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COMMONWEALTH of VIRGINIA

DEPARTMENT OF
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***DRAFT* MEETING MINUTES**
CALLED EMERGENCY MEETING

*Electronic Meeting
Thursday, April 2, 2020
9:30 a.m.

**The board met electronically, without a quorum physically assembled, in accordance with Code of Virginia 2.2-3708.2.A.3. and Executive Order 51. Note: Audio record available upon request.*

Members Present	Paula Mitchell, **Chair**; Elizabeth Hilscher, Vice Chair; Varoun Chaudhary; Rebecca Graser; Jerome Hughes; Moira Mazzi; Djuna Osborne; Sandra Price-Stroble.
Staff Present	Jae Benz, Director of Licensing Emily Bowles, Assistant Director for Licensing, Quality, Regulatory Compliance, and Training Braden Curtis, Assistant Attorney General, Office of the Attorney General Heidi Dix, Deputy Commissioner, Division of Compliance, Regulatory, and Legislative Affairs (CRLA) Alison G. Land, FACHE, Commissioner Dev Nair, Ph.D., Assistant Commissioner, CRLA Ruth Anne Walker, Director of Regulatory Affairs and State Board Liaison
Call to Order, Roll Call, and Introductions	At 9:36 a.m., Paula Mitchell, Chair, called the meeting to order and welcomed everyone. Ms. Mitchell explained that the board was meeting electronically, without a quorum physically assembled, in accordance with Code of Virginia § 2.2-3708.2.A.3. and Executive Order 51. She directed anyone interested in a full explanation of the justification and parameters of this emergency meeting to review the cover memo of the meeting packet on page 1. Ms. Mitchell explained that all board members and staff were unmuted to converse. All others on the call were muted with the ability to listen and view the screen. The meeting packet of information was located on Virginia's Town Hall, http://townhall.virginia.gov under 'Meetings.'

	Ms. Mitchell then conducted a roll call of members (Hilscher, Graser, Price-Stroble, Mazzi, Osborne, Chaudhary, Hughes), after which she confirmed that a quorum was present on the call. Ms. Mitchell also confirmed the DBHDS staff on the call: Heidi Dix, Dev Nair, Jae Benz, Emily Bowles, Ruth Anne Walker, and Alison Land.
Approval of Agenda	*At 9:40 a.m. o,n a motion by Sandra Price-Stroble and a second by Djuna Osborne the board voted unanimously to adopt the April 2, 2020, the agenda.*
Public Comment	At 9:41 a.m., Ms. Mitchell noted that in Article 5.h. of the State Board Bylaws, it states, 'The agenda for each meeting of the board shall indicate that public comment will be received at the beginning of the meeting.' She explained that for this meeting, receipt of public comment was handled differently, while still in accordance with the bylaws. Any person seeking to make comment to the state board was given the opportunity to submit comment in writing by 5 p.m. April 1, 2020, via email. Ms. Mitchell announced that one comment was received on the draft from the Henrico Community Services Board and that staff from the Office of Licensing summarized the comments and provided a response to the comment. This information was visible on screen, while also emailed to the board just before the start of the meeting, and a revised meeting packet with the summary of comments and response attached was made available on Virginia's Town Hall. Ms. Mitchell allowed all on the call a moment to access that information. Ms. Mitchell asked for a motion to receive the comments into the record to be part of the meeting record and to attach to the minutes. *At 9:43 a.m. on a motion by Elizabeth Hilscher and a second by Ms. Osborne, the board voted unanimously to adopt the April 2, 2020, comments into the record.* [Note: The excerpt of the comments and the response to comments from the revised meeting packet are attached to these minutes.] Ms. Mitchell thanked the Licensing staff for compiling that information so quickly.
Regulatory Actions and Updates	**Amendments for Final Stage (12VAC35-105): Compliance with Virginia's Settlement Agreement with US DOJ** At 9:44 a.m., Ms. Mitchell directed board members to turn to the action item for this emergency meeting on page 5 of the meeting packet. She noted that the amending language for the final stage was set out in [square brackets] to show edits to the language adopted in the proposed stage, and that it was only those bracketed edits under consideration. Before asking for discussion or a vote, Ms. Mitchell recognized staff from the Office of Licensing present: Jae Benz, Director, and Emily Bowles,

	Assistant Director for Licensing, Quality, Regulatory Compliance, and Training. Also, Dr. Dev Nair, Assistant Commissioner for the Division of Compliance, Regulatory, and Legislative Affairs was available to possibly provide comment, if needed; and liaison to the board, Ruth Anne Walker, staffed the meeting. Ms. Mitchell asked Ms. Benz if she would give a brief overview for the board. Ms. Benz stated she realized the turnaround time for review by the board was expedited (March 26, 2020), but explained that the office had been working diligently on the amendments, even before the close of the proposed stage public comment period on January 10, 2020. Staff had been on schedule to get revisions to the board no later than the usual two-week delivery when the COVID-19 crisis hit full force. The crisis then took top priority and consumed a large part of the day to day work of the office. Ms. Benz expressed appreciation to the board for taking time to review the amendments within the shortened timeframe. The amendments were made in response to public comments and due to additional, more detailed requirements agreed upon by the parties in the negotiations on the Settlement Agreement. The more detailed requirements laid out how the Commonwealth would reach compliance with each of the provisions where there is a rating of noncompliance. Some of those indicators required changes to the regulations, so the amendments are critical components to reaching Virginia's goal of exiting the Settlement Agreement. Ms. Benz stated that in fact, if the regulations were not amended, the Commonwealth could be found in violation of a federal court order. So, the board's consideration of these amendments allows the Commonwealth to address those areas that required further changes. She expressed her appreciation to the board of their consideration of the final stage amendments and asked Ms. Bowles to explain in detail. Ms. Bowles expressed the gratitude of the office to being nearing the end of a process started over two years ago. She proceeded to review and explain in detail all final stage amendments. The changes are delineated in the Town Hall agency background document. The most significant changes have to do with the requirements for providers to conduct a root cause analysis, systemic risk assessments, clarification related to risks of harm, documentation of informed choice, and serious incident reporting. Amendments were also made to clarify the necessary qualifications of risk management staff. In response to comment, the changes between the proposed stage and final stage of these regulations will improve clarity and reduce provider burdens, while increasing risk management and quality improvement processes at every level of the service delivery system. In addition, sections were rearranged and broken down largely to aid in readability and comprehension. Also, clarifying amendments were added for

	what providers should do if an approved corrective action was not successful in correcting systemic deficiencies, in order to facilitate quality improvement. Last, in response to significant public comment, language within the Emergency Regulations related to fire inspections was stricken, and the language reverted back to as it appeared before. Language related to fire safety was added below to 12VAC35-105-530 to accomplish the intent of the amendments, that is, to ensure that all providers adhere to a basic level of fire safety precautions for the health and safety of individuals. Ms. Mitchell thanked Ms. Benz and Ms. Bowles. She then asked members if there were any questions for the Office of Licensing. Ms. Hilscher did not have a question but expressed approval and appreciation of the edits to break out text into clear lists and otherwise clarify the information and improve comprehension. Mr. Hughes concurred. Ms. Osborne expressed appreciation for all of the work by staff including the consideration of all the public comment, and she particularly appreciated the training that would be offered so that providers would be better equipped to implement the required policies, i.e. root cause analysis. At 10:10 a.m., Ms. Mitchell asked for a motion to adopt the edits and initiate the final stage for the amendments to Chapter 105 to comply with the DOJ Settlement Agreement. *On a motion by Ms. Mazzi and a second by Ms. Osborne,* and after a roll call vote conducted by Ms. Mitchell *(Beth Hilscher; Becky Graser; Sandra Price-Stroble; Moira Mazzi; Djuna Osborne; Varoun Chaudhary; Jerome Hughes; and the chair), the board voted to adopt the edits as presented and the final stage was approved for initiation.* Ms. Mitchell asked that staff file the final stage as appropriate. She made note to all listening on the call that there would be a final stage public comment period as part of the final stage process.
Commissioner's Report	At 10:14 a.m., Ms. Mitchell turned the meeting over to Commissioner Alison Land to give a presentation on the current state of emergency. She asked members to make note of their questions and hold them until after the commissioner's presentation. Commissioner Land updated the board on the DBHDS and Commonwealth of Virginia COVID-19 response, stating that the department had never seen anything like COVID-19 before that disrupted personal and professional lives on such a large-scale for such a long duration. The department spent weeks preparing and building and planning, and had reached the implementation phase which was expected to be a marathon. The leadership urged state hospitals and public and private community providers take all necessary precautions available to keep staff and service recipients healthy and safe, but to please stay in the fight to deliver services with as full capacities as they possibly could. Without their efforts, the wave

	of cases to private hospitals and state hospitals likely would be overwhelming for the medical system statewide. Ms. Land stated that Virginia's response evolved rapidly over the past four weeks. The department was pushing forward in this unprecedented situation to tackle unforeseen circumstances and make key operational decisions as things proceeded. This involved a tremendous amount of effort. Statewide, Governor Northam launched a COVID-19 Task Force in the last week of March. The task force has a healthcare coordination section that would enable better coordination and collaboration between the public and private systems. Commissioner Land identified some key examples of implementation by the department: I. For community services boards (CSBs) and private providers: • Developed a new COVID-19 page on the DBHDS website for providers, healthcare workers, and individuals coping with COVID-19. This includes a comprehensive set of FAQs that are updated daily at www.dbhds.virginia.gov/covid19. • Posted new operational and functional guidance on emergency prescreening, REACH, and permanent supportive housing. There was also new guidance from DMAS surrounding the expansion of telehealth and waiving certain program requirements. • Worked closely with DMAS on many of these issues to ensure the guidance from both agencies aligns and both agencies were taking every advantage of federal resources or waivers where it would help the CSBs and other providers continue to operate, where appropriate. • Established weekly calls with CSBs, providers, and their associations about the COVID-19 response. • CSBs were asked to provide daily reports on their operational status, to include employees unable to work, lay-offs, program closures, and other critical information. • Worked with the CSB executive directors and chief financial officers to monitor their financial situation as shut downs or reduction of some of their programs began. DBHDS was using the information the CSBs were providing to discuss how Governor Northam's Administration might provide either state or federal resources to support the CSBs during this time. II. In regard to DBHDS overall: • Updated and posted facility visitation policies on the COVID-19 page on the agency website mentioned above. • Immediately established the Incident Management Team (IMT) that transitioned into an emergency operations center (EOC) staffed 12 hours a day during the week.

- Accelerated the launch of a new intranet as another communication tool for human resource guidance including teleworking information.
- Significantly ramped up resources posted to Facebook and Twitter.

III. DBHDS facilities:
Facility staff pushed forward during this extraordinarily challenging time that affected healthcare workers in such a disproportionate way. The DBHDS system has unique challenges in disaster preparedness including preparedness for COVID-19. Serving as the safety net and 'bed of last resort' for Virginia's behavioral health system results in the system operating dangerously close to maximum capacity even during non-disaster times. Since March 14, 2020, DBHDS facilities implemented strict visitation policies and began screening employees prior to each shift and monitoring for associated signs and symptoms of COVID-19 in individuals receiving services in facilities.

There were currently no individuals in state hospitals with major symptoms but given the rapid spread of the virus statewide, it was not expected to possibly stay the same at state hospitals for very long. As of April 1, 2020, two staff were confirmed positive at facilities. Department leadership was working closely with all DBHDS facilities to ensure when these situations arise precautions are taken to keep safe the individuals receiving services and staff in the facilities. Staff were working to prevent possible cases and planning for what to do should there be one within the patient population. This included following federal Centers for Disease Control (CDC) guidelines for health care organizations, restricted visitation policies, further increased infection control measures, and social distancing practices with staff and patients to minimize risk of exposure. Staff were preparing for how to isolate any individuals should there be positive COVID-19 cases. DBHDS was doing everything possible to procure additional personal protective equipment (PPE), such as masks, gloves, gowns, etc., which is an extreme challenge in the national shortage of PPE. Nationwide shortages of PPE were acutely felt at the state facilities. DBHDS was collaborating with state partners to benefit from the few distributions that were taking place and was also actively preparing for impending staffing shortages as more Virginians likely fall ill.

Notably, the census for Virginia's state psychiatric hospitals serving adults remained very high at 94.5%. Because living in a congregate setting increases risk, DBHDS was taking every opportunity to decompress the hospital census and rapidly arrange for community-based services for those who could be safely discharged. State facilities were working to minimize risk of exposure to both staff and patients, and also recognized the need to be flexible in this rapidly evolving environment.

IV. Coordination with the public and private community system included:

	• Working to ensure DBHDS-funded assisted living facilities and transitional housing programs can continue taking admissions. • Using telehealth platforms and virtual tours to enable community providers to interview potential clients, and for patients to be able to see the potential placement. • Partnering with CSBs to increase usage of crisis stabilization units as temporary placements for individuals leaving state hospitals who may not have a permanent placement or are waiting for their permanent placement to have an open bed. • Discussing with some assisted living and nursing homes to implement emergency contracts to expedite discharges from the state facilities. One of the system struggles that could significantly impact the department's ability to discharge patients who were well and clinically ready for discharge was that some mental health providers in the community had significantly decreasing service availability. But overall, the census decompression facilitated the ability of state hospitals to medically isolate or quarantine any person testing positive for COVID-19 and positioned the system as optimally as possible to care for individuals in need as the private hospital system likely becomes inundated by COVID-19 cases. The department was preliminarily successful in this decompression effort in all but the geriatric population. Unfortunately, this population appeared to be most vulnerable to the current pandemic. Finally, Ms. Land stated how impressed she was with DBHDS, CSB, and provider staff. They were all pushing forward despite uncertainty and fears, and showed unyielding commitment to those served. She further stated that all Virginians truly owed them a debt of gratitude, and DBHDS was working hard to protect them and the individuals receiving services. Ms. Graser asked for clarification of the number of approximately 200 individuals the department hoped to discharge from state hospitals. Ms. Land explained she had referred to those on the extraordinary barriers to discharge list (those ready to be discharged but for whom a community placement could not be found). Mr. Hughes stated he runs five recovery centers in Northern Virginia that have gone to virtual services. He asked about funding that was already allocated but in limbo and stated his concern with contract funding related to keeping staff on. Ms. Land did not have updates on that but expected information in coming days. Ms. Price-Stroble had a question and statement related to CSBs. As she realized services are not going to be exactly the same, she shared concerns of staff and individuals receiving services on the variation of person to person contact. For instance, at some CSBs staff come out to a car to get an individual for an appointment versus some using waiting rooms, or staff

	sharing a break room together in close proximity. Ms. Land stated she had received a number of contacts from others with these concerns. In some instances, it is not possible to do a virtual service. Some try to do in person at least six feet apart to keep the service going. Overall, she felt CSBs were trying to do the right thing. Ms. Price-Stroble asked if they are expected to do some things with consistency across CSBs, like with waiting rooms or bringing in a child; as in getting guidance from DBHDS. Ms. Land stated she did not know of any guidance on individuals coming in and out the front door, but that DBHDS could reach out to VACSB to share that idea. Ms. Mitchell thanked and commended Ms. Land and the department for all the outstanding work done with these amendments even with the state of emergency and the work-life changes that had occurred as a result, and the work going on in a larger sense outside of the crisis. She asked the commissioner to pass those comments on to the other staff.
Other Business	At 10:40 a.m., Ms. Mitchell reminded board members to watch for an email from her announcing appointments to the Nominating Committee and the Grant Review Committee. She further reminded members and all on the call that the next regular meeting of the board is scheduled for July 15, 2020, in Richmond and that per the bylaws, officer elections will be held at that time. Ms. Mitchell asked if there was any other business to come before the board. On behalf of the board, Ms. Hilscher expressed regret that the board could not be with Ms. Mitchell for the meeting that day as it was Ms. Mitchell's last meeting before her term ended on June 30, 2020. Ms. Hilscher virtually presented the gift of a plaque recognizing Ms. Mitchell's eight years of outstanding service to transform behavioral health and developmental services in the Commonwealth of Virginia. For several of those years Ms. Mitchell was chair and has been a wonderful chair; a level, good, and calm leader who made sure everyone had a chance to be heard at meetings. Ms. Mitchell has been incredibly effective, always bringing good questions to the forefront; and has an incredible wealth of knowledge about the system. She has made Virginia a better place through her work on the board. Members concurred and offered personal comments of appreciation to Ms. Mitchell for her service as a member and as chair. Ms. Mitchell thanked the board and also expressed sadness at not being able to be together.
Adjournment	There being no further emergency business, Ms. Mitchell adjourned at 10:45 a.m.

NEXT MEETING: The next meeting of the State Board will be on July 15, 2020, at the DBHDS Central Office in Richmond.

Documents	DRAFT Final Stage Amendments (Action 5040)
VAC	DBHDS Rules and Regulations For Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105], and the U. S. Department of Justice's Settlement Agreement with Virginia (United States of America v. Commonwealth of Virginia, Civil Action No. 3:12cv059-JAG)
Window:	Opened 3/26/2020/ - 4/1/2020

DBHDS response to comments are in yellow highlight.

Section	Comment	Changes to proposed draft	Comments 3/30/20
12 VAC 35-115-20 Definitions			
• **Level II Serious Incident**	The department received numerous comments on the proposed definition of "Level II serious incident." Several commenters requested additional clarification on the reporting of an "unplanned psychiatric … admission" as a "Level II serious incident", or removal of "unplanned psychiatric … admission" from the definition of a "Level II serious incident" altogether. One commenter asked whether an individual who is "ECO'd" but who later decides to voluntarily admit themselves to the hospital would be included within the definition. One commenter expressed concern about the removal of "urgent care facility visits" when not used in lieu of a primary care physician visit. The commenter noted that some injuries that do not necessitate an emergency room visit and may be treated in an urgent care facility. Conversely, several commenters expressed	Changes made. The definition of "Level II serious incident" has been amended to clarify that a psychiatric admission that is in accordance with an individual's wellness recovery action plan (WRAP) shall not constitute an "unplanned admission for the purposes of this Chapter." Additional guidance and technical assistance will be provided as needed to ensure that providers are able to meet the regulatory requirements. No changes have been made to the proposed language regarding emergency room visits. Urgent care facility visits were removed from the requirement because they often involve less serious incidents that do not rise to the severity of a Level II serious incident, and a categorical rule in this instance would result in significant over-reporting. Emergency room visits, however, are more likely	Expand to WRAP and Crisis plans: If psychiatric admission is included in an individual's crisis plan, then would an admission be considered planned as it would be if the individual has a WRAP plan? If the individual has a WRAP or Crisis plan that includes psychiatric admission and ends up being TDO'd, would that also be considered a planned admission? Original comment: The change to all emergency room visits will increase the amount of incident reports submitted to CHRIS, increase the amount of staff time in reviewing the incident for the root cause analysis. This contradicts the goal stated in the economic impact to allow for more targeted reporting and freeing up valuable staff time.

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	concern that defining all emergency room visits as Level II serious incidents would result in an increased burden on providers. These commenters recommended reverting back to language that only defines emergency room visits as Level II serious incidents when not used "in lieu of a primary care physician visit."	to evidence an injury or risk of injury of sufficient severity to constitute a Level II serious incident. Furthermore, the department received numerous comments during previous phases of this regulatory action that convincingly suggested that the phrase "in lieu of a primary care physician visit" was too vague and imprecise, and would therefore result in inconsistent interpretation and application. For these reasons, the department believes that it is important to capture all emergency room visits within the definition of Level II serious incidents.	**Response: At this point, the department does not recommend extending the exclusion of psychiatric admissions that are in accordance with an individual's WRAP plan from the definition of a level II serious incident to include psychiatric admissions that are in accordance with any crisis plan. Crisis plans can vary significantly in important ways, including in the processes by which they are produced, the degree of involvement of individuals in their development, and the frequency with which they are updated. A blanket exclusion of psychiatric admissions that are in accordance with a crisis plan, therefore, is inadvisable. However, we have reached out to our subject matter experts in the time since this comment was received to confirm they are agree.** **An admission that is in accordance with an individual's WRAP plan is not considered an unplanned psychiatric admission under the proposed amendments to the Emergency Regulations. The relevant question is whether the admission is in accordance with the individual's WRAP plan, and not whether the admission was voluntary or involuntary at the time of admission.**

Section	Comment	Changes to proposed draft	Comments 3/30/20
12VAC35-105-160. Reviews by the department; requests for information; required reporting.			
• **D.2. Incident reports – risk of harm**	A number of commenters expressed concern about the requirement in 12VAC35-105-160(D)(2) that providers report, among other things, the "consequences or risk of harm" that results from Level II and Level III serious incidents. "Risk of harm," these commenters noted, is speculative, open to interpretation, and asks providers to draw conclusions that they may not have sufficient expertise to draw. Two commenters expressed more general concerns about the Level of detail required in an incident report. These commenters noted that providers have 24 hours to gather information and report to the department.	Change made. The department agrees that "risk of harm" is speculative and will result in different interpretations. "Risk of harm" has been stricken from this subsection. The phrase "risk of harm" has been inserted, however, into subsection 12VAC35-105-160(E) discussing the purpose of the required root cause analyses, which is, in part, to mitigate the risk of future harm, while recognizing the inherent difficulties in foreseeing all risks of future harm. This change will also reduce the immediate burdens placed on providers to complete the initial incident reporting requirements.	Agree this should be removed from the CHRIS report but adding it to the Root Cause Analysis will still require speculation by investigative staff. Requesting "Risk of Harm" to be removed from RCA. **Response: In the previous draft, providers were asked to include risk of harm when they reported within 24 hours of the incident. The department recognized that this could be burdensome given the short timeframe for reporting, as that meant a lack of time to analyze.** **The "risk of harm" in the current draft refers to risk identified during the root cause analysis process, and includes the qualifier "when applicable," or of recognition that not all risks of harm are predictable. Reducing risks of harm is one of the primary reasons**

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			for performing root cause analyses.
• **E. Root Cause Analyses**	There were a number of comments on the requirement that providers conduct a root cause analysis. Several commenters noted with approval a change that requires root cause analyses for Level III serious incidents only when they occur on the provider's property or during the provision of services. Several commenters, however, requested that "during the provision of care" be defined or otherwise clarified. Several commenters also expressed concern about the inclusion of language that suggests that a "more detailed root cause analysis," including, among other steps, "convening a team" should be considered when circumstances warrant. This language, several commenters suggested, is overly prescriptive, ambiguous, and administratively burdensome. Another commenter suggested "clarification that an individual has the right to indicate they do not want the identified solution implemented" when a provider identifies solutions to mitigate the recurrence of a serious incident. This commenter noted that "individuals have the right to choice and dignity of risk."	Changes made. The department has made changes to provide greater clarity relating to when a provider should conduct a more detailed root cause analysis. The incident management and root cause analysis components of this regulatory action are at the heart of the department's efforts to fully comply with the Settlement Agreement's quality and risk management provisions. In the time since the emergency regulation became effective, the department has issued additional guidance related to what constitutes "during the provision of services." Further guidance and technical assistance to ensure that providers are knowledgeable of and equipped to comply with these requirements while respecting the rights of individuals to choice and dignity will be provided. Guidance Provided in State Memo: 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	Original Comment It would be helpful to have a definition of "during provision of care" particularly as it relates to case management services. Does this mean when staff are with the person? What happens when the case manager is called and becomes involved or gives guidance is that considered provision of care? In residential services, if a serious incident occurs while the individual is with their family/guardian or at their day program is a root cause analysis not required? The agency is asking for flexibility in defining in their policy how teams are convened. Input for development of a plan for an individual may occur with the team via emails, telephone contact or video conference. Currently staff discuss cases in a variety of ways which does not always include meeting with all providers in one meeting location. **Response: Guidance has been provided on the meaning of "during the provision of services" and additional guidance and technical assistance will be provided. There is nothing in the regulation that defines how providers must convene a team**

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		causal factors should be conducted. At a minimum, the policy shall require for the provider to conduct a more detailed root cause analysis when: 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 serviced, and the unique needs of the individuals served by the provider, of similar Level II serious incidents occur to the same individual or at the same location within a six month period; b. Two or more of the same Level III serious incidents occur to the same individual or at the same location within a six month period; Page 26 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 serviced, 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; and d. A death	during the root cause analysis process.

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		occurs as a result of an acute medical event that was not expected in advance or based on a person's known medical condition.]	
12VAC35-105-650. Assessment policy			
• F. Comprehensive Assessment		No change made, but guidance will be provided to DBHDS staff and external stakeholders to resolve confusion about these requirements in the short term, and the department will revisit these comments during the licensing regulatory 'overhaul.'	There are questions regarding this requirement and Same Day Access Services. We have received feedback that two separate assessments are needed; the initial assessment and the comprehensive assessment. The initial assessment should be at admission to agency not at every new service that may be added. This needs clarification as it relates to the State's SDA initiatives. **This is outside the scope of this regulatory action, but will be reconsidered during the regulatory overhaul. Please see formal response to public comment:** ***No change made, but guidance will be provided to DBHDS staff and external stakeholders to resolve confusion about these requirements in the short term, and the department will revisit these comments during the licensing regulatory 'overhaul.'***
General comments			

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• Economic impact on regulated entities	Six commenters disagreed with the department's economic impact statement or otherwise noted the administrative financial impact on regulated entities of the additional risk management and quality improvement components of these regulations. One commenter suggested that these requirements were not factored into the existing provider rate methodology. One commenter noted that "the financial cost for ensuring appropriate training occurs is not small and we encourage the Office of Licensing to support he provision of regular, high-quality training across the Commonwealth on topics such as root cause analysis, risk management, data analysis, and investigation skills."	No changes made. DBHDS believes these new regulations will be cost neutral. The new regulations were previously put in place with an emergency provision, meaning providers should be in compliance or in planning to utilize existing resources to come into compliance. The new requirements of the permanent regulations may impose some administrative costs to providers, but will save administrative resources by categorizing reported incidents and improving compliance and quality and risk management at facilities. Most facilities licensed by DBHDS have personnel possessing the qualifications as outlined in the regulations. The only individual required to have such qualifications is a risk manager for the facility. DBHDS will use existing resources to provide necessary trainings and support to any risk manager not previously trained. The staff time required to adhere to the new regulations is minimal and, as a result, the provider rate methodology is likely not affected. Additionally, Without these regulations, the Commonwealth, DBHDS, and all licensed providers face falling out of compliance with the DOJ Settlement Agreement, which would lead to significantly more expensive measures for all parties	The impact on entities stated in the NOIRA is not representative of the true impact providers are experiencing. Providers have needed to increase staff doing the work related to increased requirements. This work has not been absorbed without additional costs. There has not been sufficient staff to cover the increased follow-up and expected compliance time frames. Mandated time frames take precedent over other duties such as; 24 hour reporting, 10 day turn around on DD Mortality reviews, 30 day Root Cause Analysis, 10 day Human Rights investigations, CAP response, follow-up on CAPS and HR plans of corrections are examples of the what is required to be managed to avoid further corrective action plans. DBHDS has increased regulatory and guidance oversight throughout their departments. The regulatory impact providers experience from DBHDS is from several departments, such as the Office of Licensure, Office of Human Rights and disability specific program guidance, evidence based programs, and their oversight, expectations and requirements. All of the departments and DBHDS entities are transforming and increasing requirements and expectations that have an overall impact on providers. In addition, there has been an impact on staffing particularly within Case

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		than compliance with these regulations. The department is committed to supporting providers to ensure that requisite training occurs and that they have the tools necessary to carry out effective risk management and quality improvement programs. The department will continue to provide guidance and technical assistance to providers in these areas.	Management Services . Increased responsibilities for Developmental Services Case Managers/Support Coordinators is straining the system as the additional work justifies smaller caseloads, while positions remain difficult to fill and there are increasing difficulties in retaining staff members. The reporting and monitoring requirements for our agency are significant and additional funding is needed to assist with Administrative and Quality Assurance work. The financial cost for ensuring appropriate training occurs is not small and we encourage the Office of Licensing to support the provision of regular, high-quality training across the Commonwealth on topics such as root cause analysis, risk management, data analysis, and investigation skills. A coordinated study of the full impact of DBHDS requirements and the economic impact on providers is requested and needed. **Response: See response to comments related to economic impact in previous response to comments.** **DBHDS believes these new regulations will be cost neutral. The new regulations were previously put in place with an**

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			emergency provision, meaning providers should be in compliance or in planning to utilize existing resources to come into compliance. The new requirements of the permanent regulations may impose some administrative costs to providers, but will save administrative resources by categorizing reported incidents and improving compliance and quality and risk management at facilities. Most facilities licensed by DBHDS have personnel possessing the qualifications as outlined in the regulations. The only individual required to have such qualifications is a risk manager for the facility. DBHDS will use existing resources to provide necessary trainings and support to any risk manager not previously trained. The staff time required to adhere to the new regulations is minimal and, as a result, the provider rate methodology is likely not affected. Additionally, without these regulations, the Commonwealth, DBHDS, and all licensed providers face falling out of compliance with the DOJ Settlement Agreement, which would lead to significantly more expensive measures for all parties than compliance with these regulations.

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			The department is committed to supporting providers to ensure that requisite training occurs and that they have the tools necessary to carry out effective risk management and quality improvement programs. The department will continue to provide guidance and technical assistance to providers in these areas.