Virginia Regulatory Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	State Mental Health, Mental Retardation and Substance Abuse Services Board
Virginia Administrative Code (VAC) citation	12 VAC 35-115-10 et seq.
Regulation title	Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services
Action title	General revisions to clarify and update the provisions for consistency with other applicable laws and regulations and current standards of practice.
Document preparation date	January 28, 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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The current Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services (Regulations) were promulgated in 2001 to update and consolidate three separate sets of human rights regulations. All programs and facilities licensed, operated or funded by the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department) are governed by these Regulations. The Agency proposes this regulatory action to clarify terminology and various procedures in order to improve the human rights protections and the processes provided by the regulations. In addition, the Agency intends to align the provisions with applicable federal and state laws and regulations, including the federal regulations for health information that became effective on October 15, 2002 pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The goal of action is to update and clarify the processes and procedures in order to improve the legal and human rights protections provided by these regulations.

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., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The promulgating authority is the State Mental Health, Mental Retardation and Substance Abuse Services Board. The Board has the legal authority to adopt the Regulations under Va. Code § 37.1-84.1 and its authority to do so is mandatory.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

Changes are needed to update and clarify the processes and terminology, including certain definitions, provided by these Regulations. Specific aspects in need of revision were targeted by public comments submitted in response to the periodic review and by an advisory committee that was convened by the Department to represent persons and organizations that are interested and affected by the Regulations. The aspects of the Regulations that are proposed to be revised and clarified include: (i) the rights of minors and parents; (ii) requirements for services plans, emergencies and consent (relative to electroconvulsive treatment and other services); (iii) the process for determining capacity of individuals and the need for substitute decision makers; (iv) restrictive procedures including, seclusion, restraint and time out; (v) administrative processes for complaints, reporting and investigations; and (vi) the roles and duties of providers, advocates, local human rights committees (LHRC) and the State Human Rights Committee (SHRC).

The Agency will also clarify certain definitions of terms and consider reorganizing parts of the regulations to promote better understanding of the intent and processes. The Agency will also consider adding provisions to address the specific needs and circumstances of certain types of providers, such as substance abuse treatment programs and acute care facilities, in carrying out the regulatory requirements.

Additionally, as part of this action, the Agency intends to update and align the provisions with federal HIPAA Regulations and other applicable laws and regulations.

The Agency believes that the proposed revisions are essential to ensure that the legal and human rights of individuals receiving services are protected in accordance with the law. The revisions are intended to improve public understanding, simplify or reduce burdensome administrative procedures, and facilitate implementation of the processes consistent with the applicable legal requirements.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

There is a general consensus of the Agency, advocates and providers that revising the existing Regulations is the only practical alternative for addressing the issues identified during the periodic review of these Regulations. The Regulations are required by statute.

The Agency intends to consider alternatives for revising the provisions in conjunction with an advisory committee that has been appointed to represent interested persons, providers and others governed by these Regulations. This advisory committee has helped the Agency to identify the parts of the Regulations that need modification and will continue to provide assistance in resolving any contradictory views or problems identified during the public review process and comment periods. With the expertise of this group, the Agency will be able to make reasonable changes in response to the needs of the public and ensure that regulated service providers and facilities can fulfill their responsibilities under these regulations.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

The proposed Regulations should not adversely impact the institution of the family and family stability. The proposed changes will be structured to encourage family participation in planning and providing services and protecting individual rights.

Periodic review

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section. If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 21, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

A total of 29 individuals and organizations submitted comments in response to the periodic review of the Regulations. Many respondents recommended specific revisions to clarify or update current regulatory provisions. The Agency plans to consider these suggestions for specific changes when drafting the amendments to this regulation. In general, it appears that these Regulations are fulfilling an essential function and continue to be necessary to protect public health, safety and welfare of individuals who are receiving services in facilities, funded, licensed and operated by the Department. The following is a summary of the types of comments received and the agency response relative to the criteria set out in Executive Order 21.

Comment relevance	Summary	Agency response
Organization and Clarity **(9 Commenters)**	Clarify language; reduce burdensome administrative requirements; re-order sections of the regulations to make them more understandable; provide an introduction, an index, and interpretive guidelines and cross-references.	In light of these comments, the Agency will consider revising and re-organizing parts of the current regulation to clarify various provisions. The Agency may also draft non-regulatory guidance documents to help the public interpret and implement the regulations after the amended regulations have been promulgated.
Scope and Policy 12 VAC 35-115-10 12 VAC 35-115-20 **(3 Commenters)**	Update the policy statement to reflect current Department policy; Encompass more service entities in the domain of the regulation.	The Agency will consider revisions to clarify the applicability and policy to more clearly interpret the statutory mandate for the regulation.
Definitions 12 VAC 35-115-30 **(16 Commenters)**	Change the definitions to clarify or make them more consistent with current standards of practice and other laws or regulations (HIPAA), and update current terminology or references. Specific changes are suggested to the definitions of the following terms: “abuse;” “advocate;” complaint;” “consent;” “individual;” legally authorized representative;” “neglect;” “restraint;” “ seclusion;” “serious injury;” “time out;” and “treatment.”	The Agency agrees that the definitions of certain terms should be updated to clarify the language used in the regulation, to reflect current practice standards, or to be consistent with other regulatory requirements. Changes will be considered in as part of the drafting process.
Assurance of Rights 12 VAC 35-115-40 **(3 Commenters)**	Make this section consistent with HIPAA and allow more flexibility in the process for providing notice of rights to individuals who are being admitted to services or facilities.	The Agency will consider changes to make this section consistent with HIPAA privacy regulations and address notice requirements.
Dignity 12 VAC 35-115-50 **(6 Commenters)**	Provide standard statewide training for staff; provide guidance for non-routine circumstances in a facility; revise to address conditions for providers of residential substance abuse services.	The Agency will consider the suggested changes to this section of the regulation in the drafting process.

Participation in Decision Making 12 VAC 35-115-70 **(14 Commenters)**	Provide more guidance regarding minors; clarify language; revise requirements for electroconvulsive treatment (ECT); reconsider the administrative requirements and timeframes for determining capacity; revise requirements and provisions for "next friend," "legally authorized representatives (LAR)," and other types of surrogate decision makers; should develop provisions and policies to encourage professionals, family members, and others to serve as LARs.	In view of the comments, the Agency will consider changes to this part of the regulation that would promote and maintain individual rights related to participation in decision-making and eliminate any unnecessary administrative requirements. Revisions will also be considered to facilitate the interpretation and implementation of provisions.
Confidentiality 12 VAC 35-115-80 **(6 Commenters)**	Align the entire section with HIPAA privacy regulations; make provisions consistent CARF standards and the regulations for licensing; clarify requirements for minors.	The Agency intends to align the regulation with other relevant regulatory requirements. Appropriate changes will be made to clarify the provisions.
Access to and Correction of Services Record 12 VAC 35-115-90 **(1 commenter)**	Replace the term "correction" with "amendment;" eliminate provisions that allow information to be removed from service record; clarify provisions that give the provider the right to charge for copies.	The Agency will consider the proposed revisions in the drafting process.
Freedoms of Everyday Life 12 VAC 35-115-100 **(3 commenters)**	Address circumstances for specific type of service settings in the provisions (i.e. acute care, residential substance abuse etc.); add language about the security and integration of service settings.	The Agency acknowledges concerns regarding the different types of service settings and intends to consider these issues in the drafting process.
Use of Seclusion, Restraint, and Time Out 12 VAC 35-115-110 **(3 commenters)**	Revise terminology and provisions to incorporate CMS requirements; provide language to indicate that seclusion and restraint is used only when other alternatives have been exhausted; clarify language; reduce LHRC review requirements for programs using physical restraint.	The Agency intends to bring all provisions into compliance with the current relevant regulatory requirements. Changes will be considered that incorporate best practice standards and eliminate unnecessary administrative requirements.

Research 12 VAC 35-115-130 **(1 commenter)**	Revise to be consistent with Virginia Code requirements for human research; modify provisions to expedite the LHRC review requirements for comprehensive research proposals involving more than one provider.	The Agency will make any revisions needed to ensure consistency with relevant provisions of the Virginia Code and consider proposed changes to review requirements for research projects.
Complaint and Fair Hearing 12 VAC 35-115-140 **(3 commenters)**	Clarify process requirements for the resolution of complaints; distinguish the complaint process from the grievance or dispute resolution process; add provisions for complaints against Office of Human Rights staff and human rights committee members; indicates that a process for complaint management is required by JCAHO and Medicare and is already in place for acute care hospitals.	The Agency will consider the proposed changes to and clarification of this complaint process.
General Provisions 12 VAC 35-115-150 **(2 commenters)**	Appeal process is too drawn out. Increase the timeframe for resolving informal complaints.	The Agency will consider the concerns about the timeframe when drafting changes to the regulation.
Formal Complaint Process 12 VAC 35-115-170 **(1 commenter)**	Notify the director immediately rather than the next business day.	The Agency will consider the suggestion in the drafting process.
LHRC Hearing and Review Procedures 12 VAC 35-115-180 **(1 commenter)**	States "…the appeal process was not designed for providers. This is especially troublesome when a tie vote on the local human rights committee [LHRC] denies a policy change request yet demonstrates a lack of consensus amongst its own members."	The Agency will investigate this concern when drafting revisions to the regulation.
Special Procedures for LHRC Reviews Involving Consent 12 VAC 35-115-200 **(1 commenter)**	Questions the rationale for allowing the LHRC to substitute its judgment for that of clinical experts. Concerned that there is no formal training or interview process for members of an LHRC.	The agency will consider these concerns when drafting revisions to the regulation.

Provider Requirements for reporting to the Department 12 VAC 35-115-200 **(4 commenters)**	Questions the need for monthly reports in all circumstances; suggests that reporting requirements be modified to address different situations; states that the reporting process needs clarification; questions the requirement for reporting all deaths; questions whether reporting protective restraints is necessary; suggests changing the section to be consistent with Departmental instructions for reporting seclusion and restraint.	The Agency will review the reporting requirements and consider making the suggested changes to this section.
Offices, Composition and Duties 12 VAC 35-115-250 **(9 commenters)**	Provides various suggestions for clarification or changes to the roles and responsibilities of providers; human rights advocates; LHRCs; and SHRCs; Expresses concerns and difficulties about certain aspects of the system and process (i.e. communication among entities, review and oversight functions, etc.)	The Agency intends to review the aspects of the human rights system and process, as discussed by the commenters, and consider appropriate changes that will promote the goals established for the regulation.
General observations (**3 Commenters**)	Certain provisions are antiquated and unnecessary; are not compatible with the realities of acute care settings; are not essential to protect the welfare of citizens; should focus on the right to effective treatment as a basic human right.	Va. Code § 37.1-84.1 requires the Board to adopt regulations to assure certain basic rights of individuals who receive services in a hospital, other facility, or program operated funded or licensed by the Department. The Agency has promulgated the regulation in order to carry out this statutory mandate. The comments indicate that the regulation is generally fulfilling an essential function. However, it is evident from the scope of comments that parts of the current regulation should be revised or clarified. The Agency will consider revising or clarifying these provisions.