



COMMONWEALTH of VIRGINIA

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MEMORANDUM

To: DBHDS Licensed Providers
From: Jae Benz
Director, Office of Licensing
Date: August 22, 2020
RE: Guidance on Incident Reporting Requirements

Purpose: The purpose of this memorandum is to [remind](#) DBHDS licensed providers of the requirements and expectations for reporting serious incidents to the DBHDS Office of Licensing, pursuant to 12VAC35-46-1070.C. and 12VAC35-105-160.D.2., including the timeframe for reporting incidents; the process for reporting incidents; the allowable timeframe for adding to, amending, or correcting information reported to the Office of Licensing through the Computerized Human Rights Information System (CHRIS); and to inform providers of the processes that the Office of Licensing will follow for issuing citations, repeat citations, and sanctions for violations of serious incident reporting requirements. In addition to ensuring all providers understand the regulatory requirements associated with reporting incidents, the processes outlined in this memo are central to the department's efforts to address compliance indicators related to serious incident reporting as mandated by the US Department of Justice's (DOJ) [Settlement Agreement](#) with Virginia.

1. Serious Incident Reporting Requirements

REGULATIONS FOR CHILDREN'S RESIDENTIAL FACILITIES (["Children's Residential Regulations"](#)) [12VAC35-46]

Pursuant to 12VAC35-46-1070.C., providers of children's residential services shall notify the department within 24 hours of any serious illness or injury, any death of a resident, and all other situations as required by the department.

RULES AND REGULATIONS FOR LICENSING PROVIDERS BY THE DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES (“[Licensing Regulations](#)”) [[12VAC35-105](#)]

Regulation 12VAC35-105-160.D.2. of the Licensing Regulations requires providers to report all Level II and Level III serious incidents 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. Although Level I serious incidents do not need to be reported to the Office of Licensing through the CHRIS system, regulation 12VAC35-105-160.C. requires all non-children's residential providers to collect, maintain, and review all serious incidents, including Level I serious incidents at least quarterly as part of the provider's quality improvement program.

Please note that these methods of reporting an incident in place of submitting an incident report into the CHRIS system will be deemed as non-compliant and the provider will be cited:

- Reporting a serious incident to the provider's licensing specialist via e-mail or phone call;
- Reporting a serious incident to the provider's human rights advocate via e-mail or phone call;
- Reporting the incident to any other representative of DBHDS by any means other than the serious incident reporting function in CHRIS; and
- Reporting an allegation of abuse or neglect that also meets the criteria for a Level II or Level III serious incident only on the DBHDS Office of Human Rights (OHR) side of CHRIS instead of reporting the incident on both the OHR and the DBHDS Office of Licensing sides of CHRIS.

It is important to note that although providers use the CHRIS system to report serious incidents to the Office of Licensing, and to report allegations of abuse or neglect to OHR, these are two distinct reporting functions, which satisfy separate regulatory requirements. Reporting an allegation of abuse or neglect to OHR does not remove the need to report a Level II or Level III serious incident to the Office of Licensing, even if the serious incident report involves the same underlying facts as the abuse or neglect allegation. Please note that the Office of Licensing is working to ensure any future incident reporting system eliminates the need for double entry.

CHRIS System Errors and Network Outages

There may be unusual circumstances when a provider is unable to report an incident through the CHRIS system because of a CHRIS system error or a network outage. The ONLY valid reasons for not reporting a serious incident into CHRIS include: 1) The CHRIS system was not functioning at the time the incident was discovered; or 2) The provider was unable to access the CHRIS system for reasons that were not in the provider's control. If a provider is unable to report a serious incident through the CHRIS system for one of these valid reasons, then the provider must notify the Office of Licensing's Incident Management Unit (IMU) via e-mail (incident_management@dbhds.virginia.gov) of the provider's inability to report the incident through the CHRIS system within 24 hours of the discovery of the incident. In the rare circumstance when the provider is unable to access both the CHRIS system and e-mail for reasons outside of the provider's control, then the provider may notify their regional Incident Management Unit (IMU) representative by telephone.

In such a circumstance, mark the e-mail to IMU with the following subject line: “Potential Late Entry-CHRIS complications for [NAME OF PROVIDER].” Notification to other DBHDS employees or representatives, including the provider's licensing specialist or human rights advocate, will not substitute for notification to the IMU. Providers will be cited for a regulatory violation of 12VAC35-105-160.D.2. or 12VAC35-46-1070.C., as applicable, if they do not report serious incidents within the regulatory timeframe, unless they have notified the IMU of their inability to do so due to a system error in CHRIS or a network outage, even if they have notified their licensing specialist or human rights advocate.

I have noted in my [October 1, 2019 memo](#) and in [subsequent CHRIS training](#), that not having an authorized user for CHRIS is not a valid reason for late submission of a serious incident report in the CHRIS system. It is the provider's responsibility to ensure that an authorized user for CHRIS is available at all times.

Updates to Serious Incident Reports:

In some instances, a provider may need to update a serious incident report in CHRIS after its initial submission.

- A provider may be awaiting a medical report or other records related to an emergency room visit; or
- IMU staff may request that the provider update an incident report in CHRIS when the IMU identifies information that should have been included in the report, but was not included.

When the provider must update an incident report in CHRIS after the initial submission, the provider must do so **within two business days from the initial submission of the incident report, or from the time that the provider is informed by the IMU of the need to update the report, whichever is later.** If the provider is unable to obtain necessary information to update the incident report within the two business day period for reasons outside of the provider's control, such as when the provider is awaiting pertinent laboratory results that are not received within the two business day period for updating the incident report, then the provider must communicate this to the provider's regional IMU representative during the two business day timeframe. Failure to update a serious incident report in CHRIS within two business days from the initial submission of the report, or from the time that the provider is informed by the IMU of the need to update the report, will be cited as a regulatory violation of 12VAC35-105-160.F. or 12VAC35-46-230.A., as applicable, unless the provider has communicated its inability to obtain the necessary information to the provider's regional IMU representative within the two business day timeframe.

2. Office of Licensing Compliance Monitoring Activities

The Office of Licensing conducts ongoing monitoring of provider compliance with serious incident reporting requirements. The IMU within the Office of Licensing reviews serious incident reports for timeliness and compliance with all other regulatory requirements. Each business day, the IMU CAP specialist will 'pull' a report to determine if any providers have not reported Level II and Level III serious incidents through the CHRIS system within the 24-hour timeframe. The IMU CAP specialist will issue a licensing report for all late submissions of serious incident reports into the CHRIS system, except when a provider has notified IMU during the 24 hour reporting period, and the provider had a valid reason for not reporting the incident in the CHRIS system during the 24 hour reporting period, pursuant to 12VAC35-105-160.D.2. or 12VAC35-46-1070.C.

The Office of Licensing also monitors provider compliance with serious incident documentation and reporting requirements during all investigations and annual inspections. Prior to conducting an annual inspection, the licensing specialist will review the provider's history of compliance with 12VAC105-160.D.2. or 12VAC35-46-1070.C. If a licensing specialist identifies a serious incident(s) during an annual inspection that should have been reported but that was not reported at all or was not reported within 24 hours of the discovery of the incident, and for which a licensing report has not already been issued, then the licensing specialist will issue a licensing report citing the provider for late reporting pursuant to 12VAC35-105-160.D.2. or 12VAC35-46-1070.C., as applicable. If a provider made an abuse or neglect report to OHR following a Level II or Level III serious incident, but did not report the serious incident to the Office of Licensing through the CHRIS serious incident reporting function, then the licensing specialist will instruct the provider to report the serious incident, and then will issue a licensing report citing the provider for late reporting.

When conducting an annual inspection of a provider, other than a provider of children's residential services, the licensing specialist will also request evidence to verify the provider's compliance with the documentation and quarterly review of all serious incidents. If the licensing specialist determines that quarterly reviews of all serious incidents were not conducted, or identifies serious incidents that were not included in the provider's quarterly reviews, then the licensing specialist will issue a licensing report for failure to conduct quarterly reviews citing 12VAC35-105-160.C.

Finally, when conducting an annual inspection of a provider, other than a provider of children's residential services, the licensing specialist will review at least one randomly selected root cause analysis (RCA) that was conducted from a list of the serious incidents reported by the provider during the calendar year. If the licensing specialist determines that the provider did not conduct a RCA within 30 days of discovery of one or more Level II serious incidents or any Level III serious incidents that occurred during the provision of a service or on the provider's premises, or that the provider's RCA does not meet the regulatory requirements of 12VAC35-105-160.E., then the licensing specialist will issue a licensing report.

Corrective Action Plans (CAPs) – Minimum Requirements:

Corrective action plans (CAPS) will be required for ALL identified violations of serious incident documentation and reporting requirements. Providers must submit a CAP to the department within 15 business days of the issuance of the licensing report. If a provider is unable to meet the 15 business day deadline for submission of the CAP, the provider may request an extension of up to 10 business days **PRIOR** to the due date for the CAP. Failure to submit a CAP or request an extension of up to 10 business days within 15 business days of the issuance of a licensing report will result in an additional licensing report citing the provider for failure to submit a CAP pursuant to 12VAC35-105-170.D. or 12VAC35-46-80.B., as applicable.

The purpose of a CAP is to prevent the recurrence of the regulatory violation by addressing the underlying cause(s) of the violation. CAPs will only be accepted by the Office of Licensing if they meet the following minimum criteria:

- The proposed corrective actions are clearly articulated and reasonably calculated to address the underlying cause(s) of the violation and to prevent its recurrence.
- The proposed CAP includes systemic actions to ensure future compliance with the regulation. Examples of systemic actions include the implementation of ongoing quality assurance systems to ensure future compliance; and the implementation of ongoing quality assurance self-monitoring tools such as checklists, spreadsheets, tables, or forms.
- There is a realistic completion date provided for each corrective action.
- The CAP includes the means and processes by which evidence of completion of the corrective actions will be collected and provided to the Office of Licensing.

CAPs that do not meet the minimum criteria for acceptance will be returned to the provider for revisions within 15 business days.

Progressive Actions for Repeat Citations:

Beginning ~~August 22~~ October 1, 2020, the Office of Licensing will implement progressive citation protocols to address repeat violations of serious incident documentation and reporting requirements at the service level. The purpose of these protocols is to ensure that providers who demonstrate regulatory noncompliance implement effective corrective actions and quality improvement activities to prevent future violations. When a licensed service was previously cited for a regulatory violation, future violations of the same regulation within a one-year period, measured on a rolling basis, will result in the following progressive actions:

First Citation: When issued to a licensed service related to the reporting of serious incidents, deaths, or allegations of abuse or neglect within a one-year period, the provider will be issued a licensing report citing:

- 12VAC35-105-160.D.2. or 12VAC35-46-1070.C., as applicable, for noncompliance with reporting requirements.

Second Citation: When issued to a licensed service related to the reporting of serious incidents, deaths, or allegations of abuse or neglect within a one-year period, the provider will be issued a licensing report citing:

- 12VAC35-105-160.D.2. or 12VAC35-46-1070.C., as applicable, for systemic noncompliance with reporting requirements; AND
- 12VAC35-105-170.G. or 12VAC35-46-80.B., if it is determined that the repeat violation was due to the provider's failure to implement a previously pledged corrective action plan. The provider will not receive a citation for 12VAC35-105-170.G. or 12VAC35-46-80.B. if it is determined that the repeat violation was not due to the provider's failure to implement previously pledged CAPs. However, the department will verify that the provider is monitoring implementation and effectiveness of approved corrective actions as part of their quality improvement program per 12VAC35-105-170.H.

Third Citation: When issued to a licensed service related to the reporting of serious incidents, deaths, or allegations of abuse or neglect within a one-year period, the provider will be issued a licensing report citing:

- 12VAC35-105-160.D.2. or 12VAC35-46-1070.C., as applicable, for systemic noncompliance with reporting requirements; AND
- 12VAC35-105-170.G. or 12VAC35-46-80.B., if it is determined that the repeat violation was due to the provider's failure to implement a previously pledged corrective action plan. The provider will not receive a citation for 12VAC35-105-170.G. or 12VAC35-46-80.B. if it is determined that the repeat violation was not due to the provider's failure to implement previously pledged corrective action plans. However, the department will verify that the provider is monitoring implementation and effectiveness of approved corrective actions as part of their quality improvement program per 12VAC35-105-170.H.

In addition, the department may mandate serious incident reporting training for the provider's employees, with costs borne by the provider, when it is determined that a lack of training caused or contributed to the licensing or human rights violations pursuant to Code of Virginia § 37.2-419 and 12VAC35-105-100.A. or 12VAC35-46-60.G.; or require the provider to submit a signed attestation verifying that the regulations and guidance pertaining to serious incident reporting were reviewed.

Fourth Citation (and more): When issued to a licensed service related to the reporting of serious incidents, deaths, or allegations of abuse or neglect within a one-year period, in addition to the steps enumerated above for the third citation, the Office of Licensing may take additional steps as authorized by the Code of Virginia. When determining whether additional steps are warranted, the Office of Licensing will consider the number of past violations, the severity of the regulatory infraction(s), the provider's size, number of locations, and service type, and the number of individuals that the provider serves. Additional steps may include any of the following:

- Issue sanctions enumerated in § 37.2-419 of the Code of Virginia (Code of Virginia § 37.2-419 and 12VAC35-105-100 and 12VAC35-46-60.G.);
- Deny an application for a license or license renewal (Code of Virginia § 37.2-418 and 12VAC35-105-110 or 12VAC35-46-120);
- Issue a provisional license (Code of Virginia § 37.2-415 and 12VAC35-105-50A.2. or 12VAC35-46-90.B.); or

- Revoke or suspend a full, conditional, or provisional license, due to the provider's repeated failure to submit or implement an adequate CAP (Code of Virginia § 37.2-418 and 12VAC35-105-110 or 12VAC35-46-1630).

You are encouraged to sign up for the Office of Licensing's recurring CHRIS trainings on [Eventbrite](#) for helpful information related to serious incident reporting. If you have any questions or concerns regarding the content of this memo, please contact the Stella Stith, Office of Licensing Incident Management Manager, at stella.stith@dbhds.virginia.gov.

Additional resources from DBHDS related to serious incident reporting can be found at the following links:

- [DBHDS Office of Licensing Guidance for Serious Incident Reporting](#)
- [Office of Licensing Serious Incident Reporting Training](#)
- [CHRIS Reporting Expectations Memo](#)
- [Revoking a User's Delta Access](#)
- [Restructuring Within the Office of Licensing](#)
- [02.2020 CHRIS Modifications Training](#)
- [04.2020 CHRIS Modifications Training](#)

Note that all Office of Licensing guidance documents are posted on [Town Hall](#) and are numbered beginning with 'LIC.'

More information about the Settlement Agreement indicators tied to serious incident reporting and specifically indicators: V.B.3.b, V.B.3.a.i, V.B.3.a.ii, V.B.3.a.iii, V.B.3.b, V.C.6.4, V.C.6.5, V.C.6.6, and V.C.6.7 can be found within the [Joint Filing of Complete Set of Agreed Compliance Indicators](#).