Overview of Changes to the Human Rights Regulations

Text of Power Point on web site- Reference Document

Introduction

- Welcome
- Purpose of Training
  - To identify the major revisions to the human rights regulations
  - To provide a resource that can be used for training and policy revision

- This training is intended for individuals who have a good knowledge of the current regulations.
- All sections of the regulations will be presented to some degree.

Introduction

Format for the training:

Guiding Principles for revision of regulations

Summary of Substantive Changes

Review of changes to each section

Introduction

Guiding principles for the revisions to the regulations:

- Promote and maintain individual rights
- Fix problems and unintended consequences in the regulations
- Align with applicable state and federal laws
- Promote clarity of terminology and procedures
- Align with the Department vision
- Promote consumer driven care

Summary of substantive changes

Organization:

Consolidation of 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 (Dignity, Freedoms of Everyday Life)

New section on <u>Substitute Decision Making</u> (Part IV) includes:

12 VAC 35-115-145-Determination of capacity to give consent and authorization; and

12 VAC 35-115-146-Authorized Representatives

The former section on Informal Complaints is repealed and provisions moved to the Complaint resolution section.

Summary of substantive changes

Content:

Some Definitions are revised and new definitions are added.

Clarification to Dignity rights and circumstances under which these rights may be limited.

Sections on Confidentiality and Access to Records are revised to comply with HIPAA. Provisions have been added to address disclosure of information to law enforcement officers.

Changes are made to clarify the provisions for:

- consent and informed consent and the administrative requirements for each, and
- the use of seclusion, restraint and time out.

The Complaint resolution process is revised for clarity.

Provisions for local human rights committee review of consent and authorization is clarified and revised.

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

Summary of substantive changes

Themes:

Key concepts that address consumer driven care are woven through out the regulations.

Examples include:

- Definitions and uses of “person centered” and “advanced directives”;
- Identifying potential supports that may increase decision making capabilities; and
- The role of the individual in selecting his authorized representative.

Authority and applicability

12 VAC 35-115-10

- 6. Providers of services under Part C of the IDEA may comply with applicable IDEA regulations in lieu of the regulations.

Policy
12 VAC 35-115-20
- Minor language changes

Definitions
12 VAC 35-115-30
- We will present substantive changes in this section.

- **"Advance Directive"**
  - A document voluntarily executed in accordance with § 54.1-2983 of the Code of Virginia or the laws of another state where executed. This may include a wellness recovery action plan (WRAP) or similar document as long as it is executed in accordance with § 54.1-2983 or the laws of another state. A WRAP or similar document may identify the health care agent who is authorized to act as the individual's substitute decision maker.

- "**Authorization"**
  - A document signed by the individual receiving services or that individual's authorized representative that authorizes the provider to disclose identifying information about the individual. An authorization must be voluntary. To be voluntary, the authorization must be given by the individual receiving services or his authorized representative freely and without undue inducement, any element of force, fraud, deceit, or duress, or any form of constraint or coercion.

- "**Authorized Representative**" (*Note removal of term "legally")
  - means a person permitted by law or these regulations to authorize the disclosure of information or to consent to treatment and services or participation in human research. The decision-making authority of an authorized representative recognized or designated under these regulations is limited to decisions pertaining to the designating provider.
  - Legal guardians, attorneys-in-fact, or health care agents appointed pursuant to § 54.1-2983 of the Code of Virginia may have decision-making authority beyond such provider.

- **“Behavioral management”** changed to Behavioral intervention…other minor language changes

- “Behavioral treatment program” changed to **Behavioral treatment plan, functional plan or behavioral support plan.**

- “**Community Services Board”** or "CSB" means the public body established pursuant to § 37.2-501 of the Code of Virginia that provides mental health, mental retardation, and substance abuse programs and services to individuals within each city and county that established it. For the purpose of these regulations, community services board also includes a behavioral health authority established pursuant to § 37.2-602 of the Code of Virginia.

- “**Complaint”**
  - means an allegation of a violation of these regulations or a provider's policies and procedures related to these regulations.

  *Note: the new definition does not differentiate between Informal and Formal Complaints. Both are considered complaints.

- **“Consent”-** *Note-Concepts of Consent and Informed Consent are defined separately.
  - Consent means the voluntary and expressed agreement of an individual, or that individual's legally authorized representative Consent must be given freely and without undue inducement, any element of force, fraud, deceit, or duress, or any form of constraint or coercion. Consent may be expressed through any means appropriate for the individual, including verbally, through physical gestures or behaviors, in Braille or American Sign Language, in writing, or through other methods.

- “**Director”**
  - means the chief executive officer of any provider delivering services. In organizations that also include services not covered by these regulations, the director is the chief executive officer of the service or services licensed, funded, or operated by the department.

- “**Disclosure”**
  - means the release by a provider of information identifying an individual.

- **“Emergency”**
  - "Emergency" means a situation that requires a person to take immediate action to avoid harm, injury, or death to an individual or to others.

  *Note-“avoid substantial property damage”… has been removed from the definition.

- **“Governing Body of the provider”**
  - means the person or group of persons with final authority to establish policy. <u>For the purpose of these regulations, the governing body of a CSB means the public body established according to Chapter 5 or Chapter 6 of Title 37.2 of the Code of Virginia, and shall include administrative policy community services boards, operating community services boards, local government departments with policy-advisory boards, and the board of a behavioral health authority.</u>

- “**Health Care Operations”**

  means any activities of the provider to the extent that the activities are related to its provision of health care services.

  Examples include:

- 1. Conducting quality assessment and improvement activities, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives, and related functions that do not include treatment;
- 2. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, and training, licensing or credentialing activities;

- 3. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs; and
- 4. Other activities contained within the definition of health care operations in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.501.

- “**Health plan”**

  means an individual or group plan that provides or pays the cost of medical care, including any entity that meets the definition of “health plan” in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR 160.103.

- **“Individualized services plan or ISP”**
  means a comprehensive and regularly updated written plan that describes the individual’s needs, the measurable goals and objectives to address those needs, and strategies to reach the individual’s goals.
  An ISP is person-centered, empowers the individual, and is designed to meet the needs and preferences of the individual. The ISP is developed through a partnership between the individual and the provider and includes an individual’s treatment plan, habilitation plan, person-centered plan, or plan of care.

- **“Informed Consent”** (see 12 VAC 35-115-70)
  - means the voluntary written agreement of an individual, or that individual’s authorized representative to surgery, electroconvulsive treatment, use of psychotropic medications, or any other treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life or for participation in human research.
  - To be voluntary, informed consent must be given freely and without undue inducement, any element of force, fraud, deceit, or duress, or any form of constraint or coercion.

- “**Licensed Professional”**
  - means a physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed or certified substance abuse treatment practitioner, or certified psychiatric nurse specialist.

- **“Peer on peer aggression”**
  - means a physical act, verbal threat, or demeaning expression by an individual against or to another individual that causes physical or emotional harm to that individual. Examples include hitting, kicking, scratching, and other threatening behavior. Such incidents may constitute potential neglect.

- “**Person-centered”**
  - means focusing on the needs and preferences of the individual, empowering and supporting the individual in defining the direction for his life, and promoting self-determination, community involvement, and recovery.

- “**Program rules”** (formally Rules of Conduct)

- means the operational rules and expectations that providers establish to promote the general safety and well-being of all individuals in the program and to set standards for how individuals will interact with one another in the program.
- Program rules include any expectation that produces a consequence for the individual within the program. Program rules may be included in a handbook or policies and shall be available to the individual.

- "**Psychotherapy notes"**
  means comments recorded in any medium by a health care provider who is a mental health professional documenting and analyzing an individual or a group, joint, or family counseling session that are separated from the rest of the individual's health record.

  Psychotherapy notes shall not include annotations relating to medication and prescription monitoring, counseling session start and stop times, treatment modalities and frequencies, clinical test results, or any summary of any symptoms, diagnosis, prognosis, functional status, treatment plan, or the individual's progress to date.

- **"Restraint"**
  - Definition is clarified…no substantive changes to kinds of restraints or uses of restraints.

- "**Seclusion"**
  - means the involuntary placement of an individual alone in an area <u>secured by a door that is locked or held shut by a staff person, by physically blocking the door, or by any other physical or verbal means, so that the individual cannot leave it</u>.

- "Services plan"-deleted

- "**Services record"**
  - means all written <u>and electronic</u> information that a provider keeps about an individual who receives services.

- "**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.

Assurance of Rights
12 VAC 35-115-40

- Display in areas most likely to be noticed by the individual, a document listing the rights of individuals under these regulations and how individuals can contact a human rights advocate. The document shall be presented in the manner, format, and languages most frequently understood by the individual receiving services.

- 2. "Notify …provide the name and phone number of the human rights advocate and give a short description of the human rights advocate's role. The provider shall give this notice to and discuss it with the individual at the time services begin and every year thereafter.

Dignity
12 VAC 35-115-50

- A. Each individual receiving services has a right to exercise his legal, civil, and human rights, including constitutional rights, statutory rights, and the rights contained in these regulations, except as specifically limited herein. Each individual has a right to have services that he receives respond to his needs and preferences and be person-centered…

1. Use his preferred or legal name.
   - The use of an individual's preferred name may be limited when a licensed professional makes the determination that the use of the name will result in demonstrable harm or have significant negative impact on the program itself or the individual's treatment, progress, and recovery.

   - The director or his designee shall discuss the issue with the individual and inform the human rights advocate of the reasons for any restriction prior to implementation and the reasons for the restriction shall be documented in the individual's services record. The need for the restriction shall be reviewed by the team every month and documented in the services record.

- No changes to the following:

2. Be protected from harm, including abuse, neglect and exploitation.

3. Have help in learning about…
4. Have opportunities to communicate in private with lawyers…

5. Be provided with general information about program services policies and rules in writing and in the manner, format, and language easily understood by the individual.

- C. In services provided in residential and inpatient settings, each individual has the right
  2. Receive nutritionally adequate…meals…and are consistent with any individualized diet program.

3. Live in a humane, safe, sanitary environment that gives each individual, at a minimum:
   b. An adequate number of private, operating toilets, sinks, showers and tubs that are designed to accommodate individual's physical needs.

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 infringe on the freedom of others.

- a. Religious services or practices that present a danger of bodily injury to any individual or interfere with another individual's religious beliefs or practices may be limited. The director or his designee shall discuss the issue with the individual and inform the human rights advocate of the reasons for any restriction prior to implementation. The reasons for the restriction shall be documented in the individual's services record.

  b. Participation in religious services or practices may be reasonably limited by the provider in accordance with other general rules limiting privileges or times or places of activities.

5. Have paper, pencil and stamps provided free of charge for at least one letter every day upon request. However, if an individual has funds to buy paper, pencils, and stamps to send a letter every day, the provider does not have to pay for them.

6. Communicate privately with any person by mail and have help in writing or reading mail as needed.

   a. An individual's access to mail may be limited only if the provider has reasonable cause to believe that the mail contains illegal material or

anything dangerous. If so, the director or his designee may open the mail, but not read it, in the presence of the individual.

b. b. An individual's ability to communicate by mail may be limited if, in the judgment of a licensed professional, the individual's communication with another person or persons will result in demonstrable harm to the individual's mental health.

c. c. The director or his designee shall discuss the issue with the individual and inform the human rights advocate of the reasons for any restriction prior to implementation and the reasons for the restriction shall be documented in the individual's services record. The need for the restriction shall be reviewed by the team every month and documented in the services record.

7. Communicate privately with any person by telephone and have help in doing so. Use of the telephone may be limited to certain times and places to make sure that other individuals have equal access to the telephone and that they can eat, sleep, or participate in an activity without being disturbed.

a. An individual's access to the telephone may be limited only if, in the judgment of a licensed professional, communication with another person or persons will result in demonstrable harm to the individual or significantly affect his treatment.

b. The director or his designee shall discuss the issue with the individual and inform the human rights advocate of the reasons for any restriction prior to implementation and the reasons for the restriction shall be documented in the individual's services record. The need for the restriction shall be reviewed by the team every month and documented in the individual's services record.

c. Residential substance abuse service providers that are not inpatient hospital settings or crisis stabilization programs may develop policies and procedures that limit the use of the telephone during the initial phase of treatment when sound therapeutic practice requires the restriction, subject to the following conditions.

(1) Prior to implementation and when it proposes any changes or revisions, the provider shall submit policies and procedures, program handbooks, or program rules to the LHRC and the human rights advocate for review and approval.

(2) When an individual applies for admission, the provider shall notify him of these restrictions.

8. Have or refuse visitors.

Section 8 a,b,c (1) and (2) are the same as section 7,a,b,c,(1) and (2).

9. Nothing in these provisions shall prohibit a provider from stopping, reporting, or intervening to prevent any criminal act.

- D. Provider's duties.
  1. Providers shall recognize, respect, support, and protect the dignity rights of each individual at all times. In the case of a minor, providers shall take into consideration the expressed preferences of the minor and the parent or guardian.

  3. Providers shall assure the following relative to abuse, neglect and exploitation.
  b. The director shall immediately take necessary steps to protect the individual receiving services until an investigation is complete. This may include the following actions:

  - (1) Direct the employee or employees involved to have no further contact with the individual. In the case of incidents of peer-on-peer aggression, protect the individuals from the aggressor in accordance with sound therapeutic practice and these regulations.

    - e. The director shall initiate an impartial investigation within 24 hours of receiving a report of potential abuse or neglect. The investigation shall be conducted by a person trained to do investigations and who is not involved in the issues under investigation.

  - (4) In all cases, the director shall provide his written decision, including actions taken as a result of the investigation, within seven working days following the completion of the investigation to the individual or the individual's authorized representative, the human rights advocate, the investigating authority, and the involved employee or employees. The decision shall be in writing and in the manner, format, and language that is most easily understood by the individual.

Services
12 VAC 35-115-60
- Very few changes to this section.

- Some reorganization including moving the exceptions and conditions duties.

5. Providers shall not deliver any service to an individual without a services plan that is tailored specifically to the needs and expressed preferences of the individual receiving services and, in the case of a minor, the minor and the minor's parent or guardian...

7. When preparing and or changing an individual's services or discharge plan, providers shall ensure that all services received by the individual are integrated. With the individual's or the individual's authorized representative's authorization, providers may involve family members in services and discharge planning. When the individual or his authorized representative requests such involvement, the provider shall take all reasonable steps to do so. In the case of services to minors, the parent or guardian or other person authorized to consent to treatment pursuant to § 54.1-2969 A of the Code of Virginia shall be involved in service and discharge planning.

Participation in Decision-making and Consent
12 VAC 35-115-70

- Each individual has a right to participate meaningfully in decisions regarding all aspects of services affecting him. This includes the right to:

- Consent or not consent to receive or participate in services.
  - ISP and discharge plan shall incorporate the individual's preferences consistent with his condition and need for service and the provider's ability to address them;
  - Services record shall include evidence that the individual has participated in the development of his ISP and discharge plan, in changes to these plans, and in all other significant aspects of his treatment and services; and
  - Services record shall include the signature or other indication of the individual's or his authorized representative's consent.

- Give or not give **informed consent** to receive or participate in treatment or services that pose a risk of harm greater than ordinarily encountered in daily life and to participate in human research except research that is exempt under § 37.2-162.17 of the Code of Virginia.
- Informed consent is always required for surgical procedures, electroconvulsive treatment, or use of psychotropic medications.

- To be informed, consent for any treatment or service must be based on disclosure of and understanding by the individual or his authorized representative of the following information:
    1. An explanation of the treatment, service, or research and its purpose;
    2. When proposing human research, the provider shall describe the research and its purpose, explain how the results of the research will be disseminated and how the identity of the individual will be protected, and explain any compensation or medical care that is available if an injury occurs;
    3. Description of adverse consequences and risks associated with the research, treatment, or service;
    4. Description of benefits that may be expected from the research, treatment, or service;
    5. Description of alternative procedures that might be considered, along with their side effects, risks, and benefits;
    6. Notification that the individual is free to refuse or withdraw his consent and to discontinue participation in any treatment, service, or research requiring his consent at any time without fear or reprisal against or prejudice to him; and
    7. Description of the ways in which the individual or his authorized representative can raise concerns and ask questions about the research, treatment, or service to which consent is given.

- **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 form or the ISP.

- **Informed consent for electroconvulsive treatment** requires the following additional components:
  (1) Informed consent shall be in writing, documented on a form that shall become part of the individual's services record. This form shall:
  (a) Specify the maximum number of treatments to be administered during the series;
  (b) Indicate that the individual has been given the opportunity to view an instructional video presentation about the treatment procedures and their potential side effects; and
  (c) Be witnessed in writing by a person not involved in the individual's treatment who attests that the individual has been counseled and informed about the treatment procedures and potential side effects of the procedures.

(2) Separate consent, documented on a new consent form, shall be obtained for any treatments exceeding the maximum number of treatments indicated on the initial consent form.

(3) Providers shall inform the individual or his authorized representative that the individual may obtain a second opinion before receiving ECT and the individual is free to refuse or withdraw his consent and to discontinue participation at any time without fear of reprisal against or prejudice to him. The provider shall document such notification in the individual's services record.

(4) Before initiating ECT for any individual under age 18 years, two qualified child psychiatrists must concur with the treatment. The psychiatrists must be trained or experienced in treating children or adolescents and not directly involved in treating the individual. Both must examine the individual, consult with the prescribing psychiatrist, and document their concurrence with the treatment in the individual's services record.

Participation in Decision-making and Consent
12 VAC 35-115-70

- Have an authorized representative make decisions for him in cases where the individual has been determined to lack capacity to consent or authorize the disclosure of information.

- If an individual who has an authorized representative who is not his legal guardian objects to the disclosure of specific information or a specific proposed treatment or service, the director or his designee shall immediately notify the human rights advocate and authorized representative. A petition for LHRC review of the objection may be filed under 12 VAC 35-115-200.
- If the authorized representative objects or refuses to consent to a specific proposed treatment or service for which consent is necessary, the provider shall not institute the proposed treatment, except in an emergency in accordance with this section or as otherwise permitted by law.

- **Be accompanied, except during forensic evaluations, by a person or persons whom the individual trusts to support and represent him when he participates in services planning, assessments, evaluations,**

including discussions and evaluations of the individual's capacity to consent, and discharge planning.

- **Request admission to or discharge from any service at any time.**

The provider's duties:

- Providers shall respect, protect, and help develop each individual's ability to participate meaningfully in decisions regarding all aspects of services affecting him. This shall be done by involving the individual, to the extent permitted by his capacity, in decision making regarding all aspects of services.
- Providers shall ask the individual to express his preferences about decisions regarding all aspects of services that affect him and shall honor these preferences to the extent possible.
- Providers shall give each individual the opportunity, and any help he needs, to participate meaningfully in the preparation of his services plan, discharge plan, and changes to these plans, and all other aspects of services he receives. Providers shall document these opportunities in the individual's services record.

- Providers shall obtain and document in the individual's services record the individual's <u>or his authorized representative's</u> consent for any treatment before it begins.
- For **minors** in the legal custody of a natural or adoptive parent:
  - Provider shall obtain this consent from at least one parent.
  - Consent of a parent not needed if a court has ordered or consented to treatment or services pursuant to § 16.1 241 D, 16.1 275, or 54.1 2969 B of the Code of Virginia, or a local department of social services with custody of the minor has provided consent.
  - Reasonable efforts must be made, however, to notify the parent or legal custodian promptly following the treatment or services.

- Additionally, a competent minor may independently consent to treatment <u>for</u> sexually transmitted <u>or contagious</u> diseases, family planning <u>or pregnancy</u>, or outpatient services or treatment for mental illness, emotional disturbance, or <u>substance use disorders</u> pursuant to § 54.1-2969 E of the Code of Virginia.

Emergencies:

- Providers may initiate, administer, or undertake a proposed treatment without the consent of the individual or the individual's authorized

representative in an emergency. All emergency treatment or services and the facts and circumstances justifying the emergency shall be documented in the individual's services record within 24 hours of the treatment or services.
a. Providers shall immediately notify the authorized representative of the provision of treatment without consent during an emergency.
b. Providers shall continue emergency treatment without consent beyond 24 hours only following a review of the individual's condition and if a new order is issued by a professional who is authorized by law and the provider to order treatment.
c. Providers shall notify the human rights advocate if emergency treatment without consent continues beyond 24 hours.
d. Providers shall develop and integrate treatment strategies into the ISP to address and prevent future emergencies to the extent possible following provision of emergency treatment without consent.

- Providers shall obtain and document in the individual's services record the consent of the individual or his authorized representative to continue any treatment initiated in an emergency that lasts longer than 24 hours after the emergency began.

- Providers may provide treatment in accordance with a court order or in accordance with other provisions of law that authorize such treatment or services including the Health Care Decisions Act (§ 54.1-2981 et seq. of the Code of Virginia).
- Provisions of these regulations are not intended to be exclusive of other provisions of law but are cumulative.

- Providers shall respond to an individual's **request for discharge** and shall make sure that the individual is not subject to punishment, reprisal, or reduction in services because he makes a request.
  - However, if an individual leaves a service against medical advice, any subsequent billing of the individual by his private third party payer shall not constitute punishment or reprisal on the part of the provider.

Discharge of Voluntary admissions:
- Individuals admitted under § 37.2-805 of the Code of Virginia to state hospitals operated by the department who notify the director of their intent to leave shall be discharged when appropriate, but no later than eight

hours after notification, unless another provision of law authorizes the director to retain the individual for a longer period.

- Minors admitted under § 16.1 338 or 16.1 339 of the Code of Virginia shall be released to the parent's or legal guardian's custody within 48 hours of the consenting parent's or legal guardian's notification of withdrawal of consent, unless a petition for continued hospitalization pursuant to § 16.1 340 or 16.1 345 of the Code of Virginia is filed.

Discharge of Involuntary admissions:

- When a minor involuntarily admitted under § 16.1 345 of the Code of Virginia no longer meets the commitment criteria, the director shall take appropriate steps to arrange the minor's discharge.
- When an individual involuntarily admitted under § 37.2-817 has been receiving services for more than 30 days and makes a written request for discharge, director shall determine whether the individual continues to meet the criteria for involuntary admission.
- If the director denies the request for discharge, he shall notify the individual in writing of the reasons for denial and of the individual's right to seek relief in the courts. The request and reasons for denial shall be included in the individual's services record.
- Anytime the individual meets any of the criteria for discharge set out in § 37.2-837 or 37.2-838 of the Code of Virginia, the director shall take all necessary steps to arrange the individual's discharge.

- If at any time it is determined that an individual involuntarily admitted under Chapter 11 (§ 19.2 167 et seq.) or Chapter 11.1 (§ 19.2 182.2 et seq.) of Title 19.2 of the Code of Virginia no longer meets the criteria under which the individual was admitted and retained, the director or commissioner, as appropriate, shall seek judicial authorization to discharge or transfer the individual. Further, pursuant to § 19.2 182.6 of the Code of Virginia, the commissioner shall petition the committing court for conditional or unconditional release at any time he believes the acquittee no longer needs hospitalization.

Discharge of Certified admissions:

- If an individual certified for admission to a state training center or his authorized representative requests discharge, the director or his designee shall contact the individual's community services board to finalize and implement the discharge plan.

Confidentiality
12 VAC 35-115-80

- Each individual is entitled to have all identifying information that a provider maintains or knows about him remain confidential.
- Each individual has a right to give his authorization before the provider shares identifying information about him or his care unless another state law or regulation or these regulations specifically require or permit the provider to disclose certain specific information.

Provider's Duties:

- Providers must maintain the confidentiality of any information that identifies an individual.
  - If an individual's services record pertains in whole or in part to referral, diagnosis or treatment of substance use disorders, providers shall disclose information only according to the federal SA confidentiality regulations (this includes a substance abuse label)

- Providers shall obtain and document in the individual's services record the individual's authorization or that of the authorized representative prior to disclosing any identifying information about him. The authorization must contain the following elements:
  a. 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;
  b. A description of the nature of the information to be disclosed, the purpose of the disclosure, and an indication whether the authorization extends to the information placed in the individual's record after the authorization was given but before it expires;
  c. An indication of the effective date of the authorization and the date the authorization will expire, or the event or condition upon which it will expire; and
  d. The signature of the individual and the date. If the authorization is signed by an authorized representative, a description of the authorized representative's authority to act.
- Providers are obligated to tell each individual and his authorized representative about the individual's confidentiality rights.
  - This shall include how information can be disclosed and how others might get information about the individual without authorization.

- If a disclosure is not required by law, provider shall give strong consideration to any objection by individual or his authorized representative

- Providers shall prevent unauthorized disclosures of information from services records and shall maintain and disclose information in a secure manner.

Minors:

- Authorization of custodial parent or other person authorized to consent to the minor's treatment under § 54.1-2969 is required to disclose.
- **Exceptions**:
  - A minor is permitted to authorize the disclosure of information related to medical or health services for sexually transmitted or contagious disease, family planning or pregnancy (*see* Virginia Code §54.1-2969 (E))

- A minor may also authorize disclosure of information related to **outpatient** care, treatment or rehabilitation for substance use disorders, mental illness, or emotional disturbance (*see* Virginia Code §54.1-2969 (E))

- The concurrent authorization of the minor and custodial parent is required to disclose **inpatient** substance abuse records.
- The minor and the custodial parent shall authorize the disclosure of identifying information related to the minor's **inpatient** psychiatric hospitalization when the minor is **14 years of age and older and has consented to the admission.**

Redisclosure:

- When providers disclose identifying information, they must attach a statement that informs the person receiving the information that it must not be disclosed to anyone else unless the individual authorizes the disclosure or unless state law or regulation allows or requires further disclosure without authorization.
- Providers may encourage individuals to name family members, friends, and others who may be told of their presence in the program and general condition or well-being.
- Except for information governed by 42 CFR Part 2, providers may disclose to a family member, other relative, a close personal friend, or any other person identified by the individual, information that is directly relevant to

that person's involvement with the individual's care or payment for his health care, **if:**
(i) the provider obtains the individual's agreement
(ii) the provider provides the individual with the opportunity to object to the disclosure, and
(iii) the individual does not object or the provider reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

- If the opportunity to agree or object cannot be provided because of the individual's incapacity or an emergency circumstance, the provider may, in the exercise of professional judgment, determine whether the disclosure is in the best interest of the individual and, if so, disclose only the information that is directly relevant to the person's involvement with the individual's health care.

- **Exceptions**:
  In some limited circumstances (listed in the regulations) providers may disclose certain identifying information without authorization or violation of the individual's confidentiality, but only according to the following….

A**) Emergencies**: Providers may disclose information in an emergency to any person who needs that particular information for the purpose of preventing injury to or death of an individual or other person
  - The provider shall not disclose any information that is not needed for this specific purpose.
  - *NOTE: Substantial property damage deleted!!

B) **Providers or health plans**:
Providers may permit any full or part-time employee, consultant, agent, or contractor of the provider to use identifying information or disclose to another provider, a health plan, the department or a CSB, information required to give services to the individual or to get payment for services.

C) **Court proceedings:**
- If the individual, or someone acting for him, introduces any aspect of his mental condition or services as an issue before a court, administrative agency, or medical malpractice review panel, the provider may disclose any information relevant to that issue.

- The provider may also disclose any records if they are properly subpoenaed, if a court orders them to be produced, or if involuntary admission or certification is being proposed.

D) **Legal Counsel:**
Providers may disclose information to their own legal counsel, or to anyone working on behalf of their legal counsel, in providing representation to the provider.
  - State providers may disclose to the OAG or anyone appointed by or working on its behalf for representation purposes

E) **Human Rights Committees:**
Providers may disclose to the LHRC and the SHRC any information necessary for the conduct of their responsibilities under these regulations.

F) **Others authorized or required by the Commissioner, CSB or private program director:**
Providers may disclose information to other persons if authorized or required by one of the above, for the following activities:
1) Licensing, human rights, or certification or accreditation reviews;
2) Hearings, reviews, appeal or investigation under these regulations;

3) Evaluation of provider performance and individual outcomes (see § 37.2-508 and 37.2-608 of the Code of Virginia);
4) Statistical reporting;
5) Preauthorization, utilization reviews, financial and related administrative services reviews and audits; or
6) Similar oversight and review activities.

G) **Preadmission screening, services and discharge planning:**
Providers may disclose to the department, the CSB or to other providers information necessary to screen individuals for admission or to prepare and carry out a comprehensive individualized services or discharge plan (see §37.2-505 of the Code of Virginia).

H) **Protection and Advocacy Agency:**
Providers may disclose information to the P & A <u>in accordance with that agency's legal authority under federal and state law</u>.

I) **Historical Research:**

Providers may disclose information to persons engaging in bona fide historical research if all of the following conditions are met:
1) The Commissioner, or CSB/Program director has authorized the research;
2) The individual(s) who are the subject of the disclosure are deceased;
3) There are no known living persons permitted by law to authorize the disclosure; and
4) The disclosure would in no way reveal the identity of any person who is not the subject of the historical research.

- The regulations also lay out the requirements for a request for human research.

J) **Protection of the public safety:**
If an individual receiving services makes a specific threat to cause serious bodily injury or death to an identified or readily identifiable person and the provider reasonably believes the individual has the intent and ability to carry out the threat immediately or imminently, provider may disclose facts necessary to alleviate potential threat.
- "Duty to Warn"

K) **Inspector General:**
Providers may disclose to the Inspector General any individual services records and other information relevant to the provider's delivery of services.

L) **Virginia Patient Level Data System:**
Providers may disclose financial and services information to Virginia Health Information as required by law (see § 32.1-276.2 *et seq.*)

M) **Psychotherapy notes**: Providers shall obtain an individual's authorization for any disclosure of psychotherapy notes, except when disclosure is made:
1) For the provider's own training programs in which students, trainees, or practitioners in mental health are being taught under supervision to practice or improve their skills in group, joint, family, or individual counseling;
2) To defend the provider or its employees or staff against any accusation of wrongful conduct;

3) In discharge of the provider's duty, in accordance with § 54.1-2400.1 B of the Code of Virginia, to take precautions to protect third parties from violent behavior or other serious harm;
4) As required in the course of an investigation, audit, review, or proceeding regarding a provider's conduct by a duly authorized law-enforcement, licensure, accreditation, or professional review entity; or
5) When otherwise required by law.

N) **To a law enforcement official:**
1) Pursuant to a search warrant or grand jury subpoena;
2) In response to their request, for the purpose of identifying or locating a suspect, fugitive, individual required to register pursuant to §9.1-901 of the Sex Offender and Crimes Against Minors Registry Act, material witness, or missing person, provided that only the following information is disclosed:
(a) Name and address of the individual;
(b) Date and place of birth of the individual;
(c) Social security number of the individual;
(d) Blood type of the individual;
(e) Date and time of treatment received by the individual;
(f) Date and time of death of the individual;
(g) Description of distinguishing physical characteristics of the individual; and
(h) Type of injury sustained by the individual;

3) Regarding the death of an individual for the purpose of alerting law enforcement of the death if the health care entity has a suspicion that such death may have resulted from criminal conduct; or
4) If the health care entity believes in good faith that the information disclosed constitutes evidence of a crime that occurred on its premises.

O) **Other statutes or regulations:**
Providers may disclose information to the extent required or permitted by any other state law or regulation.
- See also Va. Code 32.1-127.1:03 for a list of circumstances where records may be disclosed without authorization

Other Confidentiality Laws
- The Patient Health Records Privacy Act (Va. Code § 32.1-127.1:03)
- Federal Law on the Confidentiality of Substance Abuse Records (42 U.S.C. §290dd-2 and 42 C.F.R., Part 2)

Federal Substance Abuse Confidentiality Law

- Very restrictive
- Applies to all programs receiving federal assistance and that relate to substance abuse "education, prevention, training, treatment, rehabilitation, or research"
- Release only allowed with the patient's prior *written* consent, unless one of the few listed exceptions apply
- Upon request, the provider shall tell the individual or his authorized representative the sources of information contained in his services records and provide a **written listing of disclosures** of information made without authorization, except for disclosures:
  a. To employees of the department, CSB, the provider, or other providers;
  b. To carry out treatment, payment, or health care operations;
  c. That are incidental or unintentional disclosures that occur as a by-product of engaging in health care communications and practices that are already permitted or required;
  d. To an individual or his authorized representative;
  e. Pursuant to an authorization;
  f. For national security or intelligence purposes;
  g. To correctional institutions or law-enforcement officials or;
  h. That were made more than six years prior to the request.
- The provider shall include the following information in the listing of disclosures of information provided to the individual or his authorized representative under subdivision 9 of this subsection:
  a. The name of the person or organization that received the information and the address, if known;
  b. A brief description of the information disclosed; and
  c. A brief statement of the purpose for the disclosure or, in lieu of such a statement, a copy of the written request for disclosure.
- If the provider makes multiple disclosures of information to the same person or entity for a single purpose, the provider shall include the following:
  a. The information required in subdivision 10 of this subsection for the first disclosure made during the requested period;
  b. The frequency, periodicity, or number of disclosures made during the period for which the individual is requesting information; and
  c. The date of the last disclosure during that time period.

- If the provider makes a disclosure to a social service or protective services agency about an individual whom the provider reasonably believes to be a

victim of abuse or neglect, the provider is not required to inform the individual or his authorized representative of the disclosure if:

a. The provider, in the exercise of professional judgment, believes that informing the individual would place the individual at risk of serious harm; or

b. The provider would be informing the authorized representative, and the provider reasonably believes that the authorized representative is responsible for the abuse or neglect, and that informing such person would not be in the best interests of the individual.

Access and amendment of services records
12 VAC 35-115-90

- With respect to his own services record, each individual and his authorized representative has the right to:
  1. See, read, and get a copy of his own services record, except information that is privileged pursuant to § 8.01-581.17 of the Code of Virginia, or information compiled by the provider in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding;
  2. Let certain other people see, read, or get a copy of his own services record if the individual is restricted by law from seeing, reading, or receiving a copy;
  3. Challenge, request to amend, or receive an explanation of anything in his services record; and
  4. Let anyone who sees his record, regardless of whether amendments to the record have been made, know that the individual has tried to amend the record or explain his position and what happened as a result.

- Except in the following circumstances, **minors** must have their parent's or guardian's permission before they can access their services record:
  1. A minor may access his services record without the permission of a parent only if the records pertain to treatment for sexually transmitted or contagious diseases, family planning or pregnancy, outpatient care, treatment or rehabilitation for substance use disorders, mental illness or emotional disturbance, or inpatient psychiatric hospitalization when a minor is 14 years of age or older and has consented to the admission.

  2. A parent may access his minor child's services record unless parental rights have been terminated, a court order provides otherwise, or the minor's treating physician or clinical psychologist has determined, in the exercise of professional judgment, that the disclosure to the parent

would be reasonably likely to cause substantial harm to the minor or another person.

- Providers shall tell each individual, and his authorized representative, how he can access and request amendment of his own services record.
- Providers shall permit each individual to see his services record when he requests it and to request amendments if necessary.

- Access to all or a part of an individual's services record may be denied or limited only if a physician or a clinical psychologist involved in providing services to the individual:
  - talks to the individual,
  - examines the services record as a result of the individual's request for access, and
  - signs and puts in the services record permanently a written statement that he thinks access to the services record by the individual at this time would be reasonably likely to endanger the life or physical safety of the individual or another person or that the services record makes reference to a person other than a health care provider and the access requested would be reasonably likely to cause substantial harm to the referenced person.
- The physician or clinical psychologist must also tell the individual as much about his services record as he can without risking harm to the individual.
- **If access is denied in whole or in part**, provider shall give the individual or his authorized representative a written statement that explains the basis for the denial, the individual's review rights, how he may exercise them, and how the individual may file a complaint with the provider or the United States DHHS, if applicable.
- If restrictions or time limits are placed on access, the individual shall be notified of the restrictions and time limits and conditions for their removal. These time limits and conditions also shall be specified in the services record.
- If the individual requests a **review of denial of access**, the provider shall designate a physician or clinical psychologist who was not directly involved in the denial to review the decision to deny access.
- The physician or clinical psychologist must determine within a reasonable period of time whether or not to deny the access requested in accordance with the standard in subdivision 2 a of this subsection. The provider must promptly provide the individual notice of the physician's or psychologist's

determination and provide or deny access in accordance with that determination.

- At the individual's option, the individual may designate at his own expense a reviewing physician or clinical psychologist who was not directly involved in the denial to review the decision to deny access in accordance with the standard in subdivision 2 a of this subsection. If the individual chooses this option, the provider is not required to designate a physician or clinical psychologist to review the decision.
- If the provider limits or refuses to let an individual see his services record, the provider shall also notify the advocate and tell the individual that he can ask to have a lawyer of his choice see his record. If the individual makes this request, the provider shall disclose the record to that lawyer (§ 8.01-413 of the Code of Virginia).
- Providers shall, without charge, give individuals any help they may need to read and understand their services record and request amendments to it.
- If an individual asks to challenge, amend, or explain any information contained in his services record, the provider shall investigate and file in the services record a written report concerning the individual's request.
  a. If the report finds that the services record is incomplete, inaccurate, not pertinent, not timely, or not necessary, the provider shall:
  1) Either mark that part of the services record clearly to say so, or else remove that part of the services record and file it separately with an appropriate cross reference to indicate that the information was removed.;
  2) Not disclose the original services record without separate specific authorization or legal authority (e.g., if compelled by subpoena or other court order).;
  3) Obtain the individual's identification of and agreement to have the provider notify the relevant persons of the amendment; and
  4) Promptly notify in writing all persons who have received the incorrect information and all persons identified by the individual that the services record has been corrected

- If a request to amend the services record is denied, the provider shall give the individual a written statement containing the basis for the denial and notify the individual of his right to submit a statement of disagreement and how to submit such a statement.
- The provider shall also give the individual

(i) a statement that if a statement of disagreement is not submitted that the individual may request the provider to disclose the request for amendment and the denial with future disclosures of information and
(ii) a description of how the individual may complain to the provider or the Secretary of Health and Human Services, if applicable.

- Upon request, the provider shall file in the services record the individual's statement explaining his position. If needed, the provider shall help the individual to write this statement. If a statement is filed, the provider shall:
  1) Give all persons who have copies of the record a copy of the individual's statement.
  2) Clearly note in any later disclosure of the record that it is disputed and include a copy of the statement with the disputed record.

Restrictions on freedoms of everyday life
12 VAC 35-115-100

Basic freedoms of everyday life have not changed.
Exceptions and Conditions to provider's duties have been moved to the corresponding section under provider's duties.

B. Provider's duties

3.Providers shall not impose any restriction on an individual unless the restriction is justified and carried out according to these regulations. <u>If a provider imposes a restriction, except as provided in 12 VAC 35-115-50, the following conditions shall be met:</u>

- a. A qualified professional involved in providing services has, in advance, assessed and documented all possible alternatives to the proposed restriction, taking into account the individual's medical and mental condition, behavior, preferences, nursing and medication needs, and ability to function independently.
- <u>b. A qualified professional involved in providing services has, in advance, determined that the proposed restriction is necessary for effective treatment of the individual or to protect him or others from personal harm, injury, or death.</u>
- c. A qualified professional involved in providing services has, in advance, documented in the individual's services record the specific reason for the restriction.
- <u>d. A qualified professional involved in providing services has explained, so that the individual can understand, the reason for the restriction, the criteria for removal, and the individual's right to a fair review of whether the restriction is permissible.</u>

- e. A qualified professional regularly reviews the restriction and that the restriction is discontinued when the individual has met the criteria for removal.
- f. If a court has ordered the provider to impose the restriction or if the provider is otherwise required by law to impose the restriction, the restriction shall be documented in the individual's services record.

- B. Provider's duties.
  5. Providers shall, in the development of these program rules:
  c. Give the rules to and review them with each individual and his authorized representative in a way that the individual can understand them, including explaining possible consequences for violating them;
- e. Submit the rules to the LHRC for review and approval upon request of the advocate or LHRC.;
- Note: *"before putting them into effect, before any changes are made to the rules"* was removed from e.

Use of seclusion, restraint, and time out
12 VAC 35-115-110

B. The voluntary use of mechanical supports to achieve proper body position, balance, or alignment so as to allow greater freedom of movement or to improve normal body functioning in a way that would not be possible without the use of such a mechanical support, and the voluntary use of protective equipment *are not considered restraints*.

C. provider's duties.

1. Providers shall meet with the individual or his authorized representative upon admission to the service to discuss and document in the individual's service record,

The provider shall discuss with the individual or his authorized representative upon admission:
his preferred interventions in the event his behaviors or symptoms become a danger to himself or others

AND

The provider shall discuss with the individual or his authorized representative upon admission:
under what circumstances, if any, the intervention may include seclusion, restraint, or time out.

2. Providers shall document in the individual's service record 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* and

The provider shall flag the record to alert and communicate this information to staff.

3. Only residential facilities for children that are licensed under the Regulations for Providers of Mental Health, Mental Retardation, and Substance Abuse Residential Services for Children (12 VAC 35-45) and inpatient hospitals may use seclusion and only in an emergency.

4. Providers shall not use seclusion, restraint, or time out as a punishment or reprisal or for the convenience of staff.

5. Providers shall not use seclusion or restraint solely because criminal charges are pending against the individual.

6. Providers shall not use seclusion or restraint for any behavioral, medical, or protective purpose unless . . . . .

- other less restrictive techniques have been considered AND

- documentation is placed in the individual's services plan that these less restrictive techniques did not or would not succeed in reducing or eliminating behaviors that are self-injurious or dangerous to other people

OR

- documentation is placed in the individual's services plan that no less restrictive measure was possible in the event of a sudden emergency.

<u>7. Providers that use seclusion, restraint, or time out shall develop written policies and procedures that comply with applicable</u>

- <u>federal and state laws, and regulations,</u>
- <u>accreditation, and certification standards,</u>
- <u>third party payer requirements, and</u>
- <u>sound therapeutic practice.</u>

These policies and procedures shall include at least the following requirements:

a. Individuals shall be given the opportunity for motion and exercise, to eat at normal meal times and take fluids, to use the restroom, and to bathe as needed.

b. Trained, qualified staff shall monitor the individual's medical and mental condition continuously while the restriction is being used.

c. Each use of seclusion, restraint, or time out shall end immediately when criteria for removal are met.

d. Incidents of seclusion and restraint, including the rationale for and the type and duration of the restraint, are reported to the department as provided in 12 VAC 35-115-230 C.

8. Providers shall submit all proposed seclusion, restraint, and time out policies and procedures to the LHRC for review and comment
- before implementing them,
- when proposing changes, or
- upon request of the human rights advocate, the LHRC, or the SHRC.

9. Providers shall comply with all applicable
- state and federal laws and regulations,
- certification and accreditation standards, and
- third party requirements

as they relate to seclusion and restraint.

a. Whenever an inconsistency exists between these regulations and federal laws or regulations, accreditation or certification standards, or the requirements of third party payers, the provider shall comply with the higher standard.

b. Providers shall notify the department whenever a regulatory, accreditation, or certification agency or third party payer identifies problems in the provider's compliance with any applicable seclusion and restraint standard.

10. Providers shall ensure that only staff who have been trained in the proper and safe use of seclusion, restraint, and time out techniques may initiate, monitor, and discontinue their use.
11. Providers shall ensure that a qualified professional who is involved in providing services to the individual
●reviews every use of physical restraint as soon as possible after it is carried out and
●documents the results of his review in the individual's services record.

12. Providers shall ensure that review and approval by a qualified professional for the use or continuation of restraint for medical or protective purposes is documented in the individual's services record. Documentation includes:

a. Justification for any restraint;
b. Time-limited approval for the use or continuation of restraint; and
c. Any physical or psychological conditions that would place the individual at greater risk during restraint.

13. Providers may use seclusion or mechanical restraint for behavioral purposes:

●in an emergency AND
●only if a qualified professional involved in providing services to the individual has, within one hour of the initiation of the procedure:

a.
●Conducted a face-to-face assessment of the individual placed in seclusion or mechanical restraint AND
●documented that alternatives to the proposed use of seclusion or mechanical restraint
* have not been successful in changing the behavior or
* were not attempted,
taking into account the individual's medical and mental condition, behavior, preferences, nursing and medication needs, and ability to function independently;

b.Determined that the proposed seclusion or mechanical restraint is necessary to protect the individual or others from harm, injury, or death;

c. Documented in the individual's services record the specific reason for the seclusion or mechanical restraint;

d. Documented in the individual's services record the behavioral criteria that the individual must meet for release from seclusion or mechanical restraint; and

e. Explained to the individual, in a way that he can understand, the reason for using mechanical restraint or seclusion, the criteria for its removal, and the individual's right to a fair review of whether the mechanical restraint or seclusion was permissible.

14. Providers shall limit each approval for restraint for behavioral purposes or seclusion to

- Four hours for individuals age 18 and older,
- two hours for children and adolescents ages 9 through 17, and
- one hour for children under age nine.

15. Providers shall not issue standing orders for the use seclusion or restraint for behavioral purposes.

16. Providers shall ensure that no individual is in time out for more than 30 minutes per episode.

17. Providers shall monitor the use of restraint for behavioral purposes or seclusion through continuous face-to-face observation, rather than by an electronic surveillance device.

18. 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 systematic assessment of the behavior and the situations in which the behavior occurs.

a. Providers shall develop any behavioral treatment plan involving the use of restraint or time out for behavioral purposes according to its policies and procedures, which ensure that:

- Behavioral treatment plans are initiated, developed, carried out, and monitored by professionals who are qualified by expertise, training, education, or credentials to do so.

AND

(2) Behavioral treatment plans include nonrestrictive procedures and environmental modifications that address the targeted behavior.

AND

(3) Behavioral treatment plans are submitted to and approved by an independent review committee comprised of professionals with training and experience in applied behavior analysis who have assessed the technical adequacy of the plan and data collection procedures.

b. Providers shall document in the individual's services record that the lack of success, or probable success, of less restrictive procedures attempted and the risks associated with not treating the behavior are greater than any risks associated with the use of restraint.

c. Prior to the implementation of any behavioral treatment plan involving the use of restraint or time out, the provider shall obtain approval of the LHRC. If the LHRC finds that the plan violates or has the potential to violate the rights of the individual, the LHRC shall notify and make recommendations to the director.

d. Behavioral treatment plans involving the use of restraint or time out shall be reviewed quarterly by the independent review committee and by the LHRC to determine if the use of restraint has resulted in improvements in functioning of the individual.

19. Providers may not use seclusion in a behavioral treatment plan.

Work
12 VAC 35-115-120
- Minor language changes

Research
12 VAC 35-115-130
- B. Provider's duties
  3. Providers shall obtain approval from an institutional review board or research review committee prior to performing or participating in a

human research protocol. Documentation of this review and approval shall be maintained and made available on 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 institutional review board or research 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.

Complaint and fair hearing
12 VAC 35-115-140
- Minor changes

Substitute Decision Making
Determination of capacity to give consent or authorization
12 VAC 35-115-145
- 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 evaluation from a professional who is qualified by expertise, training, education, or credentials and not directly involved with the individual to determine whether the individual has capacity to consent or to authorize the disclosure of information.

1. Capacity evaluations shall be obtained for all individuals who may lack capacity, even if they request that an authorized representative be designated or agree to submit to a recommended course of treatment.
2. In conducting this evaluation, the professional may seek comments from representatives accompanying the individual pursuant to 12 VAC-35-115-70 A 4 about the individual's capacity to consent or to authorize disclosure.
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 the individual's condition warrants, the individual requests such a review, 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 document annually that it has reviewed the individual's capacity to make decisions and whether there has been any change in that capacity.
b. Providers of acute inpatient services shall determine the need for an evaluation of an individual's capacity to consent or authorize disclosure of

information whenever the individual's condition warrants or at least at every treatment team meeting. Results of such reviews shall be documented in the treatment team notes and communicated to the individual and his authorized representative.

- **Capacity evaluations** shall be conducted in accordance with accepted standards of professional practice and shall indicate the specific type of decision for which the individual's capacity is being evaluated (e.g., medical) and shall indicate what specific type of decision the individual has or does not have the capacity to make. Capacity evaluations shall address the type of supports that might be used to increase the individual's decision-making capabilities.

- If the individual or his family objects to the results of the qualified professional's determination, the provider shall immediately inform the human rights advocate.
  a. If the individual or family member wishes to obtain an **independent evaluation** of the individual's capacity, he may do so at his own expense and within reasonable timeframes consistent with his circumstances. 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 pursuant to 12 VAC 35-115-200 B.

- The provider shall take no action for which consent or authorization is required, except in an emergency, pending the results of the independent evaluation. The provider shall take no steps to designate an authorized representative until the independent evaluation is complete.

b. If the independent evaluation is consistent with the provider's evaluation, the provider's evaluation is binding, and the provider shall implement it accordingly.

c. If the independent evaluation is not consistent with the provider's evaluation, the matter shall be referred to the LHRC for review and decision under 12 VAC 35-115-200.

Authorized Representatives
12 VAC 35-115-146

- When it is determined in accordance with 12 VAC-35-115-145 that an individual lacks the capacity to consent or authorize the disclosure of information, the provider shall recognize and obtain consent or

authorization for those decisions for which the individual lacks capacity from the following if available:

1. An attorney-in-fact who is currently empowered to consent or authorize the disclosure under the terms of a durable power of attorney;
2. A health care agent appointed by the individual under an advance directive or power of attorney in accordance with the laws of Virginia; or
3. A legal guardian of the individual, or if the individual is a minor, a parent with legal custody of the minor or other person authorized to consent to treatment pursuant to § 54.1-2969 A of the Code of Virginia.

- If an attorney-in-fact, health care agent or legal guardian is not available, the director shall designate a substitute decision maker as authorized representative in the following order of priority:

- The individual's **family member**. In designating a family member, the director shall honor the individual's preference unless doing so is clinically contraindicated.
  a. If the director does not appoint the family member chosen by the individual, the individual shall be told of the reasons for the decision and information about how to request LHRC review according to 12 VAC 35-115-200.

b. If the individual does not have a preference or if the director does not honor the individual's preference in accordance with these regulations, the director shall select the best qualified person, if available, according to the following order of priority unless, from all information available to the director, another person in a lower priority is clearly better qualified.

(1) A spouse;
(2) An adult child;
(3) A parent;
(4) An adult brother or sister; or
(5) Any other relative of the individual.

- **Next friend** of the individual. If no other person specified above is available and willing to serve as authorized representative, a provider may designate a next friend of the individual, after a review and finding by the LHRC that the proposed next friend has, for a period of six months within two years prior to the designation either:
  a. Shared a residence with the individual; or
  b. Had regular contact or communication with the individual and provided significant emotional, personal, financial, spiritual, psychological, or other support and assistance to the individual.

- In addition to the conditions set forth above, the individual must have no objection to the proposed next friend being designated as the authorized representative.
- The person designated as next friend also shall:
  a. Personally appear before the LHRC, unless the LHRC has waived the personal appearance; and
  b. Agree to accept these responsibilities and act in the individual's best interest and in accordance with the individual's preferences, if known.
- The LHRC shall have the discretion to waive a personal appearance by the proposed next friend and to allow that person to appear before it by telephone, video, or other electronic means of communication as the LHRC may deem appropriate under the circumstances. Waiving the personal appearance of the proposed next friend should be done in very limited circumstances.
- If, after designation of a next friend, an appropriate family member becomes available to serve as authorized representative, the director shall replace the next friend with the family member.
- No director, employee, or agent of a provider may serve as an authorized representative for any individual receiving services delivered by that provider unless the authorized representative is a relative or the legal guardian
- When a provider, or the director, an employee, or agent of the provider is also the individual's guardian, the provider shall assure that the individual's preferences are included in the services plan and that the individual can make complaints about any aspect of the services he receives.
- The provider shall document the recognition or designation of an authorized representative in the individual's services record, including evidence of consultation with the individual about his preference, copies of applicable legal documents such as the durable power of attorney, advance directive, or guardianship order, names and contact information for family members, and, when there is more than one potential family member available for designation as authorized representative, the rationale for the designation of the particular family member as the authorized representative.
- If a provider documents that the individual lacks capacity to consent and no person is available or willing to act as an authorized representative, the provider shall:
  1. Attempt to identify a suitable person who would be willing to serve as guardian and ask the court to appoint that person to provide consent or authorization; or

2. Ask a court to authorize treatment (See § 37.2-1101 of the Code of Virginia).

- Court orders authorizing treatment shall not be viewed as substituting or eliminating the need for an authorized representative.
- Providers shall review the need for court-ordered treatment and determine the availability of and seek an authorized representative whenever the individual's condition warrants, the individual requests such a review, or at least every six months except for individuals receiving acute inpatient treatment.
- Providers of acute inpatient services shall review the need for court-ordered treatment and determine the availability of and seek an authorized representative whenever the individual's condition warrants or at least at every treatment team meeting. All such reviews shall be documented in the individual's services record and communicated to the individual.

- When the provider recognizes or designates an authorized representative, the provider shall notify the court that its order is no longer needed and shall immediately suspend its use of the court order.

- Conditions for **removal of an authorized representative**. Whenever an individual has regained capacity to consent as indicated by a capacity evaluation or clinical determination, the director shall immediately remove any authorized representative designated pursuant to the above, notify the individual and the authorized representative, and ensure that the services record reflects that the individual is capable of making his own decisions.

- Whenever an individual with an authorized representative who is his legal guardian has regained his capacity to give informed consent, the director may use the applicable statutory provisions to remove the authorized representative. (See § 37.2-1012 of the Code of Virginia.) If powers of attorney and health care agents' powers do not cease of their own accord when a clinician has determined that the individual is no longer incapacitated, the director shall seek the consent of the individual and remove the person as authorized representative.
- The director shall remove the family or next friend authorized representative if the authorized representative becomes unavailable, unwilling, or unqualified to serve.
- The individual or the advocate may request the LHRC to review the director's decision to remove an authorized representative under the

procedures set out at 12 VAC-35-115-180, and the LHRC may reinstate the authorized representative if it determines that the director's action was unjustified.

- Prior to any removal under this authority, the director shall notify the individual of the decision to remove the authorized representative, of his right to request that the LHRC review the decision, and of the reasons for the removal decision. This information shall be placed in the individual's services record.
- If the individual requests, the director shall provide him with a written statement of the facts and circumstances upon which the director relied in deciding to remove the authorized representative.

- The director may otherwise seek to replace an authorized representative who is an attorney-in-fact currently authorized to consent under the terms of a durable power of attorney, a health care agent appointed by an individual under an advance directive, a legal guardian of the individual, or, if the individual is a minor, a parent with legal custody of the individual, only by a court order under applicable statutory authority.

Complaint Resolution, Hearing and Appeal Procedures
General provisions
12 VAC 35-115-150

- A. The parties to any complaint are the individual and the director. Each party can also have anyone else to represent him during resolution of the complaint. The director shall make every effort to resolve the complaint at the earliest possible stage.

General provisions
12 VAC 35-115-150

- I. All communication with the individual during the complaint resolution process shall be in the manner, format, and language most easily understood by the individual.

* Section 160 (Informal complaint process) was repealed

Complaint resolution process
12 VAC 35-115-170

- A. Anyone who believes that a provider has violated an individual's rights under these regulations may report it to the director or the human rights advocate, or either of them, for resolution.

- 1. If the report is made only to the director, the director <u>or his designee</u> shall immediately notify the human rights advocate. If the report is made on a weekend or holiday, then the director or his designee shall notify the human rights advocate on the next business day.

- 2. If the report is made only to the human rights advocate, the human rights advocate shall immediately notify the director. If the report is made on a weekend or holiday, then the human rights advocate shall notify the director on the next business day.

- 3. The human rights advocate or the director or his designee shall discuss the report with the individual and notify the individual of his right to pursue a complaint through the process established in these regulations. The steps in the informal and formal complaint process shall be thoroughly explained to the individual.

- The human rights advocate or the 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. The individual shall then be given the choice of pursuing the complaint through the informal or formal complaint process. If the individual does not make a choice, the complaint shall be managed through the informal process.

- 4. The following steps apply if the complaint is pursued through the informal process:
- Step 1: The director or his designee shall attempt to resolve the complaint immediately. If the complaint is resolved, no further action is required.

- Step 2: If the complaint is not resolved within five working days, the director or his designee shall refer it for resolution under the formal process. The individual may extend the informal process five-day time frame for good cause. All such extensions shall be reported to the human rights advocate by the director or his designee.

- 5. The following steps apply if the complaint is pursued through the formal process:
- C. Step 1: The director or his designee shall try to resolve the complaint by meeting with the individual, any representative the individual chooses, the

human rights advocate within 24 hours of receipt of the complaint or the next business day if that day is a weekend or holiday. The director or his designee shall conduct an investigation of the complaint, if necessary.

- Step 2: The director or his designee shall give the individual and 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 shall provide written notice to the individual about the time frame for the individual's response pursuant to Step 3 of this subdivision, information about how to contact the human rights advocate for assistance with the process, and a statement the complaint will be closed if the individual does not respond.

- Step 3: If the individual disagrees with the director's preliminary decision or action plan, he can respond to the director in writing within five working days after receiving the preliminary decision and action plan. If the individual has not responded within five working days, the complaint will be closed.

- Step 4: If the individual disagrees with the preliminary decision or action plan and reports his disagreement to the director in writing within five working days after receiving the 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, his chosen representative, and the human rights advocate within five working days after the director 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, information about how to contact the human rights advocate for assistance with the process, and a statement that if the individual does not respond that the complaint will be closed.

- Step 5: If the individual 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 12 VAC 35 115 180. If the individual has accepted the relief offered by the director, the matter is not subject to further review.

- B. If at any time during the formal complaint process the human rights advocate concludes that there is substantial risk that serious or irreparable harm will result if the complaint is not resolved immediately, the human rights advocate shall inform the director, the provider, the provider's governing body, and the LHRC.

- Steps 1 through 5 of subdivision A 5 of this section shall not be followed. Instead, the LHRC shall conduct a hearing according to the special procedures for emergency hearings in 12 VAC 35-115-180.

Local Human Rights Committee hearing and review procedures
12 VAC 35-115-180

- Minor changes
- "Satisfaction" is removed as a criteria for appeal and replaced with "does not accept the relief offered by the director or disagrees with" (see A.)

- As in the Complaint Section, the director must:
- Step 6. 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 7 (subsection H of this section) and a statement that if the individual does not respond that the complaint will be closed.

Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- The individual, his authorized representative, or anyone acting on the individual's behalf may request in writing that the LHRC review the following situations and issue a decision:

1. If an individual or his authorized representative objects at any time to the appointment of a specific person as authorized representative or any decision for which consent or authorization is required and has been given by his authorized representative, other than a legal guardian, he may ask the LHRC to decide whether his capacity was properly evaluated, the authorized representative was properly appointed, or his authorized

representative's decision was made based on the individual's basic values and any preferences previously expressed by the individual to the extent that they are known, and if unknown or unclear in the individual's best interests.

- The provider shall take no action for which consent or authorization is required if the individual objects, except in an emergency or as otherwise permitted by law, pending the LHRC review.

- If the LHRC determines that the individual's capacity was properly evaluated, the authorized representative is properly designated, or the authorized representative's decision was made based on the individual's basic values and any preferences previously expressed by the individual to the extent that they are known, or if unknown or unclear in the individual's best interests, then the provider may proceed according to the decision of the authorized representative.

- If the LHRC determines that the individual's capacity was not properly evaluated or the authorized representative was not properly designated, then the provider shall take no action for which consent is required except in an emergency or as otherwise required or permitted by law, until the capacity review and authorized representative designation is properly done.

- If the LHRC determines that the authorized representative's decision was not made based on the individual's basic values and any preferences previously expressed by the individual to the extent known, and if unknown or unclear, in the individual's best interests, then the provider shall take steps to remove the authorized representative pursuant to 12 VAC 35-115-146.

- If an individual or his family member has obtained an independent evaluation of the individual's capacity to consent to treatment or services or to participate in human research under 12 VAC 35-115-70, or authorize the disclosure of information under 12 VAC 35-115-90, and the opinion of that evaluator conflicts with the opinion of the provider's evaluator, the LHRC may be requested to decide which evaluation will control.

- If the LHRC agrees that the individual lacks the capacity to consent to treatment or services or authorize disclosure of information, the director

may begin or continue treatment or research or disclose information, but only with the appropriate consent or authorization of the authorized representative. The LHRC shall advise the individual of his right to appeal this determination to the SHRC under 12 VAC 35-115-210.

- If the LHRC does not agree that the individual lacks the capacity to consent to treatment or services or authorize disclosure of information, the director shall not begin any treatment or research, or disclose information without the individual's consent or authorization, or shall take immediate steps to discontinue any actions begun without the consent or authorization of the individual. The director may appeal to the SHRC under 12 VAC 35-115-210 but may not take any further action until the SHRC issues its opinion.

- If a director makes a decision that affects an individual and the individual believes that the decision requires his personal consent or authorization or that of his authorized representative, he may object and ask the LHRC to decide whether consent or authorization is required.

- Regardless of the individual's capacity to consent to treatment or services or authorize disclosure of information, if the LHRC determines that a decision made by a director requires consent or authorization that was not obtained, the director shall immediately rescind the action unless and until such consent or authorization is obtained. The director may appeal to the SHRC under 12 VAC 35-115-210 but may not take any further action until the SHRC issues its opinion.

- Before making such a decision, the LHRC shall review the action proposed by the director, any determination of lack of capacity, the opinion of the independent evaluator if applicable, and the individual's or his authorized representative's reasons for objecting to that determination.
- To facilitate its review, the LHRC may ask that a physician or licensed clinical psychologist not employed by the provider evaluate the individual at the provider's expense and give an opinion about his capacity to consent to treatment or authorize information.

- The LHRC shall notify all parties and the human rights advocate of the decision within 10 working days of the initial request.

State Human Rights Committee appeals procedures

12 VAC 35-115-210

- Time frame for the SHRC to conduct a hearing has been changed from "within 20 working days" to at its next scheduled meeting.

- J. Step 9: Upon completion of the process outlined in subsections B through I of this section, the SHRC shall notify the parties and the human rights advocate of the final outcome of the complaint.

Variances
12 VAC 35-115-220

- 1. When the LHRC receives the application, it shall invite, and provide ample time to receive, oral or written statements about the application from the human rights advocate, individuals affected by the variance, and other interested persons.

- Time frame for SHRC review of variance changed from "annually" to at least annually. (D.3)
- H. Following the granting of a variance, the provider shall notify all individuals affected by the variance about the details of the variance.
- I. If an individual is in immediate danger due to a provider's implementation of these regulations, the provider may request a temporary variance pending approval pursuant to the process described in this section.
- Such a request shall be submitted in writing to the commissioner, chairperson of the SHRC, and state human rights director. The commissioner, chairperson of the SHRC, and state human rights director shall issue a decision within 48 hours of the receipt of such a request.

Provider reporting requirements to the department
12 VAC 35-115-230

- D. The director shall provide to the human rights advocate and the LHRC information on the type, resolution level,and findings of each complaint of a human rights violation and implementation of variances in accordance with the LHRC meeting schedule or as requested by the advocate.

- Providers must report on all human rights complaints including those processed "informally". See definition of Complaint and 12 VAC 35-115-170.

Human rights enforcement and sanctions

12 VAC 35-115-240

- Minor changes

Offices, compositions and duties
12 VAC 35-115-250

- A. Providers and their directors

  5. Communicate information about the availability of a human rights advocate to all individuals and authorized representatives.

- 6. Assure one LHRC affiliation within the region as defined by the SHRC. The SHRC may require multi-site providers to have more than one LHRC affiliation within a region if the SHRC determines that additional affiliations are necessary to protect individuals' human rights.

- 7. Assure that the appropriate staff attend LHRC meetings in accordance with the LHRC meeting schedule to report on human rights activities, to impart information to the LHRC at the request of the human rights advocate or LHRC, and discuss specific concerns or issues with the LHRC.

- 8. Cooperate with the human rights advocate and the LHRC to investigate and correct conditions or practices interfering with the free exercise of individuals' human rights and make sure that all employees cooperate with the human rights advocate and the LHRC in carrying out their duties under these regulations.

- Notwithstanding the requirements for complaints pursuant to Part V (12 VAC 35-115-150 et seq.) of this chapter, the provider shall submit a written response indicating intended action to any written recommendation made by the human rights advocate or LHRC within 15 days of the receipt of such recommendation.

- D. Local Human Rights Committee shall:
- Membership language updated to comply with Code of Virginia.
- 2. Permit affiliations of local providers in accordance with the recommendations from the human rights advocate. SHRC approval is required for the denial of an affiliation request.
- 5. Upon the request of the human rights advocate, provider, director, or an individual or individuals or on its own initiative, an LHRC may review any

existing or proposed policies, procedures, or practices, or behavioral treatment plans that could jeopardize the rights of one or more individuals receiving services from the provider with which the LHRC is affiliated…

- 7. Receive, review and comment on all behavioral treatment plans involving the use of restraint or time out and seclusion, restraint, or time out policies for affiliated providers.
- 12. The LHRC may delegate summary decision-making authority to a subcommittee when expedited decisions are required before the next scheduled LHRC meeting to avoid seriously compromising an individual's quality of care, habilitation, or quality of life. The decision of the subcommittee shall be reviewed by the full LHRC at its next meeting.

- E. State Human Rights Committee shall:

- Membership language updated to comply with Code of Virginia.

- 9. Provide oversight and assistance to LHRCs in the performance of their duties hereunder, including the development of guidance documents such as sample bylaws, affiliation agreements, and minutes to increase operational consistency among LHRCs.
- 10. Review denials of LHRC affiliations.

For Further Information

- Check the Department web site
- www.dmhmrsas.virginia.gov
  Human Rights Section:
  - Regulation Implementation Schedule
  - Frequently Asked Questions (FAQ)
  - Training Resources
    - Slides
    - Tapes/DVDs
    - Information about training events

Questions

Submit questions to:
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