



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Mental Health, Mental Retardation and Substance Abuse Services
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 35-115 –10 et seq.
<b>Regulation title</b>	Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse
<b>Action title</b>	General Revisions to Clarify and Update Provisions
<b>Document preparation date</b>	October 13, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

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

## Legal basis

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

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

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.*

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

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

- To clearly articulate the human rights of every individual receiving care and treatment in facilities and programs licensed, funded, and operated by the DMHMRSAS.
- To clearly articulate the responsibilities of providers of mental health, mental retardation, and substance abuse care and treatment in ensuring the rights of individuals receiving services, and any exceptions and conditions placed on these responsibilities.
- To clearly articulate the complaint review and resolution process and to specify the procedures and time frames for the review of complaints of rights violations.
- To protect the public health, safety, and welfare with the least possible costs and intrusiveness to the citizens and businesses of the Commonwealth.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

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The following summarizes the substantive changes to the regulations:

- A number of definitions are revised and new definitions added. These changes have been made to clarify the provisions and to update the definitions and terms to conform to current state and federal law;
- Specific sections of the regulations are reorganized for clarity. This involved consolidation of all provisions that address a particular right into a single section about that right, by moving the content from the exceptions and conditions to the provider's duties to the section on the corresponding right.
- Changes are made to clarify provisions for dignity rights and circumstances under which these rights may be limited;
- Changes are made to clarify the provisions for consent and informed consent and the administrative requirements for each;
- Sections on confidentiality and access to records are revised to comply with federal HIPAA regulations;
- Revisions are made to clarify the language regarding seclusion, restraint and time out;
- A new part is added to address surrogate decision-making, which includes provisions to guide determinations of capacity to give consent and authorization, and provisions regarding authorized representatives;
- The section on informal complaints is repealed and provisions moved to the complaint resolution section;
- Changes are made to clarify the complaint resolution process;
- The section that provides special procedures for local human rights committee (LHRC) reviews of consent and authorization is clarified and revised; and
- There are minor changes to administrative duties of providers and LHRCs.

## Issues

*Please identify the issues associated with the proposed regulatory action, including:*

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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

- The changes will promote the protection of the public health, safety, and welfare with the least possible costs and intrusiveness to the citizens and businesses of the Commonwealth. This action should improve the administrative processes and safeguards for the human rights of every individual receiving care and treatment in facilities and programs licensed, funded, and operated by DMHMRSAS.

- The revisions clarify the responsibilities of providers of mental health, mental retardation, and substance abuse care and treatment in ensuring the rights of individuals receiving services, and any exceptions and conditions placed on these responsibilities.
- The revisions clarify the complaint review and resolution process and to expedite the process and time frames for the review of complaints of rights violations.

No disadvantage to the public or stakeholders is noted.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>General fund personnel budget: \$1,465,200</p> <p>General fund operating costs: 81,750</p> <p>Total GF budget \$1,668,331 (FY 05)</p>
<p><b>Projected cost of the regulation on localities</b></p>	<p>There is no cost to localities associated with the revisions to these regulations.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b></p>	<p>Those affected by these regulations include:</p> <ul style="list-style-type: none"> <li>■ Consumers of mental health, mental retardation and substance abuse services.</li> <li>■ Family members of consumers of mental health, mental retardation and substance abuse services.</li> <li>■ Public and private providers of mental health, mental retardation and substance abuse services including state operated mental health and mental retardation facilities, community services boards and behavioral health authorities, private psychiatric hospitals, and other licensed providers.</li> </ul>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Small business affected: approximately 300 service providers that are licensed by the Department.</p>

<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>Prior versions of the human rights regulations have been in effect since 1986. Existing licensed providers have already allocated and funded the costs to implement these regulations. There are no new costs to providers associated with the proposed revisions to the regulations.</p> <p>DMHMRSAS will conduct statewide training on the revisions to the regulations once they become effective. This training will be offered at no cost to the providers. There will some staff and travel expenses to provider/businesses to attend these training events. These costs will vary by individual provider but should be minimal.</p>

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

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

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

**Public comment**

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

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No comments were received following the publication of the NOIRA. However, the Department worked with its H3R Advisory Committee throughout the process to develop changes and obtain consultation regarding the proposed changes to the regulations. This group drafted specific recommendations for the revisions, which are referenced in the "Detail" portion of this document.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

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The proposed regulatory action should promote family and family stability by further protecting the rights of individuals receiving services for mental health, mental retardation and substance abuse services.

**Detail of changes**

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

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

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<b>Section</b>	<b>Description</b>	<b>Rationale</b>
<b>12VAC35-115-10</b> <b>Authority and Applicability</b>	Update of Code of Virginia references, minor language changes	Changed to comply with Code revisions and to promote clarity.
<b>12VAC35-115-20</b> <b>Policy</b>	Minor revisions to the language.	Intended to promote clarity.
<b>12VAC35-115-30</b> <b>Definitions</b>	Major changes to definitions including:	
Advance directive	New	Recommended by the H3R Advisory Committee (stakeholder group) and is intended to promote recovery and self-empowerment for individuals receiving services.
Authorization	New	Developed to comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

Authorized representative	Changed terminology from legally authorized representative (LAR) to authorized representative (AR) and revised the definition.	Recommended by the H3R Advisory Committee for clarity and to promote the recovery and self-empowerment for individuals receiving services.
Complaint	Revised	Recommended by the H3R Advisory Committee and others. Revisions are intended to promote clarity.
Consent	Revised definition and relocated procedural requirements from the definition to the "Participation in Decision Making" section (which has been separated from section on "informed consent").	Recommended by H3R Advisory Committee and others. Revisions are intended to promote clarity.
Disclosure	New	Added to comply with HIPAA requirements.
Emergency	Removed "substantial property damage" from the definition of an emergency.	Intended to limit the types of incidents that qualify as an emergency.
Health Care Operations	New	Added to comply with HIPAA requirements.
Health Plan	New	Added to comply with HIPAA requirements.
Informed Consent	Revised definition and relocated procedural requirements to "Participation in Decision Making" section (which has been separated from section on "consent").	Recommended by the H3R Advisory Committee and others comments. Intended to promote clarity.
Licensed Professional	New	Consistent with regulations for licensing, and consistent with the intent of H3R Advisory Committee recommendation and comments.
Peer on Peer Harm	New	H3R Advisory Committee recommendation and is intended to promote clarity.
Program Rules	New	H3R Advisory Committee recommendation intended to promote clarity.
Psychotherapy Notes	New	Compliance HIPAA requirements.
Restraint	Revised	General comments. Intended to promote clarity.

Seclusion	Revised to make it clear that blocking egress by <u>any</u> means is seclusion and thereby prohibits the use of “isolated time out”	Recommended by the H3R Advisory Committee and intended to promote clarity.
Time Out	Revised	Recommended by the H3R Advisory Committee and intended to promote clarity.
<b>12 VAC-35-115-40</b> <b>Assurance of Rights</b>	Minor language revisions.	Intended to promote clarity.
<b>12 VA 35-115-50</b> <b>Dignity</b>	There has been significant reorganization of this section including the elimination of the existing section on the “Exemptions and Conditions of Providers Duties.” The provisions for exemptions and conditions of providers’ duties are relocated to the appropriate right or provider’s duty. New language is added to support preferences of parents or guardians of minors.	Recommended by the H3R Advisory Committee and intended to promote clarity.
Use of preferred or legal name	Revised to permit a limit on use of name under certain circumstances.	Supports the intent of H3R Advisory Committee recommendation.
Right to communicate by mail and telephone	Separates and permits licensed professional to determine restrictions. Permits residential substance abuse (SA) programs to limit access to phone during initial phase of treatment.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.
Right to visitors	Permits licensed professional to determine restrictions. Permits residential SA programs to limit access to visitors during initial phase of treatment.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.



<p><b>12 VAC-35-115-60</b></p> <p><b>Services</b></p>	<p>Eliminates the “Exemptions and Conditions of Providers Duties” section and relocates provisions to the appropriate right or provider duty. Adds language to support the preferences of parents or guardians of minors.</p>	<p>Intended to promote clarity.</p>
<p><b>12 VAC 35-115-70</b></p> <p><b>Participation in Decision Making and <u>Consent</u></b></p>	<p>New title (added “<u>and consent</u>”)</p> <p>Relocated procedures from the definition of “consent” and “informed consent” to this section. Clarified procedures for obtaining consent.</p> <p>Eliminates the “Exemptions and Conditions of Providers Duties” section. Provisions from this section have been relocated to the appropriate sections on the corresponding right or provider duty. New language is added to support preferences of parents or guardians of minors.</p> <p>Moved provisions about capacity evaluations and authorized representatives to two new sections. See Part IV</p>	<p>Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.</p>
<p><b>12 VAC 35-115-80</b></p> <p><b>Confidentiality and <u>authorization to disclose information</u></b></p>	<p>New title (added “<u>authorization...</u>”)</p> <p>Aligned with HIPAA requirements</p> <p>Eliminates the “Exemptions and Conditions of Providers Duties” section and relocates provisions to the appropriate right or provider duty. Provisions are added to support preferences of parents or guardians of minors.</p>	<p>Revised to comply with HIPAA requirements.</p>

<p><b>12 VAC 35-115-90</b></p> <p><b>Access to and amendment of services records</b></p>	<p>Aligned provisions with HIPAA requirements.</p> <p>Eliminates the “Exemptions and Conditions of Providers Duties” section and relocates the provisions to the section for the appropriate right or provider duty. Provisions are added to support the preferences of parents or guardians of minors.</p>	<p>Revised to comply with HIPAA requirements.</p>
<p><b>12 VAC 35-115-100</b></p> <p><b>Restrictions on freedoms of everyday life</b></p>	<p>Includes minor language changes.</p> <p>Eliminates the “Exemptions and Conditions of Providers Duties” section and relocates the provisions to the section for the appropriate right or provider duty. Provisions are added to support the preferences of parents or guardians of minors.</p>	<p>Revised for clarity.</p>
<p><b>12 VAC 35-115-110</b></p> <p><b>Use of Seclusion, restraint and time out</b></p>	<p>There has been significant reorganization of this section including the elimination of the “Exemptions and Conditions of Providers Duties section and relocation of the provisions to the section for appropriate right or provider duty. Provisions are added to support preferences of parents or guardians of minors.</p> <p>Removed the reference to and permission to use “isolated time out”</p>	<p>Supports intent of H3R Advisory Committee recommendations and comments. Revisions are also intended to promote clarity.</p>
<p><b>12 VAC 35-115-120</b></p> <p><b>Work</b></p>	<p>Minor language changes</p>	
<p><b>12 VAC 35-115-130</b></p> <p><b>Research</b></p>	<p>Minor language changes for clarity.</p>	

<p><b>12 VAC 35-115-140</b></p> <p><b>Complaint and Fair Hearing</b></p>	<p>Minor language changes for clarity.</p>	
<p><b>New: Part IV</b></p> <p><b>Surrogate Decision Making</b></p>	<p>A new part is added to the regulations that consolidates and relocates various provisions from other parts of the current regulations.</p>	<p>Supports intent of H3R Advisory recommendation and comments. Organization is intended to promote and improve clarity.</p>
<p><b>12 VAC 35-115-145</b></p> <p><b>Determination of capacity to give consent and authorization</b></p>	<p>Addition of a new section of the regulations.</p> <p>Relocates provisions from current "Participation in Decision Making" section.</p> <p>Adds details about the requirements for a capacity evaluation.</p>	<p>Supports intent of H3R Advisory recommendation and comments. Intended to promote clarity.</p>
<p><b>12 VAC 35-115-146</b></p> <p><b>Authorized representatives</b></p>	<p>New Section</p> <p>Relocates provisions from current "Participation in Decision Making" section.</p> <p>Changes reference to "next of kin" to "family member".</p> <p>Further defines the role of the LHRC in the review of a "next friend".</p> <p>Adds a requirement for the "next friend" to act in the best interest of the individual.</p> <p>Includes new subsection regarding the conditions for removal of an authorized representative.</p>	<p>Supports intent of H3R Advisory recommendation and comments. Intended to promote clarity.</p>
<p><b>12 VAC 35-115-150</b></p> <p><b>General Provisions</b></p>	<p>Minor language changes</p>	

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

<p><b>12-VAC-35-115-210</b>  <b>State Human Rights Committee Appeals procedures</b></p>	<p>Minor language changes.  Adds a requirement that parties are notified of case outcome and closure.</p>	<p>Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.</p>
<p><b>12 VAC 35-115-220</b>  <b>Variances</b></p>	<p>Minor language changes.  Adds procedures for a temporary variance.</p>	<p>Supports intent of H3R Advisory Committee recommendations, and comments. Intended to increase protections to individuals.</p>
<p><b>12 VAC 35-115-230</b>  <b>Provider requirements for reporting to the department</b></p>	<p>Minor language changes.</p>	
<p><b>12 VAC 35-115-240</b>  <b>Human rights enforcement and sanctions</b></p>	<p>Minor language changes</p>	
<p><b>12 VAC 35-115-250</b>  <b>Offices, composition and duties</b></p>		
<p><b>250 A</b></p>	<p>Clarifies the LHRC affiliation and attendance requirements.</p>	<p>Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity.</p>
<p><b>250 D</b></p>	<p>Requires provider affiliations in accordance with recommendations of an advocate;  Updates membership provisions;  Permits summary decision making; and  Permits review of actions of a “next friend.”</p>	<p>Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity and compliance with the Code of Virginia</p>

<b>250 E</b>	Updates membership language;  Require the development of guidance documents.	Supports intent of H3R Advisory Committee recommendation and comments. Intended to promote clarity and ensure compliance with Code of Virginia requirements.
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