery
- Theft of individual's funds by staff
- Expected deaths

Mitigating, Exacerbating, and Other Factors to Consider

Organizational History

- History of similar events
- History of violations
- History of providing structured program of care and treatment
- Track record for reporting and sharing information freely
- Sound, consistent documented history of QA improvement activities
- Consistency of Staff
- Quality of internal investigations and corrective action

Provider Response to Incident

- Immediate actions taken in response to incident
- Actions prior to event to prevent/mitigate its occurrence
- Quality and timeliness of provider's responses, degree of fact finding, investigative actions and follow-up to the reported incident

Incident Related Information

- Adverse event appears to be related to provider's actions

- Severity of incident
- Potential for imminent threat to health, safety or welfare of other individual
- Conflicting information provided about incident
- Severity of injury
- Location of incident

Other Factors to Consider

- Concurrent criminal investigation
- Availability of evidence and/or persons to be interviewed
- Departmental/management priorities
- Investigator's judgment in determining what is most significant/important to investigate
- Impact of other entities-media, VOPA, government agencies, families, politicians

- **Helpful Tip**: LS/Investigators should use the Wavier Management System (WAMs) as a resource to review documents in preparation for conducting DD investigations. Documents such as Part 1-5 and Individual Support Plans can be accessed and reviewed prior to conducting onsite inspections.

- Please refer to all **Investigation Protocol Appendix in Licensing all TEAMS** for additional information regarding specific investigation types and investigation templates