**Virginia Regulatory Town Hall**

# Final Regulation
# Agency Background Document

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| **Agency Name:** | Department of Mental Health, Mental Retardation and Substance Abuse Services |
| **VAC Chapter Number:** | 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:** | Final |
| **Date:** | October 3, 2001 |

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

## Summary

*Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.*

The new regulation will replace three separate regulations:

? Rules and Regulations to Assure the Rights of Residents of Facilities Operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services (12 VAC 35-110-10 et seq.)

? Rules and Regulations to Assure the Rights of Patients of Psychiatric Hospitals and Other Psychiatric Facilities Licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services (12 VAC 35-120-10 et seq.)

? Rules and Regulations to Assure the Rights of Clients in Community Programs Licensed or Funded by the Department of Mental Health, Mental Retardation and Substance Abuse Services (12 VAC 35-130-10 et seq.)

The new regulation will protect the legal and human rights of individuals who receive treatment in programs and facilities operated, funded and licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services, excluding those operated by the Department of Corrections. To the extent that it is within the reasonable capabilities of the department or licensee, each individual is assured adequate care consistent with sound therapeutic treatment. The regulation will protect the rights of individuals with respect to the assurance of legal rights; evaluation, treatment, and discharge; treatment under the least restrictive conditions; participation in treatment decisions, research, and work activities; and disclosure of confidential information. The regulation also will delineate the process and remedies individuals can pursue to address violations of these rights.

Since the proposed regulation was published, there have been substantive revisions made to respond public comments regarding the requirements for seclusion, restraint, and time out; the process for filing complaints; reporting requirements for providers; and the roles of State Human Rights Committee (SHRC) and the Local Human Rights Committee (LHRC). In addition, requirements for "consent" versus "informed consent" were clarified. Changes have also been made to clarify the criteria under which the commissioner may exempt individuals under forensic status and individuals who are committed to the custody of the commissioner as sexually violent predators from certain human rights protections.

Following publication of the regulation for the final 30-day adoption period, the agency received requests from more than 25 members of the public asking for an opportunity to submit additional comments. Therefore, the effective date of the regulations was postponed and the Board scheduled an additional 30-day public comment period on this regulation. In response to comments received during this additional 30-day period, changes were made to the provisions for obtaining consent for electroconvulsive treatment. In addition, requirements that the LHRC approve certain restrictions were eliminated and various revisions were made to clarify the provisions.

## Statement of Final Agency Action

*Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.*

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At its meeting on May 17, 2001, the State Board for Mental Health, Mental Retardation and Substance Abuse Services adopted for promulgation the final draft of Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services, 12 VAC 35-115-10 et seq.

The final regulations were published in the Virginia Register on June 18, 2001. During the final 30-day adoption period, the Agency received more than 25 letters from members of the public requesting a suspension of the regulatory process and an opportunity for additional 30-day comment period. Therefore, in accordance with the Virginia Administrative Process Act, the Agency published a notice postponing the effective date of the regulations on July 30, 2001, and accepted additional public comments through August 30, 2001.

At its meeting on September 27, 2001, the State Board for Mental Health, Mental Retardation and Substance Abuse Services adopted for promulgation the final draft of Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services, 12 VAC 35-115-10 et seq. with the additional changes made in response to public comments.

## Basis

*Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.*

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The new regulation is promulgated pursuant to §37.1-84.1 of the Code of Virginia (1950) as amended and Chapter 969 of the 1999 Virginia Acts of Assembly. This regulation is necessary to fulfill the Board's legislative mandate pursuant to §37.1-84.1 to promulgate regulations delineating the rights of patients and residents with respect to nutritionally adequate diet; safe and sanitary housing; participation in non-therapeutic labor; attendance or nonattendance at religious services; participation in treatment decision-making, including due process procedures to be followed when a patient or resident may be unable to make an informed decision; use of telephones; suitable clothing; possession of money and valuables; and related matters. The Code also requires that such regulations be applicable to all hospitals and other programs and facilities operated, funded, or licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

The Office of the Attorney General has certified that Board for Mental Health, Mental Retardation and Substance Abuse Services has the statutory authority to promulgate the new regulation and that the regulation comports with applicable state and federal laws.

## Purpose

*Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is*

*essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.*

The Board of Mental Health, Mental Retardation and Substance Abuse Services is revising and consolidating the three sets of human rights regulations for the following reasons:

? To make the human rights regulation consistent for all facilities and programs licensed, funded, and operated by the department,

? To incorporate changes in the law at § 37.1-84.1 of the Code of Virginia,

? To clarify and provide greater specificity of rights to individuals receiving services and families,

? To clarify the responsibilities of providers,

? To clarify the complaint review and resolution process, and

? To provide timeframes for each stage of complaint review and resolution process.

Through these changes and consolidation, the new regulation will improve the internal human rights system, and strengthen the accountability of providers, and enhance the level of protection for the rights of individuals receiving services in public and private facilities and programs operated, funded, and licensed by the department.

## Substance

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.*

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The new regulation has reorganized to enhance the clarity. The text is organized into the following sections: "Authority and Applicability," "Policy," "Definitions," "Assurance of Rights," "Explanation of Individual Rights and Providers Duties," "Complaint Resolution, Hearing and Appeal Procedures," "Variances," "Reporting Requirements," "Enforcement and Sanctions," and "Responsibilities and Duties."

Part III of the new regulations "Explanation of Individual Rights and Provider's Duties" is organized to include:

? a listing of the individual's rights,

? provider duties, and

? exceptions and conditions.

New substantive provisions of the regulation include:

? Clarification and definition of the composition, roles, and functions of the department's internal human rights system, the Local Human Rights Committees and the State Human Rights Committee.

? Provision for monitoring and enforcement of the regulation through sanctions for non-compliance.

? Establishment of time frames for the processing of complaints through the department's internal human rights system.

? Establishment of more stringent procedures for application, review and approval of variances from specific standards or procedures in the regulation.

? Establishment of requirements for reporting to the department for all programs and facilities operated, funded, and licensed by the department in specific areas.

? Establishment of requirements and procedures for data submission and the release of data to the public on operations and performance of programs and facilities operated, funded or licensed by the department.

## Issues

*Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.*

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The new regulation consolidates and will supersede the three regulations that were promulgated to protect the human rights of patients and residents of public and private facilities and programs operated, funded, and licensed by the department. None of the three existing regulations has been revised since 1983. Since 1983 numerous problems have been identified with the existing regulations. These problems include:

? Inconsistencies among the regulations for facilities operated by the department, licensed inpatient programs and community programs result in different levels of protection and confusion for consumers, families and providers;

? Changes in the law since 1983 are not reflected in the existing regulations;

? Changes in practice are not reflected in the existing regulations; and

? Time frames for the review and resolution of complaints are not specified in the existing regulations, resulting in protracted case reviews.

The advantages to the public, including consumers, families of consumers, and providers of mental health, mental retardation, and substance abuse services, are as follows:

? The regulation reflects current requirements of the law;

? The regulation reflects current practice and clarifies the role of the consumers, their families and providers within the human rights system;

? The regulation establishes a single set of standards that protect the rights of persons with mental disabilities who receive treatment in public and private facilities and programs operated, funded and licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services;

? The regulation reduces the burden of multiple regulations on public and private programs and facilities that provide inpatient and outpatient services;

? The regulation reduces the confusion for consumers and families, which often results when an individual moves from one type of program to another (e.g. inpatient to community program) each with a separate set of human rights regulations; and

? The regulation establishes reasonable time frames for the review and resolution of each complaint.

In 1992, the State Board of Mental Health, Mental Retardation and Substance Abuse Services adopted a resolution to consolidate the three existing regulations into a single regulation applicable to all facilities and programs operated, funded or licensed by the department. A 1996 comprehensive review of the existing human rights regulations and the public comment received during that review demonstrated extensive public support for a single, consolidated regulation.

There are no disadvantages to the public or Commonwealth by the promulgation of this regulation.

## Statement of Changes Made Since the Proposed Stage

*Please highlight any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication.*

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Specific provisions have been added at 12 VAC 35-115-10 D to clarify the criteria under which the commissioner may exempt individuals under forensic status and individuals who are committed to the custody of the commissioner as sexually violent predators from certain human rights protections.

Various definitions have been clarified and revised to be consistent with the regulatory context and intent (i.e. definitions of “consent,” “exploitation,” “restraint,” “seclusion,” “services plan.”).

Additional terms have been defined (i.e. "complaint," habilitation," "investigating authority," "next friend, " "research review committee," and "treatment"). Changes in the text of the regulation have been made consistent with the revisions to definitions.

Requirements for "consent" versus "informed consent" were clarified throughout the regulation, consistent with the revised definition of "consent".

Section 12 VAC 35-115-40 which provides a summary of legal rights and regulatory provisions has been re-organized and clarified.

Provisions for the imposing certain restrictions (i.e. telephone, mail, visitors) have been clarified (12 VAC 35-115-50).

The role of the legally authorized representative has been more clearly explained throughout the regulation (i.e., 12 VAC 35-115-70).

Provisions were inserted into the definition of consent and at 12 VAC 35-115-70 "Participation in decision making" to require informed decision making and protections for any electroconvulsive treatment.

The provider's responsibilities and duties in providing treatment in an emergency have been described with more specificity (12 VAC 35-115-70 C).

Provisions were revised throughout the regulations to address key differences among providers of mental health, mental retardation and substance abuse services (i.e. reporting, use of seclusion and restraint, etc.)

Provisions were clarified to indicate that anyone may initiate a complaint on behalf of an individual receiving services.

A new section "Informal complaint" (12 VAC 35-115-60) was added, which is specifically distinguished from the "Formal complaint resolution process" established in 12 VAC 35-115-70.

A new section was added regarding the "Use of seclusion, restraint and time out" at 12 VAC 35-115-110 which incorporates and expands the major provisions of 12 VAC 35-115-100 from the proposed regulation. Distinct regulatory requirements for seclusion restraint and time out for U.S. Health Care Financing Administration (HCFA) certified intermediate care-mentally retarded (ICF-MR) are included. The prohibition on the use of seclusion and restraint as part of a behavioral treatment plan was eliminated.

The relationship between LHRCs and the SHRC has been clarified, responsibilities of each entity have been clarified, and the minimum number of members of the LHRC has been reduced from seven to five. The LHRC meeting requirements were revised.

The reporting requirements for abuse and neglect, deaths and serious injuries, and human rights activities in 12 VAC 35-115-230 were clarified to encompass only provider requirements for reporting to the Department and to specify time frames and report content.

A detailed description changes to the proposed regulations that have been made in response to public comment is provided in the attached summary of public comment.

The following additional revisions were made following the final 30-day public comment period:

The requirements that an LHRC approve restrictions on visitation, phone calls and mail were eliminated.

Minor revisions were made to clarify sections regarding authority, services, confidentiality, consent, work, seclusion and restraint, offices compositions and duties, and research.

Provisions were eliminated to require a second physician's opinion to be obtained when an adult is referred for electroconvulsive treatment (ECT) and replaced with provisions requiring adults to be informed that they may obtain a second opinion before obtaining such treatment. In the case of individuals under age 18, provisions were inserted to require that two qualified psychiatrists concur with any ECT treatment.

Specifications regarding the nature of informed consent required for ECT were added.

The requirement for a face-to-face meeting between individuals who are referred for ECT and members of the LHRC was removed.

## Public Comment

*Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.*

The State Mental Health, Mental Retardation and Substance Abuse Board conducted six public hearings at locations statewide to consider the proposed regulation. A total of 144 written and oral public comments were received on the proposed regulation. The subject areas that generated the most comments included the commissioner's authority to exempt forensic units and sexually violent predator units from regulatory provisions; the requirements for consent versus informed consent; the role of the a legally authorized representative in treatment and treatment decisions; the criteria for restrictions, particularly seclusion, restraint and time out; the process and procedures for filing complaints and the reporting requirements. Specific revisions have been made to the proposed regulations to respond to the public comments received in all of these subject areas.

A total of 74 written comments were received on the regulation during the additional 30-day public comment period. Provisions that generated the most comments were the definition of "consent" and the requirements for a second opinion and face-to-face meeting with LHRC

members for individuals receiving ECT. Specific revisions have been made to the proposed regulations to respond to these public comment received in these subject areas.

A summary of the specific public comments received during the initial 60-day comment period and the subsequent 30-day public comment period with has been prepared by the department and distributed to the public. These summaries are attached and will be maintained as part of the record of the promulgation process for these regulations.

## Detail of Changes

*Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.*

The proposed regulation consolidates and will supersede the three existing regulations that were promulgated by the department to protect the human rights of consumers of public and private facilities and programs operated, funded and licensed by the department. Specific changes to the proposed regulation include:

? C learly defining the composition, role, and function of the internal human rights system, the local human rights committees, and the State Human Rights Committee. A 1999 revision to the Code of Virginia requires that one-third of the appointments made to the state or local human rights committees be consumers or family members of consumers, with at least two consumers who are receiving services on each committee.

? Requiring monitoring and evaluation of provider compliance with the regulation. A 1999 revision to the Code of Virginia requires that there be periodic reviews of human rights compliance. Licensing by DMHMRSAS will be contingent upon human rights compliance.

? Establishing procedures for enforcement and sanctions for violations of human rights. A 1999 revision to the Code of Virginia authorize sanctioning providers who fail to comply with human rights regulations.

? Establishing clearer procedures and time frames for the resolution process in the internal human rights system.

? Establishing more stringent procedures for the application, review and approval of variances from specific standards or procedures in the regulation.

? Establishing requirements for reporting, data submission and the release of data to the public. A 1999 revision to the Code of Virginia requires that all programs and facilities operated, funded and licensed report information on abuse and neglect, deaths and serious injuries, instances of seclusion and restraint, and other information on human rights activities.

? Prohibiting employees of programs and facilities operated, funded, or licensed by the department from serving as the authorized representative of a consumer in the program. A 1999 revision to the Code of Virginia prohibits this practice.

? Changing the format of the regulation to clarify individual rights, provider responsibilities, and exceptions.

? Simplifying the language of the regulation such that consumer, families and providers may more easily understand the regulation.

Updating the standards and terminology to reflect current practice.

## Family Impact Statement

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

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This regulation explains the human rights of the individual as a recipient of services in an inpatient program licensed by the department. It provides some assurance to family members that the human rights of their loved ones who are receiving mental health, mental retardation, and substance abuse services are protected and that there are procedural safeguards in place to address violations to these rights. Such assurance is essential to the peace of mind of many families who have entrusted the care and well-being of their loved one to a service provider.

This regulation has no impact on the institution of the family and family stability.

1. This regulation does not erode the authority and rights of parents in the education, nurturing and supervision of their children. It clearly speaks to the responsibilities of providers to obtain the consent of at least one parent of a minor before any treatment, including medical treatment, begins. It also provides for an individual's next of kin to be designated as a legally authorized representative when an individual lacks the capacity to give consent for any treatment.

2. This regulation does not discourage the economic self-sufficiency, self-pride and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.

3. This regulation has no effect on the marital commitment; and

4. This regulation has no effect on family income.

**Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.**

| Section | Comment | Response |
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| **Part I *General Provisions*** | | |
| **12 VAC 35-115-10 *Authority and Applicability*** | | |
| General Comments | There were eight comments that pertained to the scope of regulatory authority. Several respondents recommended that this regulatory authority be expanded to cover individuals receiving services in other types of programs that have not been included in the scope of this regulation (i.e. individuals in service programs that receive state funds, regardless of the "funding stream.") One respondent asked whether the regulations are applicable to individuals with developmental disabilities. Another respondent suggested a statement be made that the regulation applies to individuals with autism. | § 37.1-84.1 of the Code of Virginia mandates the promulgation of this regulation to assure the rights of individuals in programs operated, funded or licensed by the Department of Mental Health Mental Retardation and Substance Abuse Services (DMHMRSAS). The regulation would exceed the scope of this legal authority if other types of programs were included within its purview. This regulation is applicable to any individuals with developmental disabilities or autism when they are receiving services in programs that are funded, licensed or operated by DMHMRSAS. The regulation does not list specific diagnoses. Therefore, DMHMRSAS does not agree that a specific statement should be made that the regulations apply to individuals with autism. If such individuals are receiving services in programs subject to this regulation, they are assured the protections afforded by this regulation. No changes have been made in response to these comments. |
| | One respondent suggested that Code of Virginia citation §18.2-369 be printed on the front cover of this regulation to make providers aware of their personal responsibility and the criminal consequences of abusing individuals with mental disabilities. There were several respondents who suggested including a table of contents. Many respondents were concerned that text of relevant state and federal statutes was not included in the body of the regulation. Several respondents opined that the regulation should include an appendix with relevant legal citations to assist the public to understand the regulation. | The cover or table of contents for any printed publication of the regulation is not promulgated as part of the regulation and is not subject to review as part of this regulatory process. DMHMRSAS will consider options for document covers when the final regulation is printed for distribution. DMHMRSAS will also include a table of contents.<br><br>The Virginia Registrar of Regulations, which oversees the adoption of regulations in Virginia, has advised that the text of existing statutes may not be promulgated as part of any regulation. Therefore, DMHMRSAS consider developing guidance documents with relevant statutory references when the final regulation is printed for distribution to the public. Additionally, the body of the regulation includes Code of Virginia citations wherever applicable. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item A | At least five respondents suggested inserting the word "treatment" as follows: "…individuals receiving treatment and services…" One respondent recommended language changes to emphasize the fact that the regulations are required by the Code of Virginia. | DMHMRSAS has considered all of the comments regarding this provision and concluded that the term "services" is an inclusive reference that encompasses all forms of "treatment." Therefore, no change was made to the first sentence in this statement. |
| ■ Item B | One respondent commended the proposed regulation for requiring the same protections of human right in both community and hospital programs.<br><br>Another respondent indicated that the regulation appears to be directed primarily to mental health programs, although the last item indicates that the regulation "broadly" apply to other providers that receive funding from or through DMHMRSAS. Two other respondents sought clarification regarding the applicability of this regulation. | The regulation is consistent with the scope of regulatory authority and applicable to all programs operated, funded or licensed by DMHMRSAS. In order to reflect an exclusion from applicability in § 37.1-84.1(A) of the Code of Virginia, a phrase was added to indicate that the regulation is not applicable to programs and facilities operated by the Department of Corrections. |
| ■ Item C | There were approximately twenty-five respondents who commented about the last sentence in the paragraph which states that the Commissioner has the authority to exempt forensic units and sexually violent predator units from the regulatory provisions. The respondents generally expressed concern that the Commissioner is given blanket authority to exempt such units without any specific criteria or mechanism for independent review or consultation. One respondent advised that the only reason for imposing limitations on the rights on individuals in forensic units should be "safety." Several respondents suggested that the State Human Rights Committee (SHRC) should provide an independent review function when the Commissioner uses his authority for exemption. | DMHMRSAS agrees with the majority of these respondents' comments that this part of the regulation should be more explicit in describing the rationale for the Commissioner's authority to exempt certain individuals under forensic status and those committed as sexually violent predators from the human rights protections. DMHMRSAS also agrees that a mechanism should be available for public review and comment when the Commissioner authorizes any exemption. Therefore, Item C has been divided into two parts by inserting Item C and new Item D. New provisions state that an exemption will be made only when it is necessary to protect the safety of individuals receiving services, employees or the public. Such exemptions will be in writing and submitted to the SHRC for its information (not review). In addition, the Commissioner will be required to notify the SHRC Chairperson in advance and submit a copy of any exemption he authorizes to the chairperson of the State Human Rights Committee. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| 12 VAC 35-115-20 Policy | | |
| ■ General Comment | One respondent recommended that 12 VAC 35-115-20 Policy should be replaced with a statement delineating all rights, particularly those that are stated in §37.1-84.1 of the Code of Virginia. | This part of the regulation is intended to provide general policy guidance rather than to repeat the specific legal rights that are stated in §37.1-84.1 of the Code. As stated above, DMHMRSAS will consider publishing a guidance document for the public when the regulation becomes final that will provide specific relevant statutory background and references. The Virginia Registrar of Regulations has advised that statutes cannot be promulgated as part of a regulation. Therefore, no change has been made in response to this comment. |
| ■ Item A | Three respondents recommended that the term "treatment" be included in this Item to indicate that individuals receiving both treatment and services should be assured protection.<br><br>There were at least six respondents who commented that the phrase "professionally acceptable parameters of clinical practice" which is used in "Point 3" of this provision is too vague and is not consistent with the statutory language. There were other comments that this phrase was generally too broad or too vague and difficult to interpret. Another respondent indicated that a definition of this term should be provided. | As stated above, DMHMRSAS has defined the term "services" to encompass all forms of "treatment." On this basis, there is no need to add the term "treatment" in the introductory statement. However, in order to respond to expressed concerns, a definition of the term "treatment" has been added to the regulation.<br><br>As the respondents indicated, § 37.1-84.1 of the Code assures legal rights and care consistent with "sound therapeutic treatment." Therefore, in order to be more consistent with the statute, the phrase "professionally acceptable parameters of clinical practice" was replaced with the phase "sound therapeutic practice." DMHMRSAS has also replaced "professionally acceptable parameters of clinical practice" with "sound therapeutic practice" throughout the regulation to ensure consistency.<br><br>DMHMRSAS did not define "sound therapeutic treatment" or "sound therapeutic practice" as suggested by one respondent in order to accommodate future advances in the field. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B | Several respondents recommended that the additional rights be added to the list of legal rights that is provided in this Item (i.e. right to make a living will, right to medical care, right to dispose of property.) Two respondents indicated that, in some cases, it might not be appropriate for individuals to acquire or retain certain types of property or make major life decisions when they are in treatment. | This provision was intended to list basic rights. Of the suggested additions, only the right to dispose of property can be classified as a basic right. Therefore, this right was added to the list in this Item.<br><br>This regulation provides that under, certain circumstances, rights may be restricted. Therefore, DMHMRSAS did not change the proposed regulation in response to the respondents' concerns about individuals exercising certain rights when they are in treatment. |
| **12 VAC 35-115-30 Definitions** | | |
| ■ General Comments | One respondent indicated that the definitions were clear and comprehensible. Another respondent commented that the regulations lacked precise definitions. Many respondents suggested that additional terms be defined in this section of the regulations. | Based on the general and specific comments that have been received, the following additional terms have been defined:<br><br>"Complaint," "Habilitation," Human Rights Advocate," "Investigating Authority," "Next friend," "Research Review Committee or Institutional Review Board," and "Treatment." |
| ■ "Abuse" | There were more than twenty-five comments regarding the proposed definition of "abuse." One respondent believes that the definition should take into account the individual's diagnosis. Another respondent stated that the definition is too narrow because it does not state that "a system and its management" can commit acts of abuse. Other respondents indicated that the definition was too broad because it includes acts that "…might have caused physical harm..." Several other respondents suggested other "considerations" for inclusion in the list of examples of abuse which are part of this definition. Another group of respondents recommended that the definition be made consistent with, and modeled upon, definitions used by the Protection and Advocacy for Individuals with Mental Illness (PAMII) Act and the Protection and Advocacy for Developmentally Disabled Act | DMHMRSAS has revised the proposed definition to be identical to the definition of "abuse" in § 37.1-1 of the Code of Virginia. It is not appropriate to use a federal law to define "abuse" when a state law exists.<br><br>DMHMRSAS has also adopted changes to the regulation to permit certain types of restraint as part of the behavior treatment program. See 12 VAC 35-115-110. This should address the specific concerns that have been expressed. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| "Abuse" (cont.) | (DD Act). There were several recommendations that the definition be made consistent with the definition in the Code of Virginia. Another respondent recommended adding the legal citation to this definition because the definition is "substantially identical" to the definition at § 37.1-1 of the Code of Virginia.<br><br>A group of respondents also commented about the use of restraint in relationship to the proposed definition of "abuse." This comment was made in reference to the prohibition on the use of restraint in the context of a behavioral treatment program. If a restraint is implemented as part of a behavioral treatment program by a professional acting within the ethical/legal standards of the profession, the respondents were concerned that such professional would be committing abuse and be in violation of the regulation. | |
| ■ "Advocate" | There were a number of respondents who commented that this definition does not clearly distinguish "advocates" that are employed by DMHMRSAS from other members of the public commonly referred to as "advocates." One respondent indicated that as a volunteer, she considers herself to be a patient advocate.<br><br>There were also comments that it was unclear whether these advocates are employed by the Commissioner or by the State Human Rights director. | In order to avoid confusion, DMHMRSAS has replaced the term "advocate" with "human rights advocate" when referring to any advocate who is an employee of DMHMRSAS, throughout this regulation. The term "advocate" has been eliminated from the list of defined terms and replaced with "human rights advocate." For purposes of this regulation, "human rights advocate" is defined as a person who is employed by the Commissioner based on the recommendation of the State Human Rights Director. (The advocates report to the State Human Rights Director). |
| ■ "Behavior Management" | Several respondents recommended changes to this definition that would encompass a broader range of behavior management interventions and strategies. There were also at least two respondents who recommended including a statement that physical restraint should be used only in an emergency. | DMHMRSAS agrees that the proposed definition was too narrow and has therefore has revised this definition to incorporate a more comprehensive range of behavior management principles and methods.<br><br>It is not appropriate to include regulatory mandates, such as the appropriate use of physical restraint, as part of a |

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| **Section** | **Comment** | **Response** |
| "Behavior Management" (cont.) | | definition. Rather, definitions are intended to describe the terms used in the regulation. Mandates regarding the appropriate use of physical restraint have been included in other parts of this regulation rather than in the definition of "behavior management." See 12 VAC 35-155-110. |
| ■ "Behavioral Treatment Program" | Several respondents recommended changes to the proposed definition to clearly state that a "behavioral treatment program" should be based on a functional assessment or analysis and be part of a behavioral treatment plan. There was also a recommendation that the term and definition of "behavioral treatment program" be replaced with a definition of the term "behavioral management plan."<br><br>A group of respondents recommended including a statement, as part of the definition, that an alternative decision maker, such as an authorized representative, be required to participate in the formulation of a behavior treatment plan for individuals with mental retardation (MR) and that informed consent should be a requirement. Another respondent, commended the regulations for differentiating "behavior management" from "behavior treatment," while another respondent indicated that the definition was confusing because it was unclear whether the "behavior treatment program" was the same or different from the "behavior treatment plan." | DMHMRSAS agrees with the majority of respondents who commented that the proposed definition is somewhat vague. Based on the comments that have been received, the proposed definition has been revised to clearly state that the behavior treatment program is an integral part of the individual's interdisciplinary treatment plan and may be based on a functional assessment. In order to avoid confusion about the terminology, the revised definition also states that a "behavioral treatment program" may also be referred to as a "behavioral treatment plan" or a "behavioral support plan."<br><br>DMHMRSAS does not agree that the definition should include a regulatory mandate regarding the formulation of a behavioral treatment plan. As stated above, such mandates are provided in other parts of the regulation. |
| ■ "Caregiver" | Several respondents commented that the definition is too narrow because it refers only to trained caregivers and does not include family members or others who may also be caregivers. | The use of the term "caregiver" under these regulations applies only to employees and their contractors because the services covered by this regulation must be operated, licensed, or funded by DMHMRSAS. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ "Consent" | There were twenty-three respondents who provided specific comments regarding this definition. Most of the comments recommended that the terms "consent" and "informed consent" be clearly distinguished or defined separately. There was a general consensus that "informed consent" should be "…free of force, misrepresentation, fraud, deceit, duress, or any form of constraint or coercion…" There were also recommendations that the definition provide necessary safeguards to ensure that individuals have the capacity to provide informed consent.<br><br>Several other respondents recommended that the definition stipulate what constitutes "enough information" or specify the type of information that is needed to make an informed decision. Generally, the comments indicated that more policy guidance and specificity was needed in the definition. | In order to address these concerns, DMHMRSAS revised the definition to state that "…informed consent is needed before a provider may provide treatment to an individual which poses risk of harm greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations, tests, or treatments, or before an individual participates in human research…" The definition has also been expanded to describe the kinds of information required to obtain informed consent. Changes have been made to indicate that "informed consent" is needed for certain types of treatment including, "aversive treatment" and "use of psychoactive and other medications." |
| ■ "Director" | Three respondents recommended that the definition of "director" be expanded to mean the chief executive officer or his designee or his designated agent. One respondent also recommended a statement be included that the term "director," when used in this regulation, does not mean an office director or other person who may have a title of director.<br><br>One respondent indicated that the term "director" appears to be confused with the term "provider" in some other parts of the regulation. | DMHMRSAS does not agree with the recommended changes. The responsible authority for any program delivering services is the chief executive officer. Although a director may designate someone to act on his or her behalf, the director retains the ultimate responsibility for the program. Therefore, this definition is clear and conveys the intended meaning.<br><br>DMHMRSAS has changed some of the terms "director" and "provider" throughout the regulation for clarification. |
| ■ "Discharge Plan" | Several respondents recommended expanding the proposed definition to provide guidelines regarding content of a discharge plan and the process for developing such a plan.<br><br>There were also concerns expressed that some individuals in long-term care programs will not be discharged; therefore, discharge plans should not be necessary. | DMHMRSAS does not agree that it is within the scope of this definition or the regulation to establish a process for development of a discharge plan. No change has been made in response to these comments. Guidance for community services boards is provided at § 37.1-197.1.A.3 of the Code.<br><br>This concern is not within the purview of this regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ "Emergency" | Several respondents recommended that this definition be revised to be more explicit (i.e. note should be made regarding the avoidance of "irreversible damage") It was also recommended that the definition include reference to the relevant statutes such as the Treatment Act and the Health Care Decisions Act. | DMHMRSAS does not agree that this definition should be more explicit and has not made suggested revisions. This definition, as written, does not conflict with the Health Care Decisions Act. |
| ■ "Exploitation" | One respondent suggested expanding the definition to provide guidance on what constitutes "permission." According to the respondent, an individual must give permission with full knowledge of the consequences and be free from force, misrepresentation, coercion etc., in order to avoid "exploitation." It was also recommended that the definition of "exploitation" encompass violations of the requirements for "Work" at 12 VAC 35-115-120 and "Research" at 12 VAC 35-115-130 of this regulation.<br><br>Several other respondents recommended expanding the definition to state that exploitation includes the provider's receipt of gifts or items of value, or favors from individuals receiving services or use of an individual's property for illegal purposes. | DMHMRSAS generally agrees with the respondents and has expanded the definition of "exploitation" to incorporate the recommendations and to be more consistent with the Code of Virginia. |
| ■ "Historical Research" | Two respondents suggested adding the relevant statutory references to this definition. One respondent suggested adding the reference to "confidentiality" at 12 VAC 35-115-80 of this regulation. Another respondent recommended restricting historical research to "existing" information and requiring "informed consent." | DMHMRSAS did not revise this definition based on the comments received. These respondents did not state any reason for inserting the statutory references and the respondent did not identify which specific statutory provisions should be referenced. DMHMRSAS believes the proposed definition conveys the intended meaning. Requirements for informed consent are listed in the revised definition of "consent" and do not have to be listed for each specific course of action. |
| ■ "Human Research" | Two respondents recommended changing the definition to be the same as the definitions in the relevant statutory provisions. One respondent indicated that the definition should refer to provisions regarding "Research" at 12 VAC 35-115-120 of this regulation. Another respondent recommended | In response to recommendations, the proposed definition has been revised to be identical to the definition of "human research" at § 32.1-162.16, et. seq., of the Code of Virginia. A statement has also been added that human research must |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| "Human Research" (cont.) | clarifying some of the terminology and inclusion of a reference to the requirement for "informed consent." | be conducted in compliance with relevant requirements of the Code of Virginia at § 32.1-162.16, et. seq. These sections of the Code describe the legal safeguards for human research, including requirements for "informed consent." |
| ■ "Individual" | One respondent indicated a preference for the term "consumer" rather than "individual" to denote recipients of service. No other specific changes were recommended, although several respondents advised generally that the term "individual" should be used only to refer to refer to "a person who is receiving services" and that the term be used consistently throughout the regulation. | No substantive changes were made in response to comments. However, DMHMRSAS has reviewed and made any necessary editorial revisions to the regulation to assure the consistency in the use of the term "individual." |
| ■ "Inspector General" | One respondent proposed changing the definition to be more consistent with Code of Virginia § 2.1-815. | DMHMRSAS has revised the proposed definition accordingly. |
| ■ "Legally authorized representative" | Two respondents recommended that provisions for human research be deleted fromthis definition. One of these respondents opined that only an individual who is fully and clearly capable of informed consent should be able to agree to participation in human research. Several other respondents recommended that the qualifications for alternative decision makers be included in this definition and that terms "consent" and "informed consent" should be clarified. | No changes were made to the proposed definition based on the comments received, except to clarify that a legally authorized representative may give "informed consent." The intent is to define all alternative decision makers that are sanctioned by law as "legally authorized representatives." This definition provides a general description of the term "legally authorized representative" as it is used in the context of this regulation. It is beyond the scope of this definition to mandate qualifications for alternative decision makers under separate provision of law. The concept of "consent' versus "informed consent has been addressed in the definition of "consent" DMHMRSAS has not adopted recommendations of the two respondents who seek to exclude individuals from participating in research if they have "legally authorized representatives." The Code of Virginia allows such |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| "Legally Authorized Representative" (cont.) | There were three respondents who questioned whether specific persons or entities (court appointed legal guardians, persons with legal power of attorney etc.) would be included in this definition. | participation in accordance with § 32.1-162.16, et seq. Failure to permit such participation raises questions of equal protection. This regulation is intended to provide a legal framework for protecting the human rights of any individual who lawfully consents to participate in such research.<br><br>These persons, if "permitted by law" to give informed consent are included within the term "legally authorized representative." |
| ■ "Local Human Rights Committee" | Two respondents recommended that the membership requirements for Local Human Rights Committees (LHRC) be reduced from seven to five members because of the difficulty in recruiting members to these committees. There was also a recommendation that the LHRC members be paid for their participation. | DMHMRSAS has reduced the membership requirements for LHRCs to at least five members in response to concerns expressed by the respondents. However, LHRC members remain volunteers and are not compensated for their services under the regulation. |
| ■ "Neglect" | At least six respondents recommended that the definition of "neglect" be changed to be the same as the definition of "neglect" under applicable federal law, 42 U.S.C. 10801. One respondent stated that the definition should be more inclusive and provide reference to specific definitions taken from federally required reporting forms under the Protection and Advocacy for Individuals with Mental Illness (PAMII) Act.<br><br>One respondent recommended including the qualification that an act of "neglect" must be "knowingly or intentionally" performed. | DMHMRSAS did not make any changes to the proposed definition except to provide the relevant Code of Virginia citation. The definition provided in the regulation is identical to the definition of "neglect" at § 37.1-1 of the Code of Virginia. It is not appropriate to use a federal law to define "neglect" when a state law exists. |
| ■ "Probation" | There was one comment that discussed the "probation" and "probationary status" in relationship to issuance of licenses for providers of mental health, mental retardation or substance abuse services. This respondent recommended that providers who are placed on "probation" should not have the same status as providers who are issued a provisional license. | Upon consideration of this comment, DMHMRSAS has eliminated the terms "probation" and "probationary status" from this regulation. Although providers violating human rights regulations are subject to certain licensing sanctions, this regulation is not intended to establish routine for probation or probationary status. Issues relevant to the |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| "Probation" (cont.) | | procedures for licensing providers, such as the conditions "probation" and "probationary status" of licensed providers will be considered in conjunction with the current promulgation process for new licensing regulations (12 VAC 35-105-10 et seq.). |
| ■ "Probationary Status" | see "Probation" above | |
| ■ "Protection and Advocacy Agency" | There were three respondents who recommended that the definition should specifically name the state agency that is designated "protection and advocacy agency, i.e., the Department of Rights for Virginians with Disabilities (DRVD). | In response to comments, DMHMRSAS has revised this definition to cite DRVD as the Virginia designated agency under the federal PAMII Act |
| ■ "Provider" | There were several comments questioning the scope of entities that are included in the definition of "provider." There were questions whether the definition included "solo practitioners" and one recommendation that the definition should not include "private practices." Several respondents indicated that the definition was too ambiguous. Another respondent indicated that the definition was too broad. | DMHMRSAS has revised this definition to improve the clarity and specificity consistent with the scope of legal authority for the regulation. Any entity or person that offers services that are licensed, funded or operated by DMHMRSAS is defined as a "provider" subject to this regulation. |
| ■ "Residential Setting" | One respondent suggested deleting "on a 24 hour basis" from this definition. | DMHMRSAS does not agree with this respondent. The concept that services are "available" from a provider "on a 24 hour basis" (although they may not necessarily be provided) is the key concept in defining this term. |
| ■ "Restraint" | Most of the respondents who commented about this definition recommended removing "protective devices" from the definition of "restraint" and inserting a separate definition of "protective device" in this regulation. Many respondents opined that the same type and level of scrutiny that this regulation imposes on the use of restraint, should not be imposed on the use of devices ordered by physicians and physical/occupational therapists for | DMHMRSAS is receptive to the concerns expressed regarding the conditions for the use of protective devices under this regulation. In order to respond to respondents' concerns, new provisions for the use of restraint have been inserted at 12 VAC 35-115-110.C.3. These provisions allow protective restraints to be used under certain |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| "Restraint" (cont.) | protective, supportive therapeutic reasons. Such protective devices may be used to achieve proper body position, balance, or alignment to compensate for a physical deficit or to allow greater freedom of mobility. Several of the respondents suggested specific definitions for "protective restraint" for inclusion in this regulation. | conditions, if a qualified professional determines that such protective restraint is necessary. This change will promote the appropriate therapeutic use of protective restraint and continue to define such devices as a type of restraint under this regulation. The new provisions at 12 VAC 35-115-110 also allow programmatic use of restraint when it is part of a behavior treatment plan under certain conditions. |
| | Concern was also expressed about the prohibition on the "programmatic use of restraint," according to 12 VAC 35-115-100 C. 5. d of the proposed regulation. | The definition of "restraint" has been reworked to improve the description of the types of restraints consistent with the revised regulatory provisions. |
| | There were also recommendations to include "chemical restraint" (pharmacological restraint) as a type of "restraint" in this definition. Several respondents also indicated that the definition should be changed to indicate that "mechanical restraints" are not used exclusively in an emergency. | "Pharmacological restraint" has been included as a type of restraint in the definition. The definition has also been changed to eliminate concept that a "mechanical restraint" is used exclusively in an emergency. |
| ■ "Restriction" | One respondent indicated that generally the definition is too broad. One respondent opined that the regulation restricts one's right to effective treatment by imposing certain limitations on the use of restraints. | DMHMRSAS has not made changes to this definition based on the comments. This definition was intended to broadly define "restriction" in order to afford maximum protection for individuals receiving services when a under this regulation. DMHMRSAS does not agree that the regulation restricts one's right to effective treatment. Changes have been made to respond to concerns expressed regarding the use of restraint, however, and "restraint" is now treated separately from "restriction." |
| ■ "Seclusion" | Several respondents stated generally that the definition appears to confuse "seclusion" with "isolation" or "isolated time out." Comments noted that that Health Care Financing Administration (HCFA) regulations for ICF-MR facilities define "isolated time out" generally as a programmatic separation of an individual from others behind an unlocked barrier until the well-defined target behavior is abated. Concerns were also expressed that "seclusion," as defined, cannot be distinguished from "secured living areas." | DMHMRSAS has clarified the definition of "seclusion" in response to comments. A statement has been inserted that will distinguish "seclusion" from "isolated time out" and "secured living areas." (See also revised definition of "time out" which is written to conform to HCFA regulations for ICF-MR facilities). |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ "Serious Injury" | Several respondents stated that "serious injury," should be defined as an injury requiring the attention of a physician, rather than a licensed health professional. Other respondents opined that the definition should be more detailed. | DMHMRSAS generally agrees with the respondents and has revised this definition to indicate that a serious injury requires the medical attention of a licensed physician. The proposed definition has also been expanded to indicate that a "serious injury" means a injury that results in "…bodily hurt, damage, harm or loss…" |
| ■ "Services" | There were several respondents who recommended clarifying definition by defining the terms "treatment," "habilitation" and "other supports" which are used as part of the definition of "services."<br><br>One respondent believes that the regulation should include a section that recommends the responsibilities for individuals receiving services (openness, providing accurate information, etc.) by which he or she can enhance the quality of the services received. | DMHMRSAS has defined "treatment" and "habilitation" in this section of the regulation, in response to the comments which have been received. DMHMRSAS has edited this definition for clarity and consistency with other parts of the regulation, but does not agree that additional changes are needed to this definition. This definition is consistent with DMHMRSAS regulations for licensing providers of services.<br><br>It is not within the scope of legal authority for this regulation to impose responsibilities on individuals receiving services. As stated previously, only programs licensed, operated or funded by DMHMRSAS are subject to this regulation. |
| ■ "Services Plan" | Several respondents noted that a "services plan" may also be referred to as an "individualized services plan" and recommended that the definition include a statement that such plan is designed to meet the specific needs and goals of the individual. Respondents also indicated that this plan should be prepared with the individual's participation. | In response to comments, the definition of "services plan" has been revised to indicate that the term "services plan may also be referred to as "individualized services plan, treatment plan, habilitation plan or plan of care." The definition has also been generally expanded to reflect the comments that have been received. |
| ■ "Special Order" | Several respondents questioned the applicability of this definition and noted that a special order is issued by an administrative agency. | DMHMRSAS has deleted this definition as this term is not used in the regulation and is, therefore, unnecessary. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ "Time Out" | Most of the sixteen respondents who commented on this definition recommended changes to conform with HCFA requirements for ICF-MR facilities. Several comments also stated that "time out" should be used as part of an individual's behavior treatment plan. There were also recommendations that time out should not exceed certain time limits and that individuals should be able to choose time out on their own. | DMHMRSAS agrees with most of the recommendations and has revised the definition in response to comments. DMHMRSAS has also inserted specific regulatory mandates consistent with HCFA requirements (time limits, etc.) at 12 VAC 35-115-110 of the proposed final regulation. Provisions are also included for "isolated time out" as defined by HCFA. |
| **Part II**<br>**12 VAC 35-115-40 *Assurance of Rights*** | | |
| ■ General Comments | One respondent recommended that subparagraph D, which lists the basis for provider responsibilities, be moved to subparagraph B, which is a more prominent position. Another respondent suggested that provisions be added that impose requirements or expectations on individuals who are receiving services. | DMHMRSAS agrees with the respondent and has reorganized the regulation as suggested. However, provisions have not been inserted regarding the expectations of individuals receiving services. DMHMRSAS does not agree that it is within the purview of this regulation to impose requirements on the individuals who are receiving services. |
| ■ Item A | Several respondents recommended inserting a list of all of the rights protected by this regulation pursuant to § 37.1-84.1 of the Code. Certain other specific rights were suggested for inclusion in this section (i.e. rights to time spent outdoors, communication technology, medical treatment in a residential facility, etc.). There were also recommendations that other relevant federal statutory provisions be referenced in this section. | DMHMRSAS did not change this section of the regulation to include a summary of relevant statutory provisions. All of the appropriate relevant legal rights are incorporated into the subsequent sections of the regulation. Therefore it was not deemed necessary to repeat these specific rights at this point in the regulation or to incorporate suggested additional rights. However, in order to assist the public to use this regulation, DMHMRSAS intends to develop a reference document for general distribution when the regulation is finalized, which will include the relevant legal citations. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B<br>(New Item C) | Several respondents suggested changes to clarify the provisions for seeking informal resolution to a grievance and filing a complaint. Respondents indicated that the clarification was needed to specify who has the right to file a complaint or seek an informal resolution and who has standing in the complaint process.<br><br>There was also one suggestion that a new Item B be created that lists specific "civil rights" that are protected by the regulation and that the existing Items in this section be re-ordered, accordingly. | As discussed in "General Comments" above, this part of the regulation was reorganized. Item B has been relocated to Item C in the proposed final regulation. In response to comments, DMHMRSAS revised this provision to state that every individual has the right to seek an "informal resolution" and that any person can file a complaint on behalf of an individual receiving services. Terminology has also been clarified consistent with other parts of the regulation.<br><br>DMHMRSAS does not agree that it is necessary to insert a section which lists specific civil (or constitutional) rights in this provision. |
| ■ Item C<br>(New Item D) | One respondent stated that the regulation should explicitly provide information about DRVD and other advocacy systems and agencies. Another comment suggested changing the provision to state "…to which he may be entitled under law or otherwise." | DMHMRSAS does not agree that it is necessary to provide specific information about DRVD in this general provision. However, in response to comments, the provision has been revised to state that the regulation will not prevent anyone from seeking other remedies to which he otherwise may be entitled under "federal or state" law. |
| ■ Item D<br>(New Item B) | Most of the fifteen respondents who commented on this item suggested revisions to help to ensure that individuals receiving services can understand their rights under this regulation. Several respondents opined that rights should be exp lained or displayed in "consumer friendly language" or in language most easily understood by the individual. It was also suggested that written notice be provided in "…the most frequently used languages" pursuant to Presidential Executive Order 13166. One comment suggested that Point 3 be revised to state that an authorized representative for an individual should be asked to sign a notice of rights when appropriate.<br><br>Another respondent proposed changing Item D, Point 5 to specifically reference the Department of Rights of Virginians with Disabilities (DRVD). | As discussed in "General Comments" above, this part of the regulation was re-organized. This Item has been relocated to Item B in the proposed final regulation. DMHMRSAS agrees with the majority of the respondents and has made several revisions to this Item to enhance communication efforts to help ensure that individuals understand their rights under this regulation. DMHMRSAS also agrees with the respondent's comments regarding authorized representatives in Point 3 regarding authorized representatives and has made appropriate revisions.<br><br>DMHMRSAS does not agree that DRVD should be specifically referenced in this provision |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **PART III *Explanation of Individual Rights and Provider Duties*** | | |
| ■ General Comment | One respondent commented that the format in this part of the regulation was confusing. | DMHMRSAS does not agree with this lone respondent. Every effort has been made to format this regulation to be easily understood by users. From all indications, this format does not appear to be unduly complicated or confusing for those who have participated in this review process. |
| **12 VAC 35-115-50 *Dignity*** | | |
| ■ General Comments | One respondent suggested changing the title of this section to "Treatment with Dignity." Another respondent opined that the entire section seems most relevant to facilities. (This respondent did not provide specific suggestions for change.) | DMHMRSAS has determined that the title of this section adequately reflects the intent of content of this section and has not made the suggested change.<br><br>No revision has been made in response to the comment regarding the relevance of the section. |
| ■ Item A | One respondent suggested that this provision be revised to include a statement to prohibit limitations on the rights individuals with any physical or sensory conditions that would pose a barrier to mobility or communication. Two other respondents proposed changes to the terminology used in this Item (to add "solely" and "as specifically limited herein"). | DMHMRSAS has included a statement to incorporate provisions for individuals with communication or sensory barriers. Changes were made to the terminology in response to the comments. |
| ■ Item B | **Point 1:**<br>Several respondents suggested revisions that would discourage the use of any inappropriate nicknames for individuals receiving services. One respondent suggested adding a right "…to be spoken to in a respectful way."<br><br>**Point 2**:<br>Several respondents suggested changes to the terminology for clarification. One respondent proposed inserting the word "including" as follows: "…<u>including</u> abuse, neglect, and exploitation." | **Point 1:**<br>DMHMRSAS does not agree that the proposed changes are needed. This provision allows providers the discretion to use either preferred or legal name.<br><br>**Point 2:**<br>The word "including" has been inserted, as suggested. This should help to clarify the provision. DMHMRSAS does not agree that any of the specific regulatory mandates, which |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | Several respondents opined that the most effective means of protecting an individual from harm would be to allow some form of programmatic restraint as a component of a multi-component behavioral treatment program. There were also suggestions to include a requirement for an Individual Nutritional Plan, a statement that nicotine deprivation is a form of abuse, and a statement that abuse, neglect and exploitation should be documented as federal crimes. | have been suggested by respondents, are appropriate for inclusion in this part of the regulation. However, DMHMRSAS has revised provisions for the use of restraint and protective to permit programmatic restraint under certain conditions. (See 12 VAC 115-100 and 12 VAC 115-110). This should respond to concerns that have been expressed. |
| | **Point 3:**<br>One respondent suggested inserting a requirement that bilingual/bicultural specialists are available. There were also comments that this provision should be limited to service plan related entitlements. It was noted that many entitlements might be beyond the scope of the provider's expertise. It was also suggested that a reference to U.S. Veterans benefits be inserted. | **Point 3:**<br>DMHMRSAS agrees that providers may not necessarily have full knowledge of available benefits and entitlements. Therefore, the provider's role is mainly to help an individual learn about and apply for benefits. This provision has been revised accordingly. A reference to U.S. Veterans benefits has also been added in response to the suggestion. DMHMRSAS does not agree that it is necessary to include a reference to bilingual or multicultural specialists in this provision. |
| | **Point 4:**<br>Respondents generally indicated that the right to private communication is not sufficiently clear in this provision. There were also recommendations that that family, friends and Long Term Care Ombudsmen, "ecclesiastically endorsed/ordained " clergy, DRVD and licensing representatives be specifically referenced in this provision. One respondent opined that updated communication technology, such as computers and cell phones should also be mentioned in this provision. | **Point 4:**<br>In response to comments, DMHMRSAS revised this provision to state that individuals will have the right to "communicate" in private with…" It was determined that the list of those who may communicate with individuals receiving services was sufficient and comprehensive, and no additional designations were included. |
| | **Point 5:**<br>It was suggested that the provision be changed to "to be provided … policies in a manner most easily understood..." | **Point 5:**<br>DMHMRSAS generally agrees and has revised the provision accordingly. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | Additional Considerations:<br>One respondent suggested that three additional points be added under Item B involving provisions for (1) fully informed or voluntary consent; (2) informed consent for any electroconvulsive treatment; and (3) designation of a personal advocate or representative. | Additional Considerations:<br>DMHMRSAS does not agree that the suggested provisions should be inserted at this point in the regulation. There are other parts of the regulation that fully address an individual's rights regarding informed consent and rights to representation and support in treatment decisions. These comments have been considered in regard to other sections of the regulation. |
| ■ Item C | There was one general comment that individuals receiving services would prefer not having to rise so early in the morning, and to be able to set their own bedtime. No specific revision was suggested.<br><br>**Point 1:**<br>Several respondents were concerned that this provisions does not assure indigent persons receiving services will have suitable clothing because it does not define "suitable clothing" or "sufficient funds" (see 12 VAC 35-115-50, Part F). The regulations should define what constitutes sufficient funds and suitable clothing. One respondent recommended inserting "…suitable clothing <u>for his exclusive use.</u>"<br><br>**Point 2:**<br>One respondent commented that individuals receiving services want better food. No specific revision was suggested.<br><br>**Point 3:**<br>The following revisions were suggested to the list of provisions that follow this Point:<br><br>**(a)** Concern was expressed that, in some cases, allowing individuals receiving services to have "private" storage space could jeopardize client safety and security. | No changes have been made in response to this comment.<br><br>**Point 1:**<br>DMHMRSAS generally agrees with the respondents and has inserted "…suitable clothing <u>for his exclusive use.</u>" However, DMHMRSAS believes availability of "sufficient funds" should be determined on a case-by-case basis, depending on individual situation and has not included a definition in the regulation.<br><br>**Point 2:**<br>No change was made in response to this comment because the current language addressed this issue sufficiently.<br><br>**Point 3:**<br>DMHMRSAS has inserted changes to (f) in response to the comment. However, it was determined that this provision generally conveys the intended meaning, and no other suggested changes have been adopted. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C<br>Point 3 (cont.) | **(d)** One respondent commented that "major areas" should be defined.<br><br>**(e)** It was suggested that that areas be free from "noxious fumes" and have "acceptable noise levels."<br><br>**(f)** It was recommended that this provision state "…rooms should be maintained at temperatures that are comfortable for the occupants and compatible with health requirements."<br><br>**Point 4:**<br>One respondent proposed changing the provision to state that individuals should have the right to attend religious services held away from the program setting and that individuals should also be able to engage in any religious practices that are not dangerous to self or others, and that do not infringe the freedom of others. Another respondent suggested that community programs and services should be obligated to provide religious services. One respondent was concerned about the use of the terminology "recognized religious practices."<br><br>**Point 5:**<br>One respondent recommended substitution of the words "…letter writing material and postage…" for "…paper, pencil and stamps…"<br><br>**Point 6:**<br>One respondent opined that individuals should have needed help in reading and writing requests for discharge and action plans.<br><br>**Point 7:**<br>Several respondents recommended that some restrictions be imposed on use of a telephone under certain circumstances. | **Point 4:**<br>DMHMRSAS has determined that the language in this provision is appropriate and has not made the changes in response to comments.<br><br>**Point 5:**<br>DMHMRSAS does not agree that the proposed change is necessary.<br><br>**Point 6:**<br>DMHMRSAS does not agree that the proposed change should be inserted in this provision, which is related to reading and writing mail.<br><br>**Point 7:**<br>The regulation allows restrictions to be imposed on individuals under certain circumstances (see "Variances" at 12 VAC 35-115-220). DMHMRSAS does not agree that provisions for such limitations are needed in this part of the regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C (cont.) | **Point 8:**<br>There were several respondents who recommended that limitations be imposed on visitors under certain circumstances.<br><br>**Additional Considerations**:<br>One respondent recommended that additional provisions be inserted in this section that require reasonable accommodations for disabilities and medical treatment (including private physicians at the individual's own expense). | **Point 8:**<br>DMHMRSAS does not agree that such provisions should be included in this part of the regulation. As stated above, this regulation provides a process for variances that could be used to impose individual restrictions when they have been justified. See 12 VAC 135-115-220.<br><br>**Additional Considerations:**<br>DMHMRSAS does not agree that such provisions be inserted in this part of the regulation. These considerations are covered in other parts of this regulation. |
| ■ Item D | Several respondents recommended referencing relevant statutes in this provision. There were also comments that individuals receiving services should be informed about proceedings that result in the disciplinary action of staff. There was also a suggestion to insert the provider's duty to make appropriate referrals to qualified specialists, including bilingual/bicultural specialists. | DMHMRSAS does not agree that the suggested revisions are needed and has not made changes in response to these comments. |
| ■ Item E (New 3)<br><br>**NOTE:** In order to clarify this part of the regulation, the format has been revised consistent with the general formatting scheme for the regulation. Item E has be changed to "3" and the Points following Item E have been re-numbered. | **Point 1:**<br>It was suggested that provisions be included to encourage simultaneous reporting of abuse and neglect to the protection and advocacy system and possibly other bodies like the LHRC. Several respondents stated that the provision should be clarified to note that it refers only to programs covered in these regulations. There was also recommendation that the consequences should be defined and discussed and reference be provided to appropriate state and federal statutes.<br><br>**Point 2:**<br>A recommendation was made to reference the appropriate federal and state statues as part of this provision. | **Point 1 (New a):**<br>In response to comments, DMHMRSAS clarified this provision to state that reporting is required at any program location "covered by these regulations." It was determined that no other suggested additions or changes were needed in this part of the regulation.<br><br>**Point 2 (New b ):**<br>DMHMRSAS does not agree that such references are necessary in this provision. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item E (New 3) (cont.) | **Point 3:**<br>More than fifteen respondents commented that the timeframe for notification was not clear in this provision. There were several comments recommending addition of a requirement that an individual's authorized representative be notified in cases of suspected abuse, neglect or exploitation. There was one comment that the Commissioner and the Governor be included in those who are notified. | **Point 3 (New c):**<br>In response to the comments, changes were made to clarify the timeframe for notification. In addition, the legally authorized representative has been included on the list of those who should be notified. DMHMRSAS does not agree that the Commissioner and the Governor should be included on the list of those who are notified by the Director. |
| | **Point 4:**<br>There were at least thirty comments regarding the proposed process for investigations and determinations regarding abuse, neglect or exploitation. Many respondents indicated that the responsibility and timeframe for reporting and decision-making should be clarified. There were comments that the provisions should require an independent decision-maker because the Director may have a conflict of interest. Others questioned the scope of the Director's authority to impose sanctions or take remedial action. | Point 4 (New d, e and f):<br>In response to comments, revisions have been made in this part of the regulation to clarify the timeframe for the Director's action and to clarify who should be notified of the results of such investigations. The provisions have been changed to require the investigator to report to the director or "<u>the investigating authority</u>." A definition of "investigating authority" has also been included in the regulation at 12 VAC 35-115-30. DMHMRSAS has also inserted the statement that "Unless otherwise provided by law, the standard for deciding whether abuse neglect or exploitation has occurred is preponderance of evidence." |
| Item E (New 3) (cont.) | There were also comments that the Commissioner and the Inspector General should be added to the list of those who should be notified on the results of the investigation. One respondent recommended the inclusion of a standard for decision-making for such allegations of abuse, neglect or exploitation. | DMHMRSAS has not included the Commissioner or the Inspector General in the list of those who are notified of a determination. However, in view of the concern expressed regarding the Director's decision-making authority, a new item (d) has been inserted (and the remaining list has been renumbered) which specifically prohibits the director from retaliating against anyone who reports an allegation of abuse, neglect or exploitation to an outside entity. In addition, a new item (f) has been added in this part of the regulation, which requires the Director to cooperate with <u>any</u> external investigation, (i.e. Protection and Advocacy Agency or the Inspector General). |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| | Point 4 (New d, e and f)(cont.)<br>There were also suggestions to specify who may file a petition to appeal the Director's action on the individual's behalf.<br><br>**Point 5:**<br>One respondent suggested that §18.2-369 of the Code be referenced in this provision and that the external protection and advocacy agency, <u>in addition to DSS</u> should receive the required information report.<br><br>**Point 6:**<br>One respondent opined that the Virginia State Police and local sheriffs have not been successful in uncovering criminal intent and person(s) responsible for violent crimes and deaths in state facilities. It was suggested that intra-agency crime task force (consisting of DSS, DRVD, DMHMRSAS Office of Human Rights and State Police or Sheriff) be convened to assist in conducting criminal investigations. Another comment suggested adding a Point 7 which cites certain provisions of the criminal Code. | Point 4 (New d, e and f) )(cont..)<br>Also in response to comments, Part e. [new (5)] of this provision has been changed to state that the individual, his legally authorized representative "<u>or anyone acting on his behalf</u>" may file a petition for a LHRC hearing, if they are not satisfied with the Director's decision.<br><br>**Point 5 (New g):**<br>DMHMRSAS does not agree that the suggested changes are necessary in this provision.<br><br>**Point 6 (New h):**<br>It is not within the purview of this regulation to address any injustice in the criminal justice system or repeat sections from the criminal Code. No change has been made in response to this comment. |
| ■ Item F<br>(New Item E) | **Point 1:**<br>Several respondents commented that the regulations should define what constitutes "sufficient funds" and such determinations should be made external to the provider's authority.<br><br>**Point 2:**<br>Several comments indicated that this provision is too broad. One respondent suggested adding that participation in religious services or practices may be reasonably limited by the provider, under certain circumstances. | **Point 1:**<br>DMHMRSAS does not agree and has not made changes in response to this comment.<br><br>**Point 2:**<br>DMHMRSAS has not made changes to this provision. No change has been made because reasonable limitations are possible under the current language. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item F<br>(New Item E) (cont.) | **Point 3:**<br>Several respondents recommended revising the provision to emphasize that the Director may open an individual's mail only in the individual's presence. There was also a suggestion that the word "probable" replace the word "reasonable." Comments also recommended that the director or his appropriately trained designee be allowed to open an individual's mail under the identified circumstances and that the director should be required to comply with The Privacy Act. | **Point 3:**<br>This provision is consistent with relevant legal requirements. Also, the director has the discretion to delegate authority under this regulation. Therefore, it is not necessary to repeat this authority to delegate in the specific provisions. There have been occasions on which dangerous contraband has caused harm in a program. In order to protect the staff and residents of the program, a new sentence was inserted which provides that communication by mail may be limited if, based on the judgment of a licensed physician or psychologist, such communication will result in "demonstrable harm to the individual's mental health." This means that there can be no restriction unless harm has been demonstrated in the past. |
| | **Point 4:**<br>Several respondents indicated that the LHRC should be required to approve any restriction on telephone usage. Other respondents questioned what is meant by the phrase "professionally accepted parameters of clinical practice" in reference to telephone restrictions. There several comments that suggested specific situations that should allow telephone use to be restricted. Other respondents opined that telephone use should not be restricted for any individuals calling the external protection and advocacy system. | **Point 4**:<br>In response to comments, the provision has been changed to require any telephone restriction to be approved by the LHRC. This regulation at 12 VAC 35-115-40 D.5 requires providers to display and provide information to individuals regarding their rights to contact the Protection and Advocacy Agency. This should preclude the restriction on the use of telephone to contact the advocacy system. As discussed previously, the reference to "professionally accepted parameters of clinical practice" has been replaced with the phrase "sound therapeutic practice" throughout the regulation to be more consistent with the statute.<br><br>Also in response to comments, new (c) has been inserted that allows providers to limit telephone access if communication with another person will result in demonstrable harm to the individual and is significantly impacting treatment in the judgment of a licensed physician or doctoral level psychologist. This means that there can be no restriction unless harm has been demonstrated in the past. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item F<br>(New Item E) (cont.) | **Additional Considerations:**<br>Several respondents suggested including several additional points in Item F (new E) to describe other specific exceptions and conditions to the provider's duties. These points included provisions for limiting the use of an individual's chosen name, limiting visitors and limiting individual privacy. | **Additional Considerations:**<br>This regulation allows variances to be granted under certain specific conditions. This permits individual restrictions to be imposed with justification on a case-by-case basis. Therefore, it is not necessary to provide an exhaustive list of all circumstances that would allow specific individual restrictions as exceptions to the provider's duties. However, consistent with the recommendations of the respondents, a new (5) has been inserted that allows providers to limit or supervise an individual's visitors if based on the judgment of a licensed physician or psychologist, such communication will result in "…demonstrable harm to the individual and significantly impact an individual's treatment…" This means that there can be no restriction unless harm has been demonstrated in the past. |
| **12 VAC 35-115-60 *Services*** | | |
| ■ General Comment | One respondent suggested that the title of this section be changed to "Treatment and Services." | DMHMRSAS does not agree. As discussed previously, the term "services" is an inclusive reference which encompasses all forms of "treatment." |
| ■ Item A | Several respondents objected to the use of the phrase "professionally accepted parameters of clinical practice." There were also comments recommending that the format of this part of the regulation be reorganized to distinguish the admission and discharge procedures requirements for the various types of providers or settings. | As indicated previously, the phrase "professionally accepted parameters of clinical practice" has been replaced with "sound, therapeutic practice" throughout this regulation to be more consistent with the relevant Code provision. DMHMRSAS does not agree that this section should be reorganized. This section is organized to be consistent with the formatting scheme used throughout this regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B | **Point 1:**<br>Several respondents were concerned that the regulation requires a complaint to be filed in writing. Respondents also indicated that the provision should specify who has the authority to file a complaint on behalf of an individual. Most respondents felt that it should be made clear that anyone acting on behalf of an individual may file a complaint. It was also recommended that that the legal basis for filing a complaint should be clarified.<br><br>It was also suggested that the human rights advocate should be required to be notified within 24 hours of the receipt of a complaint. One respondent opined that the director's written decision should be disseminated only to the individual, his legally authorized representative and the advocate. Employees should be excluded.<br><br>**Point 2:**<br>Several respondents questioned what is meant by "professionally accepted parameters of clinical practice." One respondent proposed additional standards for the delivery of clinical services. There was also a suggestion to add standards for the maintenance of an individual's service record.<br><br>**Point 3:**<br>Several respondents suggested replacing the words "carry out" with "ensure." There was also a suggestion to add a list of specific medical/behavioral screenings requirements for individual admission for services. Concern was expressed regarding perceived problems inherent in tailoring the regulation to fit all types of programs in relation to types of medical assessments that are needed. Several respondents also indicated that more detail was needed regarding the rights of individuals to have (or refuse) medical assessments/screenings and treatment. | **Point 1:**<br>DMHMRSAS agrees with the majority of the respondents and has made changes to indicate that anyone acting on behalf of an individual may file a complaint and that such complaints do not have to be filed in writing. Changes have also been made to indicate that complaints may be filed under this provision if an individual believes that his services have been limited or unlawfully denied "due to discrimination".<br><br>DMHMRSAS does not agree that dissemination of the Director's decision should be limited as suggested or that requirements be imposed for notifying human right advocates.<br><br>**Point 2:**<br>As stated previously, the phrase "professionally accepted parameters of clinical practice" has been replaced throughout this regulation with "sound, therapeutic practice" to be more consistent with the relevant Code provision. DMHMRSAS does not agree that the other suggested changes are needed in this provision. These issues are addressed in other parts of the regulation.<br><br>**Point 3 (New 4):**<br>DMHMRSAS has made several revisions to address the comments regarding admission assessments. Provisions have been inserted that screenings and assessments will be provided "as applicable" and changes will based on "ongoing review of the medical, mental and behavioral needs…" DMHMRSAS does not believe that it is appropriate for these regulations to contain detailed clinical requirements. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | **Point 4:**<br>Several respondents commented regarding the provision of services in an emergency relative to the service plan. Most respondents were concerned that emergency or crisis services would not be allowed under this section unless it is part of a treatment plan. Others indicated that the requirement might not allow the provision of services during the assessment phase of treatment. One respondent recommended insertion of "expressed" to modify "preferences" in this provision. Another respondent indicated that individuals should have someone that they trust be available when treatment and services are being planned. | **Point 4 (New 5):**<br>In response to comments, a statement was inserted indicating that responses to emergencies will be considered to be part of the service plan. The word "expressed" was also inserted.<br><br>Treatment planning requirements were not inserted in this provision. However, in view of the comments received, DMHMRSAS has determined that provisions for addressing emergencies at 12 VAC 115-100.B.7, "Restrictions on freedoms of everyday life," should be relocated to this part of the regulation. This provision has been inserted as 12 VAC 115-60 B.3. and the remaining points in Item B have been renumbered. |
| | **Point 5:**<br>Several respondents recommended revisions to require that the service plan be written clearly to ensure that the individual receiving services will understand it, and that assistance be made available, if necessary, to ensure comprehension. | **Point 5 (New 6):**<br>DMHMRSAS did not change this provision in response to comments. It was determined that the issues that were addressed by respondents were covered in other parts of the regulation. |
| | **Point 6:**<br>One respondent recommended replacing the word "integrated" with "coordinated" in this provision. Several other respondents recommended defining the term "integrated." | **Point 6 (New 7):**<br>DMHMRSAS did not make changes in response to these comments. It determined that this provision conveys the intended meaning. |
| | **Point 7:**<br>One respondent recommended deleting this point because it is a licensing issue. | **Point 7 (New 8):**<br>DMHMRSAS does not agree and has not deleted this provision as suggested. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item C | **Point 1:**<br>Several respondents commented that the terminology "professionally accepted parameters of clinical practice" was too broad and should not be used. One respondent recommended referencing that bilingual/bicultural specialists are available to ensure direct communication.<br><br>**Point 2:**<br>Several respondents suggested the insertion of provisions to require providers to involve significant others in discharge planning when the individual requests such involvement. Several respondents emphasized that alternative decision makers are particularly important for persons with mental retardation.<br><br>There were also recommendations that provisions be added to state that providers may involve appropriate CSBs without an individual's consent, for discharge planning purposes. There was also a recommendation to add criteria for the content and timeframes for discharge plans. One respondent stated that this provision is out of context and unnecessary.<br><br>**Additional Considerations:**<br>One respondent recommended adding Point 3 which states that providers may intervene with treatment in emergency situations in order to protect the individual or others from harm. | **Point 1:**<br>As discussed previously, the phrase "professionally accepted parameters of clinical practice" has been changed throughout this regulation to "sound, therapeutic practice." Requirements for communication have also been inserted. See, e.g., 12 VAC 35-115-40(B)(6) and 50(A).<br><br>**Point 2:**<br>DMHMRSAS has made several changes to this point to require providers to involve family members in discharge planning when the individual or his legally authorized representative requests this involvement.<br><br>DMHMRSAS facilities are covered under § 37.1-98.2 of the Code. Other providers will need to obtain consent. It was also determined that specific requirements for discharge plans should not be included in this provision (see definition of "individual discharge plan"). DMHMRSAS does not agree that this point is out of context and unnecessary.<br><br>**Additional Considerations:**<br>DMHMRSAS generally agrees with this respondent and has inserted provisions at 12 VAC 115-60.B to allow providers to take action in an emergency situation. (see response above) |
| **12 VAC 35-115-70 *Participation in Decision Making*** | | |
| ■ Item A | **Point 1:**<br>One respondent recommended using the word "significant" to clarify "decisions" in this provision. Another respondent commended the regulation for enabling consumer and family participation regarding planning and policy. | **Point 1:**<br>This provision was revised to clarify that individuals have the right to participate only in decisions regarding "all aspects of services." |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item A (cont.) | **Point 2:**<br>Inclusion of the phrase "…whether or not the provider can provide them thus documenting unmet need" was recommended. Several respondents indicated that this provision should state "…ability to provide within acceptable standards." | **Point 2:**<br>DMHMRSAS does not agree with the suggested revisions and has not made changes in response to comments. |
| | **Point 4:**<br>Several respondents indicated that specific requirements for consent or "informed" consent should be clarified in this point. A number of respondents were concerned about the implications of an individual's right to give consent for treatment. | **Point 4:**<br>In response to comments, DMHMRSAS has inserted a reference to the definition of "Consent" at 12 VAC 35-115-30 of this regulation. This definition provides specific guidance. |
| | **Point 5:**<br>It was recommended that the term "informed" be used to modify consent in this provision. | **Point 5:**<br>DMHMRSAS agrees with the comment and has made the recommended change. |
| | **Point 6:**<br>It was recommended that the term "informed" be used to modify consent in this provision. It was also opined that individuals should have the right to a review by the LHRC if capacity is questioned or if an authorized representative is asked to make a decision. | **Point 6:**<br>In response to comments, DMHMRSAS has inserted a reference to "Confidentiality" at 12 VAC 35-118-80 of this regulation that provides specific requirements and procedures for disclosure of information. |
| | **Point 7:**<br>One respondent recommended a specific change to clarify the terminology. There was also a comment that the process for appointment of a "legally authorized representative" may be cumbersome and expensive. There was also a recommendation to consider individual preferences for appointment of a "legally authorized representative" in this provision . | **Point 7:**<br>In response to the comment, DMHMRSAS clarified the terminology as suggested. The Code of Virginia requires the appointment of legally authorized representatives under certain specific conditions. While DMHMRSAS recognizes the regarding difficulties in obtaining legally authorized representatives, it is not within the scope of this regulation to address this difficulty. DMHMRSAS agrees that this provision should recognize individual preference when legally permissible. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item A (cont.) | **Point 8:**<br>There was a recommendation that reference to the section on legally authorized representatives and the Health Care Decisions Act be inserted in this provision. Two respondents indicated that professional independent assessment of capacity to consent should be done at the individual's request at service provider's expense. | **Point 8:**<br>DMHMRSAS does not agree that it is necessary to insert the recommended references in this provision. The regulation provides authority for the LHRC to require a provider to pay for an independent assessment for an individual under certain circumstances. This is covered in other parts of this regulation. No change has been made to this provision. |
| | **Point 9:**<br>One respondent recommended that this provision be separated into two parts, requests for admission and requests for discharges. It was also recommended that an individual be prohibited from requesting a discharge from a service on a daily basis. | **Point 9:**<br>DMHMRSAS does not agree with the suggested changes. |
| | **Additional Considerations:**<br>There were several suggestions for the additional rights to be added under Item A. These provide for (1) LHRC review of determinations of an individual's capacity for consent; (2) LHRC review of appointment of authorized representatives; (3) accompaniment by someone the individual trusts when participating in treatment planning; and (4) signature by the individual in the service record to indicate agreement with treatment planning decisions. | **Additional Considerations:**<br>DMHMRSAS does not agree that the additional provisions regarding the LHRC review are needed in this part of the regulation. LHRC processes and reviews are covered in detail other parts of this regulation. However, DMHMRSAS has inserted two new points under Item A, in response to suggestions ( former Point 9 has be renumbered 11). New Point 9 involves the right of the individual to be accompanied by someone he trusts when participating in treatment planning, and new Point 10 involves the right of the individual to sign his service record to indicate agreement with treatment planning decisions. |
| ■ Item B | **Point 1:**<br>One respondent suggested that this section be clarified to state that providers will assure that individuals will be able to participate in decisions regarding all aspects of services that affect him. | **Point 1:**<br>DMHMRSAS agrees with the suggestion and has made the revision. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | **Point 2:**<br>Several respondents were concerned that this provision grants too much autonomy to providers who serve persons with mental retardation and recommended clarifying this provision in relationship to statutes. One respondent suggested inserting a requirement for providers to make referrals to available bilingual/bicultural specialists, of the individual's choice, who can ensure direct communication with the client. | **Point 2:**<br>For consistency and in response to comments, this provision was clarified to limit the scope to decisions "regarding all aspects of services…" and to require providers to honor preferences "…to the extent possible…" DMHMRSAS does not agree that specific legal citations should be referenced in this provisions or that reference should be made to bilingual/bicultural specialists. These aspects are covered in other parts of this regulation. |
| | **Point 3:**<br>Several respondents recommended inserting "…and/or the individual's authorized representative the opportunity…" Two respondents questioned what is meant by "meaningful." | **Point 3:**<br>DMHMRSAS has not made changes in response to these comments |
| | **Point 4:**<br>One respondent suggested inclusion of family, friends, and the State Long-Term Care Ombudsman. | **Point 4:**<br>DMHMRSAS does not agree that the specific references are needed at this point in the regulation. |
| | **Point 5:**<br>Several respondents commented that it is difficult to obtain parental consent or notify parents in some situations. One respondent opined that a minor's ability to obtain treatment is based in part upon that child's capacity to make rational and informed choices regarding treatments and suggested defining the term "competent minor." One respondent noted that the Code reference was incorrect in this provision. | **Point 5:**<br>A reference was inserted to cover situations in which a local department of social services has custody of a minor. The Code citation has been corrected. This provision, as written, complies with statutory requirements. Therefore, no additional changes have been made. |
| | **Point 6:**<br>Several respondents expressed concern that it may be difficult to obtain consent to continue emergency treatment beyond 24 hours. | **Point 6:**<br>This regulation provides for treatment to be continued without consent under certain specific conditions. No change has been made to this provision. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | **Point 7:**<br>Several respondents were concerned that finding someone to make an independent evaluation of an individual's capacity may be difficult or costly. Another respondent suggested that the word "currently" in this provision be changed to "directly." One respondent noted that individuals might prefer that someone who has prior knowledge of the individual conduct the evaluation. | **Point 7:**<br>The word change has been made in response to the suggestion. DMHMRSAS believes that the requirement for an independent evaluation of capacity provides protection of the rights of the individual receiving services and has not made changes in response to the concerns that have been expressed. Clarification has been added regarding the meaning of a qualified professional. |
| | **Point 8:**<br>One respondent suggested that the timeframes should be more specific in this provision. Several other respondents provided suggestions for clarifying this provision. One respondent was concerned that an independent evaluation would only be available to those with resources to pay and that finding independent evaluators may be difficult in some areas. Another respondent opined that individuals should always have the right to forgo treatment. There was also a comment that the LHRC does not have time to conduct reviews as required by this provision. | **Point 8:**<br>DMHMRSAS has clarified the timeframe for obtaining an independent evaluation, as suggested, and has made revisions to the terminology for consistency and clarity. DMHMRSAS has not made other changes in response to comments. It has been determined that this process is a reasonable means to assure protections for individual rights. |
| | **Point 9:**<br>Two respondents indicated that the Director should be required to consult with the LHRC and the Treatment Team before appointing a legally authorized representative (LAR). It was also suggested that the individual be notified when an LAR is appointed. Many respondents commented about the order of priority for appointments and suggested consideration given to individual situations and preferences (i.e. common-law couples, gay and lesbian patients in long-term relationships, etc.). On respondent suggested inserting in Point 9.b "…any other relative of the individual, <u>unless the director finds that a person lower in priority is better qualified.</u>" Several respondents provided similar comments. | **Point 9:**<br>DMHMSAS has made revisions in order to respond to comments and to make this provision more consistent with the Code requirements. Point 9 (b) has been changed to allow a Director to change the order of priority in appointment of an individual LAR when a person in lower priority is clearly better qualified. This would allow greater consideration of an individual's situation and needs. However, DMHMRSAS does not agree that it is appropriate or necessary for the director to consult with the LHRC or treatment team regarding the appointment of an LAR because the parameters for such appointments are clearly prescribed by this regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | There were also approximately ten comments and questions regarding "next friend" (Point 9. c.). Several of these respondents questioned the legal authority for a "next friend" specifically in reference to the Health Care Decisions Act. There were also at least two respondents who questioned the criteria for a "next friend" (i.e. it is too restrictive to require the person to have lived with the individual for six months). At least three respondents specifically commended the regulations for including provisions for "next friend." There were two respondents who commented that LHRC review might not always be necessary for appointment of a "next friend." | To ensure consistency with the Health Care Decisions Act, DMHMRSAS has revised Point 9.c. This concept of "next friend" allows the Director to appoint an LAR who may be clearly be better qualified that someone designated on the priority list. DMHMRSAS has found that the provisions for "next friend" are do not conflict with relevant Code provisions but enhance the rights afforded under Code. However, in order ensure maximum protection for the individual receiving services, it was determined that appointment of a "next friend" should be considered by the LHRC. A definition of the term "next friend" has been included in the regulation. |
| | **Point 10:**<br>It was recommended that an exception to this provision should be made when an employee is a relative or an employee is not directly involved in the individual's treatment. One respondent indicated that this provision should be revised to be consistent with the Code of Virginia § 37.1-84.1. A.4. Two respondents indicated agreement with this provision. | **Point 10:**<br>DMHMRSAS has changed this provision to comply with the Code of Virginia § 37.1-84.1. A.4. This provision states "…unless the employee is a relative or legal guardian." |
| | **Point 11:**<br>Several respondents indicated that this provision was not clear. Two respondents suggested requiring review by the LHRC before resorting to court action when a determination of perpetual lack of capacity is made. One respondent suggested changing this provision to specifically reflect § 37.1-134.21 of the Code of Virginia. One respondent suggested inserting provisions for allowing a provider to act as a legally authorized representative if there is no other person who is available. | **Point 11:**<br>This provision has been revised in accordance with § 37.1-134.21 of the Code of Virginia. The law does not allow providers of services to act as a Legally Authorized Representative for individuals who are in their care. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | **Point 12:**<br>Several respondents were concerned about the individual's right to challenge treatment decisions. One respondent stated that if the individual has the right to challenge every treatment decision, the LHRC would be over-burdened and treatment would be delayed. One respondent suggested that the Director notify the advocate only if a resolution is not reached. Several non-substantive revisions were suggested for clarity. | **Point 12:**<br>DMHMRSAS does not agree with the substantive comments. Under this regulation, an individual (or his legally authorized representative) should always have the ability to file objections to decisions regarding service or treatment that affect him. The advocate should be notified immediately when an individual files a complaint or an objection. Several non-substantive changes were made in response to comments for consistency and clarity. |
| | **Point 13:**<br>Four respondents suggested that specific timeframes be established for reviewing and reconsidering the individual's capacity for consent. There were also comments that reconsideration and review of an individual's capacity to consent is not appropriate for individuals with mental retardation. Individuals in mental retardation facilities will require surrogate decision makers throughout their lives. | **Point 13:**<br>In response to comments, DMHMRSAS has inserted a timeframe for reconsideration of an individual's capacity to consent (every six months). It is also stated that individual's requests for such reviews will be considered in a timely manner. However, discretion will available to providers to decide whether such reconsideration is necessary in accordance with "sound therapeutic practice." |
| | **Point 14:**<br>One respondent commented that this point is confusing and suggested that a caveat be included for the different Code sections under which a person may be committed. Another respondent suggested inserting references to the appropriate Code sections. | **Point 14:**<br>In response to comments, DMHMRSAS has reorganized Point 14 to distinguish provisions for the different types of admissions/discharges according to the Code requirements as follows: (a) Voluntary admissions; (b) Involuntary commitments; (c) Certified admissions; and (d) Against medical advice. Several non-substantive changes were made to enhance clarity. |
| | One respondent believes that the timeframe for developing a discharge plan was too short. Other respondents questioned why the timeframes are different for minors and adults. One respondent was concerned that there is no requirement that the provider assist an individual in writing a request for discharge. Several respondents suggested non-substantive or editorial changes. | DMHMRSAS does not agree that additional changes are needed in response to the comments. The provisions in this part of the regulations regarding discharges comply with the applicable Code requirements. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item C | **Point 1:**<br>Several respondents indicated that the phrase "substantial property damage" should be defined. Another respondent commented that providers should be required to promptly inform to the interested parties – particularly a legally appointed guardian – of the need for taking the emergency action, and where practicable, gain the assent of the individual involved and his/her authorized representative.<br><br>Two respondents recommended adding provisions requiring that emergency treatment to be reviewed every 24 hours. One respondent recommended inserting the following:<br><br>"After 24 hours, the emergency must be reviewed by another qualified physician, and the human rights advocate notified within three hours thereafter "After 72 hours the human rights committee chair must be notified, the emergency treatment ended and a treatment plan developed and implemented…"<br><br>**Point 2:**<br>There were comments that this provision should to conform to applicable statutes—the Health Care Decisions Act, § 54.1-2983 of the Code of Virginia. | **Point 1:**<br>In response to comments, the phrase "substantial property damage" was deleted here. However, the phrase continues to appear in the definition of "emergency." The provision was expanded to include requirements for notification of the legally authorized representative when emergency treatment is provided. Requirements have also been added for treatment that extends beyond 24 hours.<br><br>**Point 2:**<br>This section is conformed to and now references the Health Care Decisions Act. |
| **12 VAC 35-115-80 *Confidentiality*** | | |
| ■ Item A | One respondent recommended the addition of specific statutory references in this provision, including reference to the Privacy Act. Another respondent proposed to add a specific statement describing provisions for release of a minor's records pursuant to § 32.1-127:03.D.1 of the Code of Virginia. Another respondent proposed adding provisions to authorization for release of information to a prospective authorized representative in an emergency. | DMHMRSAS does not agree that specific statutory references are needed in this statement. Specific statutes have been cited, when relevant, throughout this part of the regulation. Provisions for the release of a minor's records and for the release of information to an authorized representative are covered in other parts of 12 VAC 35-115-80. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B | **Point 1:**<br>There were general comments that the regulation should be partitioned to clearly relate to the "…differences in functions uniquely associated with MH, MR and SA." | **Point 1:**<br>DMHMRSAS does not agree. The protections afforded by this regulation are intended to apply equally to all individuals receiving services. The State MHMRSAS Board adopted this as a policy several years ago. The regulation allows for variances to be granted with justification, when individual circumstances warrant such variances. |
| | **Point 3:**<br>One respondent recommended adding the phrase "…records, and shall convey information in a secure manner." Another respondent suggested citing the Privacy Act in this section in order to specify the full intent of the provision and to state the remedies for breaches. | **Point 3:**<br>DMHMRSAS agrees and has added the proposed phrase regarding conveyance of records. DMHMRSAS does not agree that the Privacy Act needs to be cited. |
| | **Point 4:**<br>Two respondents proposed including a reference to a "legally authorized representative." In addition, specific clarification was suggested regarding the consent in the case of a minor pursuant to § 54.1-2969 of the Code of Virginia. There was also a comment that the age of a "minor" should be defined. One respondent indicated that this section appears to contradict 12 VAC 35-115-90 A of this regulation. | **Point 4:**<br>DMHMRSAS has inserted the reference to the "legally authorized representative" as suggested. Changes have also been made to clarify this provision in accordance with § 54.1-2969 of the Code of Virginia, which relates to consent for treatment by and on behalf of minors. Because this statutory provision specifies the age of minors in regard to consent, such guidance was not repeated in this regulatory provision. This provision was not found to contradict other parts of the regulation. |
| | **Point 6:**<br>One respondent suggested deleting the reference to "CSB or private provider" in this provision. Several respondents requested that the "appropriate" state or federal statutory references be cited. There were also comments that this provision be made compliant with HIPPA. | **Point 6:**<br>DMHMRSAS has deleted the references to "CSB or private provider" as suggested. It was determined that this provision was consistent with the relevant statutory provisions. HIPAA compliance was addressed by adding "federal regulation." |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item C | **Point 1:**<br>One respondent recommended that changes be made to require individuals to name family members and encourage family relationships. Another respondent suggested emphasizing that this should occur in the context of written consent for disclosure.<br><br>**Point 2:**<br>Several respondents recommended describing the specific circumstances under which information may be legally disclosed without violating confidentiality (i.e. emergencies, reporting diseases, child abuse or neglect).<br><br>**(a)**<br>One respondent recommended inserting specific criteria and actions required in order for a director to legally disclose information without consent. Several respondents indicated that this provision was too broad and specific statutes should be referenced.<br><br>**(b)**<br>It was suggested that this provision cite Privacy Act requirements and be related to the statutes which address MH, MR and SA. There was also one suggestion to add requirements for record keeping when information in disclosed without consent.<br><br>**(c)**<br>One respondent questioned whether this provision was consistent with specific federal and state Code requirements.<br><br>**(d)**<br>Several respondents suggested that specific statutory requirements including §32.1-127.1:03 of the Code of Virginia and others be identified and discussed in this section of the regulation. There were comments that this provision is not consistent with case law and relevant statutory requirements. | **Point 1:**<br>In response to the comment, changes have been made to indicate that consent must be obtained in order for a provider to contact family members. However, DMHMRSAS does not agree that individuals should be required to name members of their family to be contacted.<br><br>**Point 2:**<br>These specific circumstances are addressed in (a) through (m) below. Therefore, it is not necessary to include such information under Point 2. However, non-substantive revisions have been made in Point 2 for clarification.<br><br>**(a)**<br>DMHMRSAS did not insert specific criteria and required actions, as suggested. DMHMRSAS has determined that this part of the regulation is consistent with relevant statutory provisions and has not inserted additional Code citations, as suggested.<br><br>**(b)**<br>Specific statutory requirements for disclosure of information and record-keeping are addressed elsewhere in this regulation. DMHMRSAS did not make changes in response to comments.<br><br>**(c)**<br>DMHMRSAS has determined that this provision is consistent with the relevant statutory requirements.<br><br>**(d)**<br>This provision is consistent with relevant federal and state statutory requirements. DMHMRSAS has determined that additional references and discussion of such statutory requirements are not needed in this provision. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C (cont.) | **(e)**<br>There were comments that this provision is not consistent with case law and relevant statutory requirements and that appropriate statutory references should be identified and discussed. | **(e)**<br>DMHMRSAS has determined that this provision is consistent with relevant statutory requirements and has not made changes. |
| | **(f)**<br>One respondent indicated that an individual should be informed that his records may be made available to the LHRC and SHRC. Another respondent suggested that the word "may" be changed to "shall." Other respondents indicated that the provision is not consistent with case law and relevant statutory requirements and that appropriate statutory references should be identified and discussed. | **(f)**<br>Contrary to comments, DMHMRSAS has determined that this provision is consistent with relevant case law and statutory requirements. Individuals are always aware when their records are disclosed to the LHRC and SHRC. This process is covered in other parts of this regulation. The term "may" was not changed to "shall," as suggested. This provision does not mandate disclosure of information to the LHRC or SHRC. Rather, this part of the regulation allows the provider to disclose information to the LHRC or SHRC without violating confidentiality requirements. |
| | **(g)**<br>One respondent suggested replacing the word "may" with "shall" in this provision. Other respondents indicated that the provision is not consistent with case law and relevant statutory requirements and that appropriate statutory references should be identified and discussed. One respondent opined that the reference "similar activities" (g. 6.) was too vague. | **(g)**<br>In response to the comment, DMHMRSAS has clarified the term "similar activities." Contrary to comments, DMHMRSAS has determined that this provision is consistent with relevant statutory requirements. DMHMRSAS does not agree that it is appropriate to replace the term "may" with "shall," as suggested. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C (cont.) | **(h)**<br>One respondent questioned whether a CSB would need a "release of information" signed by the individual receiving services, to discuss discharge planning with the state hospital. Another respondent questioned whether information is confidential outside the "human service system." Other respondents indicated that the provision is not consistent with case law and relevant statutory requirements and that appropriate statutory references should be identified and discussed. | **(h)**<br>No change was made in response to comments. The Virginia Code allows the CSB and state hospital to share information regarding an individual receiving services without obtaining consent from the individual (but only under specific statutory requirements). This authority does not extend to other service providers. DMHMRSAS has determined that this provision is consistent with relevant statutory requirements. |
| | **(i)**<br>Several respondents suggested changing the word "may" to "shall" in this provision. Other comments suggested changes to the terminology. One respondent suggested changing "Protection and Advocacy Agency" to DRVD. | **(i)**<br>DMHMRSAS does not agree that it is appropriate to change "may" to "shall' or make other changes to the terminology. This provision, as written, is consistent with PAMII requirements under federal law. For the reasons discussed previously in this document, the reference to the "Protection and Advocacy Agency" has not been changed. |
| | **(j)**<br>Four respondents questioned whether all of the listed conditions would have to be met prior to the disclosure of information for historical research. It was suggested that the term "bona fide" be defined and references to appropriate statutes be provided in this section. One respondent made specific suggestions to add requirements regarding the process for obtaining consent and measures for assuring that individually identifiable information will not be released. One respondent opined that this section is irrelevant and should be omitted. | **(j)**<br>In response to comments, this section has been clarified to state that all of the listed conditions must be met in order to disclose information for historical research. However, it has been determined that it is not necessary, at this point, to include the suggested additional requirements for disclosure of information or to describe what may constitute bona fide research in view of the range of research topics or circumstances that may be encountered. DMHMRSAS has not deleted this section or made additional changes in response to comments. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C (cont.) | **(l)**<br>Several respondents indicated that additional information is needed to describe what is meant by a "present threat." It was suggested that the word "disclose" be changed to "communicate." There were also comments that Code citations should be referenced specifically, § 54.1-2400.1B and § 54.1-2400.1C, to describe what act or acts by the service provider will constitute taking precautions to protect third parties. There were also comments that the applicability of this provision to MH, MR and SAS populations should be provided.<br><br>**(m)**<br>One respondent suggested mandating disclosure to DRVD and the Inspector General.<br><br>**Point 3:**<br><br>**(a)**<br>There were comments that this section creates paperwork for providers and disclosures become anti-consumer. Another group of respondents opined that this section should reference controlling statutes although the respondents did not identify specific Code references.<br><br>**(b)**<br>One respondent indicated that this section was burdensome and impractical. Another group of respondents opined that this section should reference controlling statutes although these respondents did not identify specific statutory references.<br><br>**(c)** *(New 4)*<br>There were comments that that the phrase "strong consideration" should be referenced to state and local statutes to justify the "legal override" of informed consent and the Privacy Act. There were five comments that this provision as written is generally too vague and non-directive. | **(l)**<br>In response to comments, changes have been made to clarify the terminology, as suggested. However, DMHMRSAS has determined that the revised provision is consistent with the applicable Code requirements and does not believe it is useful to reference specific statutes in this section or distinguish requirements for different populations.<br><br>**(m)**<br>DMHMRSAS has determined that is not applicable for this provision to "mandate" disclosure. It provides that such information may be provided without violating confidentiality requirements. No change has been made.<br><br>**Point 3:**<br><br>**(a)**<br>In response to the respondent, the reference to "summary" has been changed to "notation" in order to reduce the burden to providers. No other change was made.<br><br>**(b)**<br>DMHMRSAS does not agree with the respondents. The requirement to notify an individual when information is disclosed not unduly burdensome. DMHMRSAS has not included references to specific statutory requirements.<br><br>**(c)** *(New 4)*<br>DMHMRSAS does not agree with the comments. This section provides direction to providers for situations when disclosure is not a requirement by law. This provision has been re-numbered as (4) to be consistent with the numbering scheme and clarify the format. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **12 VAC 35-115-90** ***Access to and Correction of Services Records*** | | |
| ■ Item A | It was suggested that this section include a reference to The Privacy Act and Health Decisions Act. One respondent commented that § 2.1-373.1 of the Code of Virginia provides that the State Long Term Care Ombudsmen has access to patients and their records in state hospitals. Several other respondents indicated that this provision was not clear regarding the minor's right to see his own service record. One respondent also suggested that a reference to the individual's legally authorized representative be inserted | DMHMRSAS does not agree that it is necessary to reference additional statutes in this provision. This section now references the Privacy Protection Act (§ 2.1-382 of the Code of Virginia). The requirement that a minor must have permission from his parent or guardian to see his service record is consistent with statute and therefore has not been changed. However, in order to clarify this provision in response to comments, the word "certain" has been inserted as follows: "… an individual has a right to let <u>certain</u> other people see his service record…" |
| ■ Item B | **Point 1**:<br>One respondent commented that the term "service record" should be defined and guidance should be given as to when an individual should be informed that he has access to his service record.<br><br>**Point 4**:<br>Most of the seven respondents that commented on this section indicated that the process for restricting an individual's access to service records should be clarified and expanded. Several respondents suggested specific changes to the proposed process, including a mechanism for review or challenge when access to a service record is denied. One respondent recommended that the regulation "recite those Code provisions on limitation of access in the body of the document."<br><br>**Point 5**:<br>One respondent was concerned about the implications of allowing individuals the right to see and correct service records. Another respondent opined that the terminology "…not pertinent, not timely or not necessary…" may be subject to dispute. (This respondent offered no suggestions for clarification.) There were several specific suggestions for | **Point 1**:<br>The term "service record" is defined in the definitions section (12 VAC 35-115-30) of this regulation. DMHMRSAS does not agree additional guidance is needed.<br><br>**Point 4**:<br>In response to comments, a new Point 5 has been added to this item (and the remaining points re-numbered) which describes the provider's duties when an individual's access to his service record is denied. This provision also describes the basis upon which an individual may appeal to the LHRC and SHRC. There are also requirements for documentation by the provider. The relevant Code citations are not recited as part of this provision. Guidance will be available from DMHMRSAS.<br><br>**Point 5**: (re-numbered **6.** in draft final regulation)<br>In response to comments one change was made to (a) of this provision to clarify record-keeping requirements. DMHMRSAS has determined that this provision conforms to the relevant federal requirements at 42 CFR Part II and § 32.1-127.1:03.F of the Code of Virginia. The Code of |

| Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq. | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | clarifying the documentation and record-keeping requirements in (a). There were five respondents who commented that this section should be re-worked in accordance with 42 CFR Part II.<br><br>There was one respondent who recommended adding the following: "The advocate shall be notified and, upon request, the provider shall disclose the record to the individual's authorized representative and/or a lawyer, physician or psychologist designated by the individual or his authorized representative." There was another respondent who suggested adding specific conditions for denying access to a service record. Another respondent suggested add a provision that access to a service records should not be denied if the purpose of the denial is to prevent him from filing a complaint with the protection and advocacy agency, LHRC or the Inspector General. | Virginia provides authority for providers to refuse access to services records under specific circumstances to the individual or anyone who is authorized to act on his behalf. DMHMRSAS has not made any additional change to this provision in response to comments. |
| ■ Item C | Several respondents objected to the requirement that a physician or a licensed psychologist must determine whether an individual's access to his service record may be denied. One respondent suggested including right of the individual to a second opinion. There were also comments that the language at Code of Virginia §32.1-127.1:03 should be included and the distinction should be made for MH, MR and SAS populations in this provision. One respondent suggested clarifying that documentation of any decision to deny access to the service record shall become a permanent part of the individual's record. | This provision is consistent with §32.1-127.1:03. F., of the Code of Virginia, which requires that an attending physician or a licensed psychologist to determine whether copies of a service record may be furnished to an individual, upon request. DMHMRSAS does not agree that it is necessary to restate this Code provision in its entirety or that changes should be made to distinguish service populations. It was determined that this provision was clear as stated and no changes have been made. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **12 VAC 35-115-100** ***Restrictions on the Freedoms of Everyday Life*** | | |
| ■ Format Note | This regulation has been reformatted to divide Section 12 VAC 35-115-100, as drafted in the initial proposed regulation, into two sections as follows: 12 VAC 35-115-100 "Restrictions on Everyday Life" and 12 VAC 35-115-110 "Use of Seclusion, Restraint and Time Out." Some provisions that were part of the initial proposed Section 12 VAC 35-115-100 have been relocated and revised in the new Section 12 VAC 35-115-110. The remaining sections of the regulation have been re-numbered in the final draft. | |
| ■ General Comment | Several respondents suggested specific revisions to this section to enable conformance with new federal requirements for seclusion and restraint and to clarify the provisions. One respondent recommended defining the term "qualified professional" which is used in this section. | DMHMRSAS has made format revisions to this part of the regulation which should help to clarify the provisions. In response to comments, this section has been re-focused to encompass general provisions for restrictions on the freedoms of everyday life. A new section, 12 VAC 37-115-110 "Use of Seclusion, Restraint, and Time Out," has been developed that provides specific provisions for seclusion, restraint and time out consistent with sound therapeutic practices and legal requirements. The term "qualified professional" has not been defined in this section because the definition would differ depending on the services setting and the type of restriction. The regulation defers to the highest standard governing each provider. |
| | Several respondents stated that different regulations should be developed for persons with mental illness and mental retardation, particularly in regard to 12 VAC 35-115-100 "Restrictions on Freedom of Everyday Life." | DMHMRSAS does not agree that separate regulations are needed for different service populations or disability groups. The human rights protections afforded by this regulation should be applied equally to all individuals receiving services in programs licensed, funded or operated by DMHMRSAS. The regulations provide that variances may be granted on a case-by-case basis if individual circumstances warrant. No change has been made in response to this comment. |

**Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.**

| Section | Comment | Response |
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| ■ Item A | One respondent opined that consideration should be given to serving individuals in the least restrictive environment before imposing physical or chemical restraints. One respondent stated that the provisions for seclusion and restraint in this section should be revised to be consistent with good professional practices and federal requirements.<br><br>**Point 1**:<br>Several respondents questioned whether this provision implies that restrictions are unnecessary. Other respondents questioned whether this provision applies to children. One respondent suggested adding specific requirements for accommodations according to the Americans with Disabilities Act in (d).<br><br>**Point 2**:<br>One respondent propose changing the provision to "Receive services …of his freedom *and ability to obtain equal access to services."*<br><br>**Point 3**:<br>Several respondents suggested listing all types of restraints in this provision. There were concerns expressed that this statement does not make clear whether all restrictions are prohibited or whether it means that unnecessary use of restrictions are prohibited. | DMHMRSAS generally agrees with the respondents and has made relevant changes to this regulation. (See new section 12 VAC 37-115-110, "Use of Seclusion, Restraint, and Time Out.") Specific references to seclusion and restraint have been eliminated from the provisions in this section and re-written in the new section 12 VAC 37-115-110.<br><br>**Point 1**:<br>This provision, as written, means that restrictions can never be used when they are unnecessary. The provisions for restriction are broad and are intended to cover all types of restrictions, including restrictions that may be imposed on children.<br><br>**Point 2**:<br>DMHMRSAS does not agree that this change is necessary.<br><br>**Point 3**:<br>As discussed previously, this section has been re-focused and specific provisions for seclusion and restraint are provided at 12 VAC 37-115-110. The definition of restraint is now far more detailed and includes both types and purposes of restraints. Therefore, this provision has been deleted from this section. |
| ■ Item B<br>■ Item C | One respondent expressed concern that restrictions may be used indiscriminately, sometimes as reprisals for assertive behaviors. Therefore, individuals should have the opportunity to report to the advocate regarding his perceptions of the circumstances surrounding restrictions. One respondent opined that the section was confusing and should be re-formatted. | DMHMRSAS agrees with this respondent that restrictions should never be used for reprisal and has built safeguards into this regulation. (See 12 VAC 35-115-110.B.1) This regulation also allows individual to have unrestricted access to advocates. All of the provisions related to seclusion and restraint have been omitted from this section. Some revisions have been made to the remaining provisions in this section for clarity and consistency. |

**Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.**

| Section | Comment | Response |
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| ■ Item B<br>■ Item C (cont.) | With the exception of the above, nearly all of the other comments received about Items A and B pertained to provisions for seclusion, restraint and time out.<br><br>The following is a summary of the substantive comments received from respondents regarding provisions for seclusion, restraint and time out:<br><br>■ The criteria for removal should be specifically documented when authorization for seclusion, restraint or time out is given<br><br>■ Programmatic use of restraint should be permitted, particularly in training centers. Restraint should be permitted as part of an approved behavior treatment plan. The LHRC should not be required to approve behavioral treatment plans prior to implementation of seclusion, restraint or time out<br><br>■ Distinguish "protective devices" from restraint. Should refer to these devices as "supports." The criteria for restraint should not apply to "protective devices"<br><br>■ Standards for time limits and environmental conditions for use with restraint and time out should be explicit. Time out should not restrict movement.<br><br>■ Requirements for the frequency and type of the staff observation required for individuals placed in seclusion or restraint should be reasonable and specific.<br><br>■ The regulation should allow "locked time out" when is used as part of a approved treatment plan for individuals in ICF-MR facilities. This is consistent with HCFA regulations.<br><br>■ Provisions should clarify what is meant by the term "qualified professional." Professionals should not have overly broad powers. | DMHMRSAS has considered all of the comments that were received regarding the provisions for seclusion and restraint in formulating the new section 12 VAC 37-115-110. The revised section:<br><br>■ Requires seclusion or restraint to end when the established criteria for removal are met<br><br>■ Specifies time limits for episodes of seclusion and restraint which are to be documented in written orders. Authorization for seclusion or restraint procedures may not be given on an "as needed" basis.<br><br>■ Establishes specific requirements for provider monitoring and observing individuals placed in seclusion or restraint<br><br>■ Requires providers to develop written policies, consistent with federal and state statutes and regulations, sound therapeutic practice etc., for seclusion and restraint. Such policies shall be submitted for review and comment by the LHRC before they are implemented, changed or upon the request of the advocate or SHRC.<br><br>■ Allows providers to use isolated time out, as defined by HCFA, at certified ICF-MR facilities<br><br>■ Allows the emergency use of seclusion and restraint under specific conditions<br><br>■ Establishes provisions for using restraint or seclusion as part of a behavior treatment plan under certain conditions |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B<br>■ Item C (cont.) | ■ The approval of behavioral treatment plans by an external review committee and the LHRC before implementation is unrealistic. The time required for its review and the LHRC review is likely to prevent the provision of treatment in a timely manner and discourage the development of behavioral treatment plans in favor of the use of emergency policies and procedures. | ■ Establishes provisions for use of restraint when determined necessary by a qualified professional for "effective treatment of the individual or to protect him or others from personal harm, injury or death." |
| **12 VAC 35-115-110 *Work* (Re-numbered 12 VAC 35-115-120 in the final draft regulation)** | | |
| ■ General Comment | One respondent commented that this section "…is an important step forward in recognition of the importance of meaningful activities and is to be commended." | DMHMRSAS appreciates this acknowledgement. No change is necessary in response to this comment. |
| ■ Item A | One respondent questioned whether the provisions in this section conflict with certain service programs that require employment, when appropriate, within a specified time period or require residents to share in housekeeping duties of the facility through assigned chores and duties. One respondent suggested revising this statement as follows: "…while receiving services, consistent with the individual's service needs." There was also a suggestion to define "therapeutic work." | In response to the comments and concerns that have been expressed, this provision has been clarified to state that "Individuals have a right to engage or not to engage in work or work related activities consistent with their service needs…" |
| ■ Item B | **Point 1**:<br>There were comments that this provision should include a reference to child labor laws. | **Point 1**:<br>Providers must comply with all applicable federal and state laws. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item B (cont.) | **Point 4**:<br>Several respondents suggested inserting revisions to ensure that access to services or housing would not be denied because an individual refuse to perform work or personal maintenance. One respondent questioned whether this provision was consistent with licensing requirements for providers. | **Point 4**:<br>DMHMRSAS does not agree that additional clarification is needed. It has been determined that this provision is consistent with licensing requirements. In order to clarify the intent and to be consistent with formatting, this provision was relocated to a new Item C in this section "Exception to the provider's duties." The remaining provisions in the section have been re-numbered. |
| | **Point 5**:<br>One respondent opined that this provision is burdensome. Providers should not be required to give the rules and regulations to individuals receiving services. | **Point 5**:<br>DMHMRSAS does not agree with this comment. |
| | **Point 6**:<br>One respondent commented that this provision conflicts with garnishment laws. Several respondents were concerned that this provision may adversely affect some individuals in substance abuse programs because traditional funding streams are frequently not available for these services. | **Point 6**:<br>To be consistent with garnishment laws, changes have been made to state that providers shall not deduct the cost of services from wages unless ordered to do so by a court. DMHMRSAS does not agree that changes are necessary to address other comments. |
| | **Point 7**:<br>There were several comments that this point should address piece-rate-wages as related to certification by the U.S. Department of Labor. Other respondents suggested including a statement requiring a vocational environment to be consistent with the individual's physical, mental, emotional and physical needs. It was also suggested that signed consent should be required. | **Point 7**:<br>In response to comments, provisions were inserted to require the purchase or selling of goods to be consistent with U.S. Department of Labor standards. Other changes suggested by respondents are addressed elsewhere in this regulation. |
| **12 VAC 35-115-120 *Research* (Re-numbered 12 VAC 35-115-130 in the final draft regulation)** | | |
| ■ Item A | Several respondents recommended inserting a reference to statutes and discussion of requirements for "informed consent" in this provision. | DMHMRSAS does not agree that such changes are needed in Item A because they are addressed elsewhere in this regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B | **Point 1**:<br>Several respondents suggested omitting the reference to legally authorized representative (LAR) in this provision. It was commented that no third party should be permitted to give consent for experimental treatment or research. One respondent indicated that reference should be made to requirements for "informed consent."<br><br>**Point 3**:<br>One respondent suggested inserting provisions requiring consultation with any "human research committee" and the LHRC prior to participating in human research. Another respondent indicated that this provision should be more specific regarding meaning and intent.<br><br>**Point 4**:<br>One respondent was concerned that this provision may result in problems with confidentiality.<br><br>**Additional Considerations**:<br>Several respondents suggested adding provisions prohibiting the use of placebos if there is a possibility that the individual may cease to be treated or be put in danger. | **Point 1**:<br>DMHMRSAS does not agree with the comments. Under the principles of equal protection, this regulation cannot lawfully prohibit a LAR from consenting on behalf of the individual. Provisions for "informed consent" are addressed in other parts of this regulation.<br><br>**Point 3**:<br>In response to comments, provisions were inserted to require consultation with an Institutional Review Board (IRB) or research review committee. In Point 4, provisions have also be revised to require permission to be obtained from the LHRC. DMHMRSAS does not agree that other changes are needed.<br><br>**Point 4**:<br>DMHMRSAS does not agree. This is designed to provide maximum protections for the individual. (See previous comment.)<br><br>**Additional Considerations**:<br>DMHMRSAS does not agree that specific provisions regarding the use of placebos should be inserted in this provision. This regulation provides the necessary protections for individuals who participate in research. |
| **12 VAC 35-115-130 *Complaint and Fair Hearing* (Re-numbered 12 VAC 35-115-140 in the final draft regulation)** | | |
| ■ General Comment | One respondent commented that individuals should be informed of the implications of initiating a formal complaint process and be required to sign a form to acknowledge that personal information might be disseminated to investigators and LHRCs. | No change has been made in response to comments. DMHMRSAS has determined that adequate protections for confidentiality are afforded by this regulation and it is not necessary to obtain a consent form, as suggested. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item A | Several respondents indicated that it is not clear who may initiate a complaint. One respondent submitted a re-write of this Item to provide a "heads up" as to who can initiate the complaint process and provide other clarifications. Another respondent indicated that this complaint process was too complex. One respondent suggested inserting provisions to state that individuals have a right to complain under any other applicable law, including right to complain to the Department for Rights of Virginians with Disabilities under the Protection and Advocacy for Developmentally Disabled Act, and Protection and Advocacy for Mentally Ill Individuals Act." | In response to comments changes have been made to clarify Item A. Provisions have been inserted to specify that the individual or anyone else may file a complaint on his behalf and they may use this or any other process to complain. It is also stated that they have the right to complain to the Protection and Advocacy Agency. |
| ■ Item B | Two respondents recommended adding requirements for providers to assist the individual to understand the complaint process, including options for resolution and elements of confidentiality. One respondent recommended requiring individuals to be advised of the services available from DRVD. One respondent commented that findings regarding complaint resolution should be noted in patient records. | In response to comments changes have been inserted to require individuals to be advised of the complaint process, including options for resolution and elements of confidentiality. DMHMRSAS believes that it is not necessary for findings to become a part of the individual's services record. The other issues are addressed in other parts of this regulation. |
| **Part IV *Complaint Resolution, Hearing, and Appeal Procedures*** | | |
| **12 VAC 35-115-140 *General Provisions* (Re-numbered 12 VAC 35-115-150 in the final draft regulation)** | | |
| ■ Format Note | Part IV of the initial proposed regulation has been revised and reformatted to clarify complaint resolution and appeals procedures. The first three sections in Part IV of the final draft regulations are as follows: 12 VAC 35-115-150 "General Provisions," 12 VAC 115-160 Informal Complaint Process (new), and 12 VAC 115-170 "Formal Complaint Resolution Process (which is the former Section 12 VAC 35-115-150 "Informal Complaint Resolution," in the initial proposed regulation).<br><br>This comment summary and responses correspond to the numbering scheme of the initial proposed draft regulation (i.e. former "General Provisions" Section 12 VAC 35-115-140 and former "Informal Complaint Resolution," Section 12 VAC 35-115-150). | |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ General Comment | One respondent commented that the regulations should address the State Long-term Care Ombudsmen's role in the complaint resolution process.<br><br>There were also several comments which indicated that the appeals process that is presented in the proposed regulation is difficult to understand | DMHMRSAS does not agree that the State Long-term Care Ombudsmen's role should be specifically addressed in this regulation. The regulation provides that individuals may have others assist them in the process, and this would include the Ombudsman..<br><br>In response to comments, this section has been revised to improve clarity and specificity of the process. A new section 12 VAC 35-115-160 has been inserted which provides for an "Informal Complaint Process" This new section is followed by 12 VAC 35-115-170 (formerly 12 VAC 115-150) which has be revised and re-named "Formal Complaint Resolution Process." This will serve to simplify and clarify the procedures. |
| ■ Item A | Several respondents indicated that the parties to a complaint and appeal and who may represent them are not clear and appear inconsistent with other parts of the regulation. There was a suggestion that other types of grievance procedures should be encouraged as an alternative to the formal or informal complaint process. Another respondent suggested that clarification be provided to indicate which LHRC should represent an individual receiving services from a "multi-jurisdictional provider." | This provision clearly states that parties to a complaint are the individual and the director. In response to comments, the provision has been changed to clarify that parties may be <u>represented</u> by <u>anyone</u> else during complaint resolution. DMHMRSAS does not agree that other provisions should be inserted. |
| ■ Item B | One respondent suggested including a discussion of "third party information flow" (i.e. DMHMRSAS to DRVD) in this provision. One respondent suggested several non-substantive wording revisions. There was also a comment that human rights complaint hearings should be open to the public at the request of the consumer. | DMHMRSAS does not agree that a discussion of information flow is relevant and has not inserted such a discussion in this provision. This provision reflects relevant requirements of Virginia's Freedom of Information Act. No changes have been made in response to comments. |
| ■ Item D | There were several comments generally recommending that any party should be able to seek extensions of time for good cause. | DMHMRSAS agrees and has made changes as suggested. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item E | One respondent opined that it was unreasonable to mandate loss of a seriously mentally disabled person's rights when there may be extenuating circumstances. Several other respondents were concerned that time extensions were not allowed for extenuating circumstances. | DMHMRSAS agrees and has made changes to allow time extensions to be granted to timeframes for any party when there are extenuating circumstances. |
| ■ Item F | One respondent recommended changing this provision to expand the authority of the LHRC to allow its review of policies, procedures or practices in connection with an appeal or hearing. | DMHMRSAS has reconsidered this provision in light of the comment and has determined that it is not relevant to the hearing or appeal procedures which are set forth in this section. Therefore, Item F has been deleted from this section and relocated to 12 VAC 35-115-220.E. (The remaining provisions are re-numbered.) |
| ■ Item G | One respondent suggested adding provisions for notifying appropriate authorities, including, DSS, DRVD and law enforcement, should they discover violations of Code of Virginia §18.2-369. | No change has been made; these notifications are mandated by other state laws. Also, such entities should already be involved in the proceedings. |
| ■ Item I | There was one suggestion that an independent decision-maker is needed to resolve disagreement between the Commissioner and the LHRC and SHRC hearing when the Commissioner overrides the findings of the LHRC and SHRC. | DMHMRSAS does not agree and has not made the indicated changes. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **12 VAC 35-115-150 *Informal Complaint Resolution* (Re-numbered 12 VAC 35-115-170 and Re-Named *Formal Complaint Resolution Process* in the final draft regulation)**<br>New 12 VAC 35-115-160 "***Informal Complaint Process***" has been inserted in draft final regulation prior to this section. | | |
| ■ Part A | It was commented that the process is too formal. Resolution should be encouraged at the lowest level. At least nine respondents generally indicated that it is not clear who can initiate the complaint and who can request an investigation of alleged rights violations. Several respondents suggested specific changes to the process for clarity. One respondent recommended substitution of the term "complainant" for "individual" and replace the reference to "advocate" in this part of the regulation with "human rights advocate."<br><br>One respondent indicated that the provision should state that any person having probable cause to suspect abuse and neglect may simultaneously report it to the external protection and advocacy agency, and shall be protected from retaliation for his disclosure. | As discussed above, DMHMRSAS is receptive to the respondents concerns and has revised this part of the regulation to include an "Informal Complaint Process" at 12 VAC-115-160 and a "Formal Complaint Resolution Process" at 12 VAC-115-170. This should help to clarify the provisions for complaint resolution and address most of the respondents concerns about the process. Changes to terminology have been made when appropriate throughout this part of the regulation. However, DMHMRSAS does not agree to substitute the term "complainant" for "individual" as this would not be consistent with the general usage in this regulation.<br><br>DMHMRSAS has not included changes to incorporate reporting to the protection and advocacy agency. This is covered in other parts of this regulation. |
| ■ Item B | One respondent questioned whether the director is responsible for the informal compliant resolution process or it is the intent for the advocate to handle this process. It was suggested that this provision be clarified. | DMHMRSAS has clarified this provision in response to the comment. |
| ■ Item C | Four respondents expressed concern about the timeframe. One respondent suggested that there should be a basis for extension under certain circumstances. One respondent indicated that the notice from the director should include the individual's right to appeal to the LHRC. | DMHMRSAS does not agree that the proposed timeframe for a decision and action plan is unreasonable and has not made changes in response to the comment. The advocate is responsible for making the notification of right to appeal; therefore, DMHMRSAS does not agree that it is necessary to require the Director to notify the individual. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item D | One respondent commented that this provision should not require a written response from the individual. Several respondents questioned whether the timeframe is sufficient for a response. | DMHMRSAS does not agree with the comments and has not made changes to this provision. |
| ■ Item E | This step should be eliminated because it unnecessarily extends the timelines. | DMHMRSAS does not agree with the respondent. |
| **12 VAC 35-115-160 *Local Human Rights Committee Hearing and Review Procedures* (Re-numbered 12 VAC 35-115-180 in the proposed final regulation)** | | |
| ■ General Comment | One respondent recommended using the term "formal" to modify "hearing" throughout this part of the regulation and to substitute the term "complainant" for "individual." | DMHMRSAS does not agree with the respondent. This section refers to LHRC hearings and this reference has been inserted when appropriate. DMHMRSAS does not agree to substitute the term "complainant" for "individual" as this would not be consistent with the general usage in this regulation. |
| ■ Item A | Several comments recommended changes to allow any person who is not satisfied with the Director's decision to file an appeal with the LHRC. The respondent also suggested provisions for participation by Inspector General (IG) in the LHRC hearing process. Several comments noted that a legally authorized representative has authority to represent an individual in LHRC proceedings. | A reference to the individual's legally authorized representative has been inserted in this provision. Only the individual or his legally authorized representative are parties with standing to file an appeal to the LHRC. DMHMRSAS does not agree that Inspector General should be included in this internal process of appeal to an LHRC. Therefore, changes have not been made in response to these comments. |
| ■ Item B | One respondent recommended inserting a statement that individuals may complain directly to the LHRC without first seeking informal resolution. Several respondents recommended increasing the timeframes for action. | DMHMRSAS has not revised this provision. DMHMRSAS does not agree that the timeframes are unreasonable. Any party to such proceedings may request an extension of time (*see* 12 VAC 35-115-150(D)). |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item C | It was recommended that the Inspector General should receive copies of all petitions. One respondent was concerned that it is a violation of confidentiality to copy the petition to the provider's governing body. | Petitions are available to the Inspector General upon request. The requirements in this provision are lawful and do not constitute a violation of confidentiality requirements. |
| ■ Item D | One respondent suggested extending the timeframe. | After taking into consideration all comments concerning time frames DMHMRSAS has determined that the timeframes balance the rights of individuals with the duties of the providers and, therefore, has not made changes. |
| ■ Item E | Several respondents indicated that the statement (2) should be revised as follows:<br>The director or his chosen representative ~~should~~ shall attend the hearing. The individual making the complaint and/or his chosen representative shall attend the hearing. ~~If this is not possible, the individual's chosen representative shall attend the hearing~~.<br><br>One respondent opined that the timeframe was too short. | DMHMRSAS agrees with the suggested revision and has changed the statement accordingly.<br><br>No change was made to the proposed timeframe. |
| ■ Item G | One respondent recommended requiring the written document to state that the individual has the right to appeal the either the LHRC decision and/or the Director's Plan. One respondent opined that the timeframe was too short. | DMHMRSAS does not agree that the changes are necessary to this provision. |
| ■ Item H | Three respondents indicated that the timeframes were too short. One respondent was concerned that needed treatment or medication may be delayed if the individual appeals an action plan and it is not implemented pending resolution of an objection. | DMHMRSAS does not agree with the comments and has not made changes. Parties may request an extension of time under this regulation |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **12 VAC 35-115-170 *Special Procedures for Emergency Hearings by the LHRC* (Re-numbered 12 VAC 35-115-190 in the proposed final regulation)** | | |
| ■ General Comment | One respondent was concerned that serious incidents are often matters for police investigation which are initiated directly by program directors. This respondent questioned the basis for LHRC involvement in matters requiring police investigation. | DMHMRSAS does not agree with the comments and has not made changes. The LHRC hearing process is not intended to address criminal matters requiring immediate action by law enforcement officials. |
| ■ Item A | Several respondents believe that timeframes should be expedited. Another respondent suggested that an "emergency response human rights committee should be formed to deal with such matters. Two respondents suggested that the individual and and/or legally authorized representative should be notified and expected to be present at hearings. | DMHMRSAS believes that the timeframes and process for emergency hearings are reasonable. Changes have been made to indicate that the individual and and/or legally authorized representative may attend the hearing. |
| ■ Item B | One respondent indicated that the Inspector General should be listed in this provision. Another respondent indicated concern that this provision violates confidentiality. | The notification requirements in this provision are lawful and do not constitute a violation of confidentiality requirements. This information will be available to the Inspector General upon request. No change has been made to this provision. |
| ■ Item E | One respondent suggested inserting a requirement that no action shall be taken while an appeal is made. | DMHMRSAS does not agree and has not made changes to this provision. The provider will be responsible for rectifying the situation if the appeal is successful. |
| **12 VAC 35-115-180 *Special Procedures for LHRC Reviews Involving Consent* (Re-numbered 12 VAC 35-115-200 in the proposed final regulation)** | | |
| ■ General Comments | Several respondents indicated that this section should be clarified as to provisions for "consent" versus "informed consent." | DMHMRSAS has revised the definition of consent in this regulation to clearly distinguish what is meant by the term "informed consent" and when "informed consent" is required. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item A | One respondent indicated that this provision is not consistent with the Health Care Decisions Act. Another respondent recommended changing the provision to state that if an individual objects to participation in research, it should not continue even if the authorized representative gives consent. There was also a comment that no action should be taken while the LHRC decides whether consent is required. One respondent noted that the Code cited should be corrected to § 54.1-2969(E.) | DMHMRSAS does not agree with the comments and has not revised this provision. This part of the regulation is consistent with the applicable statutory requirements and relevant provisions of the Health Care Decisions Act. The Code citation has been corrected. |
| ■ Item B | One respondent recommended requiring that the LHRC have a personal interview with the objecting individual. | DMHMRSAS does not agree that a personal interview is necessary in every case. This does not preclude the LHRC meeting with individuals whenever they deem it appropriate. The provision has been revised to clarify that objection concerns the determination of capacity. |
| ■ Item C | **Point 1**:<br>Two respondents suggested revising this provision to indicate that, if the individual files an appeal, then research or treatment shall be suspended.<br><br>**Point 2**:<br>One respondent indicated that the term "immediately" is inappropriate. It is not advisable to discontinue some medications immediately. Another respondent indicated that this provision violates federal law because a director cannot continue research without the individual's informed consent. | **Point 1**:<br>DMHMRSAS does not agree with recommendations that research should be suspended if an individual notes an appeal.<br><br>**Point 2**:<br>DMHMRSAS agrees that changes are needed in this provision. The word "immediately" has been removed, and the phrase "take immediate steps" is now used |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **12 VAC 35-115-190 *State Human Rights Committee Appeals Procedures* (Re-numbered 12 VAC 35-115-210 in the proposed final regulation)** | | |
| ■ General Comments | One respondent suggested development of emergency procedures for SHRC appeals. Another respondent indicated that timeframes should be clarified. | DMHMRSAS does not agree that such changes are needed. Emergency cases are heard by the LHRC, not the SHRC. The SHRC is available to hear appeals of emergency proceedings in an expedient manner. |
| ■ Item B | One respondent suggested revising the provision to state that the appeal "…shall be filed in writing, addressed to the Chair, SHRC, within 10 working days…" One respondent indicated that timeframes should be extended. Another respondent indicated that timeframes should be reduced.<br><br>**Point 4**:<br>One respondent was opined that that the governing body of a provider should not be involved in the appeals process. | DMHMRSAS does not agree that changes are necessary in response to comments.<br><br>**Point 4**:<br>Because the provider is responsible to a governing body or board, it is appropriate for such bodies to have authority in matters that affect the provider's operation and performance. DMHMRSAS does not agree with the respondent. |
| ■ Item C | One respondent believes that the timeframe should be extended. | After consideration of all timeframes, DMHMRSAS believes that this timeframe is reasonable and has not made changes. |
| ■ Item D | One respondent suggested that copies of the record should be sent to the individual or his alternative decision maker. | DMHMRSAS does not agree that this change is necessary because the individual or his decision-maker are routinely copied on all material. The advocate, individual and the legally authorized representative should, therefore, already have this information. Non-substantive changes have been made to this provision for clarity and to provide additional detail. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item E | One respondent questioned the rationale for allowing the SHRC a longer timeframe to complete an appeal proceeding than the LHRC. The regulations require the LHRC to issue a decision within 10 working days of the receipt of a request for an appeal whereas the SHRC has 20 working to issue a report following an appeal hearing.<br><br>Another respondent questioned whether the SHRC is bound by the LHRC's findings of fact given that they can decide that the LHRC's findings are clearly wrong. Several respondents commented that new evidence should be allowed. | DMHMRSAS believes that, because the SHRC is a statewide body consisting of members who reside throughout Virginia, it may be difficult for these members to collaborate to compose the report. In contrast, the LHRC is comprised of persons from a single region of the state. Therefore, the timeframes provided in the regulation, which give more time to the SHRC, are reasonable. The SHRC hearing is based on a de novo review. No new evidence may be allowed. The SHRC must consider the same evidence that was reviewed by the SHRC and consider the LHRC's findings. However, it may reach a different conclusion. No change is has been made in response to the comments. |
| ■ Item G | Several respondents recommended that separate regulations be developed for CSBs and state facilities. | DMHMRSAS does not agree. This regulation is intended to apply to all providers. |
| ■ Item I | It was suggested that there should be a means of overriding the Commissioner's action plan. One respondent suggested adding provisions to suspend the prescribed action when Commissioner's action is found to be incompatible with the purpose of the regulation. | DMHMRSAS does not agree with the respondents. The Commissioner's action plan may be reviewed but not superseded or suspended by the SHRC. |
| **Part V**<br>**12 VAC 35-115-200 *Variances* (Re-numbered 12 VAC 35-115-210 in the proposed final regulation)** | | |
| ■ General Comments | Several respondents suggested adding provisions to this section to require that variances shall be approved only for particular cases, with time limits and other conditions for duration, and for the circumstances that will end their applicability.<br><br>A number of respondents indicated that provisions should be added to allow a variance to be granted when it can be shown that it is needed to prevent harm from occurring. The approval of a variance should be contingent upon compliance with sound therapeutic standards of care and treatment. | DMHMRSAS generally agrees with the respondents. Changes have been made to this section of the regulation to address the concerns. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item B | One respondent indicated that an individual or his legally authorized representative should be able to apply for a variance. | This provision allows a provider to seek a variance from the human right protections afforded to individuals by this regulation. No change has been made in response to this comment. |
| ■ Item C | **Point 1**:<br>Two respondents suggested defining the term "ample time." Another respondent questioned whether the LHRC has the option not to permit additional information.<br><br>**Point 2**:<br>Two respondents questioned whether the regulation describes the basis upon which a variance may be granted. One respondent indicated that approval should be contingent upon compliance with sound therapeutic standards of care and treatment | **Point 1**:<br>DMHMRSAS does not agree that "ample time" should be defined because it may differ, depending on individual circumstances. Under this provision, the LHRC is required to accept additional information regarding the application for variance.<br><br>**Point 2**:<br>The basis for granting variances is stated in 12 VAC 35-115-220.A. No change has been made in response to the comments. |
| ■ Item G | One respondent suggested adding the phrase "…and shall be implemented until further notice." | DMHMRSAS does not agree with this respondent. Variances must be approved with established time limits according to provisions in this part of the regulation. |
| **Part VI *Reporting Requirements***<br>**12 VAC 35-115-210 *Reporting Requirements for Providers* Changed to: 12 VAC 35-115-230 *Requirements for Providers Reporting to the Department* in the proposed final regulation)** | | |
| ■ General Comments | One respondent commended the regulation for expanding the individual protections in relation to abuse, neglect and exploitation. Another respondent stated that this part of the regulation was generally confusing because of problems inherent in developing a single regulation to cover both DMHMRSAS facilities and private providers. Several other responses expressed concern that the reporting requirements are duplicative and burdensome for CSBs and others. | DMHMRSAS does not agree with this respondent that this regulation is unduly confusing because it regulates both public and private providers. This regulation is intended to ensure that individuals will be afforded the same human right protections in any facility operated, funded or licensed by DMHMRSAS. However, DMHMRSAS agrees that the intent of this section was somewhat unclear and has made |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| General Comments (cont.) | | several non-substantive changes and has re-organized some provisions in order to improve the clarity. The section has also been renamed "Requirements for reporting to the department" in order to focus the intent.<br><br>Reporting requirements have been streamlined so that they are consistent with statute and not unduly burdensome. |
| | There was one suggestion to insert provisions to ensure that providers will comply with any reporting requirements of the Joint Commission on Accrediting Health Care Organizations, HCFA, and the Department of Justice Civil Rights Division. | DMHMRSAS does not agree that the suggested additional provisions are needed. This is beyond the scope of this regulation. |
| ■ Item A | **Point 1**:<br>Two respondents stated that the term "exploitation" should be inserted in the provision. There were also comments that this section should reference state and federal statutes although specific statutes were not identified. | **Point 1**:<br>DMHMRSAS does not agree that changes are needed in response to comments. Even though exploitation is defined in this regulation, it is considered to be a form of abuse. |
| | **Point 2**:<br>One respondent suggesting changing this provision to "next working day." There was also a comment to require that certain facilities to report to the Office of Licensing. | **Point 2**:<br>DMHMRSAS does not agree that changes should be made to this provision. |
| | **Point 3**:<br>One respondent indicated that timeframes are too short. There was also a suggestion to insert "or investigating authority." One respondent indicated that the report or documentation should be distributed to the OAG whenever it is furnished to third parties. | **Point 3**:<br>In response to comments the provision has been revised to indicate that the "investigating authority" shall provide the report. Other changes have been made for clarity and consistency. DMHMRSAS does not agree that additional changes are needed. |
| | **Point 4, Point 5**:<br>There were a number of comments suggesting changes to clarify who is responsible reporting and to identify individuals or entities that should receive the report. There was also a suggestion that *Virginia Code* § 18.2-369 should be cited in this section. | **Point 4, Point 5**:<br>These sections have been revised and re-organized to clarify specific reporting requirements consistent with the scope of this section of the regulation. DMHMRSAS does not agree that it is necessary to cite statutory provisions. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
|---|---|---|
| **Section** | **Comment** | **Response** |
| ■ Item B | **Point 1**:<br>There was a suggestion that the statement be changed to include: "…report immediately to the department and the IG"<br><br>**Point 2**:<br>There was a suggestion that a report should be made to alternative decision makers prior to providing it to any third parties. One respondent suggested that the provision be revised to require reporting within 24 hours of becoming aware of the death. Other respondents indicated that the 24 hour period was "not acceptable." One respondent suggested the addition of provisions requiring deaths to be reported to DRVD.<br><br>**Point 3**:<br>One respondent indicated that the provider does not always discover serious injuries within 24 hours. The respondent also questioned what is meant by a serious injury. There was also a suggestion that the cause of the injury/death should be reported.<br><br>**Point 4, Point 5**:<br>There were suggestions to include provisions to require reports to be made to DRVD and to law enforcement entities, when appropriate. | **Point 1**:<br>DMHMRSAS does not agree that the change is necessary. Reports are provided to the Inspector General.<br><br>**Point 2**:<br>The provision has been revised as include a requirement that deaths are reported to a legally authorized representative within 24 hours of occurrence, if applicable. DMHMRSAS does not agree that other suggested revisions are necessary.<br><br>**Point 3**:<br>DMHMRSAS does not agree that changes are needed in response to the comments. This provision requires that the provider describe the "nature," "treatment" and "circumstances" of injuries/deaths.<br><br>**Point 4, Point 5**:<br>This section now concerns reporting to DMHMRSAS, only. Therefore, Points 4 and 5 have been deleted because they are not consistent with the revised scope of this section of the regulation. |
| ■ Item C | There were a number of respondents who were concerned that this Item requires reporting for incidents of "protective restraints." Generally the respondents opined that this was unnecessarily burdensome. One respondent indicated that the reporting requirements for state operated facilities go beyond what is required by the applicable operating instructions that have been issued by the Commissioner. One respondent indicated that "staff holds" are probably too routine to justify reporting to the Department.<br><br>Concern was also expressed that providers are required to file reports with the DMHMRSAS Quality Manager. General concern was expressed that this reporting was onerous. | This part of the regulation has been revised and clarified to require directors of services licensed or funded by the DMHMRSAS to compile monthly, and submit a single report on an annual basis, each incident of physical restraint, mechanical restraint, pharmacological restraint and seclusion, unless requested more frequently by the Department (see definition of restraint, seclusion). Facilities that are operated by DMHMRSAS are required to report in accordance with the applicable operating instructions issued by the Commissioner. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| Item C (cont.) | One respondent indicated that reports should be required immediately rather than within 24 hours of occurrence when an instance of seclusion or restraint does not comply with this regulation. Another respondent suggested that instances of non-complying use of seclusion or restraint should be reported by the next working day following discovery. | Specific requirements for reports to the DMHMRSAS Quality Manager have been eliminated. As suggested, provisions have been included to require reports to be filed with legally authorized representatives, as appropriate, when there is an incident of seclusion or restraint that does not comply with the regulation or that results in an injury. No change has been made to the timeframe in response to the comments. |
| ■ Item D | There was a suggestion that the first statement should include "as per Federal and State Statutes."<br><br>Several respondents were concerned that the reporting requirements were overly burdensome. | DMHMRSAS has determined that no change is necessary in response to the comments. |
| ■ Item F | | DMHMRSAS has been advised that this section does not comply with recent legislative changes. Therefore, this provision has been deleted and the remaining provisions have been re-numbered. |
| ■ Item G | One respondent suggested that the phrase "upon request" should be deleted. Another respondent suggested adding "in compliance with the Privacy Act" to the first sentence. | DMHMRSAS does not agree that the suggested changes are necessary. This provision has been clarified to state that data will be available "upon request." |
| ■ Item H | There was a suggestion that the provision should be expanded to cover the release of information to specific third parties (testing labs, research facilities, etc.), and sanctions should be specified for violations. | DMHMRSAS does not agree that the suggested revision is needed. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item I | There was a suggestion that "all appropriate Federal and State statutes and especially The Privacy Act" should be inserted in this provision. | DMHMRSAS does not agree that the suggested change is necessary. |
| ■ Item J | One respondent suggested that this provision should list "reportable conditions" or include such conditions in an appendix entitled "Applicable Codes Cited by these Regulations." | DMHMRSAS will provide guidance when the final regulation is printed for public distribution. |
| **Part VII *Enforcement and Sanctions*** | | |
| **12 VAC 35-115-220 *Human Rights Enforcement and Sanctions* (Re-numbered 12 VAC 35-115-240 in the proposed final regulation)** | | |
| ■ General Comments | One respondent suggested that licensing sanctions for facilities that violate this regulation should be stated in this section. There was also a suggestion that sanctions should be listed for employees that resign under abuse cases/incidents. One respondent indicated that sanctions for DMHMRSAS facilities should be provided in this section. It was also commented that additional "enforcement specificity" is needed in this section.<br><br>There were also several respondents that provided specific comments and recommendations regarding the informal fact-finding conference process that was described in this section of the proposed regulation. | DMHMRSAS has referenced the specific statute that authorizes sanctions for violations in this part of the regulation. Section 37.1-185.1 of the Code of Virginia delineates specific actions that the Commissioner may take to lawfully sanction providers for non-compliance with human rights regulations.<br><br>DMHMRSAS has not quoted such sanctions in this regulation pursuant to the requirements of the Virginia Registrar of Regulations. However, as stated previously, DMHMRSAS will provide guidance that will encompass relevant Code citations to be made available when the final regulation is printed for public distribution.<br><br>DMHMRSAS has also deleted the specific procedures for the informal fact-finding conference, which were provided in 12 VAC 35-115-220(B), (C) and (D) of the proposed regulation. The law prescribes the requirements for this proceeding. Therefore, DMHMRSAS has determined that is it is not necessary to detail the specific legal requirements in this regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| **Part VII Responsibilities and Duties**<br>**12 VAC 35-115-230 *Offices, Composition and Duties* (Re-numbered 12 VAC 35-115-250)** | | |
| ■ General Comments | Several respondents indicated that the term "advocate" should be clarified in this section. There were also opinions expressed generally that the LHRC is designed to have a consumer perspective and should not have authority on issues that are outside its competence, in accordance with this regulation. | DMHMRSAS has clarified the term advocate in this section (see definition of advocate). DMHMRSAS does not agree with the opinion that has been expressed regarding the LHRC and does not believe that changes are necessary. |
| ■ Item A | Two respondents questioned whether CSBs or providers are required to have a human rights advocate position on staff. There were several respondents who suggested revisions to clarify the provisions in this Item. One respondent opined that the director does not have the ability to assure compliance with this regulation.<br><br>There were also a suggestion to insert statutory references and provisions for "…zero-tolerance for attempts to influence members or proceedings of the LHRC or SHRC." | CSBs are not required to employ a "human rights advocate" as defined by this regulation (see definition of human rights advocate). However, the regulation requires all providers to identify someone on staff who will be accountable for assisting individuals to exercise their rights under this regulation. In response to the comments that were received DMHMRSAS has inserted additional provisions requiring the provider to (1) ensure that employees receive "competency based training on these regulations upon employment; and (2) assure that appropriate staff attend all LHRC meetings. DMHMRSAS has determined that the additional provisions should help providers to comply with this regulation.<br><br>12 VAC 35-115-250 now provides oversight of the LHRCs by the SHRC. |
| ■ Item B | One respondent recommended that provisions be inserted to require new employees to review the human right protections afforded by this regulation upon employment and periodically thereafter. | DMHMRSAS generally agrees with the suggestion and has including provisions for employees' competency based training in Item A of this Section of the regulation. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
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| **Section** | **Comment** | **Response** |
| ■ Item C | One respondent suggested that individuals should be advised that certain types of information might be disclosed if a complaint is filed with the LHRC. Another respondent questioned whether the advocate is supervised by a CSB. There was also a suggestion to insert appropriate statutory references. One respondent recommended requiring the following duty for the human rights advocate: "Provide orientation, training and technical assistance to LHRCs for which they are responsible." | Disclosure is addressed in other parts of this regulation. The human rights advocate, as defined by this regulation, is not supervised by the CSB (see definition of human rights advocate). DMHMRSAS does not agree that it is necessary to insert statutory references in this provision.<br><br>In response to the suggestion, DMHMRSAS has inserted the additional duties for the human rights advocate. |
| ■ Item D | There were several respondents who commented that recruitment of LHRC members was difficult for a number of reasons.<br><br>One respondent suggested that members should be required to be drawn from culturally and geographically diverse populations. There was one suggestion that CSBs should be required to approve LHRC nominations. There was also a suggestion that DMHMRSAS should offer reimbursement to LHRC members. It was also stated that relatives of employees should be prohibited from membership on the LHRC. One respondent questioned whether the proposed number of meetings was reasonable. Respondents also suggested several specific suggested additional requirements for LHRC membership, process and structure. | In response to comments, DMHMRSAS has made several revisions to more clearly reflect Code of Virginia membership requirements, to reduce the size of the LHRC and to reduce the number of annual meetings. There have also been revisions to make the LHRC responsibilities consistent with the provisions in other parts of this regulation. DMHMRSAS has not added provisions for compensation of LHRC members or CSB approval of LHRC nominations. |
| ■ Item E | There was a comment that long distances make it difficult to become involved with the SHRC. One respondent suggested inserting provisions requiring that SHRC members be drawn from culturally and geographically diverse populations. It was also suggested that a requirement be added that at least one member of the SHRC shall be a psychiatrist and at least one member shall be a licensed clinical psychologist. One respondent provided several additional specific suggestions regarding organization, conflict of interest and compensation for SHRC members. | In response to comments, DMHMRSAS has made several revisions to more clearly reflect the Code of Virginia membership requirements. There have also been revisions to make the SHRC responsibilities consistent with the provisions in other parts of this regulation. DMHMRSAS has not added provisions for compensation of SHRC members or to require membership to include a psychiatrist and a license clinical psychologist. Although, such members are desirable, recruitment of such members cannot be reasonably assured. |

| **Summary of Public Comments: Rules and Regulations to Assure the Rights of Individuals Receiving Services From Providers of Mental Health, Mental Retardation and Substance Abuse Services 12 VAC 35-115-10 et seq.** | | |
|---|---|---|
| **Section** | **Comment** | **Response** |
| ■ Item F | One respondent suggested adding a requirement that the State Human Rights Director (SHRD) be responsible for publishing an annual report of the status of human rights in mental health, mental retardation, and substance abuse treatment and services in Virginia, and make recommendations for improvement. | DMHMRSAS does not agree that the SHRD should develop the recommended report. The SHRC provides the report, and the SHRD assists in the preparation of that report.<br><br>DMHMRSAS has also deleted Point 8 of this section, as it was determined that such data collection efforts are not appropriately the responsibility of the State Human Rights Director. Data collection is now a responsibility of DMHMRSAS. |
| Item G | One respondent recommended that the SHRD should be employed by an independent agency rather than the Commissioner. There were other comments that the Commissioners responsibilities should include taking action to extract remedies in a timely manner in each case. | DMHMRSAS does not agree that the SHRD should be employed by an independent agency. Because the human rights program is an internal advocacy program, the SHRD should be employed by the Commissioner. |
| Item H | One respondent suggested that the board should appoint members of the SHRC with participation of the Inspector General. It was also suggested that the Board should be required to set a reimbursement schedule for SHRC member expenses. | DMHMRSAS does not agree and has not made the recommended changes; these requirements are prescribed by § 37.1-84.3 of the Code of Virginia. |

**Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services**

**12 VAC 35-115-10 et seq.**

**Summary of 30-day Public Comment**

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| General Comments | Two respondents expressed support and overall concurrence with the existing version of the regulation. There were also approximately six respondents that commented generally that the regulation was ambiguous, too complex and/or created potential legal issues. | | No changes are proposed in response to these general comments. |
| **Part I *General Provisions*** | | | |
| **12 VAC 35-115-30** *Definitions* | | | |
| ■ "Abuse" | Five respondents commented that the definition was too broad. Specifically, the respondents indicated that the meaning of the phrases "failure to act" and "might have caused harm" are unclear and should be eliminated from the definition. | Minor revisions were made to the definition of "abuse" following the 60-day public comment period to make this definition identical to the definition of "abuse" in §37.1-1 of the Code of Virginia. | No additional change is recommended in response to these comments because this definition must be consistent with the Code definition. |
| ■ "Consent" | One respondent was concerned that requiring informed consent for "psychoactive and other medications" implies that the risk associated with such medications is the same as the risk of surgery and anesthesia. By requiring informed | After consideration of all comments following the 60-day public comment period, the definition of "consent" was revised to state that *informed* consent is specifically required before treating | Based on the recent comments, the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS) recommends deleting the words "and other" before the word "medications." |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| "Consent" (cont.) | consent for such medications, the respondent believes that the regulation establishes a different standard of care for hospitalized psychiatric patients versus other hospitalized patients and would increase paperwork for the provider without appreciable patient benefit. The respondent notes that a patient who objects to medication can refuse to take it.<br><br>Several other respondents indicated that requiring informed consent for all medications poses an undue burden on physicians, which could increase cost and delay patient care. These respondents noted that only a physician has the authority to obtain informed consent from an individual. The requirement imposed by this regulation to obtain informed consent for "psychoactive and other medications," goes beyond the requirements that are imposed on providers by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). There was also concern expressed about the lack of practitioner agreement on what constitutes a psychoactive medication and the lack of guidance on which "other" medications would require informed consent. One respondent explained that all patients sign a form to consent to treatment upon admission to a provider setting, which defines what constitutes treatment such as surgery or electroconvulsive therapy (ECT).<br><br>More than ten respondents indicated support for requiring full disclosure about ECT and medications. | individuals with electroconvulsive therapy (ECT), using "psychoactive and other," medications, performing surgery and the use of aversive therapy. | This means that informed consent is required for "psychoactive" medications but not for all types of medications. According to this revised definition, the standard for requiring informed consent is that the treatment or service "…poses a risk of harm greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations…" Informed consent would be specifically required for surgery, aversive treatment, electroconvulsive treatment, and psychoactive medications. DMHMRSAS intends to provide training and guidance to assist in the implementation of this regulation.<br><br>DMHMRSAS also recommends that certain provisions for obtaining consent for ECT be deleted at 12 VAC 35-115-70 and replaced with a new provision to ensure that individuals are informed that they may request a second opinion when referred for ECT treatment. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| "Consent" (cont.) | Several respondents recommended that separate definitions be provided for "consent" and "informed consent." | | Similar comments recommending separate definitions for "consent" and "informed consent" were received during the 60-day public comment period. In response to these comments, the definition was revised to provide specific guidance on "consent" versus "informed consent." DMHMRSAS does not recommend separate definitions. |
| ■ "Local Human Rights Committee" | One respondent commented that the definition of consumers who can serve on the local human rights committee (LHRC) is too narrow. There is inadequate consideration of child and adolescent programs in defining who may serve on an LHRC. | Following the 60-day public comment period the definition of LHRC was revised to require a minimum of five rather than seven members. | DMHMRSAS does not agree with the respondent's suggestion for additional substantive changes and does not recommend revisions to this definition. |
| ■ "Restraint" | Five respondents indicated that this definition is generally too broad. It was suggested that this definition specify exceptions such as hugging or holding an infant, guiding someone, steadying a body which should not be considered a "restraint." | This definition was expanded following the 60-day public comment period in order to provide explicit descriptions of types of restraints, consistent with the other regulatory provisions for restraint. | DMHMRSAS does not recommend that the additional suggested changes are needed. However, DMHMRSAS proposes to conduct provider training following the adoption of the regulations to help providers to understand and implement the provisions. |
| **Part II**<br>**12 VAC 35-115-40** ***Assurance of Rights*** | | | |
| ■ Item B | There were approximately six respondents who commented that written notice of rights should not be required for "non-literate" individuals. These respondents generally believe that such written notification has not been shown to | Following the 60-day public comment period, minor changes were made to these provisions for clarification and to help ensure individuals understand their rights under this regulation. These | DMHMRSAS believes that the requirements in this part of the regulation are reasonable and does not recommend additional revisions. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| Item B (cont.) | accomplish the desired result and has minimal value.<br><br>Several respondents questioned the intent of the requirement that providers post a written notice of rights in "*frequently used languages*." (B.6). This provision was added following the 60-day public comment period. | changes were made in response to numerous comments suggesting the addition of provisions to enhance communication efforts between providers and individuals receiving services. The provisions require providers to explain the individual's rights "…in writing and in any other form most easily understood by the individual..." | |
| **12 VAC 35-115-50 *Dignity*** | | | |
| ■ Item B | **Point 3**:<br>One respondent commented that the word "help" in the phrase "…Have *help* in learning about…" is vague and does not provide sufficient guidance to providers.<br><br>Six respondents opined that this provision should be limited to service plan-related entitlements.<br><br>One respondent indicated that helping individuals learning about entitlements is not the focus of treatment in a short-term inpatient program. | **Point 3**:<br>DMHMRSAS considered similar public comments made on this provision during the 60-day public comment period and made minor revisions to clarify some of the provisions. The word "help" was used in the original proposed regulation and was not changed. | **Point 3**:<br>DMHMRSAS does not recommend additional changes to this provision in response to the recent comments. DMHMRSAS believes that it is reasonable for any provider to help individuals to learn about public service benefits to the extent possible, even though the provider may not necessarily have full knowledge of such programs or benefits. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| ■ Item C | **Point 1**:<br>One respondent opined that providing clothing for an individual's exclusive use, other than hospital gowns, is unreasonable and expensive.<br><br>**Point 3**:<br>Several respondents commented that the specific physical and/or environmental requirements imposed by this regulation are issues that should be addressed by licensing regulations and therefore should be deleted from this human rights regulation. | **Point 1**:<br>DMHMRSAS added the phrase "for his exclusive use" following the 60-day public comment period.<br><br>**Point 3**:<br>Provisions for a safe, sanitary, and humane physical environment were included in the initial proposed version of the regulations. The only change made to this provision, after the 60-day public comment period, was the insertion of "…and compatible with health requirements…" in Item (f). | **Point 1**:<br>Under this provision, a hospital gown used by a single individual during a hospital admission would be clothing "for his exclusive use." DMHMRSAS does not recommend changing this provisions in response to this comment.<br><br>**Point 3**:<br>DMHMRSAS believes that such provisions are reasonable human rights protections and does not propose revisions based on these comments. |
| ■ Item D | **Point 3:**<br>**Part c. and part e.**<br>Approximately ten respondents opined that the requirement that a director notify the human rights advocate and initiate an investigation within 24 hours of a report of abuse, neglect or exploitation is overly burdensome. Many complaints are minor and do not warrant the 24 hour reporting. One respondent also indicated that the requirement for reporting the results of an investigation within ten business days was not a reasonable requirement. | **Point 3:**<br>**Part c. and part e.**<br>DMHMRSAS received many comments addressing the timeframes and the process for notification and for reporting allegations of abuse, neglect or exploitation, following the initial 60-day public comment period. The 24-hour requirement for reporting and initiating a complaint investigation was part of the proposed regulation. Although there were some minor revisions for clarification, the provision was not changed substantively, in response to the comments received during the initial period. | **Point 3:**<br>**Part c. and part e.**<br>DMHMRSAS believes that these provisions are reasonable and does not recommend additional changes to this part of the regulation based on comments. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item D (cont.) | One respondent commented that a requirement for investigating and reporting the results should not apply to a director unless the program that generated the complaint is within the director's span of control. | | In response to the comment regarding the applicability of the reporting requirements, the director is defined by this regulation as the chief executive officer of any program delivering services. Therefore, such director, as defined by the regulation, would not be responsible for any investigations or reporting that is outside his span of control. No change is recommended. |
| | **Part e. (2)**<br>Two respondents questioned the meaning of the standard "preponderance of evidence" for deciding whether abuse neglect or exploitation occurred. One respondent suggested using the higher standard of "reasonable doubt." | **Part e. (2)**<br>"Preponderance of evidence" is standard that is applied by the civil court system to determine whether there has been a violation of regulations. This standard was inserted after consideration of comments received during the 60-day public comment period. | **Part e. (2)**<br>The legal standard of "reasonable doubt" is applied in criminal proceedings and is not appropriate for this regulatory provision. No change is recommended based on this comment. |
| | **Part e. (4)**<br>Approximately five respondents commented that the provision requiring the director to provide notice to all concerned parties is not good practice. Such notice should be restricted to substantive matters that should be defined. One respondent was concerned that this written notice may violate an individual's confidentiality. | **Part e. (4)**<br>The requirement that the director provide written notice was part of the original proposed regulation and was not changed. | **Part e. (4)**<br>DMHMRSAS believes that the notification requirement is reasonable. Such notice does not obviate any legal requirements for the protection of individual privacy. No change is recommended based on this comment. |
| ■ Item E | **Point 3, Point 4, and Point 5**:<br>There were numerous comments protesting the burden placed on providers and local human rights committees (LHRC) by requiring all providers to seek approval of an LHRC before | **Point 3, Point 4, and Point 5**:<br>Following the 60-day public comment period, changes were inserted to this part of the regulation to require an LHRC to approve certain restrictions that | **Point 3, Point 4, and Point 5**:<br>Upon reconsideration based on the recent comments, DMHMRSAS recommends changing these provisions to eliminate the requirement that an LHRC approve certain |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| Item E (cont.) | imposing certain types of restrictions on individuals who are receiving services. | providers may impose on individuals receiving services. | restrictions on mail, telephone, and visitors. The revised version would require providers to notify the human rights advocate prior to imposing these restrictions. This change should help alleviate the burden on providers and maintain sufficient oversight of individual rights in such cases. |
| **12 VAC 35-115-60 *Services*** | | | |
| ■ Item A | Several respondents opined that the reference to "sound therapeutic practice" is vague and does not provide sufficient regulatory guidance. | Following the 60-day public comment period, the phrase "sound therapeutic practice" was inserted in this provision and in other appropriate parts of the regulation in order to be consistent with the relevant provisions of the Code of Virginia, including § 37.1-84.1. | DMHMRSAS believes that this reference is reasonable and consistent with the Code. No change is recommended in response to the recent comments. |
| ■ Item B | **Point 1**:<br>Approximately seven respondents recommended re-inserting the provision in **Part 1.a** to require all complaints to be made in writing. | **Point 1**:<br>The provision in **Part 1.a** requiring complaints to be made in writing was deleted after considering comments made during the 60-day comment period. Respondents had expressed concern that some individuals receiving services may not have the ability to write and therefore they should not be required to complain in writing. A provider should be able to record any complaint that is not filed in writing. | **Point 1**:<br>DMHMRSAS does not recommend re-inserting the provision to require complaints in writing, in response to the recent comments. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item B (cont.) | There were several respondents who objected to provisions in **Part 1.c.,** requiring a copy of the director's decision sent to all parties regarding a complaint. | This provision was not changed from the original proposed regulation. DMHMRSAS considered similar comments made during the 60-day comment period regarding **Part 1.c** and concluded that the provision is reasonable as written. | No change is recommended in response to recent comments. |
| | **Point 4:** One respondent expressed concern that the regulation does not specifically repeat statutory provisions at § 37.1-197.A.3. This legal provision requires that discharge plans be prepared with the participation of the individual receiving services and reflect that individual's preferences to greatest extent possible. | **Point 4:** Provisions regarding the discharge plan at **Point 4.c**. were not changed following the 60-day public comment period. | **Point 4:** DMHMRSAS does not believe it is necessary to repeat the statutory provisions regarding discharge plans and does not recommend changes in response to this comment. |
| | **Point 3**: One respondent opined that the provision should provide a definition of the term "emergency situations." | **Point 3**: This provision to address emergency situations was inserted following the 60-day public comment period. The regulation provides a definition of "emergency" at 12 VAC 35-115-30. | **Point 3**: DMHMRSAS does not recommend adding a definition of "emergency situation" in this provision. |
| | **Point 5**: Approximately seven respondents commented that this provision was not clear in terms of the documentation or other responsibilities of the provider in response to emergencies. | **Point 5**: This provision was changed in response to comment, following the 60-day public comment period. | **Point 5**: In order to respond to the recent comments seeking clarification, DMHMRSAS recommends a minor language change to be more explicit. The last sentence in this provision should be changed to state that "…Services provided in response to emergencies or crises shall be deemed part of the services plan…" |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item B (cont.) | **Point 8**:<br>Six respondents opined that this provision regarding documentation in the service record, is not appropriate for inclusion in this regulation because it is a licensing issue. | **Point 8**:<br>This provision was included as part of the original proposed regulation and has not been changed. | **Point 8**:<br>DMHMRSAS does not agree with the respondents and does not recommend changes in response to the comments. |
| **12 VAC 35-115-70 *Participation in Decision Making*** | | | |
| ■ Item A | One respondent suggested that this Item include specific provisions for the use of placebos.<br><br>**Point 5**:<br>Nearly fifty comments were received which address the provisions for ECT in this part of the regulation. Many of the responses expressed serious concern about the requirement that the Local Human Rights Committee (LHRC) review all decisions to provide ECT treatment by meeting personally with the individual seeking treatment. Many respondents believe that this would unnecessarily delay treatment or restrict access to treatment when needed or increase the cost of treatment. There was also opinions expressed that sufficient protections currently exist in the system to protect the rights of individuals who receive ECT.<br><br>There were also approximately fifteen respondents who expressed support for the provisions as currently written which require the LHRC to review ECT treatment decisions and individuals who are referred for ECT to obtain a second opinion from a qualified physician who is not involved in the individual's treatment. | Provisions to address placebos were not part of the original proposed regulation.<br><br>**Point 5**:<br>Provisions requiring a second opinion and the LHRC to review ECT treatment decisions were inserted in the regulations in response to comments received following the 60-day public comment period. | DMHMRSAS does not agree with the respondent and does not recommend that such provisions be inserted.<br><br>**Point 5**:<br>Upon consideration of the recent comments in response to these provisions, DMHMRSAS believes that the requirement for a second opinion and the LHRC review of ECT treatment decisions may be considered overly burdensome. Therefore, DMHMRSAS recommends eliminating these provisions (**a** and **b**). However, DMHMRSAS also proposes inserting a second sentence in **Point 5** which states that "*Providers shall inform the individual receiving services or the legally authorized representative, as applicable, that the individual may obtain a second opinion before receiving electroconvulsive treatment and shall document such notification in the individual's services record.*" |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| ■ Item B | **Point 2**:<br>One respondent opined that the provision is impractical in that it requires individual preferences to be honored to the extent possible and asked that the original language from the proposed regulations be restored.<br><br>**Point 5**:<br>One respondent opined that this provision is legally inconsistent because it requires that a parent be notified when the Department of Social Services has legal custody of the child.<br><br>**Point 6**:<br>Several respondents indicated that it is not possible to obtain consent in all cases within a 24-hour time frame and suggested revising this provision accordingly.<br><br>**Point 9**:<br>One respondent suggested that the procedure for appointing a legally authorized representative be made more precise. Several respondents specifically questioned the authority for a director to select another person lower in priority to give consent if such person is "clearly better qualified." This question was posed "…in part to ensure that by so doing, the director and the patient do not lose the protection of § 54.1-2986, establishing procedures in the absence of an advanced medical directive" **(Part b)**. | **Point 2**:<br>This provision was inserted following the 60-day public comment period.<br><br>**Point 5**:<br>This provision was not substantively changed from the original proposed regulation (minor revisions for clarity were made following the 60-day public comment period.)<br><br>**Point 6**:<br>No change was made to this provision following the 60-day public comment period.<br><br>**Point 9**:<br>**Part b** was revised to allow a director to change the priority of appointment when another person is "clearly better qualified," following the 60-day public comment period. | **Point 2**:<br>DMHMRSAS believes that the provision is reasonable as currently written and does not recommend that the original language be restored.<br><br>**Point 5**:<br>DMHMRSAS does not agree with the respondent and does not recommend changes to this provision. This provision indicates that either a parent **or** the legal custodian be notified following the treatment, as appropriate.<br><br>**Point 6**:<br>DMHMRSAS does not recommend changing the provision. Under **12 VAC 35-115-70, Item C** "Exceptions and conditions to the provider's duties" emergency treatment may be extended beyond 24-hours when the provider meets the conditions listed.<br><br>**Point 9**:<br>DMHMRSAS believes that this provision in **Point 9** is reasonable and does not recommend additional changes in response to recent comments. However, providers only benefit from the protections of the Health Care Decisions Act when the provisions of the Act are followed. As provided in **12 VAC 35-115-70**, **Item C.2,** provisions of this regulation are not exclusive of other provisions of law but are cumulative (e.g., Health Care Decisions Act §54.1-2891 et seq.). DMHMRSAS intends |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item B (cont.) | There were five respondents who questioned the legal authority for a "next friend" (**Part c**). Another respondent stated that the procedure for appointing a "next friend" was unduly complicated.<br><br>**Point 11**:<br>One respondent commented that if this provision means that a provider is required to file a petition with the court to seek authorization to initiate treatment, then this provision constitutes an un-funded mandate.<br><br>**Point 14**:<br>Four respondents commented that the provisions which pertain to an individual who leaves a service "against medical advice," should be reinserted into the regulation at this point. | DMHMRSAS received similar comments regarding provisions for "next friend" during the 60-day public comment period. Certain revisions were made to **Part c** for clarity and to ensure that the provision does not conflict with the relevant Code sections.<br><br>**Point 11**:<br>In response to comments received on this provision during the 60-day public comment period, this provision was revised in accordance with § 37.1-134.21 of the Code of Virginia.<br><br>**Point 14**:<br>This provision was inadvertently deleted from the regulation following the 60-day public comment period. | to offer provider training following the adoption of the regulations, which will address "next friend" and issues regarding the director's authority to select another person "lower in priority." This should help providers to understand and implement these provisions.<br><br>**Point 11**:<br>DMHMRSAS does not recommend additional changes to this provision.<br><br>**Point 14**:<br>DMHMRSAS agrees with the respondents and recommends reinserting this provision. |
| ■ Item C | **Point 1**:<br>Several respondents questioned appropriate means for notifying the human rights advocate. | **Point 1**:<br>This provision was inserted following the 60-day public comment period. | **Point 1**:<br>DMHMRSAS does not recommend changes in response to this comment. Providers have the discretion to determine the appropriate means for notifying the human rights advocate should emergency treatment continue without the consent of the individual beyond 24 hours. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-80** ***Confidentiality*** | | | |
| ■ General Comments | There were four respondents who indicated that provisions regarding "confidentiality" were confusing, particularly the various exceptions which allow the disclosure of confidential information.<br><br>General concern was expressed that the entire section may not be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) . | Following the 60-day public comment period, several minor revisions were made to this part of the regulations for clarity and legal consistency. | DMHMRSAS does not agree that this section is confusing and does not recommend changes to this part of the regulations in response to these comments. Once this regulation is promulgated, DMHMRSAS intends to conduct training with providers to facilitate the implementation of provisions.<br><br>Federal HIPPA regulations are not yet effective. Therefore, the relevant existing laws and regulations provide the legal basis for these provisions. However, in order to address general concerns regarding the compliance of this regulation with HIPPA**, Section 12 VAC 35-115-10 et seq. Item C** has been changed to state " Unless another law takes priority, ***and to the extent that they are not preempted by the Healthcare Insurance Portability and Accountability Act of 1966,*** these regulations apply to all individuals receiving services…" |
| ■ Item C | Five respondents recommended that the regulation should provide a means to recruit a legally authorized representative for an individual, when necessary, without violating confidentially. | Following the 60-day public comment period, a sentence was inserted into this provision to indicate that consent must be obtained from the individual in order for the provider to contact family members, friends or others. | In response to this comment, DMHMRSAS recommends adding the following sentence to clarify the provision: "*Nothing in this provision shall prohibit providers from taking steps necessary to secure a legally authorized representative.*" |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-90** ***Access to and Correction of Services Records*** | | | |
| ■ Item B | **Point 4**:<br>One respondent indicated that it is cumbersome and unnecessary to require a provider to notify the human rights advocate if he refuses to let an individual see his service record.<br><br>Six respondents suggested clarifying this provision to indicate that a service record may be shown to the individual's lawyer in cases when individual has been denied access for therapeutic reasons only when the request is made pursuant to § 8.01-413 of the Code. This section of the Code applies when such records pertain to a patient who is a party to a cause of action in any state court and applies only to requests made by an attorney or his client in anticipation or in the course of litigation.<br><br>**Point 6**:<br>Five respondents commented that it is not appropriate to have two clinical records for individuals receiving services. This provision, which requires the provider to remove contested material from the record, is bad practice. The regulation should state that the information may not be removed from the record, but rather that information must be placed in the record to show that an individual or legally authorized representative is alleging an error and seeking a correction. | **Point 4**:<br>This provision was not changed following the 60-day public comment period.<br><br>**Point 6**:<br>This provision was not changed based on comments received during the 60-day comment period. It was determined that the requirements for record-keeping were reasonable and compliant with applicable statutory provisions. | **Point 4**:<br>DMHMSAS does not agree that with the respondent and believes that it is reasonable to require notification of the human rights advocate when a provider refuses to let an individual see his service record. No change is recommended.<br><br>It is the intent of DMHMRSAS that an individual need not invoke a specific Code section to access records or for these provisions to be applicable. DMHMRSAS believes that this provision is reasonable and does not recommend changes in response to the comments.<br><br>**Point 6**:<br>DMHMRSAS does not recommend changes in response to comments. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| ■ Item C | One respondent indicated that there was no basis in law for this provision which states that a provider may deny access to an individual's service record only if a physician or licensed psychologist first ***talks*** to the individual. | This provision was included as part of the original proposed regulation and has not been changed. This provision is consistent with § 32.1-127.1:03.F of the Code of Virginia. | DMHMRSAS does not recommend changing this provision. DMHMRSAS believes that it is reasonable for a provider to talk to an individual before denying access to his services record. |
| **12 VAC 35-115-100** ***Restrictions on the Freedoms of Everyday Life*** | | | |
| ■ Item A | **Point 1, Item b.** Two respondents commented that the regulations should allow for exceptions to this provision in certain therapeutic settings. | DMHMRSAS considered similar comments during the 60-day public comment period and did not change this provision. This regulation allows for variances or exceptions to be granted on a case-by-case basis if individual circumstances warrant. | DMHMRSAS does not recommend changes in response to comments. |
| ■ Item C | One respondent commented that provisions for implementing restrictions, which had been deleted from this section, should be reinserted.<br><br>There were several comments that **Point 3, Item e.,** which requires all rules of conduct to be reviewed in advance by the LHRC prior to implementation, is not practical. | The provisions in this section were reorganized following the 60-day public comment period and the provisions for implementing restrictions were inadvertently eliminated.<br><br>This provision was included as part of the original proposed regulation and has not been changed. (It was relocated as part of the re-organization of this part of the regulation following the 60-day public comment period.) | DMHMRSAS recommends reinserting these provisions (new **Point 1**).<br><br>DMHMRSAS does not agree with the respondents' view that the LHRC review of a provider's rules of conduct is impractical and does not recommend changes. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-110** ***Use of Seclusion, Restraint and Timeout.*** | | | |
| ■ Item B | Nine respondents expressed support for the provisions for seclusion and restraint as currently written. The following is a summary of the specific public comments that have been received on the various points in this part of the regulation:<br><br>**Point 2**:<br>Two respondents indicated that this Point should be clarified to read "…each written order or authorization for seclusion or behavioral restraint."<br><br>**Point 3**:<br>One respondent opined that the regulations should not prohibit the use of surveillance cameras to monitor seclusion and restraint.<br><br>**Point 5, Item b**:<br>One respondent recommended the addition of "…or termination of a plan for medical or protective restraint" at the end of the sentence in this provision.<br><br>**Point 8**:<br>Two respondents objected to the requirement for providers to send changes in the seclusion and restraint policies and procedures to the LHRC for review and comment prior to implementation. It was stated that such policies and procedures apply to the entire community hospital.<br><br>One respondent recommended several non-substantive language changes to this provision. | Following the 60-day public comment period, this part of the regulation was relocated and various changes were made to address the public comments and conform the provisions to applicable legal requirements. | DMHMRSAS believes that this part of the regulation is reasonable and reflects current standards of practice. However, several minor are recommended to clarify the intent in response in response to additional comments:<br><br>**Point 2**:<br>Replace the words "written order" with "authorization" and insert the word "behavioral" before the word "restraint."<br><br>**Point 3**:<br>Insert the word "solely" after the word "not."<br><br>**Point 5, Item b**:<br>DMHMRSAS does not agree that the recommended change is necessary.<br><br>**Point 8**:<br>This requirement that the LHRC review seclusion and restraint policies were part of the proposed regulation and was not changed following the 60-day public comment period. DMHMRSAS does not agree with the respondents and does not recommend changes to this section of the regulation. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item B (cont.) | **Point 10**:<br>Several respondents indicated that provisions should clarify whether seclusion and restraint is permitted in residential treatment settings. | | **Point 10**:<br>DMHMRSAS recommends revising this Point to clarify the intent of the provision to apply to residential treatment facilities for children that are licensed under 12 VAC 35-40-10 et seq., Mandatory Certification/Licensure Standards for Treatment Programs for Residential Facilities for Children. |
| | **Point 12**:<br>One respondent indicated that this provision should be clarified. This Point requires providers to notify the Department whenever an accreditation or regulatory agency finds problems with the provider's compliance with a seclusion or restraint standard. | | **Point 12**:<br>DMHMRSAS does not agree that this provision requires clarification and does not recommend changes. |
| | **Point 13**:<br>One respondent opined that the time limit restriction on time-out may be problematic. | **Point 13**:<br>The time limit restriction was added to the provision after review of comments following the 60-day public comment period. | **Point 13**:<br>DMHMRSAS believes that this time restriction is reasonable and does not recommend changes in response to this comment. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| ■ Item C | **Point 3**:<br>One respondent indicated that LHRC review of all plans for the use of seclusion and restraint will be a significant burden of time for committee members.<br><br>Several other respondents indicated that the review of individual services plans by the treating professionals, independent review committees and the LHRC in accordance with the provisions in **part b** is too burdensome and could delay service and add cost. | **Point 3**:<br>The review process for services plans was part of the original proposed regulation and was not substantively changed following the 60-day public comment period. | **Point 3**:<br>DMHMRSAS believes that this review process is reasonable. This process also permits an LHRC role in approval of plans in ICF/MR facilities, as required by federal regulations. However, in view of the comments, DMHMRSAS recommends minor revisions to clarify that the provisions in Item C apply only to providers who use seclusion and restraint.<br><br>DMHMRSAS also recommends that "treating professional" be eliminated from **part b** for clarification and to eliminate the redundancy in the provision. |
| **12 VAC 35-115-120** ***Work*** | | | |
| ■ Item A<br>■ Item C | Four respondents commented that the regulation does not provide a clear distinction between therapeutic work and work as it is commonly understood.<br><br>Several other respondents commented that individual job assignments may be viewed as part of the therapeutic process.<br><br>Four other respondents opined that a provider should be allowed to impose sanctions, as part of the therapeutic process, when an individual refuses to keep his immediate living area clean. | Clarification was added to **Item A** in response to comments received during the 60-day public comment period. In addition, a new **Item C** was added to clarify the intent of this section relative to personal maintenance or personal housekeeping. | In view of the recent comments, DMHMRSAS recommends adding the following sentence in **Item A** to clarify this applicability of this part of the regulation: *"Personal maintenance and personal housekeeping by individuals receiving services in residential settings are not subject to this provision."*<br><br>In addition DMHMRSAS recommends deleting **Item C** in this section, "*Exceptions and conditions on the providers duties*" for internal consistency. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| ■ Item B | Four respondents opined that **Part 2** of this provision is misleading and should be clarified. **Part 2** indicates that providers shall consider individuals receiving services for employment opportunities on an equal basis with other employment applicants, consistent with the Americans with Disabilities Act. | **Part 2**, as written, was part of the original proposed regulation. No comments were submitted on this provision during the 60-day public comment period. | DMHMRSAS does not recommend changing this provision in response to these comments. |
| **12 VAC 35-115-130** ***Research*** | | | |
| ■ Item B | Nine respondents objected to the requirement that providers obtain permission and provide updates to the LHRC regarding human research. Comments stated that this requirement is burdensome and offers minimal value to individuals receiving services. | The requirement that providers obtain permission from the LHRC prior to pursuing human research in **Part 4** of this Item was inserted following the 60-day public comment period. The regulation, as originally proposed, required that providers notify the LHRC regarding human research. | In view of the recent comments, DMHMRSAS recommends deleting the requirement for the LHRC review and restoring the original provision requiring the provider to inform the LHRC regarding of an individual's participation in human research. DMHMRSAS current protections in the system, i.e. Regulations to Assure the Protections of Participants in Human Research. |
| **12 VAC 115-140** ***Complaint and Fair Hearing*** | | | |
| ■ Item A | One respondent opined that this section is repetitive and confusing and should be incorporated into other parts of the regulation. | Minor revisions were made to clarify this Item following the 60-day public comment period. | DMHMRSAS does not recommend additional revisions to clarify this provision. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-150** ***Complaint Resolution Hearing and Appeal Procedures General Provisions*** | | | |
| ■ Item A | One respondent recommended the addition of a reporting requirement to this provision. | This provision was part of original proposed regulation. No substantive change was made following the 60-day public comment period. | DMHMRSAS does recommend adding reporting requirements to this provision. |
| ■ Item B | One respondent asked for clarification to the hearing provisions in Part 1 of this Item. | This provision was part of original proposed regulation and was not changed following the 60-day public comment period. | No revisions are recommended in response to this comment. |
| ■ Item D | Four respondents opined generally, that it is not appropriate that only the LHRC or State Human Rights Committee (SHRC) may waive required time periods for actions established under the regulation. This may restrict the establishment of mutually agreeable time frames by the provider and complainant. All parties should be able to agree to reasonable exceptions to time periods. | This provision was part of the original proposed regulation. In response to comments made during the 60-day public comment period, revisions were made to clarify that any party may seek extensions of time frames from the LHRC or SHRC. | DMHMRSAS does not recommend changes in response to the comments. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-160** ***Informal complaint process*** | | | |
| ■ General Comments | Five respondents commented that there is lack of clear distinction between the informal and formal complaint processes. One respondent objected to the process because it would dilute the objectivity and cause duplication of effort. | This section was inserted in the final version of the regulation following the consideration of comments following the 60-day public comment period. DMHMRSAS believes that the provisions in this part of the regulation are reasonable and should help to expedite the complaint resolution process. | No change to this part is recommended in response to the recent comments. However, DMHMRSAS recommends inserting provisions at 12 VAC 35-115-170.A to help clarify the applicability of the formal versus the informal complaint process (see below). |
| **12 VAC 35-115-170** ***Formal complaint resolution process*** | | | |
| ■ Item A | Approximately 12 respondents provided comments pertaining to determinations of when the formal rather than the informal complaint process should be used. | This process in this part of the regulations was revised in response to comments, following the 60-day public comment period. | In consideration of the recent comments, DMHMRSAS recommends inserting the additional explanatory provision prior to Item A, and re-numbering the existing provisions:<br><br>"*The following process steps apply if:*<br>1. *The informal complaint process did not resolve the complaint to the individual's satisfaction within five working days; or*<br>2. *The individual chooses to not pursue the informal complaint process."* |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-180** ***Local Human Rights Committee hearing and review procedures*** | | | |
| ■ Item F | One respondent opined that this provision might create certain types of boundary and legal problems by allowing the LHRC to make suggestions regarding disciplinary/termination issues. | Provisions that concern the LHRC's role in making personnel recommendations to the director, were added following consideration of comments received during the 60-day comment period. | DMHMRSAS does not agree that this provision is problematic as written and does not recommend changes in response to the comment. |
| **12 VAC 35-115-210** ***State Human Rights Committee appeals procedures*** | | | |
| ■ Item E | Four respondents commented that **Part 2. (b)** is not clear. If this provision is intended to allow the SHRC to review findings and re-examine facts and procedures, this should be explicitly stated. | This provision was revised for clarification following the 60-day public comment period by citing a reference to another part of the regulation that describes the specific procedures to follow when the SHRC determines that the LHRC's findings of fact are wrong. However, the regulation was changed to inadvertently reference the wrong citation. | DMHMRSAS recommends correcting the citation to E.. 3. This should eliminate the confusion. |
| **12 VAC 35-115-220 Variances** | | | |
| ■ Item A | Several respondents indicated that this provision is not logical because it does not allow the provider to be proactive in seeking variances. | This provision was part of the original proposed regulation and was not changed following the 60-day public comment period. | DMHMRSAS does not recommend changes in response to these comments. DMHMRSAS proposes to provide training sessions with providers to help to clarify this part of the regulations. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| **12 VAC 35-115-230 Provider requirements for reporting to the department.** | | | |
| ■ Item A | Two respondents asked what would constitute "notification" under this provision. | This provision requiring reporting to the human rights advocate within 24-hours of alleged abuse or neglect, was part of the original proposed regulation and was not changed following the 60-day public comment period. | No change is recommended in response to these comments. DMHMRSAS plans to conduct training with providers to assist in implementing this regulation. |
| ■ Item D | One respondent asked for clarification regarding the content and procedure for submitting monthly reports to the human rights advocate, that are required by this provision. | This provision requiring monthly reports to the human rights advocate was part of the original proposed regulation and was not changed following the 60-day public comment period. | No change is recommended in response to this comment. DMHMRSAS proposes to conduct training with providers to facilitate implementation of this regulation. |
| **12 VAC 35-115-250 Offices, compositions and duties.** | | | |
| ■ Item A | One respondent indicated that the training requirement in **Part 3** of this Item is burdensome and should be clarified. | DMHMRSAS inserted provisions for annual "competency-based training," for employees in response to comments received following the 60-day public comment period on the proposed regulation. | DMHMRSAS believes that this requirement is reasonable and does not recommend changes to **Part 3**. |
| | One respondent was concerned that this Item does not explicitly require providers to affiliate with a LHRC. | **Part 5** in this Item was revised following the 60-day public comment period to require providers and their directors to specifically communicate information about the availability of a human rights advocate and an LHRC to all individuals receiving services. The provision inadvertently omitted the requirement to assure providers affiliate with an LHRC. | In response to the comment, DMHMRSAS recommends clarifying the intent of **Part 5** by stating that providers shall ***assure*** an LHRC to all individuals receiving services. This will address the comment by requiring providers to affiliate with an LHRC. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
|---|---|---|---|
| ■ Item D<br>■ Item E<br>■ Item H | Two respondents commented that the regulation imposes a great a burden on the LHRC because it will have to review many provider policies and procedures. | Following the 60-day public comment period, provisions were inserted in this part of the regulation (**Item D, Part 4**), allowing the LHRC to review any provider's policies, procedures or practices if requested by the provider, human rights advocate, individual receiving services or on its own initiative. | DMHMRSAS does not agree that this requirement is overly burdensome and has not made any changes based on the recent comments. |
| | There were five respondents who commented that both the LHRC and SHRC are lay bodies who are created to protect the interests of individuals receiving services relevant to human rights. These respondents were generally concerned that some of the rights defined in the regulations are licensing or professional regulatory issues that exceed the purview of the two lay bodies charged with oversight responsibilities.<br><br>There were also several comments that the regulation provides no mechanism to assure accountability of the LHRC and the SHRC. There were related comments that **Item D, Part 10** should provide a means to remove LHRC members for "nonfeasance, misfeasance or malfeasance."<br><br>Three respondents indicated that **Item D, Part 4** should include provisions to require LHRC members to maintain the confidentiality of information, as appropriate. | In response to the comments received during initial 60-day public comment period, several provisions were revised in this part of the regulation for clarity, consistency with the Code of Virginia, and to reflect the responsibilities of the LHRC and the SHRC, consistent with other parts of the regulation. However, no substantive change was made to the authority of the LHRC or SHRC. | DMHMRSAS does not agree that the responsibilities of the LHRC and SHRC, which are created by this regulation, exceed the purview of these bodies. No change is recommended in response to these comments about the oversight responsibilities of the SHRC and LHRC.<br><br>The power of the SHRC to remove LHRC members for cause is implied in **Item E, Part 17,** which confers the power to the SHRC to appoint LHRC members. The power of the State Board to oversee appointments and the activities of SHRC can also be implied from provisions in **Item H,** which requires the State Board to approve the bylaws and appoint members of the SHRC. These provisions provide mechanisms for accountability of the LHRC and SHRC. No changes are recommended in response to these comments. |

| Section | Comment | Changes after 60-day Public Comment Period | Proposed Response for Consideration |
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| Item D<br>Item E<br>Item H<br>(cont.) | Several respondents recommended that **Items D, Part 1(b)** and **E, 1(b)** be changed to more closely track the statutory provisions at § 37.1-84.3, which do not specifically prohibit provider board members from serving on the State Human Rights Committee (SHRC) or Local Human Rights Committees. The regulation, as written, is confusing and prohibits provider board members from serving as members of an LHRC or SHRC.<br><br>It was also noted that these provisions do not clearly prohibit Community Services Board members from serving as members of a LHRC or SHRC. This is inconsistent with § 37.1-84.3. | Following the 60-day public comment period, DMHMRSAS inadvertently deleted the specific reference that prohibited CSB members from serving as members of the SHRC. Changes were made which would prohibit provider board members from serving on the SHRC and the LHRC. | DMHMRSAS recommends deleting the words "or provider" and re-inserting "CSB" in **Item E, Part 1(b)**. This change will prohibit CSB members from serving as members of the SHRC consistent with the statutory provisions at § 37.1-84.3. |