



Proposed Regulation Agency Background Document

Agency Name:	Board of Mental Health, Mental Retardation and Substance Abuse Services
VAC Chapter Number:	12 VAC 35-40-10 et seq. and 12 VAC 35-45-10 et seq.
Regulation Title:	<i>Mandatory Certification/Licensure Standards for Treatment Programs for Children (repeal)</i> <i>Regulations for Providers of Mental Health, Mental Retardation and Substance Abuse Residential Services for Children (replacement)</i>
Action Title:	Repeal and promulgate replacement regulations
Date:	June 27, 2002

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

These regulations are an addendum to 22 VAC 42-10-10 et seq., *Standards for Interdepartmental Regulation of Children's Residential Facilities (Standards)* which are generic standards governing a wide variety of residential facilities licensed by the Departments of Mental Health, Mental Retardation and Substance Abuse Services (Department), Social Services, Education and Juvenile Justice. The standards in this addendum or "Mental Health Module" (Module) as it is operationally called, apply to all providers of residential treatment services for children who are mentally ill, mentally retarded or chemically dependent. Services covered by these regulations include a wide range of residential services from small group homes to large residential treatment facilities.

The intent of this Module is to provide more specific standards governing the provision of mental health, mental retardation, and substance abuse services in children's residential facilities licensed by the Department. The Module regulates practices and requirements that are unique to the facilities licensed by the Department, such as the use of seclusion and restraint and compliance with the Board's *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. (Human Rights Regulations).

The Module requires the provision of more intensive services by specifying requirements for behavior management therapy, medication administration, formal arrangements for the provision of treatment, resident rights, and crisis intervention services. This module is designed to help protect the health, safety and welfare of children receiving mental health, mental retardation, or substance abuse services by ensuring those with significant needs in those areas receive an increased level of services and protections. Facilities must meet additional requirements of the Module to be certified to receive Medicaid residential treatment funding.

The Board published a Notice of Intended Regulatory Action (NOIRA) proposing to amend the existing Module (12 VAC 35-40-10 et seq.) on December 17, 2001. The purpose of the proposed action was "...to eliminate standards the duplicate other regulations and to revise and update provisions." Because extensive editing and reorganization was necessary to accomplish this purpose, the Board has revised its plan and is now proposing to repeal the existing regulations and promulgate replacement regulations.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The Office of the Attorney General advised that the State Mental Health, Mental Retardation and Substance Abuse Board (Board) has the authority to promulgate the regulations in accordance with §§ 37.1-10, 37.1-179.1 and 37.1-182 and is required to do so.

The OAG has reviewed the proposed *Regulations for Providers of Mental Health, Mental Retardation and Substance Abuse Services for Children*, 12 VAC 35-45-10 et seq. and confirms that the Board has the statutory authority to take action to promulgate these regulations and that the proposed regulations are constitutional, and do not conflict with existing federal or state laws or regulations.

The OAG also stated that the Board has the statutory authority to repeal the existing *Mandatory Certification/Licensure Standards for Treatment programs for Residential Facilities for Children*, 12 VAC 35-40-10 et seq.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed 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 Module has not been revised since 1992. There has been a significant change in the needs of the populations served that are protected by these regulations. Mental health and substance abuse residential facilities, in particular, are now serving the needs of residents who, ten years ago, were generally receiving such services in long term or in acute care settings. With the emphasis now on community-based services, many of these children and adolescents are being served in residential group homes.

The promulgation of the revised *Standards for the Interdepartmental Regulation of Children's Residential Facilities* in July 2000, and new *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services* in November 2001, made entire sections of the current Module redundant and in some cases conflictual. For example, the Standards prohibit the self-administration of medication by children while the current Module allows it. Also, the Module cites references to the former human rights regulations, which have been repealed. Many of the definitions in the current Module are either no longer needed because they are addressed in other applicable regulations, or are outdated.

The basis for this regulatory action has remained consistent with the intent of the original NOIRA filed by the Board. An advisory group was convened compare the existing provisions with more recently promulgated applicable regulations and with current standards of practice in treatment. Provisions that duplicated other regulations (e.g. *Standards for the Interdepartmental Regulation of Children's Residential Facilities*, and the *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services*) were not included in the proposed replacement regulations. Provisions that were outdated as a result of changes in current treatment practices were either deleted or revised in the proposed Module to reflect current standards of care. Regulatory provisions in the existing Module that were in conflict with other recently promulgated regulations were also deleted. Since many of the providers of children's residential services also provide adult services, changes in the language used in the replacement Module was, where possible, made consistent with the *Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services* recently promulgated by the Board.

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 providing detail of the regulatory action's changes.

Provisions that duplicate other regulations have been stricken from the proposed Module. In addition, revisions have been made in consultation with providers, the Comprehensive Services Act Office, (CSA), The Department of Medical Assistance Services, (DMAS), the Department's Office of Mental Health (OMH), and other consultants to ensure that the content of the revised Module reflects current treatment practices in children's residential programs.

Regulatory provisions included in the proposed Module are more specific the needs of residents served in programs that are governed by the Module. They require providers to specifically define the services they will provide to the disability group they intend to serve. A working definition of a residential treatment facility, taken in part from DMAS regulations, has been added to the definitions section of the proposed Module. This term has not been previously defined in the licensing regulations promulgated by the Board. Significant provisions incorporated into the replacement Module include requirements that providers comply with their own policies and complete and submit acceptable corrective action for areas of noncompliance. There are also significant revisions to provisions regarding behavior management and time out practices. Many of the changes from the current Module are intended to address areas where it was determined that there is a significant need for improvement in performance based on the review of provider violations. For example, provisions are included to require providers to monitor medication errors on a quarterly basis and use that information to aid in staff development. These revisions were made consistent with the *Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services* that were recently promulgated by the Board.

Issues

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

There are no anticipated disadvantages to the proposed replacement Module. Significant advantages to the public, providers, residents being served, and to the Department's mandated responsibility of enforcing of these regulations include revisions that reflect current standards of practice in the treatment of children in residential

facilities, eliminating duplication with other existing regulations, deleting outdated and conflicting regulations, and adding regulations that reflect current standards of practice in behavioral healthcare regarding quality improvement. The revised provisions are concise and intended to allow the Department to effectively fulfill its statutory responsibility.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Significant revisions to the Module are consistent with the Department's existing licensing regulations and have been developed to be clear, concise and direct. Therefore, there should be no additional staff training or associated cost to implement the provisions.

As of June 24, 2002 there were 115 licensed providers affected by these regulations. Promulgating revised regulations will not, by itself, increase the number of providers (new applications for these services are received almost weekly; revised regulations will not effect the number of applications received). No new staff members will be required as a result of promulgating these regulations. No significant financial impact is anticipated on providers to achieve compliance, since most new requirements reflect current standards of care. The current budget for the Department's Office of Licensing (for fiscal year 2003) is: \$1,121,391. No change in this budget is expected as a result of promulgating 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. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The proposed replacement Module will effectively streamline the regulatory requirements. There are a total of total of twenty (20) regulatory sections proposed in the replacement Module compared to thirty-four (34) in the existing Module. The twenty (20) sections in the proposed Module will effectively address the specific issues required of providers of children's residential mental health, mental retardation, and substance abuse services that other applicable promulgated regulations do not address.

The proposed replacement Module complies with the purpose for the regulatory action as described in the NOIRA published by the Board. The replacement Module was developed in consultation with workgroups consisting of staff members from the Department of Mental Health, Mental Retardation and Substance Abuse Services, members of the public, and providers. Workgroups considered whether the existing provisions were duplicative, outdated, reflected current standards of practice, and were consistent with the Virginia Code and other applicable regulations that govern the operation of children’s residential services.

The following table describes the proposed regulatory changes by comparing the section number in the existing regulations (12 VAC 35-40) to the equivalent section number in the proposed replacement regulations (12 VAC 35-45)

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
10	Definitions	10	<p><u>Defined Terms</u> Advocate—deleted Aversive stimuli—deleted Behavior management—deleted Care or Treatment—added Case coordinator—deleted Chemotherapy—deleted Client—deleted Client data base—deleted Client goal—deleted Client objective—deleted Commissioner—added Core standards—deleted Counseling—added & clarified Counseling/psychotherapy—deleted Crisis—added and clarified Crisis intervention—revised Department—added Direct services—deleted Discipline—deleted Generic services—deleted Growth services—deleted Individual service plan—deleted Intrusive aversive therapy—deleted Local human rights committee—deleted Medication—added Medication administration—added Mental retardation—added (definition taken from the Virginia Code) On-site—added On-site training—deleted Preplacement services—deleted Regional advocate—deleted Residential treatment program—added Restraint—added Seclusion—deleted Serious injury—added Service or Services—added (definition taken from the Virginia Code) Social skills training—revised Stabilization services—deleted State Human Rights Committee—deleted Task and skill training—deleted Time out—added and revised (replacement definition for “time out procedures”) Time out procedures—deleted</p>

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
30	Rights	30	Non-substantive changes for clarification
40	Audio and visual recording	40	Non-substantive changes for clarification
	Compliance with applicable laws, regulations and policies	50	NEW. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> (12 VAC 35-105-10 et seq.) recently promulgated by the Board.
	Written plans of correction for noncompliance	60	NEW. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board.
	Service description; requirements	70	NEW. Specific to services licensed by the Department.
	Minimum service requirements	80	NEW. Specific to services licensed by the Department.
	Admission applications	90	NEW. Specific to services licensed by the Department.
50	Client behavior		DELETED. Addressed in the "human rights regulations," <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> (12 VAC 35-115-10 et seq.)
60	Least restrictive programming	100	Non-substantive revisions and clarification
70	Client growth		DELETED. Addressed in Section 80 of the proposed replacement regulations
80	Therapy; general		DELETED. Refers to intrusive aversive therapy now addressed in the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
90	Therapy; requirements		DELETED. Refers to Intrusive aversive therapy now addressed in the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
100	Therapy; approval		DELETED. Refers to Intrusive aversive therapy now addressed in the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
110	Therapy; advocate notification		DELETED. Refers to Intrusive aversive therapy now addressed in the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
120	Therapy; review		DELETED. Refers to Intrusive aversive therapy now addressed in <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
130	Administration		DELETED. Referred to medications. Now addressed in Section 130 of the proposed replacement regulation.
140	Authorization		DELETED. Referred to medications. Now addressed in Section 130 of the proposed replacement regulation.
150	Self administration; general		DELETED. Current provision conflicts with <i>Standards for the Interdepartmental Regulation of Children’s Residential Facilities</i> (12 VAC 42-10-10 et seq.)
160	Self administration; requirements		DELETED. Current provision conflicts with <i>Standards for the Interdepartmental Regulation of Children’s Residential Facilities</i>
170	Storage		DELETED. Referred to medications. Now addressed in Section 130 of the proposed replacement regulations

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
180	Documentation	110	REVISED. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
190	Side effects notification		DELETED. Referred to medications. Addressed in Section 130 of the proposed replacement regulations.
200	Chemotherapy		DELETED. Referred to medications. Addressed in Section 130 of the proposed replacement regulations
210	Records		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
220	Requirements		DELETED. Referred to releasing records. Addressed in <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
230	Policies		DELETED. Addressed in the <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
240	Requirements		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
250	Criteria		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
260	Development		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
270	Stabilization plan		DELETED. Not relevant, this refers to services delivered in inpatient acute care settings
280	Case review		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i> .

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
290	Documentation		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities</i>
300	Requirements		DELETED. Addressed in <i>Standards for the Interdepartmental Regulation of Children's Residential Facilities.</i>
	Record reviews	120	NEW. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board
130	Medication administration	130	REWORDED. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board and, <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> and the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
	Medication error reviews	140	NEW. Specific to services licensed by the Department
310	Policies	150	REVISED. Refers to policies on crisis or clinical emergencies
320	Policies		DELETED. Refers to growth activities now addressed in Section 80 of the proposed replacement regulation
330	Policies		DELETED. Refers to counseling now addressed in Section 80 of the proposed regulation
340	Policies		DELETED. Refers to case coordination activities now addressed in Section 80 of the proposed replacement regulation
	Documentation of crisis intervention and clinical emergencies	160	NEW. Specific to services that are licensed by the Department.

Existing Section	Subject	New Section	Changes Proposed in the Replacement Regulation
70	Behavior management	170	REVISED. consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board and the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
50	Time out	180	REWORDED. consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board and the <i>Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services</i>
	Seclusion room requirements	190	NEW. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board
	Emergency reporting	200	NEW. Consistent with <i>Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services</i> recently promulgated by the Board

Alternatives

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

The agency considered several alternatives to address the deficiencies in the current Module and determined that the repealing and replacing the existing Module is the least burdensome and intrusive means for establishing licensing requirements for providers of mental health, mental retardation and substance abuse residential services for children.

Alternative 1 - No regulations. This alternative was rejected. The Board is required to promulgate regulations for licensing residential services for children to comply with statutory requirements. Additionally, repealing the Module without replacing it would eliminate requirements specific to the provision of mental health, mental retardation and substance abuse services in residential services for children.

Alternative 2 - No change to the regulations. This alternative was also rejected. The Module has not been revised since its promulgation in 1992 and revisions are necessary to eliminate duplication, conflicts with other regulations, and to assure that provisions reflect current treatment practices.

Alternative 3 - Repeal the existing regulations and promulgate revised replacement regulations. This alternative was initially rejected because the Board believed that the desired changes could be accomplished by amending the existing regulations. However, because extensive editing and reorganization was needed to incorporate the required revisions into the current regulations, it was determined that the development of the replacement regulations would be the least burdensome alternative and most easily understood by the regulated providers, staff and the public. Therefore, the Board now proposes to promulgate replacement regulations rather than amending the current regulations in order to update the provisions consistent with the recently promulgated *Standards for the Interdepartmental Regulation of Children's Residential Facilities*, and the *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services*.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No public comment was received during the NOIRA comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency has developed the proposed replacement regulations through consultation with the Department's licensing specialists and an external workgroup that included providers of children's residential services, including both group homes and large residential treatment facilities, representatives from the Comprehensive Services Act Office, the Department of Medical Assistance Services, the Office of Mental Health, the Coordinator of the Office of Interdepartmental Regulation, and all staff members from the Office of Licensing. Further revisions were made by an internal workgroup that included management staff of the Department, and the Office of the Attorney General. This collaborative effort assisted the agency to develop regulations that are understandable by affected individuals and entities.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The regulations will be reviewed three years after they are promulgated, or, consistent with any effective Executive Order.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.

This proposed amended Module should improve assurances that children in residential programs will receive comprehensive and quality mental health, mental retardation and substance abuse treatment services. This Module respects the authority and rights of parents educating, nurturing, and supervising their children and affirms the marital commitment. It also supports individuals in their efforts to achieve economic self-sufficiency and to accept personal responsibility by its continued focus on consumer choice and involvement in treatment decisions. This Module has no discernable negative impact on family income. Its consumer choice focus encourages and promotes healthy economic competition among provider organizations.