



Virginia
Regulatory
Town Hall

Periodic Review and
Notice of Intended Regulatory Action
Agency Background Document

Agency Name:	Department of Mental Health, Mental Retardation and Substance Abuse Services
VAC Chapter Number:	12 VAC 35-102-10 et seq. and 12 VAC 35-105 et seq.
Regulation Title:	Rules and Regulations for the Licensure of Facilities and Providers of Mental Health, Mental Retardation and Substance Abuse Services
Action Title:	Repeal Regulation 12 VAC 35-102 -10 et seq. and Promulgate Replacement Regulation 12 VAC 35-105 et seq.
Date:	June 12, 2000

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

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.

This regulation provides standards for licensing of organizations and facilities by the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department). The regulation provides specific standards, governing the administration, clinical services, support functions and physical environment of a licensed provider organization, that are designed to protect the health, safety and welfare of clients that receive services from such providers and

facilities. The regulation also identifies the types of provider organizations that require a license and describes the process for obtaining a license from the Department. In addition, the regulation outlines the procedures to be used by the Department to monitor providers' compliance with the specific requirements for licensing, describes the basis for revocation or refusing to issue a license, and the circumstances under which a provisional license and/or sanctions may be issued.

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.

There are several Virginia Code sections that authorize the promulgation of this regulation. Va. Code § 37.1-179.1 grants permissive authority to the Mental Health, Mental Retardation and Substance Abuse Services Board (Board) to promulgate regulations authorizing the Commissioner to issue licenses for the operation of facilities or institutions providing "...care or treatment for mentally ill persons, mentally retarded persons, or persons addicted to the intemperate use of narcotic drugs, alcohol, or other stimulants..." In addition, Va. Code § 37.1-182 indicates that "institutions, hospitals and homes" licensed under these provisions shall be subject to on-site inspections by the Department and grants the Board permissive authority to promulgate regulations to carry out such inspections.

There are also several sections of the Code that mandate promulgation of regulations that pertain to the licensing of mental health, mental retardation and substance abuse services facilities and providers. Va. Code § 37.1-182.1 requires promulgation of regulations to "ensure that programs licensed to provide substance abuse treatment develop policies and procedures which provide for timely and appropriate treatment for pregnant substance abusing women." Va. Code § 37.1-185.1 requires the Board to promulgate regulations for imposing civil penalties on licensed facilities that violate certain legislative mandates regarding human rights and licensing requirements. Violations of these regulations can result in the imposition of civil penalties. Va. Code § 37.1-186.1 requires the Board to adopt regulations to enforce the prohibition against licensed facilities that "knowingly and willfully offer to pay any remuneration directly or indirectly, in cash or in kind, to induce any practitioner of the healing or any clinical psychologist to refer an individual or individuals to such facility or institution." Va. Code § 37.1-188.1 requires the Board to promulgate regulations to govern advertising practices of any licensed institution to ensure that advertisements are not false or misleading.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

The Department contacted more than 400 interested persons and organizations, including all licensed programs, to request comments as part of the periodic review of this regulation. Seven responses were received as a result of this effort. The Department also convened an external work group of providers and interested persons to seek technical assistance in the review of the regulation. Generally, commentors found no serious problems with the current regulation although many indicated that changes were needed to clarify or update the current regulatory provisions. The Department generally agrees that some revision and updates are necessary and is now proposing to initiate regulatory process to make the appropriate changes. The Department intends to use an external workgroup which includes public and private providers, state advocacy organizations and related state agencies to assist in this process. The following is a summary of the specific public review comments that were received in conjunction with the review of this regulation and the agency response:

1. Santara Norfolk General Hospital: This provider believes that facility licensing is necessary to protect the "safety and well being of our clients." However, this respondent thinks that the Department should disseminate any regulatory changes to providers on a more timely basis and sponsor provider workshops, develop interpretive guidelines, etc. to promote better communication about any new regulatory requirements.

Agency Response: The Department disseminates any changes in regulatory interpretation in as timely a manner as possible. The Office of Licensing currently has Interpretive Guidelines for its current regulations which are available upon request at no cost. Provider organizations routinely request technical guidance from the Office of Licensing concerning regulatory interpretations and at any time can request a meeting with licensing staff to further discuss any regulatory concerns.

2. Parents and Associates of the Institutional Retarded (PAIR): This commentor recommended specific, detailed revisions to the current regulation. Some of these revisions were evidently directed toward improving the clarity of the current provisions. However, most of the suggested changes apparently are directed toward improving client services and pertain specifically to the regulatory requirements for staff supervision, crisis intervention, physical environment and the administration of licensed facilities and programs. The commentor also noted that the current regulation is not entirely consistent with current statutory mandates for human rights and special education.

Agency Response: The Department has identified as a top priority in the revised regulations improving the clarity and precision of the regulatory language. The Department's External Workgroup, of which PAIR is a member, is currently identifying content areas of the current regulations which need strengthening and improvement. Consumer service planning, the provision of crisis intervention services, staff qualifications and supervision, physical and environmental requirements, and congruence with human rights and special education regulations are among those areas under review.

3. Family Preservation Association in the Tidewater Area: This commentor indicated that this organization supports "intensive in-home services" rather than a "client-specific medical model of care that is typical to psychiatric and residential facilities." On this basis, this commentor believes that the current licensing regulations conflict with the goals of this organization to promote family focused, home-based care as an alternative to the "medical model." The commentor requested an opportunity to meet personally with a Department representative to discuss the organization's specific concerns about the regulation.

Agency Response: Intensive In-Home Services is a program that has been licensed under the current regulation since its promulgation in 1995. The Department respectfully disagrees with the provider's contention that this regulation inhibits the development and growth of providers of Intensive In-Home services. Under the current regulatory structure, all providers must develop their own program descriptions which form the basis for subsequent reviews. Therefore, the Regulation does not prohibit providers of Intensive In-Home Services from offering programs that are consistent with the individual organizational goals. There are a number of viable and thriving intensive In-Home Services providers currently licensed by the Department. The Department also disagrees with the assertion that this regulation promotes a "client-specific medical model of care that is typical to psychiatric and residential facilities." This regulation does not advocate or promote the development of any type of program model at the expense of another type. The Office of Licensing has contacted the provider to schedule a meeting to discuss its particular concerns.

4. Tucker Pavilion: This respondent encouraged the Department to conduct meetings with provider representatives as part of the review of this regulation. The provider indicated that generally the rules and regulations are "straightforward in principle and intent" but believes that more specificity is needed regarding the criteria for program accountability and compliance.

Agency Response: The Department agrees with the points and is examining, as part of its regulatory review process, specific regulations whose language and wording need to be strengthened and/or clarified. The Department's External Workgroup will offer ideas and guidance in the development of these revised regulations. The workgroup has met once and a second meeting is being planned for early Summer 2000.

5. Mount Rogers Community Mental Health and Mental Retardation Services Board: The commentor believes that the regulation is understandable, user-friendly, and has no recommendations for revisions at this time.

Agency Response: The Department intends to make its new regulations understandable and user-friendly.

6. St. Joseph's Villa: This commentor indicated that the regulations are generally "pertinent and appropriate" but is concerned about the requirement that providers maintain separate designations for clients with dual diagnoses (DD), mental retardation (MR) and substance abuse (SA). This provider believes that "decision-making in regards to program composition, i.e., separate or integrated placement of individuals with DD, MR and MH, should be left up to the organization/provider."

Agency Response: This issue has elicited feedback from a number of provider organizations. The Department wants to insure two things with its designations: (1) that consumers receive the most appropriate clinical services in the licensed program and that the services are delivered by qualified and trained staff and; (2) that program designations continue to allow the Department to collect and use data regarding the types of programs available for consumers and their families. The Department agrees with the idea that provider organizations have the responsibility for determining where consumers should be served. The Department, however, has the responsibility for insuring that consumers are served in programs that are appropriately licensed and staffed to serve them. The designations on "Licensed As" statements are being examined in the regulatory revision process.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The regulation has three identifiable goals:

- o Provide protections for consumers that receive services from organizations and facilities;
- o Assure that providers are accountable for the services that they provide to consumers;
- o Assure the regulation is flexible and easy to understand and enforce.

There was a general consensus among the participants in this review the regulation complies with these basic goals although there are several areas that should be improved. For example, one provider indicated the criteria for program accountability should be more specific. Another provider indicated that the current regulation is not entirely consistent with current statutory mandates for human rights. The Department proposes to consider revisions to the regulations which would address the concerns expressed as part of this review process. In addition, the Department proposes to consider expanding the applicability of the regulation to a wider range of public and private mental health, mental retardation and substance abuse programs and provider organizations that are currently outside the purview of the regulation.

Recently, there has been an a significant increase in the number programs that are licensed by the Department. These programs are serving clients with increasing complex psychiatric and medical needs. Therefore it is imperative that the licensing regulations are clear and unambiguous if they are to provide a reliable means for the Department to ensure consumer protections and provider accountability. This growth in licensed programs and changes in client population is reflective of the recent utilization trends experienced by the Department. There has been a significant decrease in the utilization of state mental health and mental retardation facilities. From FY 98 to FY 99, there was a 16% decrease in adult admissions to state facilities.

By annualizing the 2,951 adult admissions through 4/30/2000, it is projected that number of adult admissions to state facilities will decrease by 43% from FY 99 to FY 2000. A concurrent growth in community based programs is occurring. The number of licensed programs increased by 3% from June, 1999 to June, 2000 with a 10% increase in the number of community program locations. In addition, consumers returning to the community from Virginia's state facilities are evidencing increasingly complex psychiatric and medical needs. These trends emphasize the need to update the licensing regulations in order to ensure sufficient consumer protections and appropriate plans of care and treatment.

In summary, it has been determined, based on the periodic review, that the current regulation should be replaced with a new regulation that will reinforce provisions for consumer protection and provider accountability. This would be accomplished by eliminating ambiguities that have been found in the existing regulation and strengthening minimum standards and administrative procedures to assure the protection of the health, safety and welfare of individuals receiving mental health, mental retardation and substance abuse services. The regulation also would include elements of process and procedure that are currently included in the "Preamble" section. The specific regulatory requirements to be considered for revisions encompass environmental and life safety practices, assessment, treatment planning and discharge planning.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The Department and the State Board have conducted an analysis of the applicable law, public comments and have considered several alternatives for resolving the issues identified by this Periodic Review of the existing licensing regulations.

Alternative 1 - No regulation. This alternative was rejected. Repealing the licensing regulations without replacing them would eliminate an important tool for protecting the health and safety of consumers who receive services from providers of mental health, mental retardation and substance abuse services in Virginia. The Department has opted to use the authority granted by § 37.1-179, et seq. of the Code of Virginia to license such providers.

Alternative 2 - No change to the Licensing Regulations. This alternative was rejected. The existing licensing regulations have not been revised since their promulgation in January 1995 and revisions are necessary to:

- o Improve consumer protections and safety by updating current requirements to reflect current practice and technology.
- o Improve provider accountability by clarifying provisions to make them more understandable for consumers and providers; and

- o Incorporate recent statutory changes regarding human rights.

Alternative 3 - Amend the regulation. This alternative was rejected. It is expected that changes to this regulation will be too extensive involving the reorganization of format as well as modification of the specific requirements.

Alternative 4 - Repeal the existing licensing regulations and promulgate a revised regulation. This alternative was accepted. Revision of the licensing regulations, with an emphasis on upgrading consumer protections and safety, increasing provider accountability and, wherever possible, maintaining the flexibility of the current regulation, will result in a regulation that meets the Department's stated goals and allows provider organizations to continue to develop models of clinical programming that reflect current practices and technologies.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The Department and the State Board recommend "Alternative 4" which will involve repealing the current regulation concurrent with the promulgation of a new replacement licensing regulation. The Department and the State Board propose to develop a new regulation that will improve the focus on consumer protections and provider accountability, retain flexibility, and enable the Department to meet its statutory requirements in a manner that is most protective of consumer health, safety and welfare and least burdensome to provider organizations.

Substance

Please detail any changes that would be implemented.

The Department anticipates changing the overall format and structure of the licensing regulations as well as some of the language and specific regulatory requirements of a number of specific requirements. These changes will cover such areas as consumer life safety, the provision of care and treatment services, and current definitions.

The changes will also incorporate a description of the process for initiation of negative action against a provider, and description of the licensing subjectivity and issuance process, into the body of the licensing regulations.

Additionally, these revised regulations will be linked with the Department's promulgated Human Rights Regulations. This linkage is to reflect changes to Title 37.1 of the Virginia Code, effective July 1, 1999, which require that the licensing of providers be contingent upon satisfactory compliance with the proposed human rights regulations and that annual compliance reviews be

conducted by the Office of Licensing. This linkage to the Human Rights Regulations will also include a detailed description of the sanctions available to the Department for possible imposition against providers for failure to maintain substantial compliance with the licensing and human rights regulations. The process for imposition of these sanctions will also be described.

Family Impact Statement

Please provide a preliminary 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 regulation better affords consumers and families the assurance of receiving comprehensive and quality mental health, mental retardation and substance abuse treatment services delivered in a safe and therapeutic manner. This regulation respects the authority and rights of parents in education, nurturing and supervising their children and affirms the marital commitment. This regulation supports individuals in their efforts to achieve economic self-sufficiency and to accept personal responsibility by its focus on consumer choice and involvement in treatment decisions. This regulation has no discernable negative impact on family income. Its consumer choice focus also encourages and promotes healthy economic competition among provider organizations.