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Final Regulation Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services (DBHDS)
Virginia Administrative Code (VAC) citation(s)	12 VAC 35-115-10 et seq.
Regulation title(s)	Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by DBHDS
Action title	Streamline the administrative process, improve program efficiencies and eliminate redundancies.
Date this document prepared	July 27, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The revisions to the Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by DBHDS (12 VAC 35-115-10 et seq., "Human Rights Regulations") were made to improve the ability of the DBHDS Office of Human Rights to perform its Code-mandated responsibilities and maximize resources in a manner that promotes the department's vision of recovery, self-determination, empowerment, and community integration for individuals receiving services. The intent of these proposed changes is to streamline the administrative process, improve program efficiencies, and eliminate redundancies.

Acronyms and Definitions

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Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

- § "CHRIS" Computerized Human Rights Information System (the DBHDS web-based reporting system).
- § "DBHDS" Virginia Department of Behavioral Health and Developmental Services.
- § "DOJ" United States Department of Justice.
- § "ICFID" Intermediate care facilities for individuals with intellectual disability (ICF/ID) is an optional Medicaid benefit.
- § "LHRC" Local Human Rights Committee.
- S "SCC" Specially constituted committee serving an intermediate care facility as described in the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (42 CFR 483.440(f)(3)).
- § "SHRC" State Human Rights Committee.

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

The action was approved in the proposed stage by the Governor on November 13, 2015. At a quarterly meeting on Wednesday, July 13, 2016, the State Board of Behavioral Health and Developmental Services (State Board) approved this package as final changes to the Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by DBHDS (12 VAC 35-115-10 et seq., "Human Rights Regulations").

The State Board started the standard regulatory action on April 17, 2014. Prior to requesting action by the State Board, DBHDS used an inclusive process to obtain stakeholder feedback on how to change the regulations, which included the following activities:

- S An expert panel was convened in November 2012. It approved the goals and recommended hiring of an outside consultant to conduct stakeholder feedback.
- Contracted with the ODU Social Science Research Center:
 - o 5 distinct stakeholder groups were surveyed-800 responses;
 - 3 stakeholder focus groups;
 - Final report issued in June 2013. In addition to findings, it recommended obtaining additional feedback from individuals, family members, and LHRC members.
- Held 5 Town Hall meetings across the state in partnership with VOCAL to talk with individuals.
- S Convened one Town Hall meeting attended by LHRC members and providers.
- S Contacted other individuals and family members for feedback.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including:

1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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The State Board has the legal authority to promulgate regulations under Section 37.2-203 of the Code of Virginia. These particular regulations are promulgated by the State Board pursuant to Section 37.2-400 of the Code of Virginia.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Through streamlining the administrative process, improving program efficiencies, and eliminating redundancies, individuals receiving services will be better served. The DBHDS human rights system will be better able to protect the public health, safety, and welfare with the least possible costs and intrusiveness to the citizens and businesses of the Commonwealth.

Specifically, the goals of the changes are to clearly articulate the:

- Muman rights of every individual receiving care and treatment in facilities and programs licensed, funded, and operated by the agency.
- Responsibilities of providers of mental health, developmental or substance abuse services in ensuring the rights of individuals receiving services, and any exceptions and conditions placed on these responsibilities.
- S Complaint review and resolution process, and to specify the procedures and time frames for the review of complaints of human rights violations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

A summary of major proposed changes follows:

- S Operational functions of the system are removed from LHRCs, providers, and the SHRC, and placed with DBHDS.
- S DBHDS has an increased responsibility for the overall functioning of the human rights system by supporting LHRCs with resources, training, and consultation.
- § In consultation with the SHRC, DBHDS will set the number of LHRCs.
- S LHRC duties focus on the individual's due process rights (complaints, behavior plans, variances, program rules). The duties to monitor providers are eliminated (review of policies, reporting requirements, attendance requirements, etc.).
- § LHRC review of plans that restrict an individual's rights is expanded.
- § Human rights advocates have an increase in responsibility to train all stakeholders on the regulations.

Providers no longer affiliate with a local committee, but ensure access to a committee in their area if there is an issue for LHRC review. Providers are no longer required to attend LHRC meetings unless there is an issue.

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- **S** Complaint processes are consolidated into one section.
- S The use of prone restraints is prohibited.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

At the start of this regulatory action in 2014, there were more than 70 LHRCs. The regulatory changes will reduce the number of LHRCs and fundamentally modify their role and function by shifting from a focus on provider administrative and support activities to review and approval of planned restrictions on the rights of individuals receiving services, approval of variances, and conducting hearings.

The regulatory changes reorganize the information regarding the complaint process to clarify expectations and responsibilities. The primary advantages are to:

- Improve administrative and program efficiencies to increase the availability and flexibility of advocates for direct involvement with individuals receiving services and other critical functions by clarifying the role of the advocate, LHRC, and SHRC;
- 2. Simplify the administrative processes of dispute resolution, behavioral treatment plan review, and substitute decision making, and eliminate redundant or duplicative activities; and
- 3. Enhance the usability of the regulations by reorganizing sections and simplifying language.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements that are more restrictive than the federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

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There are no localities that will bear a disproportionate impact.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no direct impact of this regulatory action on families, family stability, or family income. This regulatory action should have a generally positive impact on families and family stability because it will enhance the community resources available to ensure the human rights of individuals receiving services are protected.

Changes made since the proposed stage

Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC35-115-30	The proposed regulations added, but did not define, "administrative hearing bodies."	DBHDS agreed and added a definition of "administrative hearing."	DBHDS agreed that this section needed further clarification. Technical clarifying and corrective edits were made in six places.
12 VAC35-115-60. Services	The regulation included a list of what would be considered a basis for a discrimination complaint. "On the basis of race, color, religion, ethnicity, age, sex, disability or ability to pay".	The list was removed from the regulation.	It was brought to the attention of DBHDS that this list might limit complaints of discrimination if other identified protected categories are added to other laws at some point.
12 VAC35-115- 100. Restrictions on Freedoms of Everyday Life (B)(5)	The proposed regulation required that the LHRC approve any restriction imposed on an individual's rights under this subsection or subsection 50 that lasts	"Multiple times" was deleted and replaced with "three or more" times in a 30-day period.	DBHDS agreed that this section needed further clarification.

Section number	Requirement at proposed stage	What has changed	Rationale for change
	longer than seven days or is imposed multiple times during a thirty-day time period.		
12 VAC 35-115- 105. Behavioral treatment plans (E)	Providers would be required to submit any behavioral treatment plan that does not require SCC approval, and its independent review committee approval, to the LHRC.	DBHDS added language to (E) to clarify that only behavioral treatment plans that involve the use of restraint or time out shall be submitted for review.	Multiple comments were received requesting further clarification in the regulations that only restrictive plans should be reviewed. Without this clarification, this regulatory requirement would create a negative burden on the system.
12 VAC 35-115- 145	Under 5.c., add "and 12 VAC35-115-210."		Corrective edit deleted the proposed new citation reference to section 210.
12 VAC 35-115- 150 General provisions (A)	The proposed regulations added, but did not define, "administrative hearing bodies."	DBHDS agreed and added a definition of "administrative hearing" to section 12 VAC 35-115-30.	DBHDS agreed that this section needed further clarification.
12 VAC35-115- 175. Human Rights Complaint Process (D)	This section stated that providers shall have complaint resolution policies and procedures that address "all of the requirements of subsection C."	DBHDS changed this section to include, <u>"all of the requirements of subsections C and E."</u>	DBHDS received comments that subsection E should be added to this section.
12 VAC 35-115- 230. Provider requirements for reporting A(3)	The regulation required the investigating authority to provide a written report of the results of the investigation of abuse or neglect to the director and human rights advocate within 10 working days from the date the investigation began.	A change was made to indicate that reporting to the advocate will be via CHRIS.	DBHDS agreed with commenters that submitting the findings of an abuse investigation to the advocate in writing as well as entering it in CHRIS was redundant.
12 VAC 35-115- 270. State and Local Human Rights Committee responsibilities (A)	As in 12 VAC 35-115-100, Restrictions on Freedoms of Everyday Life (B)(5), the proposed regulation required that the LHRC approve any restriction imposed on an individual's rights under this subsection or subsection 50 or 100 that lasts longer than seven days or is imposed multiple times during a thirty- day time period.	"Multiple times" was deleted and replaced with "three or more" times in a 30-day period.	DBHDS agreed that this section needed further clarification.

Public comment

Please <u>summarize</u> all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

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A public hearing was held for the sole purpose of receiving public comment on the proposed changes on December 16, 2015. The public comment period was held from December 14, 2015, to February 12, 2016. See Attachment 1 of this document for a summarized list of comments received.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes.

Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 10. Authority and Applicability	N/A	N/A	Language change.
Section 30 Definitions	N/A	N/A	NEW "SCC, Specially Constituted committee" re: ICFID behavioral treatment plan reviews. NEW "Administrative hearing." NEW "Independent Review Committee."
Sections 50. Dignity and 60. Services	Section 175	Both sections 50 and 60 contained language pertaining to investigation of allegations.	The language on investigations of abuse and neglect and complaints of discrimination was deleted and incorporated into one comprehensive section on human rights complaints.
Section 60. Services	N/A	N/A	Language change. Code section added that references authorization to consent to treatment of a minor.
Section 90. Access to and amendment of services record	N/A	N/A	Language change. Added "unless prohibited by 42 CFR Part 2" to provisions governing when a minor may access his service record. Added "authorized insurer" as referenced by 8.01-413 of the Code of Virginia.
Section 100-	N/A	LHRC approval was not	Strengthened rights protections

Current section	Proposed new section	Current requirement	Proposed change and rationale
number	number, if applicable		
Restrictions on freedoms of everyday life.		necessary for restrictive plans.	by adding a requirement for LHRC approval of some restrictions of an individual's rights.
N/A	Section 105-Behavioral treatment plans.	N/A	New section clarified the development and implementation of behavioral treatment plans.
Section 110. Use of Seclusion, restraint and time out.	N/A	Regulation requires that the LHRC review and comment on all of a provider's seclusion and restraint policies.	This requirement was deleted because this is an operational duty and should be completed by DBHDS. There was clarifying language
			added for the prohibition of prone restraints.
Section 130. Research	N/A	N/A	Language change.
Section 140. Complaint and Fair hearing.	Section 175	Section 140 was repealed and section 175 was added.	This section was combined with abuse/neglect to clarify and streamline the process.
Section 145. Determination of capacity to give consent or authorization.	N/A	The requirement for the professional designated to complete a capacity evaluation is broad. It only requires that the professional is "qualified by expertise, training, education or credentials".	Clarified that a capacity evaluation shall be obtained by or under the supervision of a licensed professional.
Section 150. General Provisions.	N/A	N/A	To clarify it was added that any actions taken by judicial system and administrative hearing bodies are not subject to review under the human rights complaint resolution process.
Section 170. Complaint resolution process.	Section 175	Section 170 Complaint resolution process. Repealed	NEW: Section 175 Human Rights Complaint Process combines, reorganizes, and simplifies all complaint and investigation processes into one section. Provider must develop their own process for managing complaints
			that complies with all requirements of notice, time, individual participation, and communication.
Section 180. Local Human Rights Committee hearing and review procedures.	N/A	Current regulations did not allow for the appeal of the findings of an abuse/neglect investigation.	Clarified that ANY decision as a result of a complaint brought under these regulations may be appealed.
			Added clarifying language to LHRC hearing practices to

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			 include: The hearing is an informal administrative process and is not bound by the rules of legal proceedings The hearing shall be conducted in a non-adversarial manner, only LHRC members may ask questions (no cross examination).
Section 190. Special procedures for emergency hearings by the LHRC	N/A	N/A	Added clarifying language.
Section 200. Special procedures for LHRC reviews involving consent and authorization	N/A	N/A	Added clarifying language. Corrected Code citations.
Section 210. State Human Rights Committee appeals procedures	N/A	N/A	Added clarifying language.
Section 230. Provider and department reporting requirements.	N/A	N/A	Changed the reporting requirement to reflect new webbased reporting system.
Section 250. Offices Composition and Duties (Repealed).	250 is being divided into two new sections, 260 Provider and Department Responsibilities and 270 State and Local Human Rights Committee Responsibilities	N/A	 NEW Section 260 Provider and Department Responsibilities: Removed Provider's duty to provide clerical support LHRCs Removed Provider's duty to "affiliate" with a LHRC. Replace with "assure access, as needed to the LHRC" Significant refinement of the Advocates responsibilities to focus on representing individuals making complaints, providing training to individuals, family members, and providers, investigations of violations and conditions that may interfere with an individual's rights. Removed separate duties of State Human Rights Director. Included duties of the State

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			Human Rights Director in the Department's duties. • Significant changes to the Department's responsibilities with respect to 12 VAC 35-115 administrative processes.
N/A	NEW Section 270 State and Local Human Rights Committee Responsibilities	N/A	Significant changes to the duties and responsibilities of the LHRC: First and most important duty is to provide due process for any individual served by a provider under the LHRCs jurisdiction. Hold hearings Review certain restrictions of an individual's rights Receive, review, and act on variances Removed review of provider policies and receiving of provider reports of abuse and neglect. Removed providers' required attendance at meetings; attendance is only necessary if there is a due process issue before the committee for an individual served by that provider; the provider is seeking a variance or the advocate has asked them to attend to discuss general concerns.

Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.

SUMMARY OF 60-DAY PUBLIC COMMENT RECEIVED (12/14/15 – 2/12/16)

Section	Comment	Changes after 60-day Public Comment Period
General Comments	There were fourteen general comments to the regulations. Of those fourteen, five respondents expressed support and overall concurrence with the proposed changes. General concerns noted were about adequate services available in the community and a lesser level of protections for individuals. There were also two identical comments regarding the need for additional guidance on mechanical restraints. One comment suggested that all references to Intellectual Disabilities (ID) be changed to Intellectual and Developmental Disabilities (IDD) One comment recommended that several sections should be deleted or revised to require the submissions of policies and procedures to DBHDS and not the LHRC.	 DBHDS understands why this request is made, but recommends leaving it as is for now because it needs to match current language in the Code of Virginia. DBHDS does not recommend this change. Human Rights policies should be reviewed for compliance by the advocates/DBHDS.
Part 1-GENERAL P		
12 VAC 35-115-30 D		
 Independent 	There 6 comments on this definition. The concerns were	DBHDS does not recommend any changes to
Review	limiting the professional representation on the team to one	this definition because the LHRC does not
Committee	discipline or specialty, requests to leave the definition broad. Comments also received that the Independent Review Committee should be appointed and overseen by the LHRC/SHRC.	have the clinical expertise to provide oversight to the independent review committee.

• Informed Consent	One comment suggested that informed consent should apply to any treatment, intervention or service, especially restrictive or punishment procedures.	DBHDS does not recommend this change because this would be overly cumbersome and not legally required. Also, there is no consent for punishment, which is prohibited.
Licensed professional	One comment suggesting the addition of physician's assistant to the definition.	DBHDS does not recommend this change because it believes the definition is sufficient as written.
Neglect	One comment suggested that we need to better define med errors that need to be reported as neglect.	DBHDS does not recommend this change. Additional guidance will be offered during the rollout.
Peer on peer aggression	One comment suggested that this only apply to licensed services with direct staff supervision.	DBHDS does not recommend any changes to this definition because the issue of peer on peer aggression affects many services areas, not only those with direct staff supervision.
Pharmacological restraint	One comment recommended highlighting the word involuntary to limit confusion.	DBHDS does not recommend any changes to this definition because the definition is clear as written.
Restraints for protective purposes	One comment suggested that protective restraints ordered by the doctor should be restrictive but not a restraint.	DBHDS does not recommend this change because any type of restraint should be monitored as such, and many aspects of restraint are governed by Federal law.
Serious injury	One comment recommended changing "licensed physician" to health care professional.	DBHDS does not recommend any changes to this definition as it is consistent with use of the term throughout the Code of Virginia.
• Specially Constituted Committee	One comment suggesting that the definition is revised if it is supposed to apply to inpatient psychiatric facilities.	DBHDS does not recommend any changes to this definition. It only applies to ICF/ID's.

Part II 12 VAC 35-115-	-50 Dignity	
C.(3)(b)	One comment made that this section does not seem consistent with CMS expectations for people served under "HCBS waivers."	DBHDS believes that the requirements in this part of the regulation are reasonable and does not recommend additional revisions.
D(3)(b)(f)	One comment suggested that we reinstate the wording in "f" requiring the report of abuse or neglect to local DSS.	This has not been removed from the regulations, only this section. This reporting requirement is reflected in 12 VAC 35-115-260(A)(8).
12 VAC35-115-	-60. Services	
B (1)	One comment recommended that the listing for discrimination be removed as new items may be added at some point.	DBHDS agrees, and this listing has been removed.
12 VAC35-115-	90. Access to and amendment of service record	
C(2)(b)	One comment recommended that we add "any licensed professional operating in their scope of practice."	DBHDS does not recommend this change because it is too broad.
C(2)(c)	Multiple comments made to define "authorized insurer."	DBHDS does not recommend defining this term because it only appears in one section of the regulations and comes from Va. Code § 8.01-413, where it is not defined.
12 VAC35-115-	-100. Restrictions on Freedoms of Everyday Life	
A(1)(g)	Two comments requesting that we remove the word "canteens."	DBHDS does not recommend this change. These regulations also cover programs where canteens and snack areas are available to residents.
A(2)	One comment suggested that we add provisions to ensure safe, clean, affordable housing within a community of people who are of similar age."	These regulations are to provide guidance and oversight to existing licensed providers. The regulations do not allow for provider development.

B(2)	One comment requesting that there needs to be further clarification to prevent abusive practices.	DBHDS does not recommend any changes to this section because safeguards and protections are addressed throughout the regulations.
B(5)	8 comments received in response to this change as well as clarification of what constitutes "multiple times." There were concerns that this change will create a negative burden on the system.	DBHDS agrees that there needs to be clarification on what constitutes "multiple" events. Therefore, propose changing this to "three or more" times in a 30-day period.
B(6)	ISP needs to be further defined.	DBHDS does not recommend any changes to this section because it is further defined in section 30 and in the licensing regulations licensing regulations.
B(7)	Two comments made regarding LHRC review of program rules and consistency across advocates and LHRCs.	No recommendations are made to change this section; however, additional guidance will be offered during training at implementation.
	One comment suggested that rules that do not impact human rights should not be submitted to the LHRC.	DBHDS does not recommend changing this section. Rules may in fact impact rights. The LHRC review adds additional protections.
12 VAC 35-11	5-105. Behavioral treatment plans	
A	One comment recommended that that a description of a behavioral treatment plan include language that is more applicable to inpatient psychiatric facilities.	DBHDS does not recommend any changes to this description because behavioral treatment plans are used in all types of facilities.
В.	 One comment made expressed concern that this section implies that a plan needs to be done for any behavioral restraint, even those used in an emergency A concern was noted as to whether or not we have sufficient "licensed" professionals to complete the assessment. 	 No recommendations are made to change the section. The section applies only when such a restriction is part of a behavioral treatment plan DBHDS agrees. No recommendations are made to change the section.
C(3)	Multiple comments expressed concern that all behavioral treatment plans would need to be brought forward to an	DBHDS does not recommend any changes to this section. Section (C)(3) requires review of

	LHRC for review. They requested further clarification in the regulations that only restrictive plans should be reviewed.	all behavioral treatment plans by an independent review committee, not the LHRC.
D	One comment expressed concern that all plans will need to be reviewed by the Independent Review Committee.	This is correct. DBHDS does not recommend any changes to this section.
	2) One comment suggested that ALL behavioral treatment plans should be reviewed by the LHRC.	2) DBHDS does not recommend any changes to this section because to require review of all plans would be unnecessary and overly burdensome. Some are required by federal law to be reviewed by the Specially Constituted Committee.
	3) Multiple comments recommended adding a timeframe for LHRC approval, within 3 months of implementation.	3) DBHDS does not recommend any changes to this section, but notes that section D does not pertain to LHRCs. The proposed LHRC system will be able to meet the implementation needs of the providers.
E.	Same as C(3). Multiple comments expressed concern that all behavioral treatment plans would need to be brought forward to an LHRC for review. They requested further clarification in the regulations that only restrictive plans should be reviewed.	DBHDS agrees and has proposed adding language to (E) to clarify that only behavioral treatment plans that involve the use of restraint or time out but do not require review by an SCC because they are not in an intermediate care facility require review by an LHRC.

G.	One comment requested specificity in determining the type of restraints that would require review by the Independent Review Committee and LHRC.	DBHDS does not recommend any changes to this section because it should be left broad allowing for review of all Behavioral Treatment Plans involving restraint or time out. General guidance will be provided.
H.	One comment asked for clarification as to whether powering off an electric wheelchair would be considered seclusion.	General guidance will be provided.
12 VAC35-11	5-110. Use of seclusion, restraint and time out.	
A.	One comment was made that seclusion and time out should not be used outside of acute care facilities.	DBHDS does not recommend any changes to this section because the use of seclusion outside of acute care facilities is already covered in the regulation.
C(6)	 One comment recommended that we add the definition of "prone restraint" in the definition section. One comment suggested there may be, "transient moments when use of such restraints is necessary." 	 DBHDS does not recommend this change. "Prone" only appears in Section 110(C)(6) and is defined there in a parenthetical. DBHDS does not recommend any change. Such restraint is prohibited.
C(7)	One comment expressed concern that this regulation seems to imply that ALL ISP's will need to have this regulation wording in them even if a client has no history of needing restraint.	DBHDS does not recommend any changes to this section. The intent of this regulation is already addressed in this section.
C(8)	Comments were made requesting that this section not be removed from the regulations and that any proposed seclusion, restraint, and time out policies and procedures be sent to the LHRC for review and comment before implementing them.	DBHDS does not recommend adding back prior section C(8) because review of these policies will take place by the Office of Human Rights, not the LHRC.
C(14)	One comment received stated that "IF the purpose is to specify an upper limit on restraints this is way too high. This should be clarified and lowered such that this type of restraint	DBHDS does not recommend this change. This is a policy decision. This isn't just for Behavioral Treatment Plans, it's any restraint

	is highly unlikely in residential or day support settings with minimally trained staff."	for behavioral purposes.
12 VAC 35-115-145	. Determination of capacity to give consent or authorization.	
1	Two comments requested clarification if two capacity evaluations are required before capacity can be determined	DBHDS does not recommend any changes to this section. General guidance will be provided.
	 One comment contained multiple questions: What is meant by capacity evaluations being conducted by or under the supervision of a licensed professional? Which licensed staff may conduct the evaluation? Does this mean that QMHP's etc. can also do the evaluation if signed by a licensed professional? What if two providers disagree if they feel the person has capacity? If a private provider questions the capacity of an individual and the CSB doesn't, is the private provider required to obtain the capacity evaluation and not the CSB? 	General guidance will be provided.
4	One comment requested clarification on this standard and where are they published?	General guidance will be provided.
5	One comment expressed concerns regarding how to proceed when the individual declines to participate in the evaluation process.	General guidance will be provided.
Add a new section	One comment suggested that a new section be added (new language): 6. Under no circumstances shall restrictions be placed on an incapacitated person's right to speak with an attorney, an ombudsman, or a representative of the state protection and advocacy organization as defined under section 51.5-39.13 of the Virginia Code.	DBHDS does not recommend this change. It is already addressed in 12 VAC 35-115-50(B)(4), Dignity.
Part V 12 VAC 35-115-150	General provisions	

A.	Three comments requested clarification on an administrative hearing body.	DBHDS agrees and has added a proposed definition of "administrative hearing" to section 12 VAC 35-115-30.
12 VAC35-115-175.	Human Rights Complaint Process.	
General Comment	One comment suggested this section before section 150 to improve the flow.	DBHDS does not recommend this change because the flow of these sections makes sense as amended.
	2) Multiple comments were received regarding the removal of the expedited informal complaint process.	2) DBHDS does not recommend changes because by removing the informal process, additional protections are being created for individuals receiving services in a provider directed process. Guidance will be provided.
B(5)	4 comments received requesting clarification of the timelines for complaint resolution.	The timeline is specified in this section of the regulations. General guidance will be provided.
C(1)	One comment asking for clarification of how providers notify the department.	1) DBHDS does not recommend a change. The section on reporting requirements (12 VAC35-115-230) specifies reporting to the department using the web-based reporting system (CHRIS)
	2) One comment thanked the department for recognizing the impact of reporting within 24 hours for weekends and holidays.	2) DBHDS will use the language "as soon as possible but no later than the next business day." The 24 hour required reporting applies to certain types of incidents, which are addressed in other places in the regulations and Code.

C(5)	One comment was made recommending additional language to ensure that the individual is aware of the availability of alternate formats for materials (e.g. Braille, large-print, etc.)	DBHDS does not recommend this change. The requirements in this part of the regulation are sufficient.
C(7)	Three comments were received that requested consideration of changing 10 working days to report the Director's action plan to AR/individual to 5 working days after the completion of the investigation.	DBHDS does not recommend this change because it feels 10 days is an appropriate amount of time.
D	There was one comment suggesting that we modify this section to include, "all of the requirements of subsections C and E."	DBHDS agrees, and this change has been made.
Е	Three identical comments were made regarding the process for reviewing complaint resolution policies and procedures. Clarification was requested to address whether the Office of Human Rights or the Office of Licensing will review provider policies. Also, maintaining this does not serve to streamline the administrative process or to eliminate redundancies.	General guidance will be provided.
F(3)	Two comments made in this section also, regarding amending to include "or the next business day"	DBHDS does not recommend this change because it is consistent with licensing regulations.
	2) One comment asked for clarification on how a provider is to notify the department.	2) DBHDS does not recommend a change because the section on reporting requirements (12 VAC35-115-230) specifies reporting to the department using the web-based reporting system (CHRIS).
F(4)	One comment made recommended that medication errors being investigated as potential neglect can be investigated by the program since these investigations are more routine and clear.	DBHDS does not recommend this change. Guidance will be provided.
F(5)	One comment received suggested that submitting the investigation and findings in writing to the human rights advocate is redundant.	DBHDS does not recommend a change to this section because reporting into the CHRIS system meets this standard. Guidance will be provided.

	2) Four comments suggested that the regulation no longer provides information about a timeframe for requesting an extension and recommended that this be able to be done solely via the CHRIS system, versus both CHRIS and the Regional Advocate, to streamline the process and reduce redundancy.	2) DBHDS does not recommend this change because a discussion with the advocate should take place before an extension is granted to any timeframes.
F(7)	Two comments recommended that this section be amended to only require submission of the final decision and action plan to the individual/AR within 10 days of completion; OHR has this information already, which results in redundancy.	DBHDS does not recommend any changes to this section because reporting into the CHRIS system meets this standard. Guidance will be provided.
G	One comment received recommended that the Advocate (as a mandated reported) must report their concerns to the local DSS either directly or through the state abuse hotline.	DBHDS does not recommend adding this to the section. Mandatory reporting requirements are already addressed in other laws.
12 VAC 35-115-1	80. Local Human Rights Committee hearing and review procedu	ures
В	Two comments were received suggested changing the section to require filing the petition for a hearing with the Regional Advocate, who would then follow up by arranging the hearing with the LHRC Committee.	DBHDS does not recommend any changes to this section because the regulation already allows for the assistance of the regional advocate in this process.
12 VAC 35-115-1	90. Special procedures for emergency hearings by the LHRC	
С	Three comments were received that recommended that the timelines in this section be revised from 24 hours to, "24 hours or by the end of the next business day."	DBHDS does not recommend any changes to this section because the current timeframe is sufficient.

Part VII. Reporting Requirements 12 VAC 35-115-230. Provider requirements for reporting		
A(1)	One comment suggested we add "or other approved system" in case the web based system becomes obsolete.	DBHDS does not recommend any changes to this section because this is broad enough to cover potential changes.
A(2)	Five comments were made recommending that the notification of abuse be changed from 24 hours to, "within 24 hours, or the next business day, of receipt of the allegations."	DBHDS does not recommend any changes to this section because the current timeframe is sufficient.
A(3)(a)(b)(c)	1) One comment requested that we change this section to require the investigation report and determination letter to be sent to the Human Rights advocate together.	DBHDS does not recommend any changes to this section because the letter should be sent directly to the complainant by the provider.
	2) Two comments were made requesting that submitting the findings of an abuse investigation to the advocate in writing as well as entering it in CHRIS is redundant.	2) DBHDS agrees and made the requested change to indicate that reporting to the advocate shall be via CHRIS.
	3) Two comments recommended that we add that the director has 5 working days to complete his report which shall include a. b. and c.	3) DBHDS does not recommend any changes to this section because the current timeframes are sufficient.
B(2)	Three comments recommended adding," or by the end of the next business day" for reporting to the department"	DBHDS does not recommend this change because this is consistent with licensing regulations.
	2) Two comments recommended that we clarify, "in writing or via the web-based reporting application."	2) DBHDS does not recommend any changes to this section. However, a clarification was added to be clear it is the "department's" system that must be used.
C(2)	One comment received recommended that the data should be reported monthly and reviewed by DBHDS to determine if there are patterns that should be addressed.	DBHDS does not recommend any changes to this section. The Department maintains the authority to request more frequent reporting.

C(3)	Two comments recommended clarification that the monthly compilation is just for the provider and that an annual report continues to be submitted to DBHDS by January 15 ^{th.}	DBHDS does not recommend any changes to this section because this is clearly stated in the regulation.
C(4)	Two comments recommended adding "within 24 hours" to reporting requirement.	DBHDS does not recommend any changes to this section. It already says within 24 hours.
D	Two comments made suggested that reporting at LHRC should be required on all founded and unfounded complaints.	DBHDS does not recommend that change to this section, but added "when requested."
F(2)	Two comments requested the removal of names of all staff involved in human rights allegations.	DBHDS does not recommend any changes to this section. It is inherent in the removal of "provider identifying information."
G	Two comments requested the names of all staff involved in human rights allegations will not be disclosed to the public.	DBHDS does not recommend any changes to this section. FOIA dictates what is and is not disclosed to the public.
12 VAC 35-1	15-260. Provider and department responsibilities	·
A(7)	Two comments received recommended that we add, "or in the provider's learning management system with reports made available to the Department as requested."	DBHDS does not recommend any changes to this section because maintaining it in the employee's personnel file permits easier access upon audit of a provider.
A(9)	Two comments were made recommending that the shift to review of policies to the Office of Licensing, thereby streamlining the administrative process, improve program efficiency, or eliminate redundancy.	DBHDS does not recommend any changes to this section because the Office of Human Rights advocates are the subject matter experts on human rights compliance.
C(5)	One comment recommended the addition of a #6 to this section to say," Review the reports entered into the web based abuse/neglect/complaint reporting system, resolve outstanding issues with the provider and, if all parties are satisfied, "close" the case within 30 working days of receiving the provider's disposition or notice of appeal.	DBHDS does not recommend any changes to this section because this process will be addressed in the revised Office of Human Rights Protocols, Procedures and Practices Manual.

12 VAC 35-115-270. State and Local Human Rights Committee responsibilities		
A(1)	Three comments were made requesting clarification of what is meant by "multiple" times during a 30-day period.	DBHDS agrees that there needs to be clarification on what constitutes "multiple" events. Therefore, it was changed to "three or more" times in a 30 day period.
A(6)(a)	Two comments recommended that the language in this section be changed from consumer to individual.	DBHDS agrees and made this recommended change.