Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	State Mental Health, Mental Retardation and Substance Abuse Services Board
Virginia Administrative Code (VAC) citation	12 VAC 35-115-10 et seq.
Regulation title	Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers [~~of Mental Health, Mental Retardation~~] ~~and~~ [, ~~or Substance Abuse Services~~ Licensed, Funded or Operated by the Department of Mental Health, Mental Retardation, and Substance Abuse Services]
Action title	General revisions to clarify and update provisions
Date this document prepared	April 29, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Provisions have been revised to align them with the applicable state and federal law, including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the re-codification of Title 37.1 of the Code of Virginia, which became effective on October 1, 2005. The regulations have been substantially reorganized and modified to improve the clarity. Some administrative processes are expedited and simplified, (i.e. process to address complaints).

Since the publication of the proposed regulations, the agency has made some minor language and editorial changes for clarity in response to public comments. Provisions are revised to make clear that the voluntary use protective equipment is not considered a restraint under these regulations. The list of providers subject to these regulations is updated to exclude providers of services under Part C of the Individuals with Disabilities Education Act (IDEA) that are governed by federal IDEA regulations. Provisions are added, consistent with the recent revisions to Virginia law, to describe the conditions under

which a provider may disclose specific information about an individual receiving services to a law enforcement official. The title of the regulations has been simplified.

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.

On May 4, 2007, the State Mental Health, Mental Retardation and Substance Abuse Services Board adopted the amended *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded or Operated by the Department of Mental Health, Mental Retardation, and Substance Abuse Services* for final promulgation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The State Mental Health, Mental Retardation and Substance Abuse Services Board has the authority to adopt these regulations under Va. Code §§37.2-203 and 37.2-400 and is required to do so.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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.

The purpose of the proposed action is to clarify terminology and various procedures in order to improve the human rights protections provided by these regulations. This action will also align outdated provisions with applicable federal and state laws and regulations, including regulations for health information pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

These regulations are essential to ensure the protection of the legal and human rights of individuals who are receiving services from providers who are funded, licensed and operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS). These changes are being made to respond to the needs of the individuals that receive services, service providers, and the public and are intended to provide a practical administrative framework and the necessary legal guidance to implement these protections of human rights. The following are the goals of these regulations:

- To clearly articulate the human rights of every individual receiving care and treatment in facilities and programs licensed, funded, and operated by the DMHMRSAS.

- To clearly articulate the responsibilities of providers licensed, operated or funded by DMHMRSAS in ensuring the rights of individuals receiving services, and any exceptions and conditions placed on these responsibilities.

- To clearly articulate the complaint review and resolution process and to specify the procedures and time frames for the review of complaints of rights violations.

- To protect the public health, safety, and welfare with the least possible costs and intrusiveness to the citizens and businesses of the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The following summarizes the substantive changes to the regulations:

- A number of definitions are revised and new definitions added, e.g. "persons centered." These changes have been made to clarify the provisions and to update the definitions and terms to conform to current state and federal law;

- Specific sections of the regulations are reorganized for clarity and to simplify provisions. This involved consolidation of all provisions that address a particular right into a single section about that right, by moving the content from the exceptions and conditions to the provider's duties to the section on the corresponding right.

- Changes are made to clarify provisions for dignity rights and circumstances under which these rights may be limited;

- Changes are made to clarify the provisions for consent and informed consent and the administrative requirements for each;

- Sections on confidentiality and access to records are revised to comply with federal HIPAA regulations. Specific provisions are added to address the disclosure of information to law enforcement officials;

- Revisions are made to clarify the provisions governing the use of seclusion, restraint and time out;

- A new part is added to address surrogate decision-making, which includes provisions to guide determinations of capacity to give consent and authorization, and provisions regarding authorized representatives;

- The section on informal complaints is repealed and provisions are relocated to the complaint resolution section;

- The complaint resolution process has been revised for clarity and simplicity;

- Provisions for local human rights committee (LHRC) reviews of consent and authorization is clarified and revised; and

- Minor changes are made to administrative duties of providers and LHRCs.

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.

The proposed action is intended to clarify and update the existing human rights regulations. The following are the primary advantages of this action to the public and stakeholders:

- The action should improve the safeguards for the human rights of every individual receiving care and treatment in facilities and programs licensed, funded, and operated by DMHMRSAS. This is intended to promote the public health, safety, and welfare of citizens of the Commonwealth.

- The revisions clarify the responsibilities of service providers to ensure the rights of individuals receiving services, and articulate any exceptions and conditions placed on these responsibilities. This should facilitate the implementation of the regulatory requirements and reduce the administrative burden for these service providers.

- The revisions clarify and expedite the complaint review and resolution process. The process has been structured to improve communication between providers and individuals receiving services and allow complaints to be resolved at the earliest possible stage. This should promote quality assurance for providers and individuals receiving services.

No disadvantage to the public or stakeholders is noted.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	■ Required any provider that receives funding from DMHMRSAS to be subject to the regulations.	■ Providers of services under Part C of the Individuals with Disabilities Education Act (IDEA) that would be subject to these human rights regulations solely because they receive IDEA funds, must comply with federal IDEA regulations in lieu of these human rights regulations	■ Compliance with IDEA regulations obviates the need for compliance with these human rights regulations, which afford similar protections. This will eliminate an unnecessary regulatory burden on these IDEA providers.

Section number	Requirement at proposed stage	What has changed	Rationale for change
30	■ The definitions of the following terms were somewhat unclear or inconsistent with other terminology or language usage: "authorized representative" "behavior management," "behavioral treatment program", community services board," "director", "disclosure" "governing body of a provider" "habilitation," "human research" "individualized services plan," "peer on pear harm," " program rules" "research review committee," "services" and "treatment."	■ Minor, non-substantive or editorial revisions were made to the definitions of these terms.	■ The revisions were made in response to public comments, for clarity, or for consistency with use of language in other parts of the regulations.
	■ The proposed regulations provided a definition of "mechanical restraint."	■ This was deleted.	■ This definition was redundant and unnecessary. "Mechanical restraint" is defined as a type of "restraint" as part of the general definition of "restraint."
	■ The definition of "restraint" included several parts explaining the use of restraints for "behavioral," medical," and "protective purposes." The definition also explained the use of "pharmacological" and "physical" restraint.	■ The definition of "restraint" was revised to summarize the three general types of restraint: "mechanical," "pharmacological," and "physical" restraints. Three new definitions were added: "restraints for behavioral purposes," "restraints for medical purposes," and "restraints for protective purposes."	■ The definition was revised to avoid misunderstanding and to clearly distinguish the three types of restraint from the uses of restraint (i.e. mechanical restraints may be used for medical purposes). The changes were made in response to public comment and questions about the meaning of these terms.
	■ The proposed regulations did not include a definition of "person centered."	■ A definition of "person centered" was inserted in the final regulations.	■ This was added in response to public comments to incorporate this concept into service planning and provision of services.
40	■ The proposed regulations did not clearly state how individuals will receive notice of their rights and will have access to a human rights advocate.	■ Minor language revisions were made to ensure that individuals receiving services receive appropriate notice their rights under the regulations and to they have reasonable access to a human rights advocate.	■ Changes were made for clarification in response to public comment.

Section number	Requirement at proposed stage	What has changed	Rationale for change
50	■ The provisions in this section did not clearly indicate that individuals have a right to services that reflect their needs their needs and preferences.	■ Language was added throughout this section to more clearly articulate the provider's duties to ensure that services are "person centered." (See definition of person centered.) Language has also been added to various provisions to require providers to communicate with individuals receiving services in the manner that is most easily understood by the individual.	■ Changes were made for emphasis and in response to public comment.
60 and 70	■ Some of the language used in these sections was not clear. Some terms were not consistent with the defined terms (the regulations define "services" although the term "clinical services" was used in 60.B.2). In one case the provision did not specifically state that the individual's authorized representative should be involved in services or actions when the individual has an authorized representative.	■ Several provisions were reworded or revised. There were editorial revisions (the term "surgery" was changed to "surgical procedures" in 12VAC 35-115-70 A.2.) None of the changes were substantive. Reference to the "authorized representative" was inserted where appropriate (see 70.B.1.c.).	■ Change was made in response to public comments and to clarify the meaning of these provisions. The terminology was revised to correspond to other parts of the regulations.
80	■ Reference to the authorized representative was not provided in 80.B.2. The provisions for disclosure of a minor's information by a parent did specify a "custodial" parent. Statutory reference to the Virginia Government Data Collection and Dissemination Practices Act was not necessary and the reference to Virginia Code § 32.1-127.1:03 was out of place per the Office of the Attorney General.	■ Reference to the "authorized representative" and "custodial parent" were inserted where appropriate. Statutory references were relocated and deleted. Several non-substantive editorial changes were made to the provisions (80-B.8.a.) for specificity and clarity.	■ These revisions were made to clarify or simplify the provisions in response to public comment.
	■ Legal provisions for disclosure of an individual's information to a law enforcement official were not included and several other requirements for disclosure were not clear.	■ Provisions were inserted for disclosure of individual information to law enforcement officials to reflect recent amendments to the Code of Virginia.	■ The addition of provisions for disclosure to law enforcement officials was inserted to comply with 2007 amendments to the Code of Virginia.

Section number	Requirement at proposed stage	What has changed	Rationale for change
90	■ The proposed regulations prohibited individuals receiving services from accessing psychotherapy notes that are included in their own medical record. ■ The provisions stated that the individual and authorized representative had a right to ***amend***…anything in his services record (90.A.3).	■ The regulations were revised to permit individuals to access psychotherapy notes in their own services records. ■ The provision was revised to state that individuals can …***request to amend***… their services record.	■ The change was made in response public comment that objected to the restriction. Access to psychotherapy notes is allowed under the current human rights regulations. ■ The change was made to clarify the intent of the provision.
110	■ The voluntary use of mechanical supports to improve body position or voluntary use of protective equipment was classified as a restraint subject to the requirements for restraint. ■ Some of the language used to describe the providers duties, with respect to the use of seclusion or restraint, was confusing or ambiguous.	■ Provisions were inserted at 110.B to state that the voluntary use of mechanical restraint to improve body position or voluntary use of protective equipment is not considered a restraint for the purpose of these regulations. ■ Several non-substantive and editorial revisions have been made to the provider's duties. Clarification was added to documentation requirements. The statement in 110.C.12 that approval for the use of restraint may not be given on an "as-needed basis" was relocated to 110.C.15 for emphasis.	■ This change was made in response to public comment and for clarification of provisions. The revision is intended minimize the regulatory requirements for the use of voluntary supports or protective devices. ■ These revisions were made to clarify the requirements in response to public comment.
120	■ Section 120.B.4 referred to "…***consumer*** wages…"	■ The word "***consumer***" was deleted.	■ This change was made in response to public comment. The word was not needed in the provision.
130	■ Providers were required to obtain review and approval from an institutional review board (IRB) or research review committee prior to performing or participating in human research. Providers were also required to inform and update the local human rights committee (LHRC) on the status of an individual's participation in human research.	■ The provisions were revised to state that providers must maintain documentation of the required approvals and make them available to the LHRC prior to beginning a research project.	■ The change was made in response to public comment and to ensure accountability for compliance with the requirements.

Section number	Requirement at proposed stage	What has changed	Rationale for change
145	■ There were no specific guidelines for capacity evaluations. ■ The provisions in 145.A.4 implied that treatment planning required informed consent.	■ Revisions were made in 145.A.4 to provide guidelines for capacity evaluations. ■ The reference to treatment planning was deleted in this provision. ■ Several non-substantive editorial changes and corrections were made in this section.	■ These changes to 145.A.4 were made for clarification in response to public comments.
146	■ The provision did not state that a provider shall obtain consent from a substitute decision maker only if one is available. ■ The intent of 146.B. was not clearly stated. The provision requires the provider to honor an individual's preference in designating a substitute decision-maker unless it is clinically contraindicated. ■ The provisions in 146.G. were technically inaccurate. The powers of health care agents do not automatically cease upon the individual's regaining capacity.	■ The words "***if available***" were inserted in 146.A. ■ The provision was reworded to require a provider to honor an individual's preference. ■ Provision was revised to reflect Virginia Code § 37.2-1012.	■ The change was made for clarity in response to public comment. ■ This change was made in response to public comment to clarify that an individual's preference should be "paramount" for determining a substitute decision-maker. ■ The change was made to correct the provision in response to public comment.
150	■ The provision did not emphasize that a complaint should be solved at the earliest possible stage of the process. ■ This section did not address the mode of communication with the individual during the complaint resolution process.	■ A statement was inserted in 150.A to indicate that every effort shall be made to resolve complaints at the earliest possible stage. ■ A statement was inserted in 150.I to require communication with the individual to be in the manner, format, and language most easily understood by the individual.	■ The change was made in response to public comment for clarification. ■ The change was made in response to public comments and to be responsive to individual communication needs.
170	■ The provisions did not specifically require the individual to be provided with an explanation of the complaint process. ■ Step 4 of the process did not state that the individual must report his disagreement within five working days for the process to continue.	■ Language was inserted in 170.A.3 and 170.A.4 to require that an individual receives a thorough explanation of the process. ■ Step 4 of the process was revised to state that an individual must report his disagreement in writing to the director after receiving the decision or action plan.	■ The change was made in response to public comments and to ensure that the individual is informed of his rights under these regulations. ■ The change was made to clarify the process in response to public comment and to facilitate the administrative requirements.

Section number	Requirement at proposed stage	What has changed	Rationale for change
200	■ Procedures in 200.A.1 were not specific with regard to the role and review of decisions to appoint an authorized representative. ■ Typographical errors were made in 200.A.2.a. and b.	■ Language was inserted in 200.A.1 to specify that an individual ***or his authorized representative*** may object to ***the appointment of a specific person as authorized representative***. ■ Commas were inserted where appropriate. The word ***with*** was corrected to ***without*** in 200.A.2.b.	■ The change was made for clarity in response to public comment. ■ The changes corrected typographical errors.
220	■ The provisions did not specifically describe the role of the affected individuals receiving services in the process for variances.	■ Changes were made to 220.C.1 and 220.H. to indicate that individuals affected by the variance may comment and will be notified of decisions regarding variances.	■ Changes were made for clarity and in response to public comment.
230, 240	■ Some terminology was unclear or inconsistent with the terminology used in other parts of the regulations.	■ Several non-substantive editorial revisions were made in these sections.	■ The changes were made for clarity.
250	■ The provisions in 250.B.2 did not articulate that employees are required to report all cases of suspected ***neglect or exploitation***. ■ The description of LHRC membership in 250.D was vague and somewhat confusing. ■ Some terminology was unclear or inconsistent with terminology used in other parts of the regulations.	■ The provision was clarified to state that employees must report "…suspected abuse, ***neglect or exploitation***…" ■ The description of LHRC membership was re-written without substantive change. ■ Several editorial changes were made to the provisions in this section.	■ The changes were made for clarity and in response to public comment. ■ The change was made to clarify the provisions and to respond to public comment. ■ The changes were made for consistency and clarity.

Public comment

Please summarize 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.

Section	*Comment*	*Agency Response*
12VAC35-115-20 Policy	**B.3** Add statement that some listed rights may not apply to minors. ■ Add "appoint an attorney-in-fact" as an example.	■ No change. Addressed in other parts of the regulations. ■ No change. Addressed later in the regulations.
12VAC35-115-30 Definitions		
"Abuse"	■ Align with definition used by the Department of Social Services. Add examples of assault and battery.	■ Definitions of "abuse" and "neglect" are taken from Virginia Code §37.2-100.

Section	*Comment*	*Agency Response*
	■ Add "neglect" to the definition of "abuse" in the same way that it is included in the definition of "exploitation." ■ Add pharmacological restraints in this definition. ■ Clarify Part 7. Providers are rarely willing to acknowledge that they are being punitive.	Will provide training to assist in interpretation and application of regulatory requirements.
"Advance directive"	■ Consider an advance directive as presumptively controlling absent an emergency.	■ No change. Refer to the Health Care Decisions Act.
"Authorization"	■ Clarify with regard to the statement that "an authorization must be voluntary" particularly with regard to criminal justice system practices.	■ Not needed. Regulations do not apply to the criminal justice system.
"Authorized representative"	■ Change "may" to "shall" have decision making authority for "legal guardians, attorney's in fact, or health care agents…" ■ Include legal guardians in the definition. ■ Clarify the reference in the second sentence, referring to authority of authorized representative (AR) being *"…specific to designating provider…,"* ■ Clarify the role of a friend or of an AR when the consumer has the capacity to give consent and add provisions that govern the role of ARs. ■ Add "or persons and microboards duly incorporated under the laws of the Commonwealth, or circles of support…" ■ Add …**on behalf of an individual represented** at the end of the definition. ■ Requests that the term "legally" authorized representative be retained.	■ Not necessary. Authority is granted in Virginia Code §54.1-2983. ■ Legal guardians are mentioned and considered as part of the definition. ■ The authority of an AR is recognized only by the specific provider that designated the AR. Further clarification is provided in 12VAC 35-115-146. ■ Not necessary. Clarification is provided in 12 VAC35-115-145, 146 and 70. Provisions to govern ARs are not included in the definition. ■ No change. Anyone who meets the requirements in 12 VAC 35-115-146 and relevant sections of the Code of Virginia may serve as an AR. Determination is made on a case-by-case basis. ■ No change. This definition and terminology responds to the recommendations of a broad stakeholder group (H3R Advisory Committee) that concluded that the term "legally authorized representative" was confusing to constituents.
"Behavior management"	■ Change "management" to "support" or "intervention". **Behavioral ~~management~~ supports**" means those principles and methods employed by a provider to help an individual ~~receiving services~~ to achieve a positive outcome and to address ~~and correct inappropriate~~ **challenging** behavior in a constructive and safe manner **in accordance with current best practice manuals and professional standards for positive behavioral supports**.	■ Changed to "behavioral intervention." ■ Changed "inappropriate" to "challenging."

Section	*Comment*	*Agency Response*
"Behavioral treatment plan"	■ Change "serious" to "challenging or unwanted" behaviors." Clarify "systematic" data collection. ■ Eliminate this definition replace with a definition of "positive behavioral supports."	■ Changed to "challenging behavior" and added "systematic." ■ No change.
"Circle of support"	■ Add new definition: "Circle of Support" means a group of 3 of more people who have been designated by the individual with a disability to assist him or her to accomplish personal life goals and to support the individual in making decisions and, if so designated, act as a substitute decision-maker. "	■ No change. The term is not used in the regulations. Language has been added to support this concept.
"**Community services board**"	■ Change "consumer" to "individual" ■ Clarify whether the "CSB" refers to the board or staff. Suggests that the citizens' board be referred to as a "board" and the service provider be referred to as an "agency."	■ Changed "consumer" to "individual". ■ Clarified the definition of "governing body".
"Complaint"	■ Retain current language. Consumers should not have to know that a specific human right has been violated to make an allegation. Under "consent" the regulations allow for the expression of consent in any manner that is appropriate to the person's communication skills. The same should apply to a "complaint."	■ No change. Consumers do not have to know that a specific regulatory provision or human right has been violated to make a complaint.
"Consent"	■ Move the paragraph that begins "Consent should be given freely…" to Section 70 with other consent provisions because it is a substantive qualification placed on consent rather simply an element of the definition. ■ Change as follows: "Consent" means the voluntary ~~and expressed~~ agreement of an individual or that individual's ~~legally~~ authorized representative ~~if the individual has one~~ **given freely and without undue inducement, any element of force, fraud, deceit, or duress, or any form of constraint or coercion—to specific services. Consent may be expressed through any means appropriate for the individual, including verbally, through physical gestures or behaviors, in Braille, through ~~or~~ American Sign Language, in writing, or through other methods**."	■ No change. The H3R Advisory Committee recommended the revised definition.
"**Director**"	■ Revise to allow appropriate flexibility to account for the hierarchy of executive leadership in hospitals and health systems.	■ Change made.
"Disclosure"	■ Delete "by a provider".	■ Change made.
"Emergency"	■ Include psychiatric emergency… " or when a delay in treatment might adversely affect the recovery of an individual." ■ Retain the phase " or to avoid substantial property damage".	■ No change. Would expand the scope beyond the intent of these regulations. ■ No change. Phrase is redundant.

Section	*Comment*	*Agency Response*
"Governing body"	■ Clarify definition. Change "who have " to "with." ■ Add language clarifying the definition of CSB governing body.	■ Changes made.
"Habilitation"	■ Change as follows: "Habilitation ~~refers to~~ means the provision of **individualized** services conforming **to professionally acceptable practices**, that enhance the strengths of, teach functional skills to, or reduce or eliminate ~~**problematic**~~ **challenging** behaviors of an individual ~~receiving services~~ in a manner that ~~**These services occur in an environment that**~~ **suits the individual's needs, responds to his preferences, and promotes social interaction and appropriate adaptive and communicative behaviors**. ~~**In order to be considered sound and therapeutic, habilitation must conform to current acceptable professional practice.**~~"	■ Change made.
"Human research"	■ Add "professional" as follows "…or contribute to generalized **professional** knowledge."	■ No change.
"Individualized service plan" or "ISP"	■ Change definition as follows: "**Individualized services plan (ISP) means a comprehensive and regularly updated written plan that includes but is not limited to an individual's treatment plan, functional plan, habilitation plan, or plan of care that meets the needs and preferences of an individual and describes the measurable goals, objectives and expected outcomes**." ■ Specify the interval at which the ISP should be updated, in compliance with other regulations such as Medicaid regulations, and require that the ISP is signed.	■ Revised to reflect intent of the comment. ■ No change. Providers are subject to various regulatory and accreditation bodies with differing update requirements. Consumer participation requirements are found in 12 VAC 35-115-70.
"Informed Consent"	■ Objects to use of "informed" because as applied in hospitals, it requires physician communication with the patient or decision-maker. This is not a requirement in these regulations. Additionally, the definitions and Section 70 are duplicative; elements of consent and other consent requirements should be addressed in the body of the regulation and not in the definitions. ■ Should clearly specify what will be considered a "psychotropic medication." ■ Include an exception to these consent requirements for such medications prescribed and administered prior to admission. ■ Why are psychotropic medications are "singled out" in the definition? ■ Add specific components of the process for obtaining informed consent, as part of the definition. ■ Add "authorization to disclose PHI" as example of things that require informed consent.	■ No change. The definition of informed consent was recommended by the H3R Advisory Committee. ■ No change. The definition states that this provision applies to . . . "any [other] treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life." ■ No change. This would put the consumer and provider at risk. ■ These medications often pose risks that are greater than those encountered in everyday life. ■ No change. Substantive provisions should not be included in a definition. ■ Not necessary. Covered in the definition of "authorization."

Section	*Comment*	*Agency Response*
	■ For minors, consent should be obtained from the guardian	■ No change.
"Investigating authority"	■ Change to mean any person or entity **with the legal authority and independent responsibility to conduct investigations of abuse and neglect.** ~~**that is approved by the provider to conduct investigations of abuse and neglect.**~~ ■ Clarify "approved by the provider to conduct *internal* investigations of abuse..." ■ The investigating authority should be trained not just approved.	■ No change. Refers to internal investigations. Other entities have "legal authority" to investigate pursuant to other laws…DSS, police etc. ■ No change. Will address though training or consultation.
"Licensed professional"	■ Eliminate the definition to avoid confusion with additional licensed practitioners (RNs, nurse practitioners and others) that have responsibility for patient care in inpatient settings. ■ Add "…**and any other professional licensed or certified by the Commonwealth of Virginia."**	■ No change. Used in 12 VAC 335-115-50. ■ No change. Definition applies to these regulations only.
"Local Human Rights Committee" or "LHRC"	■ Change to mean: " a group of at least five **people who are appointed by the State Human Rights Committee to monitor and address human rights issues in a specified jurisdiction.** See 12VAC35-115-250 D for membership and duties"	■ No change.
"Microboard"	■ Add a definition of "microboard"	■ Not necessary. This term is not used in the regulation.
"Neglect"	■ Acknowledge the controlling role of the Health Care Decisions Act (§ 54.1-2986) with respect to *"...*withholding or withdrawing a specific medical treatment or course of treatment*..."* when the requirements of the act are met. Revise to "…a person **or persons**, and "…welfare of ~~*a person*~~ **an individual.**"	■ No change. The definition is consistent with the Virginia Code.
"Next friend"	■ Change to "…means a person ~~whom a provider may appoint~~ designated **~~by a director~~** in accordance with…"	■ Change made.
"Peer on peer harm"	■ Inclusion of "verbal expression" in the definition adds uncertainty and judgment as "harm" is not precisely defined. ■ No definition of "harm." ■ An incident should be reported only if it results in a serious injury. ■ Suggests revisions "…that results in harm to the individual **or his property**. Harm includes hitting ~~**and or**~~ threatening behavior **by an individual who has ~~*with*~~** the means to carry out the threat…" ■ Harm should not be limited to hitting or threatening; tripping, pushing, etc. could all also cause harm.	■ Definition has been revised.

Section	*Comment*	*Agency Response*
"Person-centered planning"	■ Add the following: " Person-centered planning means a process-oriented approach which focuses planning on the needs of the individual with a disability, puts the individual in charge of defining the direction for their lives, and does not base planning on system needs or services that may or may not be available to them."	■ Added a definition of "person centered."
"Positive behavioral. supports"	■ Add a definition of "positive behavioral supports.	■ Not necessary. Term is not used in the text of the regulations.
"Program rules"	■ If program rules are included in a policy, the policies must be available to the consumers and the public.	■ Change made.
"Provider"	■ Expand to include other health care providers.	■ Not necessary. Regulations are applicable only to the providers included in the definition.
"Research review committee"	■ Revise to state: "Research review committee or institutional review board means a committee of professionals **that ~~to~~ provides** complete and adequate review of research **activities in order to safeguard the rights and welfare of participants in human research**. The committee shall be sufficiently qualified through maturity, experience**, training,** and…	■ No change. Language consistent with agency regulations on human research 12 VAC 35-180-10 et.seq.
"Restriction"	■ Clarify with regard to doctor's orders (i.e. limiting cigarettes due to health issues). Also, clarify the role of the local human rights committee in reviewing doctor's orders.	■ These regulations have no authority to limit, restrict or oversee the prescribing practices of physicians that are granted by Code or by other regulations.
"Restraint"	■ Change "medication" to "psychotropic medication for behavioral purposes"	■ Not necessary or appropriate. Any medication that has the effect of immobilizing an individual or a portion of his body can be used as a restraint.
	■ Restraints are used in an emergency. Clarify how this relates to behavioral plans when the intervention is used prior to the person being out of control.	■ When a restraint or time-out is used in a behavioral treatment plan it must be based on a detailed and systematic analysis of the behavior that clearly identifies the antecedents to the behavior so that staff may act before injury occurs.
	■ Is it considered a restraint when a doctor prescribes medications before an appointment.	■ It is difficult to respond to this question without further information. If the physician prescribes medication to immobilize the individual before an appointment for a medical procedure and this medication is not the generally accepted practice, it is considered a restraint. For example, if a patient is given a drug to cause drowsiness before a dental appointment it would be considered a restraint, unless the patient gives consent for the use of the drug.
	■ Are protective devices for physical deficits really restraints?	■ A device is a restraint when it restricts the freedom of movement of the individual and it is an adaptive device if it enables an

Section	*Comment*	*Agency Response*
		individual to engage in normal activities. A wheelchair is a restraint for an individual who is capable of walking but not a restraint for an individual who is non-ambulatory and needs the chair to move normally.
	■ Revise as follows: "Behavoral purposes means using a physical hold, psychotropic medication, or mechanical device to control behavior or involuntarily restrict the freedom of movement of an individual in an instance when ~~all~~ **one** of the following conditions are met: (i) there is an emergency; (ii) nonphysical interventions are not viable; and (iii) when safety issues require an immediate response."	■ "Psychotropic" removed. No other change. There are often emergency situations that can be addressed by nonphysical interventions or when there are no safety issues that require an immediate response. It would be a violation to the individual's rights to seclude or restrain him under such circumstances.
	■ Add or clarify to cover 'Standard Medical Immobilization' practices that are excluded from the restraint definition in Departmental Instruction 213.	■ Language added in 12VAC 35-115-110 B.
	■ Eliminate the statement: "Physical restraint does not include the use…" and the accompanying qualifiers stipulated in (a) and (b). Reinstate provisions regarding "hands on" approaches.	■ Deleted "hands on approaches that occur for brief periods…" because some providers define "brief periods" as 60 seconds, one minute, and even 5 minute durations. A restraint is always a restraint. At the same time, there are brief instances of holding that are not true restraint, such as holding a child's hand while crossing a street, physically separating two adolescents who are fighting (without continuing to hold them once separated), or holding a crying child to comfort the child. The regulations now allow providers to use judgment to determine if such brief instances of holding are restraint rather than assigning some arbitrary time limit on what is or is not restraint.
	■ "Mechanical restraint" is defined differently here from its definition under the "restraint" definition.	■ Unable to respond to this commenter. There is no other definition of restraint the text of the regulations.
	■ The first sentence is included in the definition should be included in the body of regulation in Section 110.	■ No change. All of the information is definitional and not procedural.
	■ Revise "…portion of his body **and that does not allow** ~~when~~ the individual ~~does not have~~ the option to remove the device.	■ Change made.
	■ Revise as follows: "the use of an approved mechanical device, medication, physical intervention or hands-on hold~~,~~ ~~or pharmacological agent~~ to ~~involuntarily~~ prevent an individual ~~receiving services~~ from moving his body to engage in a behavior that places him or others at **imminent** risk of harm **and to de-escalate a dangerous situation.**	■ No change. Restraint should not be used as a de-escalation technique. De-escalation techniques are non-physical and non-chemical interventions to prevent an emergency. Inserted "imminent" in response to this comment.
	■ Suggests adding "… **body when that individual's behavior places him or others at imminent risk….to each type of restraint.**"	■ Change made.

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	■ This section is guidance rather than definition. Move to 12VAC35-115-110. ■ Concerned about "...means the use of an approved mechanical device..." All three definitions should be written similarly and without regard to "approved" or not. The section governing use of restraint is the proper place to specify that the device, medicine or technique must be approved. ■ Clarify "...that cannot be removed by the individual..." Would a helmet be considered a passive restraint? In many cases the individual has the ability to remove it.	■ No change. Language is definitional and intended to clearly distinguish between the various purposes for the use of restraint ■ Deleted the word "approved." ■ No change. Any time an individual has the option to remove a device it is not considered a restraint. A restraint refers to the effects of the use of a physical hold, medication, or device on an individual and not on the type of holding, the type of medication or the type of device.
"Seclusion"	■ Sometimes seclusion is interpreted to apply to situations where an individuals egress from home or work is prevented for health and safety reasons or to maintain the person on his work environment. Is that seclusion? ■ How is seclusion is carried out by "verbal means" when there is a locked or secured door? These concepts seem inconsistent.	■ Seclusion is more than confining an individual in a given setting. Seclusion is isolating the individual from others and from normally stimulating activities in an area from which egress is prevented. Egress alone does not define seclusion ■ An individual who is prevented from leaving an isolated room or area by staff's verbal threats is technically secluded. Egress also may be prevented by a locked or secured door. No change needed.
"Serious injury"	■ Clarify and add limits to specify that professional ongoing care by a licensed physician is required past initial diagnosis. This would address incidents now required to report such as bee stings, scrapes etc. ■ States that the definition should be aligned with the licensing regulations.	■ Not needed. The H3R Advisory Committee did not recommend changes. This definition was not revised in the proposed regulations.
"Services"	■ Suggests adding " assessment" after "SA"	■ Revised to cover the scope of the regulation.
"Services record	■ Add "that" after " information" ■ Acknowledge that electronic records also a part of the services record.	■ Changes made for clarity.
"Time out"	■ Time-out from positive reinforcement is a basic principle in the practice of applied behavior analysis. This clinical term refers to a continuum of procedures by which an individual's access to positive reinforcers is systematically interrupted contingent upon the occurrence of a target behavior. Past versions of Virginia's Human Rights regulations have recognized the importance of the procedure and permitted its use in all forms in the training centers. The current draft does not include the more restrictive form of time-out from positive reinforcement known as 'locked time-out', 'isolated time-out', 'time-out room', or 'secure time-out'.	■ No change. Although there are technical differences between the various types of time out that are recognized in the professional literature and even in federal regulations, these regulations are intended to create greater safeguards for the human rights of consumers. Although secure time-out, isolated time-out or other forms of time out that place the consumer in a location away from positive reinforcement and from which egress is prevented are professionally recognized as being technically different from seclusion, the

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	Recommends the following paragraphs to expand the time-out definition in the revised regulations. Time-Out from Positive Reinforcement: The withdrawal of the opportunity to earn positive reinforcement or the loss of access to potential reinforcers for a specified period of time contingent upon the occurrence of a behavior. Two forms of "time-out from positive reinforcement" are defined below and are subject to restrictions in these regulations. 1. 1 "Time-out" means the involuntary removal of an individual by a staff person from a source of reinforcement to a different, open location for a specified period of time or until the problem behavior has subsided to discontinue or reduce the frequency of problematic behavior. 2. "Secure time-out" means the involuntary relocation of an individual to a room from which egress is prevented by a door secured with a mechanism that requires continuous staff contact to remain engaged in order to limit access to sources of reinforcement for a specified behavior.	experiences of consumers in both are the same.
	■ "Time out" is not clear. "Involuntary removal" is particularly unclear.	■ The involuntary removal may be physical, in which case it would be a restraint but it may also be in the form of a verbal order or threat by a staff person.
	■ Indicates that if staff members physically move the client to a time out area, the movement would constitute a physical restraint rather than time out.	■ See explanation above.
	■ Believes there should be differentiation between time out that is used to address a challenging behavior when less restrictive alternatives have failed and time out that is used by the individual as a strategy to self calm or reduce stress: "Time out" means ~~assisting an individual to regain emotional control by removing the individual from his immediate environment to a different, open location until he is calm or the problem behavior has subsided~~ **(1)** the involuntary removal of an individual by a staff person from a situation or location ~~source of reinforcement~~ to a different, open location for a specified period of time or until the problem behavior has subsided **for the purpose of** discontinu~~i~~**ing** or reduc**eing** the frequency of future **challenging** ~~problematic~~ behavior; **or (2) the voluntary removal by the individual of his/herself from the current environment to an agreed upon environment in order to self calm or reduce immediate stress.**	■ Time-out can be both involuntary and voluntary. There is no need to regulate a voluntary activity. These regulations are intended to safeguard an individual's human rights and do not address procedures, such as voluntarily going to a quiet place to self calm or reduce stress that have no potential to violate those rights. No change has been made in response to the comment.
"Treatment"	■ Suggests changing "**sound**" to "**clinically appropriate**"	■ Revised to cover the scope of the regulation.

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12 VAC-35-115-40 Assurance of Rights	**B.** Delete requirement that providers give notice at the time an individual begins service **and every year thereafter**. ■ Require the written notice of rights to be in alternate format and languages to ensure communication is effective for those who receive and request such notice. ■ Add : The notice shall tell an individual the **name and telephone number of the current** human rights advocate, how he can contact the human rights advocate and give a short description of the human rights advocate's role. ■ Suggests changes **"the provider shall give a written notice to the individual at the time services begin and every year thereafter."** ■ Revise to ensure that the notice of human rights have been discussed with the individual. ■ Add a requirement that the Department work with CSBs to develop a standardized curriculum to train persons on how to conduct an investigation. ■ The signed notice in the record does not help the consumer…it holds no value…makes it hard to move to an electronic record….suggest documenting the that the rights were reviewed with the individual in the progress notes. **D**. Require the human rights advocate to assist an individual identify and pursue other rights and remedies that may be available and he may be entitled to under federal or state law, such as the Center for Medicaid and Medicare Services, the Social Security Administration, or the fair housing board of Virginia.	**B**. No change**.** Individuals should receive notice of their rights at least annually. This standard is also consistent with other requirements for notification (HIPAA). ■ Revised for clarification. ■ Change made. ■ Will address in training or consultation. ■ No change **D.** No change.
12 VAC 35-115-50 Dignity	**A**, Recommends retaining **"receiving services"** in the provision. **B.1. Use of Preferred Legal Name—** ■ Requests clarification of the meaning of preferred legal name. Some may not be appropriate for treatment settings. Indicates that review of the restriction appears to be excessive. Questions whether the restriction requires review by the local human rights committee (LHRC) or is part of program rules. ■ Providers should not be required to take the steps listed in this section to limit the use of a legal name. ■ Require a licensed professional to discuss limits on the use of the preferred legal name and explore acceptable alternatives with the individual who is being restricted. ■ The requirement that a licensed professional can restrict dignity rights is not a high enough standard. ■ Should document all reasons to restrict a dignity right.	**A**. No change. **B.1**. A preferred name is what a person wants to be called. Providers can use of a name in accordance with the provisions in this section of the regulations. This does not require review by the LHRC. The restriction may be applied on a case-by-case basis depending on the circumstances. There may be a general statement included in program rules. ■ No change. ■ No change. ■ No change. This standard was recommended by the H3R Advisory Committee. ■ No change.

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	B.2. Be protected from harm ■ The use of "harm" is too broad. "Harm" should be clarified in the definitions section. States "the harm should be greater than that which occurs in everyday life…"	**B.2** No change. The concept of "harm" depends on the individual. Harm must be determined on a case-by-case basis.
	B.4. Have opportunities to communicate ■ Too restrictive. Consumers, like anyone else, should have the right to privacy when communicating with anyone.	**B. 4**. No change.
	B.5. **Be provided with general information**-- ■ Suggests inserting "…**given a written copy** of general information about program services, policies, **and rules** in a manner easily understood by the individual."	**B.5**. Change made.
	B: **Insert new provisions in subsection B--** **1. Receive services in an environment that: meets the individual's needs; responds to his preferences; is person-centered and directed; and promotes participation in community and social activities that enhance personal growth and full community participation to the maximum extent.**	**1.** Change made in 12 VAC 35-115-50 A
	7. Exercise maximum self-determination regarding daily routines, such as bedtime and meals, social relationships and other activities, consistent with sound therapeutic practices, the individual's ISP, and applicable laws and regulations.	**7.** No change.
	C. Several commenters suggested the following revisions: **2**. Receive a nutritionally adequate, varied, and appetizing **meals that are ~~diet~~** prepared and served under sanitary condition, served at appropriate times and temperatures**, and** consistent with any individualized diet program **and the individual's preferences, including cultural and religious preferences as they affect diet.**	**2**. Changes made.
	3. Live in a **humane, safe, and sanitary, ~~and humane physical~~** environment that gives each individual, at a minimum: **Reasonable privacy, including private visits with friends, family members, or others of the individual's choice. Privacy shall be afforded to the individual except when the provider has documented a potential threat of abuse, a threat to the individual or others' safety, or when disallowed as part of an individual's treatment plan based upon standard accepted clinical practices.** **Private storage space;** An adequate number **~~and design~~** of private, operating toilets, sinks, showers, and tubs **that are designed to accommodate/address individuals' physical needs;**	**3.** Change made.

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	4. **Participation in religious services or practices may be reasonably limited by the provider if such participation is inconsistent with the individual's ISP or significantly affects the activities of others in a demonstrated negative manner. Any restriction on religious activity participation shall be documented and include justification for such restriction.**	**4.** No change.
	4. Practice a religion and participate in religious services subject to their availability, provided that such services are not dangerous to the individual or others and do not **unreasonably** infringe on the freedom of others.	**4.** No change.
	5. Have paper, pencil and stamps provided free of charge for at least one letter every day upon request, **if an individual does not have adequate personal funds**. ~~**If an individual has funds for clothing and to buy paper, pencils, and stamps to send a letter every day, the provider does not have to pay for them.**~~	**5.** Changes made for clarity.
	6. ~~Have~~ Communicate privately with any person by mail**, or e-mail if the individual has access to a computer**, and have help in writing or reading mail as needed.	**6.** No change.
	Insert **"email"** into the provisions that refer to "mail."	**6.a.** Change made**.**
	In **6.a**. insert "**or designee**."	
	6.a. Suggests inserting language to require that the director discuss any limitations imposed on mail access with the individual.	**6.a.** Changed to require that mail limitations are discussed with the individual.
	In **6.b.** the basis for restricting mail contact "is too limited." Concerned that this restriction may not be invoked in potentially dangerous circumstances.	**6.b**. Issue addressed in subsection 6.a. of this section.
	6. b. The standard "demonstrable harm to the individual's mental health" as the basis for limiting mail "…is so broad that almost anything would be covered…."	**6.b.** No change. Standard can be applied on a case-by-case basis depending on individual circumstances.
	In **6.c** add "professional staff" after treatment team**.**	**6.c.** Clarifying change made to sections 6, 7, and 8.
	6.c. This section seems to contradict the idea that consumers have all of their rights and is also contrary to recovery, empowerment and self-determination. When a restriction is necessary it should be discussed with the consumer in order to reach a compromise. There also should be a means to appeal the decision to restrict.	**6.c.** No change. A consumer can file a human rights complaint any time he believes his rights under these regulations have been violated.
	7.c.(1) This provision is too restrictive. Restrictions should not require LHRC review. .	**7.c.(1)** No change The process and steps for imposing the limitations has been recommended by the H3R Advisory Committee .
	7.c.(1) Proposes requiring a response within five working days from the LHRC and the human rights advocate	
	7 and 8 Should not require LHRC approval of phone and visitor restrictions in residential substance abuse programs. Should only require the program to inform the human rights advocate of the restriction**.**	**7 and 8** See above response to **7.c.(1).**

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	8. Questions the role of the LHRC in this provision. Recommends that the exceptions for substance abuse programs should apply to mental health programs. **8.a**. Inserting the word **"only**" as emphasis on visitor restriction. **8.a.** Concerned that "harm" is used without a working definition in this provision. Believes that consumers should be able to have visitors unless there is some legal reason to restrict them. **D**. **The provider's duties** Several commenters suggested revisions: **1.** Regarding minors' preferences, in referencing "the parent" this creates ambiguity about which parent. Custodial? The one who signed for the individual? Both? What if the parent is not the care taker or custodian? **3.a**. Remove **"employment**" or "**volunteering**" **3.b**. Insert in the last sentence This **"shall"** include **"at least of "** the following actions "**and any other action as deemed appropriate."** **3.c**. Add …**In the case of incidents of peer-to-peer harm, protect the individuals from the aggressor in accordance with sound therapeutic practice and these regulations.** **3.c**.It is not always practical to notify the advocate within 24-hours. **3.d** Clarify that no punishment or retaliation applies to reports made by staff in "good faith." **3.f**. Add…The investigation shall be conducted by an **impartial independent investigator ~~person~~ with training and experience in the knowledge, skills, and abilities necessary to conduct effective investigations** and who is not involved in the issues under investigation **or an employee of the provider**. **3.e.4 and 5** Add language such as **If needed, the decision shall be provided to the individual in alternate format and/or explained in the mode of communication or language most effective for the individual."** or **This process shall be clearly explained in the mode of communication and language most appropriate to the individual's functional abilities.** **3.e.** The state should offer training for investigators.	**8**. No changes. These provisions were recommended by the H3R Advisory Committee. The agency intends to provide training to providers and staff in the application of these regulations. **8.a.** Change made. **8.a.** No change. **D. The provider's duties** **1.** No change is needed. Each circumstance involving minors is considered on a case-by-case basis. **3.a, 3.b, 3c**, and **3.f.** No changes. **3.e.4 and 5.** Changed sections **3.e.4 and 5** in response to the comment. **3.e.** No change. Will address through training or consultation.
12 VAC-35-115-60 Services	**B. The providers duties** **4.d.** Provision is not clear. What is meant by "approval of seclusion and restraint" **5**. With regard to the parent's preferences… Would it be	**4.d.** Change made for consistency. **5.** No change.

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	better to state "a parent?" Should also be an exception to this requirement for those minors who seek services without the knowledge or permission of a parent. **7.** Change wherever it appears in this document "With the individual ~~**or**~~ **and,if applicable**, the authorized representative's consent . . ." And, "When the individual ~~**or**~~ **and,if applicable,** his authorized representative requests. . . " The use of the conjunction "or" implies that the individual does not need to be involved in planning services, giving consent, or participating to the degree he is able in decisions about his life. **7.** Change **…providers "may"** to …**providers "shall"** involve family members in services and discharge planning. **8.** Change… Providers shall ensure that the entries in an individual's services record are at all times authentic, accurate, complete, timely**,** ~~**and**~~ pertinent, **and meet professional standards.** ■ Proposes the addition of the following: i) With the exception of emergency situations or unforeseen circumstances outside of the provider's control, the scheduled medical, mental health appointments shall not be cancelled. ii) If an unforeseen circumstance or emergency requires cancellation of a scheduled appointment, the cancellation and its justification shall be documented in the individual's record, and the appointment shall be rescheduled immediately.	**7.** No change. **7.** No change. This should be an option rather than a requirement. **8**. No change. ■ No change
12 VAC 35-115-70 **Participation in Decision Making and consent**	**A.1.a.** The individualized service plan (ISP) should also include goals, strengths and natural supports…the plan belongs to the individual not the provider. **A.1.b.** Include a reference to "authorized representative" as in Section A.1.c to account for individuals who lack capacity to participate in such planning. **A.2.(a) subsections 1-8.** Should eliminate sections115-70 (A) 2(a) (1-8) from this section since they are included in the definition. The qualifications regarding informed consent are integral to the concept of consent being "informed" and therefore should remain a part of the definition. **A.2.** Change "surgery" to "surgical procedures." **A.2.b.** Suggests the following**:** Evidence of informed consent shall be documented in an individual's services record and indicated by the signature of the individual or his authorized representative on a **designated** form ~~**or**~~ **and** the ISP. **A.2.c.(1) (a) and (b)** Add a statement of the risks and benefits of the procedures to these provisions.	**A.1.a.** Revisions made to the definition of ISP. **A.1.b.** No change. Revision made to 12 VAC 35-115-A 1.c. **A.2.(a) subsections 1-8.** No change. **A.2.** Change made. **A.2.b** No change. **A.2.c.(1) (a) and (b)** No change.

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	A.2.c.(2) Change "separate" to "distinct."	**A.2.c.(2)** Change "separate" to "new."
	A.2.c(3) Proposes changes: Providers shall inform the individual ~~**receiving services**~~ or his authorized representative that: the individual may obtain a second opinion before receiving electroconvulsive treatment; and the individual is free to refuse **consent** or **later** add (4) **For any individual under age 18 years,**	**A.2.c(3**) No change.
	A.3. Add "**has been determined**" after "where the individual …"	**A.3.** Change made**.**
	A.3.a. This provision establishing review rights and processes for objecting individuals who do not have decision-making capacity and have authorized representatives, will disrupt treatment in acute care hospitals. If any such individual can appeal decisions of his authorized representative to the LHRC, the appeal likely will exceed the patient's length of stay given an average acute care hospital stay of 4-5 days. Further, prohibiting the hospital from initiating treatment in this situation will force the hospital to deny treatment that has been approved by a legally authorized surrogate decision-maker; such denial of treatment puts the hospital in a difficult position legally, possibly subjecting the hospital to liability for failure to provide the authorized treatment. Suggest that this provision not apply to acute care hospitals given the nature of acute hospital services as compared to services provided in other regulated mental health programs.	**A.3.a**. No change.
	A.3.a. Concerned that **t**he interpretation of the term "authorized representative" is broadened to include any number of legal instruments, including Medical Powers of Attorney. In some cases, an individual may have assigned an authorized representative, but have capacity to provide informed consent. Should the regulations permit the provider to simply follow the individual's directions rather than require a hearing.	**A.3.a.** No change.
	B.1. Legal guardians should be included in decision-making when an individual is not capable of making his own decisions.	**B.1.** No change.
	B.2. Add**:** "**shall honor these preferences unless contraindicated in the individual's ISP"** at the end of the sentence.	**B.2** No change. This language is too restrictive.
	B.4. Provisions should reference competent minors consenting to treatment. Does this mean that when the parent is involved, that both the parent and minor must consent when required, or is just the minor's consent is adequate.	**B.4.** No change.
	B. 6. Suggests changes**: In the event that the treatment lasts more than 24 hours, the provider shall.** ~~**Providers shall obtain…**~~	**B.6.** No change.

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	B. 8. Cite the referenced statute for clarification. **B.8.c.** Proposes the following revision: If an individual certified for admission **to a state Training Center** under § 37.2-806 of the *Code of Virginia* requests discharge, the director**, or designee, shall contact the individual's Community Services Board to initiate discharge planning.** ~~shall determine whether the individual continues to meet the criteria for admission. If the director denies the request for discharge, the individual and the individual's authorized representative shall be notified in writing of the reasons for the denial and of the individual's right to seek relief in the courts. The request and the reasons for denial shall be included in the individual's services record~~. **Add the following:** ■ Providers shall provide Program Rules to individuals in writing, or in alternative form of communication appropriate to the individual's needs and explained to the individual in a manner that will ensure that they understand the expectations placed upon them. Alternative formats and modes of communication include but are not limited to large print, Braille, picture communication, American Sign language, writing, or other methods. ■ Providers shall make available information, or access to information, about inclusive recreational, civic, and social activities or resources available in the community; and shall promote, to the extent appropriate to the individual's ISP and services, the individual's participation in community life. ■ Should be a notice for discharge and transfers in case an individual wishes to appeal.	**B. 8.** No change. Deleted reference to statute**.** **B.8.c**. Changes made to clarify this section. ■ No change. ■ No change. ■ No change.
12 VAC 35-115-80 **Confidentiality and authorization to disclose information**	**A**. Clarify why "federal" is deleted. **B.2.** Clarify requirements for release of information to other health care providers involved in an individual's treatment. The regulations restrict the release of information without authorization to providers who are licensed, operated or funded by the Department. Expand the definition of provider to include other health care providers. **B.2.a** Clarify: "The name of the organization and the name or other specific identification of the person or persons or class of persons to whom the disclosure is made." Proposes that the regulations be written such that the name of the organization to whom the disclosure will be made will be sufficient. **B.2.b** Clarify**:** " …an indication whether the authorization extends to the information placed in the individual's record after the authorization was given but before it expires."	**A**. Not needed. **B.2.** No change. Permits disclosure of information for treatment, payment or health care operations to any person or persons the extent required or permitted by state law. **B.2.a.** No change. Requires an individual to be specific about the information that can be disclosed when signing an authorization for release of information in a medical record. **B.2.b**. No change. The person completing the authorization must specify whether the authorization applies to the information currently in the record on the day it is signed

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	■ Should delete requirement. **B.2.d** Clarify "…If the authorization is signed by an authorized representative a description of the authorized representative's authority to act. " **B.3.** Clarify the reference to the Virginia Government Data Collection and Dissemination Practice Act. Implies that it gives an individual the right to object to disclosure and have those objections addressed. **B.8.** Delete **B.8.** because it repeats the provisions in **B.2**. **B.8.h.** Add an exception to allow reports to be submitted to the Department of Social Services. **B.8.j.** Clarify the agency intended to eliminate reporting threats to "the public." Indicates that the regulations only allow reporting threats against individuals. **B.9.** A time period should be specified for the reporting required in this provision. **B.12.** Add "**or his representative**" after "**individual**" in this provision. This should be written more broadly to include the discretion to withhold this accounting of disclosures from anyone if there is risk of harm–including disclosures regarding threats of harm and not just abuse. **General comments:** ■ Clarify whether programs that are not subject to Health Insurance Portability and Accountability Act of 1996 (HIPAA) should be required to comply with HIPAA. Will HIPAA override Family Education Rights and Privacy Act (FERPA). ■ Psychotherapy notes should not be protected from the individual's scrutiny.	or whether it authorizes information that is subsequently added to the record. **B.2.d.** No change. Requires a general response such as "legal guardian" or "authorized representative under the Human Rights Regulations." Does not require a specific code citation. **B.3.** Reference deleted. **B.8.** No change. **B.8.h.** No change. Disclosure to the Department of Social Services is allowed under these regulations. **B.8.j.** No change. Conforms to § 54.1-2400.1(B) of the Code of Virginia**.** **B.9**. Change made. (see 12 VAC 35-115-80 B 9.h.) **B.12.** Change made. ■ No change. These regulations do not impact whether a provider is subject to HIPAA. A provider subject to these regulations must comply with these regulations and any other state or federal law or regulations that may be applicable to it. ■ Change made. Under the current regulations individuals have the right to access psychotherapy notes.
12 VAC 35-115-90 **Access to and amendment of services records**	**C.2.a**. No provision is made in this phrasing for the professional judgment of a physician or psychologist to determine that access to the record may endanger the psychological or emotional safety of the individual. Physicians and psychologists treating the child should be allowed to protect their clients' emotional stability. ■ Add "**Requests to**" for items **A.1**., **A.3**., **C.1** and **C4.**...to indicate that consumer and authorized representative may only request to see, read, get a copy of, challenge, amend, or receive an explanation of anything in service record. ■ Individuals should be permitted to have access to psychotherapy notes in there own services record. This is allowed under the current regulations.	**C.2.a.** No change. The language conforms to the HIPAA privacy rule. ■ No change in **A.1**. and **C.4**. Change made to **A.3** to be consistent with HIPAA. ■ Agree. Change made to **A.1**.

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	■ Authority for certain other restrictive decisions (i.e. access to record) should be standardized by placing them under the judgment of licensed professional staff. ■ There may be a contradiction between 12VAC35-115-80 (B).(5).(c). and 12VAC35-115-90. ■ Individuals should be permitted to appoint someone else to review their record. ■ There should be a third party to review the request for an amendment. Believes that the author of the record in question should be taken out the picture if the director believes that the integrity of the review will be compromised.	■ No change. Determination by physician or treating clinical psychologist is required by Virginia Code § 32.1-12.71:03(F). ■ No change. There is no contradiction. 12 VAC 35-115-80(B)(5)(c) deals with disclosure of a minor's record while 12 VAC 35-115-90 deals with access to a minor's record. ■ No change. The regulations provide that individuals may provide authorization to disclose their record to person, including another professional, for review. ■ No change. The provider has the option to permit someone other than the author of the record to perform the investigation.
12 VAC 35-115-100 **Restrictions on freedoms of everyday life**	**A.1.** Exceptions will have to occur for <u>every</u> substance abuse (SA) residential consumer for several of freedoms included in the list. Indicates that exceptions for SA residential programs should be built into to the document related to items a, b, and f **"when sound therapeutic practice requires the restriction."** This authority should not be limited to initial phases of treatment. Programs often find out about dangerousness or vulnerabilities after initial phase of treatment. These same assumptions apply to some intensive residential mental health programs (e.g. crisis care) that admit persons in psychiatric crisis who require the specialized structure/supervision that such programs provide. **A.1**. Suggests the following revisions: Add: "**or any other public setting"** **g**. Freedom to make purchases in canteens, vending machines, **<u>or appropriate retail establishments consistent with his preference</u>**. **~~stores selling a basic selection of food and clothing.~~** **h**. **<u>Freedom to determine his own activities and personal schedule to the maximum extent feasible consistent with personal preference and goals.</u>** **i. <u>Freedom to fully participate in any other activities of community life, consistent with the civil and legal rights of free citizens.</u>** **B. 2** and **B. 4** change "**orderly**" to "**clean**" **B.3.** "Qualified professional" should be defined in the regulations. ■ A "qualified professional" should be one "who is	**A.1.** No change. **B.2.** and **B.4.** No change. **B.3.** No change.

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	provider of services to the individual"	■ No change.
	B.3 a Revise "… behavior**, preferences**, nursing and medication needs, ~~**ability to function independently**~~ **level of independence, and** ~~**promotion of everyday life**~~ **facilitation of self-determination."**	**B.3.a.** No change.
	B.5.d. Allow for the "rules" to be "given to the individual and, if applicable, his authorized representative upon admission and at any time they are requested."	**B.5.d.** No change.
12 VAC 35-115-110 **Use of Seclusion, restraint and time out**	■ The use of involuntary seclusion, restraint and time out should be identified in the regulations as an intervention of "last resort". Providers should make every effort to intervene in the least intrusive, least restrictive, dignity preserving, clinically sound manner before resorting to involuntary measures.	■ No change.
	■ Regulations do not define "qualified professional. Questions whether this means "standards of practice."	■ No change. A "qualified professional" must meet standards of practice for his profession.
	■ Change all reference from "behavioral treatment" to "behavioral support."	■ No change.
	■ The restraint uses section should be relocated from the definition of "restraint" in 12 VAC 35-115-30 to a new 12 VAC 35-115-15.B entitled "Restraints used for the following behavioral, medical or protective purposes."	■ No. change**.**
	■ Is blocking egress from a building is considered "seclusion."	■ Seclusion is considered more than confining an individual in a given setting. Seclusion is isolating the individual from others and from normally stimulating activities in an area where egress is prevented. Egress alone does not define seclusion.
	■ Change the title of the section to "Time out for behavioral purposes."	■ No change.
	■ Will rear facing seat belts, lap trays, etc…be reviewed as part of the behavior plan. Asks whether these devices will be allowed.	■ See new section 12 VAC 35-115-110 B.
	B.1. It is inappropriate for providers to meet with the individual/authorized representative upon admission to discuss the individual's preferred interventions because the type of restraint used is a clinical decision that requires a physician's order under federal conditions of participation. Further, it is alarming and unsettling to individuals to be asked this question at admission, indicating the possibility of the use of restraints, however unlikely, at a time when they may feel frightened and vulnerable.	**B.1.** No change.
	B.1. There should be sufficient flexibility that the provider not be required to discuss the "preferred" interventions for an individual with no history of behavior which might require the use of a behavioral restraint…It might be more	**B.1.** No change**.**

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	appropriate for the regulation to require the provider to provide a copy of their applicable policy and to answer any questions asked by the individual and, if applicable, his authorized representative. **B.1.** Suggests the following revision: Providers shall meet with the individual or his authorized representative upon admission **to the service** to discuss the individual's preferred interventions **in the event that his behaviors or symptoms become a danger to self or others~~;~~ and under what circumstances, if any, the intervention may include seclusion, restraint, or time out. ~~it become necessary to use seclusion, restraint, or time out.~~** **B.2.** It is imprecise and impractical to record all known contraindications to use of restraint in the service record. This assessment should be unnecessary because contraindications to any form of treatment should already be in the record. **B.2.** Suggests revisions: Providers shall: **(i) document the circumstances under which seclusion, ~~and~~ restraint and time out are to be used that include the individual's preferences;** (ii) document all known contraindications to the use of seclusion, time out, or any form of physical or mechanical restraint, including medical contraindications and a history of trauma, in the individual's services record**; and (**iii) shall flag **~~and~~** the record **~~shall be flagged~~** to alert and communicate this information to staff. **B.3.** Only residential facilities for children that are licensed under the Regulations for Providers for Mental Health, Mental Retardation and Substance Abuse Residential Services for Children (12 VAC 35-45-10 et seq.) and inpatient hospitals may use seclusion. **The use of seclusion in the case of a minor shall be used only in an emergency situation and shall not be a component of a behavioral support plan.** **B.7.b.** Suggests the revision: **When using restraint or seclusion for behavioral purposes**, trained qualified staff **will monitor** the individual's medical and mental condition continuously for the duration of the restriction. **B.7.d.** Suggests the revision: Incidents of seclusion and restraint **when used for behavioral purposes, are reported the department as provided in 12 VAC 35-115-230** including the rationale for and the type and duration of the restraint. **B.11.** Explain the purpose of the review.	**B.1**. Change made. **B.2.** Revised for clarity. **B.3.** No change. **B.7.b.** Changes made. **B.7.d**. No change. Required by Code. **B.11**. The purpose of the review, which is outlined in detail in 12 VAC 35-115-110.B.13, is to assess the continued need for the procedure, establish behavioral

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		criteria for release, and document the rationale for use of the procedure.
	B.11 Suggests revisions: Providers shall ensure that a qualified professional who is involved in providing services to the individual reviews every use of any **behavioral** restraint as soon as possible after it is carried out.	**B.11** No change.
	B.11 Clarify "ASAP" regarding a qualified professional reviewing every use of any restraint as soon as possible after it was carried out.	**B.11** Not defined.
	B.12 Can the time limited approval be "until calm."	**B.12** No, the time-limited approval cannot be specified as "until calm." Provisions in 12 VAC 115-110.B.14 specifies the maximum time that an individual may remain in seclusion or restraint. 12 VAC 115-110.B.15 establishes the maximum time for time-out. In addition, the provider must establish clear and measurable behavioral criteria that are used by staff to determine when the consumer must be released from the procedure.
	B.12 Revise the first line as follows: Providers shall make sure that review and approval by a qualified professional for the use or continuation of restraint **for behavioral purposes** is documented in the individual's services record."	**B.12** No change.
	B.13. Change **behavioral** to **specific** in this provision.	**B.13** No change.
	B. 13. Can the staff person who performs the restraint do the required assessment? The requirement for emergency restraint appears more appropriate for hospital rather than community programs, where there may only be a single staff person.	**B.13** This should be addressed in the provider's emergency policy. There should always be back-up staff for an emergency.
	B. 13.a, b, c, d, and e. Remove "mechanical."	**B.13 a, b, c, d, and e.** No change.
	B.13.a The required assessment as to "why alternatives to proposed use of seclusion and mechanical restraint have not been successful" is unrealistic, especially with respect to use of medications…. Because seclusion and restraint are used rarely and only in emergencies, the CMS and JCAHO prerequisites imposed on hospitals (i.e. that all available alternatives be tried and found ineffective to protect the patient or others from harm) should be sufficient safeguards.	**B.13.a**. Changes to clarify.
	13. e. Recommends inserting **"…to include alternate communication formats where necessary…"** after "understand."	**B.13.e** No change.
	B.14 Remove "**or seclusion"** and add "… **to specific instances in which lesser restrictive intervention has**	**B.14**. No change.

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	not worked and each episode shall be limited to no longer than it takes for the individual to meet the specific criteria established for the release up to a maximum of…"	
	B.15. The requirement that "Providers shall limit each approval for time-out to no more than 30 minutes." is imprecise because it is not clear what is meant by an "approval".	**B.15**. Change made.
	B.17. Recommends changing **:** "Providers may use restraint or time-out in a behavioral treatment plan to address behaviors that present an immediate danger to the individual or others, but only after a qualified professional has conducted a detailed and systemic **assessment ~~analysis~~** of the behavior and situations in which the behavior occurs".	**B.17.** Change made.
	B.17 Indicates that "**systemic assessment"** should be revised to **"systematic assessment."**	**B.17.** Change made.
	B.17. Suggests this section be revised as follows: Providers may use restraint or time-out in a **positive behavioral support ~~behavioral treatment plan~~** to address behaviors that present an immediate danger to the individual or others, but only after a qualified professional has conducted a detailed and systemic **~~analysis of the behavior and the situations in which the behavior occurs~~. functional behavioral analysis to include but not be limited to: the antecedents to the behavior, the environments, situations, and times, in which the behavior occurs, and the communicative function of the behavior and the professional has determined that safety cannot be achieved with the use of positive interventions and that no lesser restrictive alternative will be effective. This determination shall be reevaluated at least every 6 months.** **a**. Providers shall develop any behavioral **~~treatment~~ support** plan involving the use of restraint or time-out for behavioral purposes according to its policies and procedures, which ensure that: (1) Behavioral **~~treatment~~ support** plans are initiated, developed, carried out, and monitored by professionals who are qualified by expertise, training, education, or credentials to do so. (2) Behavioral **~~treatment~~ support** plans **~~include~~ emphasize** nonrestrictive procedures and environmental modifications that **(i) address the communicative function of the targeted behavior and seek to replace it with a more acceptable means of communication and (ii) the individual's preferences for interventions as identified in the ISP.** (3) Behavioral **~~treatment~~ support** plans are submitted to and approved by an independent review committee	**B.17.** No change.

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	comprised of professionals with training and experience in applied behavior analysis **and/or positive behavioral supports** who have assessed the technical adequacy of the plan and data collection procedures.	
	b. Providers shall document in the individual's services record **that** ~~that~~ the lack of success, or probable success, of less restrictive procedures attempted and **that** the risks associated with not **using restrictive procedures** ~~not treating the behavior~~ are greater than any risks associated with the use of restraint. **This documentation must reflect trials of less restrictive procedures employed within an appropriately developed, data-based positive behavioral support plan and not an assumptions that the less restrictive procedures will not work.**	b. No change.
	B.17.c. Revise the process to require review of a behavioral plan by and provisional approval of the advocate prior to implementation rather than delaying this review until the LHRC is scheduled to meet. The plan would then be submitted for approval to the LHRC at its next scheduled meeting.	**B.17.c**. No change.
	■ Consider giving the LHRC chair the authority temporarily approve a behavioral plan.	■ Nothing in these regulations prohibits the LHRC from establishing its own procedures for granting temporary approval.
	■ The required LHRC approval of behavior health plans using restraint or time out is impractical for interventions used only in emergencies (as is the rule for acute care hospitals). If this requirement is intended to apply only in certain programs, the regulations should clearly state its scope.	■ Hospitals may use seclusion or restraint or time-out in emergencies without behavioral treatment plans. However, if a provider elects to include the use of a restrictive procedure in a behavioral treatment plan, the requirements in this section of the regulations apply. No change to **B17.c.**
	B.17.d. Should the LHRC determine its schedule for review of behavioral treatment plans.	**B.17.d**. While the regulations specifies that the LHRC must review behavioral plans quarterly, this does not prohibit a LHRC from conducting more frequent reviews if it is considered appropriate.
	■ Add new **12 VAC 35-115-110-B.19** to govern and allow the use of "secure time out" in training centers in compliance with federal ICF/MR regulations maintained by the Centers for Medicaid and Medicare Services (CMS).	■ Have not included specific provisions for "secure time out." There are differences between the various types of time-out that are recognized in the professional literature and even in federal regulations. However, these regulations are intended to create greater safeguards for the human rights of consumers. While secure and, isolated time-out or other forms of time out that place the consumer in a location away from positive reinforcement and from which egress is prevented are professionally recognized as being technically different from seclusion, the experiences of consumers in both are the same.

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12 VAC 35-115-120 **Work**	**B**. The term "consumer" should be changed to "individual" for consistency.	**B**. "Consumer" deleted.
12 VAC 35-115-130 **Research**	■ Recommends some impartial, routine oversight of the research projects that allows the individual to share candidly and frankly of the benefit, preferences and concerns about the research. **B**. Suggests that the provisions be revised as follows: **3.** Providers shall obtain review and approval from an institutional review board (IRB)or research review committee prior to performing or participating in a human research protocol. **Documentation of this review and approval must be maintained and made available upon request by the individual or his authorized representative.** **4. Prior to participation by individuals in any human research project, the provider shall inform and provide a copy of the IRB or review committee approval to the LHRC. Once the research has been initiated, the provider shall update the LHRC periodically on the status of the individual's participation.** **B. 4**. It seems impractical and unnecessary to require prior approval by the LHRC for each individual seeking participation in research when there is also a requirement for an institutional review board. It is reasonable for the LHRC to be informed of the research and possibly even to approve the research in advance–but not to approve individual participation.	■ No change. The LHRC could, of its own accord, oblige the provider to comply with this type of oversight. **B**. Changes made. **B. 4**. No change.
12 VAC 35-115-140 **Complaint and Fair Hearing**	■ Change to "…informal and formal processes."	■ No change.
New: Part IV **Substitute Decision Making**	■ At a minimum individuals should be informed of their rights at every step of the process. Human rights advocates should meet with each individual and explain his rights in clear language and offer the opportunity for LHRC review before an AR is appointed.	■ Changes made.
12 VAC 35-115-145 **Determination of capacity to give consent and authorization**	■ There are no clear guidelines for determining capacity. ■ Individuals should be permitted to appeal all capacity evaluations to the LHRC. **A.** Paragraph **A.1**. contradicts the statement in the introduction that "…If the capacity . . . is in doubt, the provider shall obtain . . ." **A.1.** requires capacity evaluations even for those individuals for whom there is no doubt or controversy about their inability to give informed consent. This is burdensome, unnecessary and expensive	■ Provisions added to describe what the capacity evaluation should include. ■ Provisions for appeal are provided in 12 VAC 35-115-200. **A.** No change. Some type of capacity evaluation must be on file for each person that has a substitute decision maker.

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	for providers. The documentation suggested in A. 3. a. should suffice initially and obviate the need for a formal evaluation.	
	A.1 Suggests revisions:	**A.1.** No change.
	Capacity evaluations shall be obtained for all individuals who may lack capacity ~~**even if they requested that an authorized representative be designated or**~~ to agree to a recommended course of treatment. **However, if an individual agrees they may lack capacity and desires to have a family friend or next friend for representation, and there is no known reason to suspect such choice could be injurious to their welfare, their desire will be respected and no capacity evaluation shall be necessary.**	
	A. Suggests revisions:	**A.** No change.
	A. If the capacity of an individual to consent to treatment, services, or research, or authorize the disclosure of information is in doubt, the provider shall obtain an **independent** evaluation from a professional who is qualified by expertise, training, education, or credentials and **who is** not directly involved with the individual **or the provider** to determine whether the individual has capacity to consent or to authorize the disclosure of information.	
	3. Providers shall determine the need for an evaluation of an individual's capacity to consent or authorize disclosure of information and the need for a substitute decision maker whenever: **(i)** the individual's condition warrants, or **(ii)** the individual requests such a review~~,~~ . **Once a determination has been made that the individual lacks such capacity, the provider shall have the individual's capacity evaluated** at least every six months, and at discharge, except for individuals receiving acute inpatient services.	
	a. If the individual's record indicates that the individual is not expected to obtain or regain capacity, **the provider shall have the individual's capacity reevaluated and documented annually** ~~**that it has reviewed the individual's capacity to make decisions and**~~ to determine whether there has been any change in that capacity.	
	b. Add **in mode of communication that is appropriate and effective for the individual.**	
	4. Add **Decision-making supports should be person-centered and least restrictive to the liberty of the individual. Consideration should be given to administration of a capacity evaluation that will address ability to provide both general and informed consent.**	
	A. 4. It is not clear from the definition of treatment that "treatment planning" should necessarily require informed consent.	**A. 4.** Change made in **paragraph 4.**

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	A.5.a. It is not clear who pays for the independent evaluation…	**A..5.a.** This provision requires the individual or family to pay for the independent evaluation under the circumstances addressed in the section. Otherwise, the provider pays for the evaluation.
	A.5.a. "…If the individual or family member cannot pay for an independent evaluation the individual may request that the LHRC consider the need for an independent evaluation." What happens once the LHRC has considered this.	**A.5.a.** The regulations establish the process for LHRC reviews in 12 VAC 35-115-200.B.
12 VAC 35-115-146 **Authorized representatives**	**General Comments:** ■ Changes require every service provider to have an authorized representative (AR) for every person out of fear of breeching the regulations and increasing their liability. ■ An unintended consequence of the regulations could lead to an increasing use of AR to the detriment of consumer decision- making as providers seek to reduce liability. ■ Expanding the scope of the AR to include all services implies that all individuals with disabilities are incompetent to decide which services they would and would not like to receive. ■ Regulations related to authorized representatives, consent, and substitute decision-making are less clear regarding the relationship of the AR to simple consent and informed consent. In the current regulations it is clearer that the involvement of the AR is necessary regarding decisions related to informed consent. In the proposed regs, the AR seems to have a role in any consent. The term "informed consent" no longer appears in the definition of an authorized representative. Concern that this takes away the individual's ability to make all decisions, or makes the process of assessing capacity to consent much more involved.	**General Comments:** ■ These comments suggest that the regulations will accomplish the opposite of what is intended. This will be addressed in training and consultation.
	■ Proposes to include "microboard" and "circles of support" in the title and to insert new provisions in sections **A. and B**. to allow a "microboard duly incorporated under the laws of the Commonwealth or Virginia" or a "circle of support" to act as a substitute decision-maker for an individual who has been determined to lack the capacity for his own decisions.	■ "Mircroboards" and "circles of support" are not specifically mentioned in these regulations but revisions in the appropriate parts of the regulations support these concepts.
	■ The regulations refer to "authorized representative" but do not clarify who this would be nor that it would inherently include the parent or guardian for an individual under the age of eighteen. Requests clarification. **A**. Insert "…When it is determined…the provider shall recognize and obtain consent or authorization for those decisions for which the individual lacks capacity from the following**, if one is available**…"	■ The guardian (AR) of a minor depends on the situation of the minor. This could be a parent or parents, the Department of Social Services or other entity. The AR is determined on a case-by-case basis. **A**. Change made.

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	B. The individual's preference for an AR should be paramount. The regulations state that if a next friend is appointed and a relative becomes available, the next friend is removed. We would recommend that the following language be added to the end of the sentence: "**unless the individual objects after consultation with the HR Advocate**."	**B**. Change made to 12 VAC 35-146.B.2. to address the comment.
	B.2. The requirement "…within two years prior to the designation" makes the identification of someone who can serve as next friend even more challenging. Programs should be able to identify a volunteer in the same way that guardianship program recruit volunteers who meet the other requirements specified in the regulations.	**B.2.** A next friend is the only type of AR who is not a relative or designated through an external legal process such as guardian or power or attorney. This provision was the recommendation of the H3R Advisory Committee. No change needed.
	B.2. For an acute care hospital, it is impractical for the LHRC to approve the appointment of a "next friend." For patients with an average length of stay of 4-5 days, the patient will be discharged before the process can be completed, leaving the patient with no decision-maker. This section should not apply to acute care facilities.	**B.2.** This is an available option but not a requirement.
	B.2. a. and b. Why is the threshold for qualification to be a next friend much higher than that required for a guardian who would have almost complete authority in the life of the individual. On the other hand, despite the difficulty of finding appropriate authorized representatives, providers cannot use professional judgment about whether a volunteer, with the approval of the LHRC, might be an appropriate advocate for the individual. As a result there are individuals with *no* advocate other than the service provider. A community based, trained and interested volunteer would better serve the individual than a for profit guardianship service.	**B.2. a. and b**. The provisions for next friend were reviewed, considered and revised based on recommendations from the H3R Advisory Committee. A next friend is the only type of AR who is not a relative or designated through an external legal process such as guardian or power or attorney. A volunteer or friend, of course, could be an advocate for or support to an individual, but that is different than being the authorized representative with authority to consent to treatment. We support the idea of individuals having many friends or supporters assisting with services or decisions but only certain types of persons qualify to be authorized representatives.
	B.3 Insert the following: In addition to the conditions set forth in subdivision 2…. **a. The LHRC shall conduct a criminal background check on the nominated next friend; and** **b.** the ~~**individual**~~ **the nominated next friend** must have no objection to the proposed next friend being designated as the authorized representative.	**B.3.** No change.
	C. Employees of the provider should not be appointed as AR and with an exception if the employee is a relative or guardian. Add an exception if the individual has named the employee as attorney-in-fact in a valid power of attorney. Providers should be required to develop policies, approved by the LHRC, to protect any individual in this situation from a conflict of interest.	**C.** No change.

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	E. This is not a viable option in areas without volunteer guardianship programs.	**E.** Agree that there is a problem identifying substitute decision-makers. Recently, the Department has received funding to expand the public guardianship program, which will be used to address the problem.
	G. The consumer should initiate the re-evaluation to have an AR discontinued and should ask to have the AR rescinded.	**G.** Change is not needed. This is addressed in 12 VAC 35-115-200.
	G. The last sentence before subsection 1 states that "Powers of attorney and health care agents' powers should cease of their own accord when a clinician has determined that the individual is no longer incapacitated." This is technically inaccurate. Unless the POA is a "springing" POA, the powers do not cease upon the individual's regaining of capacity.	**G.** Changes made.
	G. Re-write this section to place the burden for the "use of the applicable statutory provisions to remove the authorized representative (see § 37.2 – 1012)" when that authorized representative is the legal guardian, on the Department after the Office of Human Rights has been informed by the provider that capacity has been restored. The Code would allow the guardian to initiate the proceeding to modify or eliminate the guardianship, should they fail to do so and the provider initiates the petition to the Court, it is a virtual certainty that the guardian will remove the individual from the provider's program before the Court acts.	**G**. No change.
	G. If the individual disagrees with a decision made by an AR, the regulations state that the advocate must be notified and that a petition for LHRC review **may** be filed. Recommends that the petition **shall** be filed unless the individual chooses not to do so after consultation with the advocate.	**G.** No change.
	G.1. Insert "…**or is clearly acting against the best interests or express preferences of the individual.."** after the word "serve."	**G.1.** No change**.**
	G.2. Add "**and expressed preferences**" after "**interests.**"	**G.2.** No change.
	G.3. Insert "**a Microboard duly authorized under the laws of the Commonwealth"** between "directive" and "a legal guardian.	**G.3.** No change.
12 VAC 35-115-150 **General Provisions**	■ Revisions to this section: A. The parties to any complaint are the individual and the director. **Each party can designate someone to represent him.~~also have anyone else to represent him~~** during **resolution of the** complaint ~~**resolution**~~. B. ~~**Meetings, reviews, and hearings will generally be closed to other people unless the individual making the complaint requests that other people attend or if an open meeting is required by the Virginia Freedom**~~	■ No change.

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	~~of Information Act.~~ **To protect the confidentiality of the individual, meetings, reviews, and hearings are closed to other people except under the following circumstances:** **(1) When the individual making the complaint requests that the meeting, hearing, or review be open to other people.** **(2) When an open meeting is required under the Virginia Freedom of Information Act (§2.2-3111 of the Code of Virginia)** **C** ~~1.~~ The LHRC and SHRC may conduct a closed hearing to protect the confidentiality of persons who are not a party to the complaint, **even if the individual requests an open hearing,** but only if a closed meeting is otherwise allowed under the Virginia Freedom of Information Act (**'~~2.2-3700 et seq.~~ § 2.2-3711 of the Code of Virginia**). ■ Indicates that the section needs to begin with the principle of conflict resolution…solve the problem at the earliest stage.	■ Inserted "…The director shall make every effort to resolve the complaint at the earliest possible stage..." in **A**.
12 VAC 35-115-160 **Informal complaint process** *(repealed section)*	■ The formal and informal complaint process should be monitored or have some oversight by an impartial person appointed by the Department, rather than the provider. This would help to decrease perceptions of conflicts of interest. Indicates that the process is very lengthy and time consuming. ■ The current complaint process has a better flow.	■ No change. The complaint resolution process is monitored by the advocate and the local human rights committee (LHRC). ■ No change.
12 VAC 35-115-170 **Complaint resolution process**	■ Who fills the directors role if there is a conflict of interest. ■ The complaint process time frame should be limited to 5-10 business days. ■ Insert "…or authorized representative…" in the provisions when reference is made to the rights or decision of an individual. **A.** Change "**may**" to "**shall**" report to the director "**or**"… **A.3.** Suggests inserting the following: **The steps in the informal and formal complaint process shall be thoroughly explained to the individual using the mode of communication most effective to the individual, including using alternate formats as needed. The human rights advocate, director, or his designee shall ask the individual if he understands the complaint process and the choice that he has before asking the individual to choose how he wishes to pursue the complaint.** ■ ~~D. Step 3~~ Step 2: The director or his designee shall give the individual and **the person the individual has chosen to represent him during the complaint**	■ This would be decided on a case-by-case basis. ■ No change. ■ Agree and have made the revision. **A**. No change. **A.3.** Changes made. ■ No change. Addressed in other parts of the regulations.

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	process, ~~his chosen representative~~ a written preliminary decision and, where appropriate, an action plan for resolving the complaint, within 10 working days of receiving the complaint. Along with the action plan, the director **or designee** shall provide written notice to the individual about the time frame for the individual's response pursuant to Step 3 of this subdivision and a statement the complaint will be closed if the individual does not respond. **This decision, the action plan, and the written notice, shall be provided in alternate format if appropriate and explained to the individual in the mode of communication effective for him.** ~~E. Step 4~~ Step 3: If the individual ~~is not satisfied at this step~~ disagrees with the director's preliminary decision or action plan, he can respond to the director within ~~5~~ five working days after receiving the ~~director's or the designee's written~~ preliminary decision and action plan. **This response shall be in writing or or in alternative form of communication appropriate to the individual's need.** If the individual has not responded within five working days the complaint will be closed **unless there are emergency or extenuating circumstances beyond the control of the individual which prevent a timely response (e.g., an unexpected hospitalization)**. ~~F. Step 5~~ Step 4: ~~The~~ If the individual disagrees with the preliminary decision or action plan the director shall investigate further as appropriate and shall make a final decision regarding the complaint. The director shall forward a written copy of his final decision and action plan to the individual, **the person representing the individual during the complaint process,** ~~his chosen representative~~, and the human rights advocate within ~~10~~ five working days after the director ~~received~~ receives the individual's written response. Along with the action plan, the director shall provide written notice to the individual about the time frame for the individual's response pursuant to Step 5 of this subdivision and a statement that if the individual does not respond that the complaint will be closed **unless there are emergency or extenuating circumstances beyond the control of the individual which prevent a timely response (e.g. an unexpected hospitalization). The decision, the action plan, and the written notice, shall be provided in alternate format if appropriate and explained to the individual in the mode of communication effective for him.** ~~G. Step 6~~ Step 5: If the individual ~~is not satisfied~~ disagrees with the director's final decision or action plan, he may file a petition for a hearing by the LHRC, using the procedures prescribed in 12VAC35-115-180. **The human rights advocate shall thoroughly explain the steps in the hearing process to the individual using the mode of communication most effective to the individual,**	

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	including using alternate formats as needed. The human rights advocate shall ask the individual if he understands the hearing/appeal process. If the individual has accepted the relief offered by the director, the matter is not subject to further review **A.4. Step 2:** Provide examples of " good cause". How is the individual's decision to extend the informal time frame documented. **A..5. Step 1**: This is not a reasonable timeframe. **A..5. Step 1:** The Office of Human Rights (OHR) in the Department should not have to be notified every time a person complains. They should be notified only if there is a problem in resolving the complaint or if the individual requests this notification. **A. 5. Step 4.** The complaint process should indicate that the informal process is followed unless the individual requests the formal process. ■ Also, recommends the following change: **Step 4***:* If the individual disagrees with the preliminary decision or action plan **and reports such disagreement to the director in writing within 5 working days after receiving the preliminary decision or action plan,** the director shall investigate further… **B.** Not clear. Can the director appoint a designee to receive complaints and if not, what happens when the director is unavailable?	**A.4. Step 2**: No change. Providers policies will govern this. Decision is reported to the human rights advocate. **A.5. Step 1**: No change. **A.5.Step 1:** No change. **A.5. Step 4.** Changes made changes to address this comment in 12 VAC 115-150.A. ■ Inserted change in **Step 4.** **B.** No change. Provider may appoint designee.
12 VAC-35-180 **Local Human Rights Committee hearing and review procedures.**	■ Add "or authorized representative" to each provision referring to rights or decision of an individual." ■ Add "emergency or extenuating circumstance" and "alternative format" language in the provisions.	■ Change made. ■ No change.
12 VAC 35-115-190 **Special procedures for emergency hearings by the LHRC**	■ Add "or authorized representative" to each provision referring to rights or decision of an individual." ■ Add "alternative format" language in the provisions. ■ The individual's appointed representative should be permitted to participate	■ Changes made. ■ No change. ■ No change is required to address this comment.
12 VAC 35-115-200 **Special procedures for LHRC reviews involving consent and authorization.**	■ An Individual cannot be forced into treatment in community programs if he continues to refuse treatment, even if the LHRC concludes that the authorized representative was properly appointed. ■ Members of an LHRC are not qualified to make a determination of which evaluation will control when there are two conflicting evaluations. A third independent evaluation should be obtained or a court determination sought.	■ No change needed to address this comment. ■ No change.

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	2. Suggests the following be added to this provision: … the LHRC may be requested to decide whether the individual's personal consent is required for any treatment or participation in research which evaluation will control. **To facilitate its review, the LHRC shall ask that a ~~physician or~~ licensed clinical psychologist, not employed by the provider, evaluate the individual at the provider's expense, and give a third opinion about his capacity to consent to treatment or authorize information.** **2.a and 2.b** Suggests non-substantive language revisions to this section.	**2.** No change. The LHRC is not making a clinical determination but is choosing which evaluation controls. **2.a and 2.b** No change.
12-VAC-35-115-210 **State Human Rights Committee Appeals procedures**	■ Require the human rights advocate to explain the process to the individual and to ensure that all communication, submissions, and explanations are provided and accepted in alternative formats in response to individual needs. **E. Step 4:** Retain the 20 day time frame **C. Step 3**: Revise as follows: …Within 5 working days of noting or being notified of an appeal, the director shall include a complete record of the LHRC hearing to the SHRC **and shall send notification of the appeal to the office of the inspector general.** **H. Step 7:** Suggests inserting: **In the case of appeals involving CSBs and private providers, ~~both~~ the commissioner and the provider's governing body shall each outline in writing the action or actions they will take in response to the recommendations of the SHRC. They shall also explain any reasons for not carrying out any of the recommended actions. Copies of their responses shall be forwarded to the SHRC, the LHRC, the director, the human rights advocate, and the individual.**	■ No change. **E. Step 4.** No change. **C. Step 3**: No change. **H. Step 7:** No change.
12 VAC 35-115-220 **Variances**	■ Recognize the unique dynamics of substance abuse programs in the regulations and not require them to seek variances. ■ Notice of variances should be published in local newspapers. Recommend a new Section I relating to notification. **F.** Add the following: Providers shall develop policies and procedures for monitoring the implementation of any approved variances **and documenting the impact of the variance on the individuals being served.** **F.** Suggests adding the following: **When a variance is approved, the individuals being served by the provider granted the variance should be**	■ No change. ■ No change. **F**. No change. **F**. Change made in new part H.

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	informed about the details and specifications of the variance. **G.** The process for obtaining a variance should be streamlined rather than adding provisions for a temporary variance.	**G**. No change.
12 VAC 35-115-230 **Provider requirements for reporting to the department**	■ Include an expectation for provider and the Department to conduct data analysis of the reported incidents. Compiling numbers of incidents is not sufficient. ■ More specificity should be required about the deaths that are reportable. ■ Require the Office of Human Rights of the Department to post details on its website of all substantiated cases of abuse, neglect and exploitation. **A.1.** Require the Department to report to the protection and advocacy agency as required under §51.5-39.12 of the Code of Virginia and to the Office of the Inspector General pursuant to access granted under §37.2-424(4) and(8) of the Code of Virginia. Also add these reporting provisions in **B.1.** of this section. **A.2.** Add: "**The director shall also inform the human rights advocates as to whether he has reported the allegation to Department of Social Services, Adult Protective Services, or in the case of a minor child, Child Protective Services.**" **C.** Add **"…including all actions taken, the rationale for employing seclusion or restraint, and documentation of all other interventions utilized and why they were unsuccessful."** **C.2.** Change annual report to monthly report. ■ Proposes changing the annual reporting requirement to reporting on requests when the provider is following a physicians order for restraint. **C.3.** Delete C.3. Items preceding it (C.1. and C.2.) mandate that incidents of seclusion and restraint be reported in accordance with 'applicable operating instructions' issued by the Department. The effect of these deletions would be to eliminate the requirement for reporting the duration of protective and medical restraints such as bedrails, safety straps, restraints for medical purposes. **F.** Add new part 3. to require the Department to post all provider's data on its website.	■ No change. ■ No change. ■ No change. Information about substantiated cases of abuse and neglect is currently available to the public on request. **A.1.** No change. **A.2.** No change**.** **C.** No change. **C.2.** No change. **C.3.** No change**.** **F**. The information is currently available to the public on request.
12 VAC 35-115-240 **Human rights enforcement and sanctions**	■ Make any sanctions imposed on providers public information. ■ Add a requirement that the Department post information on its website about any sanctions that are imposed on providers.	■ This information is currently available to the public on request. ■ No change.

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	A. Change "may" to "shall".	**A**. No change. Imposing sanctions is an option not a requirement.
12 VAC 35-115-250 **Offices, composition and duties**	■ Insert "or authorized representative" in each instance referring to rights or decision of an individual.	■ Not all situations in these provisions require an authorized representative (AR). The scope of authority of the AR depends on the type of AR and the circumstances.
	■ Insert a new provision to ensure that reasonable accommodation is made for the individual's to understand his rights in his primary mode of communication.	■ No change. Addressed in other parts of the regulations.
	■ In several sections certain provider actions and circumstances are required to be reported to the human rights advocate. However, the regulations do not provide any expectation for the advocate to do anything with that information or to even monitor the situation. There should be an expectation of action by the advocate upon receipt of the information.	■ No change. Section 12VAC 115-35-250.C explicitly requires the human rights advocate to monitor, investigate, and perform other duties.
	A. 1. The liaison referenced in this provision should be identified ahead of time, not on an ad hoc basis	**A.1.** No change. Providers generally identify the liaison ahead of time in their policies.
	A.6. Concerned that local human rights committees (LHRC's) are unavailable in some geographic areas of the state which makes it difficult for providers to affiliate. Also concerned about lack of resources that are available to some LHRCs which may create hardships in performing duties that are imposed on them.	**A.6.** Will address in training and consultation on these regulatory requirements.
	A.12. The state should fund clerical support for the LHRC's. Providers should not have to draft minutes for LHRC meetings.	**A.12.** No change.
	A.14. Suggest the following: Post in **prominent** program locations information about the existence and purpose of the human rights program **and the protection and advocacy system.**	**A.14.** This is addressed in 12VAC35-115-40.
	A.17. Add a new paragraph to Section A: "**Comply with all requirements set forth in the affiliation agreement with the LHRC as approved by the SHRC**"	**A.17.** No change. The state human rights committee does not approve this affiliation agreement.
	B.2 Suggests insertion of : …(iii) by reporting all suspected abuse, **neglect, and exploitation** to the program director. Protecting individuals receiving services from abuse also includes using the minimum force necessary **to restrain an individual who is abusing another individual.**	**B.2.** Inserted "neglect and exploitation."
	C.5. Revise to state… **Whenever appropriate or when requested by the individual or his authorized representative…**	**C.5.** No change.
	C.13. Add requirements that human rights advocates shall be employed in consultation with stakeholders, evaluated annually by the LHRCs they serve and by the consumers and family.	**C.13**. No regulatory requirement needed. The Department's Office of Human rights always has consumers and frequently has family members on interview panels for its employees.

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	C.14. Add provisions that allow consumers to complain about the human rights advocate and for these complaints to be heard by the State Human Rights Committee (SHRC) and the brought to the attention of the Commissioner of the Department.	**C.14**. No change.
	D. The SHRC may require multi-site programs to have more than one LHRC affiliate if SHRC determines that additional affiliates are necessary to protect rights. Clarify requirement for programs that have all sites are in the same region or city. What constitutes a region?	**D**. No change. The SHRC is responsible to determine regions for affiliation purposes (see 12 VAC 35-250.D.2).
	■ Providers with multiple locations should affiliate with an LHRC in each community services board (CSB) area in which they have operations.	■ No change.
	■ Suggests several non-substantive language changes to this section to that re-write the description of the LHRC membership.	■ Changes made**.**
	■ CSBs should provide administrative support to LHRCs.	■ No change.
	■ LHRC and SHRC by-laws should set the procedural aspects of the meeting.	■ No change.
	D.2. The provision removes the authority of the LHRC to determine its affiliations and transfers this authority to a state employee. Indicates that there are no criteria for determining affiliations. Concerned about the increase in workload and cost that may result. The Department's Office of Human Rights should find a way to create more capacity in the human rights system. This is not the responsibility of the LHRC.	**D.2.** No change. This provision does not transfer authority of the LHRC to a state employee. The SHRC is the "supervisor" per se of the LHRC and as such may review any action or activity of the LHRC. This provision puts some parameters around such a review if a provider is denied affiliation and also helps to ensure that the rights of individuals will be protected.
	E.5. Add **"the respective LHRC, the human rights advocate**," after "advice of…"	**E.5**. Change made.
	E.9. Add "**and review**" after "development".	**E.9**. No change.
	E.17. Add a requirement that the Department publish the report of human rights activities, etc. on its website and make it available in alternative formats upon request. Also insert in paragraph **F.5.** in this section.	**E.17**. The annual report is routinely posted on the Department's website and can be made available in alternative formats, if requested.
	F. Suggests adding a new provision: **Provide due process rights for members of LHRC in proceedings for removal, assuring the right to counsel, to know the charge, to confront accusers, to present evidence and witnesses on their own behalf, including prior review of charges by their own LHRC.**	**F**. Included the by-laws of the SHRC.
General Comments	■ In all places where the regulations state "**the individual and his AR as required"** add **"and the legal guardian of a minor".**	■ No change. The scope of authority of an AR is dependent on the type of AR and circumstances.
	■ Organize the regulations in a format that includes "Intent" of standard, "Interpretation," and "Compliance	■ Will develop a companion document to assist providers to comply with the

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	Determination" to create consistency in application of the regulations for all clients and providers.	requirements.
	■ Indicate that the SHRC appeal is the last level of appeal.	■ Changes made in 12 VAC 35-115.J.9.
	■ The Department's Office of Human Rights, the LHRC and SHRC should be more cognizant of and lend credence to how an individual's disability plays a major role in the complaint process.	■ Individual's rights to the human rights process do not change because of his specific type of disability.
	■ The Department should reconsider the organizational structure for abuse and neglect investigations and implement a similar structure to that of the Office of Human Rights in which the human rights advocates report to the State Director of Human Rights in the Central Office who reports directly to the Commissioner. This avoids the conflict of interest that arose when the human rights advocates were directly employed by the facility. This same practice should be in place for abuse and neglect investigatory staff. Recommends that the Office of Human Rights post all substantiated cases of abuse or neglect for all providers, including facilities…"	■ The information is currently available to the public, on request.
	■ Individuals served by, or potentially served by mental health, mental retardation and substance abuse providers may have sensory or physical impairments that require alternative forms of communication such as American Sign Language, Braille, or assistive technology; or may have cognitive impairments that require adjustment in the language used for documents and signs or the way in which messages are imparted. Recommends that "in writing" be accompanied by the phrase, "or in alternative form of communication appropriate to the individual's needs".	■ Added provisions in several areas to address this …" in the manner, format and language…"
	■ The Office of Human Rights should include private interviews with individuals about services to ascertain the extent to which restrictions occur.	■ The Office of Human Rights conducts interviews with consumers as a means to evaluate services and extent of restrictions.
	■ Include "Microboards" and "Circles of Support" as accepted means of providing assistance for decision-making to individuals with disabilities.	■ Change made in various parts of these regulations to support these concepts.
	■ Concerned about the deletions of "…These legal rights include, but are not limited to. . ." By deleting "but are not limited to," the agency has closed the door to human rights not specifically articulated in those sections, and has made the sections more restrictive.	■ No change. The deletion of this phrase does not limit any individual rights
	■ Add words "… **recovery, community integration, consumer direction, and empowerment…"**throughout the regulations.	■ Changes made in support of the concepts throughout these regulations.
	■ Consumers should be provided training in human rights and in how to file a complaint; annual notification of the rights existence is insufficient.	■ Provisions inserted to require notification and discussion of the process with consumers at several key points throughout the regulations.
	■ The Department should foster an expectation that	■ These regulations have been developed

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	services be provided in a person-centered, consumer directed planful manner. Individuals should have respectful and genuine opportunities to discuss and share their strengths, preferences and own goals and ideas about recovery and real community integration.	to promote and require participation of the individual in all aspects of service delivery.
	■ Ensure that references to consumers are inclusive. They should include brain injury and developmental disabilities because the licensing regulations include these populations.	■ These regulations apply to providers that are licensed, funded or operated by the Department. Tthese regulations apply any individual receiving services from those providers.
	■ Regulations should be written in gender neutral language.	■ The Virginia Registrar of Regulations mandates the style and format of agency regulations that are promulgated in the Commonwealth. The agency must adhere the style guidelines of the Virginia Register.
	■ Regulations are hard to use. It is difficult to locate certain items.	■ The Department will develop documents to assist in the use and application of the regulations.
	■ The Department should study the LHRC model and determine what is the most efficient and effective way to ensure oversight… including looking at integrating the Office of Human Rights and the Office of Licensing.	■ The Department plans to study the efficiency and effectiveness of the human rights system.
	■ Regulations should require the posting of the Virginia Freedom of Information Act in all service settings	■ No change. The Virginia Freedom of Information Act does not mandate that providers post this Act. The agency does not impose this standard on providers in these regulations.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Section	Description	Rationale
12VAC35-115-10 **Authority and Applicability**	Update of Code of Virginia references, minor language changes. Providers of services under Part C of the Individuals with Disabilities Education Act (IDEA) that would be subject to these human rights regulations solely because they receive IDEA funds, were exempted from these regulations. These providers are subject to and must comply with federal IDEA regulations in lieu of these human rights regulations.	Changed to comply with Code revisions and to promote clarity. Changed to avoid an unnecessary and duplicative regulatory burden on these providers.

Section	Description	Rationale
12VAC35-115-20 Policy	Minor revisions to the language.	Intended to promote clarity.
12VAC35-115-30 Definitions	Major changes to definitions including:	
Advance directive	New	Recommended by the H3R Advisory Committee (stakeholder group) and is intended to promote recovery and self-empowerment for individuals receiving services.
Authorization	New	Developed to comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations.
Authorized representative	Changed terminology from legally authorized representative (LAR) to authorized representative (AR) and revised the definition.	Recommended by the H3R Advisory Committee for clarity and to promote the recovery and self- empowerment for individuals receiving services.
Behavior management	Changed term in final regulations to behavior intervention. The term inappropriate was replaced with challenging.	Recommended by public comments. Intended to promote recovery and self-empowerment of individuals receiving services.
Complaint	Revised	Recommended by the H3R Advisory Committee and others. Revisions are intended to promote clarity.
Consent	Revised definition and relocated procedural requirements from the definition to the "Participation in Decision Making" section (which has been separated from section on "informed consent").	Recommended by H3R Advisory Committee and others. Revisions are intended to promote clarity.
Disclosure	New	Added to comply with HIPAA requirements.
Emergency	Removed "substantial property damage" from the definition of an emergency.	Intended to limit the types of incidents that qualify as an emergency.
Health Care Operations	New	Added to comply with HIPAA requirements.
Health Plan	New	Added to comply with HIPAA requirements.
Informed Consent	Revised definition and relocated procedural requirements to "Participation in Decision Making" section (which has been separated from section on "consent").	Recommended by the H3R Advisory Committee and others comments. Intended to promote clarity.

Section	Description	Rationale
Licensed Professional	New	Consistent with regulations for licensing, and consistent with the intent of H3R Advisory Committee recommendation and comments.
Peer on Peer Harm	New	H3R Advisory Committee recommendation and is intended to promote clarity.
Person centered	New	Added in response to public comment and to integrate this concept into the provision of services.
Program Rules	New	H3R Advisory Committee recommendation intended to promote clarity.
Psychotherapy Notes	New	Compliance HIPAA requirements.
Restraint	Revised	General comments. Intended to promote clarity.
Seclusion	Revised to make it clear that blocking egress by <u>any</u> means is seclusion and thereby prohibits the use of "isolated time out"	Recommended by the H3R Advisory Committee and intended to promote clarity.
Time Out	Revised	Recommended by the H3R Advisory Committee and intended to promote clarity.
12 VAC-35-115-40 Assurance of Rights	Minor language revisions.	Intended to promote clarity.
12 VA 35-115-50 Dignity	There has been significant reorganization of this section including the elimination of the existing section on the "Exemptions and Conditions of Providers Duties." The provisions for exemptions and conditions of providers' duties are relocated to the appropriate right or provider's duty. New language is added to support preferences of parents or guardians of minors.	Recommended by the H3R Advisory Committee and intended to promote clarity.
Use of preferred or legal name	Revised to permit a limit on use of name under certain circumstances.	Supports the intent of H3R Advisory Committee recommendation.
Right to communicate by mail and telephone	Separates and permits licensed professional to determine restrictions. Permits residential substance abuse (SA) programs to limit access to phone during initial phase of treatment.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.

Section	Description	Rationale
Right to visitors	Permits licensed professional to determine restrictions. Permits residential SA programs to limit access to visitors during initial phase of treatment.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
12 VAC-35-115-60 **Services**	Eliminates the "Exemptions and Conditions of Providers Duties" section and relocates provisions to the appropriate right or provider duty. Adds language to support the preferences of parents or guardians of minors.	Intended to promote clarity.
12 VAC 35-115-70 **Participation in Decision Making and Consent**	New title (added "and consent") Relocated procedures from the definition of "consent" and "informed consent" to this section. Clarified procedures for obtaining consent. Eliminates the "Exemptions and Conditions of Providers Duties" section. Provisions from this section have been relocated to the appropriate sections on the corresponding right or provider duty. New language is added to support preferences of parents or guardians of minors. Moved provisions about capacity evaluations and authorized representatives to two new sections. See Part IV	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
12 VAC 35-115-80 **Confidentiality and authorization to disclose information**	New title (added "authorization…") Aligned with HIPAA requirements Eliminates the "Exemptions and Conditions of Providers Duties" section and relocates provisions to the appropriate right or provider duty. Provisions are added to support preferences of parents or guardians of minors.	Revised to comply with HIPAA requirements.

Section	Description	Rationale
12 VAC 35-115-90 **Access to and amendment of services records**	Aligned provisions with HIPAA requirements. Eliminates the "Exemptions and Conditions of Providers Duties" section and relocates the provisions to the section for the appropriate right or provider duty. Provisions are added to support the preferences of parents or guardians of minors. Allows individuals to have access to all information in their services record, including psychotherapy notes.	Revised to comply with HIPAA requirements and ensure individual access to services records.
12 VAC 35-115-100 **Restrictions on freedoms of everyday life**	Includes minor language changes. Eliminates the "Exemptions and Conditions of Providers Duties" section and relocates the provisions to the section for the appropriate right or provider duty. Provisions are added to support the preferences of parents or guardians of minors.	Revised for clarity.
12 VAC 35-115-110 **Use of Seclusion, restraint and time out**	There has been significant reorganization of this section including the elimination of the "Exemptions and Conditions of Providers Duties section and relocation of the provisions to the section for appropriate right or provider duty. Provisions are added to support preferences of parents or guardians of minors. Removed the reference to and permission to use "isolated time out"	Supports intent of H3R Advisory Committee recommendations and comments. Revisions are also intended to promote clarity.
12 VAC 35-115-120 **Work**	Minor language changes	
12 VAC 35-115-130 **Research**	Minor language changes for clarity.	
12 VAC 35-115-140 **Complaint and Fair Hearing**	Minor language changes for clarity.	

Section	Description	Rationale
New: Part IV **Surrogate Decision Making**	A new part is added to the regulations that consolidates and relocates various provisions from other parts of the current regulations.	Supports intent of H3R Advisory recommendation and comments. Organization is intended to promote and improve clarity.
12 VAC 35-115-145 **Determination of capacity to give consent and authorization**	Addition of a new section of the regulations. Relocates provisions from current "Participation in Decision Making" section. Adds details about the requirements for a capacity evaluation.	Supports intent of H3R Advisory recommendation and comments. Intended to promote clarity.
12 VAC 35-115-146 **Authorized representatives**	New Section Relocates provisions from current "Participation in Decision Making" section. Changes reference to "next of kin" to "family member". Further defines the role of the LHRC in the review of a "next friend". Adds a requirement for the "next friend" to act in the best interest of the individual. Includes new subsection regarding the conditions for removal of an authorized representative.	Supports intent of H3R Advisory recommendation and comments. Intended to promote clarity.
12 VAC 35-115-150 **General Provisions**	Minor language changes	
12 VAC 35-115-160 **Informal Complaint**	Repealed this section. Relocated provisions to Section 170.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.

Section	Description	Rationale
12 VAC 35-115-170 **Complaint resolution process**	Title change-(removed the term"~~formal~~") Reorganized section to include provisions from section 160. Changed standard for pursuing a complaint from "satisfaction" to "disagrees". Clarifies notification requirements. Clarifies under what circumstances a complaint may be appealed to the LHRC.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
12 VAC-35-180 **Local Human Rights Committee hearing and review procedures.**	Minor language changes. Adds a requirement that parties are notified of case outcome and closure.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
12 VAC 35-115-190 **Special procedures for emergency hearings by the LHRC**	Minor language changes for clarity.	
12 VAC 35-115-200 **Special procedures for LHRC reviews involving consent and authorization.**	Major changes to clarify the procedures in this section and the duties of the parties.	Based on comments. Changes intended to promote clarity and conform to other changes to the regulations.
12-VAC-35-115-210 **State Human Rights Committee Appeals procedures**	Minor language changes. Adds a requirement that parties are notified of case outcome and closure.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.

Section	Description	Rationale
12 VAC 35-115-220 **Variances**	Minor language changes. Adds procedures for a temporary variance.	Supports intent of H3R Advisory Committee recommendations, and comments. Intended to increase protections to individuals.
12 VAC 35-115-230 **Provider requirements for reporting to the department**	Minor language changes.	
12 VAC 35-115-240 **Human rights enforcement and sanctions**	Minor language changes	
12 VAC 35-115-250 **Offices, composition and duties**		
250 A	Clarifies the LHRC affiliation and attendance requirements.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
250 D	Requires provider affiliations in accordance with recommendations of an advocate; Updates membership provisions; Permits summary decision making; and Permits review of actions of a "next friend."	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity and compliance with the Code of Virginia
250 E	Updates membership language; Require the development of guidance documents.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity and ensure compliance with Code of Virginia requirements.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less

stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The proposed revisions to the regulations are the only viable alternative to address the legal requirements and update provisions. These regulations are required by statute.

As part of the revision process, a stakeholders group, Human Rights Regulation Advisory Committee (H3R Advisory Committee), was convened representing the interested persons, providers and others who are governed by the Regulations. This group met numerous times over a seven month time period to develop revisions and review drafts of regulatory changes. With the assistance of the H3R Advisory Committee the agency believes it has made necessary changes to the regulations, which will simplify or reduce some burdensome administrative procedures and facilitate implementation of the regulatory requirements. Public comments were also incorporated to help clarify and refine the provisions.

After consultation with the Office of the Attorney General, it was decided that providers of services under Part C of the Individuals with Disabilities Education Act (IDEA) would be exempted from these human rights regulations. These providers include small businesses or other entities that would be regulated under the human rights regulations solely because they receive IDEA funds. These providers are now subject to federal IDEA regulations, which are consistent with and duplicate these human rights regulations. This exemption will reduce the regulatory burden on these providers.

Family impact

Please assess the impact of the proposed 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.

The proposed regulatory action should promote family and family stability by further protecting the rights of individuals receiving services for mental health, mental retardation and substance abuse services. The regulations should promote and encourage parents to participate in provision of services to their children and provide a vehicle for encouraging other family members to have a role in the provision of services in their family members. The regulations are intended to protect the rights of individuals receiving services and allow them to assume responsibility for the quality of their services, to the greatest extent possible. The regulations should not have any impact on a family's disposable income.