Virginia Regulatory Town Hall

Final Regulation
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., 12 VAC 35-170-10 et seq. and 12 VAC 35-105 et seq.
Regulation Title:	Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services
Action Title:	Repeal Regulations 12 VAC 35-102-10 et seq. and 12 VAC 35-170-10 et seq. promulgate Replacement Regulations 12 VAC 35-105 et seq.
Date:	April 25, 2002

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Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed.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or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed.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.

These regulations provide standards for licensing of providers by the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department). The regulations include specific standards governing the administration, clinical services, support functions and physical environment of a licensed provider that are designed to protect the health, safety and welfare of individuals receiving services from such providers. The regulations also identify the services for which a provider may be licensed and describe the process for obtaining a license from the Department. In addition, the regulations outline the procedures to be used by the

Department to monitor providers' compliance with the specific requirements for licensing, describe the basis for revocation or refusing to issue a license, and the circumstances under which a provisional license or sanctions may be issued.

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.

At its meeting on April 25, 2002, the Board for Mental Health, Mental Retardation and Substance Abuse Services adopted final Rules and Regulations for the Licensure of Facilities and Providers of Mental Health, Mental Retardation and Substance Abuse Services (12 VAC 35-105) and voted to repeal the existing Rules and Regulations for the Licensure of Mental Health, Mental Retardation and Substance Abuse Services (12 VAC 35-102) and Regulations for the Certification of Case Management (12 VAC 35-170).

The Board also voted to delay implementation of the new regulations to 90 days following the final adoption period (projected September 19, 2002) to allow sufficient time for staff and provider orientation to the new licensing requirements.

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.

There are several Virginia Code sections that authorize the promulgation of these regulations. Section 37.1-179.1 of the Code of Virginia grants permissive authority to the Mental Health, Mental Retardation and Substance Abuse Services Board (Board) to promulgate regulations authorizing the Commissioner to issue licenses to "any suitable provider to establish, maintain and operate, or to have charge of any service for persons with mental illness, mental retardation or substance addiction or abuse." In addition, Section 37.1-182 of the Code of Virginia indicates that "all services provided or delivered under any such license shall be subject to review or inspection at any reasonable time by any authorized inspector or agent of 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 and providers. Section 37.1-182.1 of the Code of Virginia requires adoption of regulations to "ensure that

providers licensed to offer substance abuse treatment develop policies and procedures which provide for the timely and appropriate treatment for pregnant substance abusing women." Section 37.1-185.1 of the Code of Virginia requires the Board to promulgate regulations for imposing civil penalties on licensed providers that violate certain legislative mandates regarding human rights and licensing requirements. Violations of these regulations can result in the imposition of civil penalties. Section 37.1-188.1 of the Code of Virginia requires the Board to promulgate regulations to govern advertising practices of any license provider to ensure that advertisements are not false or misleading.

Section 37.1-219 of the Code also requires the Board to "…adopt reasonable regulations prescribing standards for substance abuse treatment programs to ensure proper attention, service and treatment to persons treated in such programs." Section 37.1-221 requires the Board to "…adopt regulations for acceptance of persons into approved substance abuse treatment programs."

The Office of the Attorney General (OAG) has certified that the proposed regulations are "…constitutional and do not conflict with existing federal or state laws or regulations." In addition the OAG has confirmed that the Board for Mental Health, Mental Retardation and Substance Abuse Services has the statutory authority to promulgate the 12 VAC 35-105-10 et seq. repeal 12 VAC 35-102 et seq. and 12 VAC 35-170-10 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 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 Department of Mental Health, Mental Retardation and Substance Abuse Services is proposing to replace the current licensing regulations and the regulations for certification of case management for the following reasons:

- To reorganize and clarify the regulations consistent with current practice and terminology;
- To include the process for licensing in the text of the regulations, including provisions for variances and sanctions. Such provisions are not included in current regulations;
- To provide greater specificity in the providers' responsibilities, especially for qualifications of employees and supervisors, requirements for assessments and service planning, and requirements for responding to the medical needs of individuals receiving services;
- To incorporate the recent changes in licensing laws, including requirements for staff background checks;

- To ensure that provisions for licensing comply with the Board's regulations for human rights. Recent changes to the law require compliance with human rights regulations as a prerequisite for licensing providers; and
- To incorporate provisions for licensing additional services (i.e. case management, community gero-psychiatric residential services) consistent with amendments to the law that were enacted in 2001.

These changes and updates are necessary to conform the regulations to recent changes in the law; to ensure the protection of individuals receiving services; to increase the accountability of providers and to provide greater flexibility in tailoring programs and services to meet individual needs.

With the proposed changes and updates, the regulations will provide the basis for the Department to issue licenses, as required by § 37.1-183.1, to persons who establish services "…for the care or treatment of mentally ill or mentally retarded persons, or persons addicted to the intemperate use of narcotic drugs, alcohol or other stimulants…"

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.

The new regulations include new sections that explain the authority and applicability of the regulations and the licensing process that are not included in the current regulations. Specific requirements for sponsored residential home services, case management services, community gero-psychiatric residential services and intensive community treatment and programs of assertive community treatment services have also been included in the proposed regulations.

The regulations require all residential and inpatient locations to be in compliance with specific residential physical environment requirements. The Office of Licensing will apply these regulations to all residential and inpatient locations. The number of licensed beds will be specified on the license addendum and all residential and inpatient locations will be regularly reviewed for compliance with the residential physical environment requirements, regardless of the number of beds.

New definitions have been added including, "corrective action plan," "crisis," "individual," "medication error," "neglect," "provider," "restriction," and "serious injury" and many definitions have been updated and revised. Documentation requirements are added and policies are required to be implemented.

The regulations have been reorganized, especially Part III "Services and Supports," and provisions have been strengthened. Supervision requirements have been added to the provider staffing plan. The admission process must include a preliminary assessment to determine eligibility for services and to develop a preliminary individualized services plan. The

preliminary individualized services plan must be developed and implemented within 24 hours of admission and the complete individualized services plan must be developed and implemented within 30 days. Health care policy regulations are also strengthened.

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.

The new regulations will build on the current regulations by clarifying and reorganizing the requirements. This should facilitate compliance by reducing ambiguity and providing more detailed guidance to providers regarding the specific requirements. This clarification should also improve the agency's ability to monitor the provider's compliance with the standards.

The revisions should also provide greater protection for individuals receiving services and their families in response to individual needs. The agency has generally found that individuals receiving services in licensed programs have more complex disabilities and needs than those that have been served in the past. The proposed amendments are needed to effectively safeguard this population. The new regulations strengthen the requirements in areas such as physical environment, staff supervision, and individualized service planning.

There are no disadvantages to the public or the Commonwealth associated with the promulgation of the proposed regulations.

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.

The following revisions were made in the proposed regulations since its publication for public comment:

- Modification of definitions to clarify meanings;
- Deletion of the list of persons or organizations that are not required to be licensed;
- Incorporation of the Virginia Department of Health's recommendations for sewer and water inspections;
- Revision to weapons section based on questions about limitations;
- Removal of specific requirement for changing bed linen every seven days;
- Revision of criminal history background check section to comply with current statute;
- Change in requirement for orientation of new employees from 14 calendar days to 15 business days;

- ?? Adoption of Virginia Department of Health's recommendations for tuberculosis (TB) screening;
- ?? Reduction in the number of required drug screens in Opioid treatment services from twelve to eight;
- ?? Change in the allowance for take home medication in Opioid treatment services from absence of recent alcohol and drug use to "recent alcohol abuse and other illicit drug use";
- ?? Deletion of the regulatory requirements and the references to sobering-up centers; and
- ?? Modification of Program of Assertive Community Treatment (PACT) regulations significantly based on the national model.

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 following matrix provides a summary of public comments received on the proposed regulations and the Agency's response:

Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services

12 VAC 35-105-10 et seq.

Summary of Public Comments

Section	Comment	DMHMRSAS Recommendation
Part I Article 1-- Authority and Applicability **12 VAC 35-105-10**		
✍✍ General Comment	Questions whether the absence of an exclusion for Department of Corrections operated facilities is intentional.	**No change:** The Department currently licenses the Department of Correction's mental health inpatient and residential services.
✍✍ Item B	Believes the description of substance abuse is too narrow because it appears that drugs that are neither narcotics nor stimulants are excluded. Recommends wording "abuse or addiction to alcohol or other prescribed or illegal drugs..."	**Change** to reflect language in Va. Code § 37.1-179.1. No ~~person or organization , except as provided for in subsection C of this section, may~~ ~~provide care or treatment~~ provider shall establish, maintain, conduct or operate any service for persons with mental illness or mental retardation or persons ~~addicted to the intemperate use of narcotic drugs, alcohol or other stimulants, including the detoxification, treatment or rehabilitation of drug addicts through the use of opioid treatment~~ with substance addiction or abuse without first receiving a license from the commissioner.
✍✍Item C	**Point 1**: Recommends that the Department license its own programs. The Department should hold its own programs accountable to the same standards to which it holds others. **Point 6:** Indicates that the exclusion based on Department of Social Services (DSS) licensure is too broad. Recommends the addition of the phrase "…providing services covered under the license issued by DSS. Indicates that the language which describes the private practice group exemption may need to be re-considered.	**No change:** Virginia Code § 37.1-42.1 authorizes the Department to supervise and manage the state facilities. The Department agrees that it should hold its own programs accountable to the same, or even higher, standards to which it holds others and does so through supervision and management. **Change:** Delete this section because it is not necessary. Exemptions are located in other parts of the law. See above response. The definition will be deleted also. Subjectivity to licensing will be determined in accordance with the Code of Virginia §37.1-179.

Section	Comment	DMHMRSAS Recommendation
Item C (cont.)	**Point 7:** Indicates that Juvenile Detention facilities are operated by local governments not the Virginia Department of Corrections. However, these are considered "correctional facilities." Recommends clarifying the definition of "correctional facility" to include the facilities listed here.	**Delete this section**. Juvenile Detention facilities are licensed by the Department of Juvenile Justice under the Interdepartmental Regulation for Children's Residential Facilities.
Article 2—Definitions **12 VAC 35-105-20**		
✍✍ General Comments	Recommends that definitions of diagnostic disorders be consistent with those defined by the DSM IV.	**No change:** Definitions of mental illness, mental retardation and substance abuse are based on the *Code of Virginia* § 37.1-1.
✍✍ "Abuse"	Indicates that this term is poorly defined. "It should not include a blanket statement covering all unperformed acts…Provider responsibility with regard to abuse may occur between or among individuals receiving services is also not clear."	**No change:** The definition is consistent with § 37.1-1 of the *Code of* ***Virginia*** **.**
✍✍ "Behavior Treatment Program"	Suggests that the term "serious" be described with regard to serious behaviors. Add destructive, violent, etc.	**No change:** This definition is consistent with the *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services* ("Human Rights Regulations")**.** (See 12 VAC 35-115-30).
✍✍ "Case Management Service"	Suggests that the definition be reworded as "assisting individuals and their families to access, or referring them to, appropriate services and supports…." As written, this definition implies that services are being provided. Also recommends adding: "Case management tracking and consumer monitoring for purposes of determining potential needs for services shall be considered screening and referral, not admission into licensed case management services, and therefore are not licensed services."	**Change to read:** "Case management service" means assisting individuals and their families to access services and supports that are essential to meeting their basic needs identified in their individualized service plan, which includes not only accessing needed mental health, mental retardation and substance abuse services, but also any medical, nutritional, social, educational, vocational and employment,

Section	Comment	DMHMRSAS Recommendation
"Case Management Service" (cont.)	Recommends putting a frequency of contact to be called case management and be licensed. Definition currently too broad and very inclusive. Questions how often must a person see a client to be defined case management and when does consumer monitoring begin. Suggests that a frequency would uniformly distinguish between case management and consumer monitoring.	housing, economic assistance, transportation, leisure and recreational, legal, and advocacy services and supports that the individual needs to function in a community setting. **Change** **Add to "Case Management Service" definition**: Maintaining waiting lists for services, case management tracking and periodically contacting individuals for the purpose of determining the potential need for services shall be considered screening and referral and not admission into licensed case management. **No change:** The revised definition for "case management" addresses this concern.
✍✍ "Clubhouse Service"	Suggests clarifying that the program must be open a minimum of two hours a day, five days a week; not that an individual must participate for two hours a day, five days a week.	**No change:** The time frame in the definition applies to the hours of service, not to individuals receiving services.
✍✍ "Community Intermediate Care Facility/mental retardation" (ICF/MR)	Suggests changing the wording to "individuals who have mental retardation."	**Change to read:** "Community intermediate care facility/mental retardation (ICF/MR)" means a service licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services in which care is provided to individuals who ~~are mentally retarded~~ <u>have mental retardation</u> are not in need of nursing care, but who need more intensive training and supervision than may be available in an assisted living facility or group home. Such facilities must comply with Title XIX of the Social Security Act standards, provide health

Section	Comment	DMHMRSAS Recommendation
"Community Intermediate Care Facility/mental retardation" (ICF/MR) (cont.)		or rehabilitative services, and provide active treatment to individuals receiving services toward the achievement of a more independent level of functioning or an improved quality of life.
✍✍ "Day Support Services"	Indicates that in the definitions of Day Support and Day Treatment "…services are generally provided for two or more consecutive hours per day." A client adjusting to a *new environment, recuperating from illness, etc., may spend less than two* hours…." While this is a funding issue, it should not be a licensing issue. Requests clarification.	**No change:** The time frames in the definitions apply to the services offered, not to the number of hours each individual must attend.
✍✍ "Dispense"	Recommends adding a definition of the term "deliver" in reference to medications. Some licensees "deliver" medications by simply handing the consumer prepackaged medication. Medication administration requires a greater level of documentation and oversight than delivery.	**No change:** The word "deliver" is used in the definition, but is not used in these regulations and, therefore, does not need to be defined. However, the definition in Virginia Code § 54.1-3401 will be used in interpreting regulations relating to dispensing of medications.
✍✍ "Group Home Residential Service"	Suggests that the definition clearly include those programs that offer supervision only when residents are present (not 24-hours per day, 7-days per week). "Counseling" should be included. Proposes the following: "*Group home residential service* means a residential service providing supervision in a community-based, homelike dwelling, other than the private home of the operator, at all times residents are present. These services are provided for individuals needing assistance, counseling and training in activities of daily living or whose service plan identifies the need for the specific type of supervision or counseling available in this setting."	**No change:** The definition addresses the availability of staff supervision when residents are present. **Change to read:** "Group home residential service means a congregate residential service providing 24-hour supervision in a community-based, homelike dwelling. ~~other than the private home of the operator.~~ These services are provided for individuals needing assistance, counseling and training in activities of daily living or whose service plan identifies the need for the specific type of supervision or counseling available in this setting."

Section	Comment	DMHMRSAS Recommendation
"Group Home Residential Service (cont.)	Proposes eliminating the clause " other than the private home of operator." Recommends that residential services in the home of the principle services providers be allowed to be licensed as group home when three or four individuals are to be served in the home.	See above response.
✍✍ "Inspector General"	Indicates that no reference is made to the Office of Inspector General (IG). Since by Code of Virginia the IG now has the authority to conduct reviews in programs that are licensed by the Department, it seems appropriate to make reference to the Inspector General. A suggestion might be to have the following under Definitions: **Add Inspector General**: Under 2.1-816, the Inspector General has the authority to "provide inspections of and make policy and operational recommendations for providers as defined in 37.1-179 in order to prevent problems, abuses and deficiencies in and improve the effectiveness of their programs and services." Inspection activities conducted by the Inspector General may include review of conditions and physical environment of care, interviews with current and former staff and consumers, review of policy and review of clinical records.	**No change:** The Inspector General can fully exercise statutory authority without any specific authorization granted by the licensing regulations**.**
✍✍ "Intensive Community Treatment (ICT) Service"	Recommends the deletion of the phrase "self-contained" in the definition of ICT. This would seem to limit the any member of these teams to have other duties.	The word "self-contained" does not mean staff cannot have other duties. **For clarification, Change to read:** "Intensive Community Treatment (ICT) service" means a self-contained interdisciplinary team of at least five full-time equivalent clinical staff, a program assistant, and a full- or part-time psychiatrist that: 1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illnesses; 2. Minimally refers individuals to outside service providers;

Section	Comment	DMHMRSAS Recommendation
"Intensive Community Treatment (ICT) Service" (cont.)		3. Provides services on a long-term care basis with continuity of caregivers over time; 4. Delivers 75 percent or more of the services outside program offices; 5. Emphasizes outreach, relationship building, and individualization of services. The individuals to be served by ICT are individuals who have severe symptoms and impairments not effectively remedied by available treatments or who, because of reasons related to their mental illness, resist or avoid involvement with mental health services.
✍✍ "Intensive In-Home Service"	Recommends the deletion of the phrase "time limited." This service should be covered by licensing even if it is long-term. Indicates that this service appears to be limited to preservation interventions for children and adolescents. The target population should be expanded to adults by replacing "such individuals" with "both youth and adults."	**Change to read:** "Intensive in-home service" means ~~time-limited~~ family preservation interventions for children and adolescents with or at-risk of serious emotional disturbance, including such individuals who also have a diagnosis of mental retardation. Services are usually time limited and are provided typically in the residence of an individual who is at risk of being moved to out-of-home placement or who is being transitioned back home from an out-of-home placement. These services include crisis treatment; individual and family counseling; life, parenting, and communication skills; case management activities and coordination with other services; and emergency response. **No change:** Intensive in-home is a family preservation service. A service for adults would be properly licensed as a Supportive In-Home (formerly supportive residential) service.

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✍✍ "Intensive Outpatient Service"	Recommends changing several hours per day per week to multiple outpatient visits per week. There is no need to limit time period.	**Change to read:** "Intensive outpatient service" means treatment provided in a concentrated manner (~~several hours per day~~ involving multiple outpatient visits per week) over a ~~limited~~ period of time for individuals requiring stabilization. These services usually include multiple group therapy sessions during the week, individual and family therapy, individual monitoring, and case management.
✍✍ "Licensed mental health professional" (LMHP)	Suggests revising the following terms to be more accurate: "Licensed psychiatric clinical nurse specialist" should be "certification as a clinical nurse specialist." "Licensed substance abuse treatment practitioner" is the correct title.	**Change to read:** "Licensed Mental Health Professional" (LMHP) means a physician, licensed clinical psychologist, licensed professional counselor, licensed clinical social worker, licensed substance abuse treatment ~~provider~~ practitioner, or certification as a ~~licensed~~ psychiatric clinical nurse specialist.
✍✍ "Medical Evaluation"	Proposes changing "<u>the</u> individual's" to "<u>an</u> individual's."	**Change to read:** "Medical evaluation" means the process of assessing an individual's health status that includes a medical history and a physical examination of ~~the~~ <u>an</u> individual conducted by a licensed medical practitioner operating within the scope of his license.
✍✍ "Medication Error"	Indicates that (i) and (ii) say essentially the same thing. Suggests that one of these be eliminated. A time frame should be provided for considering medication to be late. Two hours may be an appropriate time frame for defining the medication to be late. If an ACT client may not be home when a medication is delivered. This is not a staff error. Medication "irregularity" or "noncompliance" should be a category that does not imply the staff is at fault.	**No change:** This is the same definition that is used in the Interdepartmental Regulation for Children's Residential Services (22 VAC 42-10-10) and summarizes the definition used in the Board of Nursing curriculum. A time frame cannot be added to define lateness as the time frame may vary dependent on the specific medication and how it is prescribed. This definition refers to medication administration, not delivery of medication.
✍✍ Medication Storage	Indicates that there is no clear definition of "storage." Delete this word from the provision.	**Change to read:** <u>"Medication storage" means any area where medications are maintained by the provider, including a locked cabinet, locked room, or locked box.</u>

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✍✍ "Mental Health Community Support Service (MHCSS)"	Indicates that this definition is too broad to be considered a distinct service. If it cannot be limited, it should be dropped.	**Change to read:** Mental Health Community Support Service (MHCSS)" means ~~a comprehensive combination of case management services and psychosocial rehabilitation that is provided in accordance with a psychosocial rehabilitation service plan~~. the provision of recovery-oriented psychosocial rehabilitation services to individuals with long-term, severe psychiatric disabilities including skills training and assistance in accessing and effectively utilizing services and supports that are essential to meeting the needs identified in their individualized service plan and development of environmental supports necessary to sustain active community living as independently as possible. MHCSS Services are provided in any setting in which the individual's needs can be addressed, skills training applied, and recovery experienced.
✍✍ "Mentally Ill"	Recommends that definitions of diagnostic disorders be consistent with those defined by the DSM IV.	**Change to read:** "~~Mental illness~~" "Mentally ill" means any person afflicted with mental disease to such an extent that for his own welfare or the welfare of others, he requires care and treatment, or with mental disorder or functioning classifiable under the current edition of the Diagnostic and Statistical Manual of the American Psychiatric Association that affects the well-being or behavior of an individual.
✍✍ "Mental Retardation"	Recommends that this definition should be based on the DSM IV and DSM IV definitions.	**Clarify as follows:** "Mental retardation" means substantial subaverage general intellectual functioning that originates during the development period and is associated with impairment in adaptive behavior~~,~~ . It ~~existing~~ exists concurrently with related limitations in two or more of the following applicable adaptive skill areas: communication, self-care, home living, social skills, community use, self-direction, health and safety, functional academics, leisure, and work.

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✍✍ "Opioid Treatment Service"	Indicates that the phrase should be "…strategy that combines outpatient or residential treatment with…"	**Change to read**: "Opioid treatment service" means an intervention strategy that combines ~~outpatient~~ treatment with the administering or dispensing of opioid agonist treatment medication. An individual-specific, physician-ordered dose of medication is administered or dispensed either for detoxification or maintenance treatment.
✍✍ "Outpatient Service"	Recommends the following changes: Delete jail-based services. This is a location, not a service type. Eliminate *"Outpatient service" specifically includes*: (and 1, 2 [as the Code of Virginia section applies to many services other than outpatient], and 3 which follow) and replacing with the sentence, *"This includes services operated by a community services board (except that these services fall under the definition of Private Practice Group as defined below) established pursuant to Chapter 10 (37.1-194 et seq.) Of Title 37.1 of the Code of Virginia of Virginia)"* which would cover those CSB outpatient services which are licensed but whose staff, although fully capable, do not hold individual professional licenses. Indicates the definition should not include CSBs. They are not service types. They are oversight bodies or contractors for programs being licensed.	**No change:** This is the same as the definition in the current regulations, and no change in the current definition is needed.

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✍✍ "Program of Assertive Community Treatment (PACT)"	Indicates that this is a weak definition of PACT. The definition of PACT should not be relative to another service.	**Change to read:** *"Program of Assertive Community Treatment (PACT) service" means a self-contained interdisciplinary team of at least ten full-time equivalent clinical staff, a program assistant, and a full- or part-time psychiatrist that:* 1. Assumes responsibility for directly providing needed treatment, rehabilitation, and support services to identified individuals with severe and persistent mental illnesses; 2. Minimally refers individuals to outside service providers; 3. Provides services on a long-term care basis with continuity of caregivers over time; 4. Delivers 75 percent or more of the services outside program offices; 5. Emphasizes outreach, relationship building, and individualization of services. The individuals to be served by PACT are individuals who have severe symptoms and impairments not effectively remedied by available treatments or who, because of reasons related to their mental illness, resist or avoid involvement with mental health services.
✍✍ "Private Practice group"	Indicates that this definition is not clear. If all licensed professionals are practicing within the scope of their professional licenses, to require additional licensing for the group is redundant and burdensome both for the practice and for DMHMRSAS, which should leave the professional licensure business to the appropriate regulatory body (e.g., the Board of Medicine).	**Delete definition.** See comments to *Part I Article 1-- Authority and Applicability*, 12 VAC 35-105-10 (C), above.

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✍✍ "Qualified Mental Health Professional" (QMHP)	Recommends a service equivalent qualification for a QMHP. This definition should include "any other licensed mental health professional."	**Change to read:** "Qualified Mental Health Professional" (QMHP) means a clinician in the health professions who is trained and experienced in providing psychiatric or mental health services to individuals who have a psychiatric diagnosis; including a (1) physician: a doctor of medicine or osteopathy; (2) psychiatrist: a doctor of medicine or osteopathy, specializing in psychiatry and licensed in Virginia; (3) psychologist: an individual with a master's degree in psychology from an college or university with at least one year of clinical experience; (4) social worker: an individual with at least a bachelor's degree in human services or related field (social work, psychology, psychiatric rehabilitation, sociology, counseling, vocational rehabilitation, human services counseling or other degree deemed equivalent to those described) from an accredited college and with at least one year of clinical experience providing direct services to persons with a diagnosis of mental illness; or (5) Registered Psychiatric Rehabilitation Provider (RPRP) registered with the International Association of Psychosocial Rehabilitation Services (IAPSRS); ~~or~~ (6) registered nurse licensed in the Commonwealth of Virginia with at least one year of clinical experience; or (7) any other licensed mental health professional.
	Questions whether this definition consistent with the Medicaid definition of QMHP. Inconsistent definitions could present problems for providers of MH services, who have both DMHMRSAS licensed services, as well as VA Medicaid billable services.	This definition is consistent with the Medicaid QMHP definition.
✍✍ "Residential Service"	Questions whether these are separate licenses for Residential Services or just a subsection or a related service under the Residential Services license i.e., will a provider need to apply for another separate license for these services?	Residential services are defined as a category, because some of the regulations apply only to residential services, and this is a method for categorization of those regulations. Whether a provider has to have separate licenses depends upon the services being provided. If the services, admission, staffing, and regulatory requirements are significantly different, the provider may have to be licensed separately.

Section	Comment	DMHMRSAS Recommendation
"Residential Service" (cont.)		**Change to read:** "Residential service" means a ~~type~~ category of services providing 24-hour care in conjunction with care and treatment or a training program in a setting other than a hospital. Residential services provide a range of living arrangements from highly structured and intensively supervised to relatively independent requiring a modest amount of staff support and monitoring. Residential services include, but are not limited to: residential treatment, group homes, supervised living, residential crisis stabilization, community gero-psychiatric residential, community intermediate care facility-MR, sponsored residential homes, medical and social detoxification, ~~sobering-up~~, and substance abuse residential treatment for women and children.
✍✍ "Respite Care Service"	Indicates that this phrase should be deleted. This definition implies the need to be licensed if one is "*arranging for*" respite care from a licensed provider.	**Change to read:** "Respite care service" means providing ~~or arranging~~ for a short-term, time limited period of care of an individual for the purpose of providing relief to the individual's family, guardian, or regular care giver. Individuals providing respite care are recruited, trained, and supervised by a licensed provider. These services may be provided in a variety of settings including residential, day support, in-home, or in a sponsored residential home.
✍✍ "Restraint"	Suggests adding wording at the end of the first paragraph: "*This term does not include restraints employed in the usual and customary usual care of infants which may include physically holding a child or placing the child in a child safety device such as a highchair, playpen, crib, car seat or other device specifically designed to contain and/or protect an infant*." Item 5 indicates that a pharmacological restraint is given involuntarily. This implies that it is forced rather than given for as needed for emergency control of behavior. Item 6, physical restraint, should more clearly define what is meant by a few seconds so there is consistency across the State (e.g., A	**No change:** The definition used in these regulations is consistent with the definition of restraint that is used in the Human Rights regulations.

Section	Comment	DMHMRSAS Recommendation
"Restraint" (cont.)	hold for 4 seconds is not a restraint but one for 5 seconds is a restraint). A physical escort should be clearly defined as a restraint (or not). Suggests that the numbering be corrected under the definition of "restraint." Points out that a restraint for protective purposes should be Item 3 of this definition, not Item 4.	 This numbering was corrected prior to publication in the Virginia Register.
✍✍ "Seclusion"	Suggests adding wording such as "*This term does not apply to the usual and customary care of infants and such seclusion as may occur when placing an infant in an environment designed to reduce unnecessary stimulation as in a bedroom with the door closed*."	**No change:** There may be times when it is appropriate to place an infant in an environment designed to reduce unnecessary stimulation such as when the infant is ready to nap. But even then, it is not recommended to close the door, but re-structure the surrounding environment to eliminate noises and distractions. The suggested language would allow staff to put an agitated, crying infant in an unsupervised room with the door closed. This situation not only constitutes seclusion, but it has the potential to put the child at risk of harm.
✍✍ "Substance Abuse"	Indicates that the definition is appropriate for substance dependence, not substance abuse. Should be consistent with DSM IV.	**Change to read:** "Substance abuse" means the use, without compelling medical reason, ~~any substance~~ of alcohol and other drugs, which results in psychological or physiological dependency or danger to self or others as a function of continued use in such a manner as to induce mental, emotional or physical impairment and cause socially dysfunctional or socially disordering behavior~~ (§ 37.1-203 of the *Code of Virginia*)~~.
✍✍ "Supervised Living Residential Service"	Questions how these two services (Supervised Living Residential Service & Supportive In-Home (formerly supportive residential) Service) differ in definition Residential services is defined as a service "providing 24 hour care," but includes "supervised living" as an example of a service type. "Supervised living residential service" is defined as providing	See the definitions of "Supportive In-Home (formerly supportive residential)" and "supervised living" that follows: **Change to read:** "Supervised living residential service" means the provision of significant direct supervision and community support services to

Section	Comment	DMHMRSAS Recommendation
"Supervised Living Residential Service" (cont.)	supervision "up to 24 hours per day." This seems to be an internal contradiction**.** Asks which service definition would apply to people with mental retardation and/or mental illness living in their own home with less than 24 hour supervision. In the Department of Medical Assistance Services (DMAS) regulations only Supportive In-Home (formerly supportive residential) services are mentioned not Supervised Living. Questions whether they are considered interchangeable.	individuals living in apartments or other residential settings. These services differ from supportive in-home service because the provider assumes responsibility for management of the physical environment of the residence, and staff supervision and monitoring are daily and available on a 24-hour basis. Services are provided based on the needs of the individual in areas such as food preparation, house keeping, medication administration, personal hygiene, and budgeting. If supervision is not provided when the resident is in the home, including over night or on-site, then the service would be Supportive In-Home (formerly supportive residential). DMAS currently funds Supervised Living under Supportive In-Home (formerly supportive residential).
✍✍ Supportive ~~Residential~~ In – Home Service"	See Supervised Living comments above.	**Change to read:** "Supportive in-home service" (formerly supportive residential) means the provision of community support services and other structured services to assist individuals. Services strengthen individual skills and provide environmental supports necessary to attain and sustain independent community residential living. They include, but are not limited to drop-in or friendly-visitor support and counseling to more intensive support, monitoring, training, in-home support, ~~in-home~~ respite and family support services. Services are based on the needs of the individual and include training and assistance. These services normally do not provide 24-hour care, however, due to the flexible nature of these services, overnight care may be provided on an occasional basis.

Section	Comment	DMHMRSAS Recommendation
Part II--Licensing Process **12 VAC 35-105-30**		
✍✍ Item A	**General** Indicates that the definition of the 26 different licensing categories overlap and duplicate one another. No guidance is provided regarding the differences between types of licenses. This makes it difficult for staff to determine which type of license is appropriate for a given service. Suggests that specific categories of licensure are limited to six broad categories. (See Item B below) In the service definitions there is only one service for day support: Mental Retardation Day Support: a. Asks whether this covers day support programs that serve dually diagnosed (MR/MH) as well. b. Indicates that on the application for services there is a box that states MR/MH as the population served: Asks if this box is checked, does that indicate that both day support and residential support serve people who are dually diagnosed.	**No change:** Section 37.1-179 of the *Code of Virginia* lists specific services. The recommended categorization does not account for services that have specialized requirements. Definitions are to be used to identify differences in services to be licensed. Services can be categorized administratively, when appropriate. This will be addressed in training. a. Yes b. The Department will change the application to reflect the changes in the new regulations.
✍✍ Item B	Suggests categorizing the license types as follows: 1. Case Management	The Department does not agree. See response to Item A above. Minor changes have been made to reflect consistency with changes made

Section	Comment	DMHMRSAS Recommendation
	2. Clubhouse, psychosocial rehabilitation program or mental health community support services 3. Community/Residential treatment: Community gero-psychiatric residential Group Home Residential Community Intermediate MR facility Residential Treatment Residential Crisis Stabilization Respite Care Service Sobering up Social Detoxification Sponsored Home Substance Abuse Residential Treatment for Women and Children	elsewhere in the regulations.
Item B (cont.)	Supervised Living Supportive In-Home (formerly supportive residential) Service 4. Day treatment MR Day Support Services Partial Hospitalization 5. Inpatient psychiatric treatment Medical Detoxification 6. Outpatient treatment Emergency Intensive Community Treatment (ICT) Intensive In-Home Intensive Outpatient Opioid Treatment Service Program of Assertive Community Treatment (PACT)	
	Indicates that there is a requirement to be licensed for "Emergency" yet this is specifically included in the definition of Outpatient. Requests clarification.	Eliminate "emergency service" as a separate category; it is a type of Outpatient service.

Section	Comment	DMHMRSAS Recommendation
Application Requirements **12 VAC 35-105-40**		
✍✍ Item B	Believes the requirement that a separate application for each service to be licensed is burdensome. Suggests one application for licensing should be submitted by each organization.	An application is not required for each service. For clarity, change to read: B. <u>Providers must submit an application listing each new service to be provided and submit the following items for each service</u>:…
	Suggests that applications require proposed providers to give 30-days public notice of intent to obtain a license. This creates an opportunity for local input and would not be expensive for DMHMRSAS if the provider is required to pay for the notice.	**No change:** This suggestion would be an extra burden for providers.
	Point 2: Indicates that it is excessive to require that all employee credentials or job descriptions be included.	**No change:** A determination of whether a service has appropriate staff cannot be made without this information. This is required in the current regulations.
Item B (cont.)	**Point 5:** Indicates that certificates of occupancy (CO) may not exist for certain homes or settings. This requirement is more applicable to institutions. Suggests that such certificates only be required when locally required or applicable for new construction.	**No change:** Most buildings have a certificate of occupancy (CO). If a locality has not issued a CO, the provider does not need to provide a CO. The CO is used to determine the allowed capacity in a home. (See 13 VAC5-61-95)
✍✍ Item C	Delete the requirement for a renewal application for a provisional license. Suggests that language be added to clarify that new or existing providers only be required to submit applications for proposed new services.	**Change to read:** <u>The provider shall confirm intent to renew the license prior to the expiration of the license and notify the Department in advance of any changes in service or location</u>.

Section	Comment	DMHMRSAS Recommendation
Issuance of Licenses **12 VAC 35-105-50**		
✍✍ Item C	Provisional licenses: Believes that if violations are "serious" enough to justify a provisional license, unannounced visits should be required at least twice in each six month period.	**No change:** Not necessary. The Department has a variety of ways to monitor. Visits are tailored to circumstances resulting in the provisional licenses.
✍✍ Item C and D	Recommends that the standards, including "*serious violation"* and "*minor violation,* be more clearly defined to give providers and the Department clearer guidelines as to the type of license that is appropriate, perhaps by distinguishing between violations that pose a serious threat to patient health or safety and those that do not. Are unclear where the line is drawn between "*compliance"* and "*noncompliance"* in determining licensure status.	**C. Change to read:** A provisional license may be issued to a provider or service that has demonstrated an inability to maintain compliance with regulations, has ~~a serious violation~~ violations of human rights or licensing regulations that pose a threat to the health or safety of individuals being served, has multiple violations of human rights or licensing regulations, or has failed to comply with a previous corrective action plan. **D.2 Change to read:** **2.** If a full license is granted for three years, it shall be referred to as a triennial license. A triennial license shall be granted to providers who have had no noncompliances or only ~~minor~~ violations that did not pose a threat to the health or safety of individuals being served during the previous license period. The commissioner may waive this limitation if the provider has demonstrated consistent compliance for more than a year or that sufficient provider oversight is in place.
✍✍ Item D	**Point 2:** Suggests using the phrase "substantial compliance" to replace "no noncompliance or only minor violations." Recommends deemed status for any program accredited by a major national accreditation program such as CARF or JCAHO. This would be more expedient and eliminate unnecessary paperwork for providers.	**No change:** See above response. **No change:** The *Code of Virginia* requires that all providers be licensed and that the Department conduct annual inspections and investigate all complaints with a focus on preventing specific risks to consumers. There is a public health interest for the state in maintaining direct monitoring of these services. It is unclear why the respondent views the regulations as requiring "unnecessary paperwork."

Section	Comment	DMHMRSAS Recommendation
✍✍ Item G	Recommends the deletion of the sentence "A license shall not be issued or renewed unless the provider is affiliated with a local human rights committee".	**No change:** The Department disagrees with the respondent. Section 37.1-182.3 of the *Code of Virginia* provides that "Licensing … is contingent upon the substantial compliance with Section 37.1-84.1 and acceptable implementation of the human rights regulations…." 12VAC 35-115-250 (A) (5) states "Providers and their directors shall: … assure an LHRC to all individuals receiving services."
***Onsite Reviews* 12 VAC 35-105-70**		
✍✍ General Comment	Questions whether the OIG office should be mentioned under 12 VAC 35-105-70.	**No change:** Authority is not needed under these regulations for the OIG to inspect licensed providers.
✍✍ Item B	Does not believe it is feasible or necessary for the Office of Licensing to conduct unannounced site visits to all providers' service sites on an annual basis. Recommends this be changed to <u>may</u> conduct unannounced visits…	**No change:** The *Code of Virginia* §37.1-182 requires the Commissioner or his authorized agents to make at least one annual unannounced inspection of each service offered by each licensed provider.
***Variances* 12 VAC 35-105-120**		
✍✍ General Comments	Suggests deleting "unique to the provider." This may impose an unnecessary burden, especially to DMHMRSAS to prove that a provider's situation is unique. At issue is whether or not compliance with the regulation poses a hardship and why. Recommends that the language require that the initial variance be time limited to six months, not that it "may be time limited." During the period of this initial variance, at least one unannounced onsite visit should be conducted to ensure the variance is not damaging to health or welfare of the individuals being served. Should there be concerns identified at the review or through complaint investigation, the variance should be terminated. Otherwise, the variance could be extended. Suggests that the provision make clear that variances under 12 VAC 35-105-120 cannot include variances of the human right regulations	**No change**: The provider must prove the burden is "unique to the provider" or poses a hardship, not the Department. **No change**: Existing provisions are reasonable. **No change**: Variances to Human Rights regulations cannot and will not be

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	and that these must be addressed through the alternate requirements of 12 VAC 35-105-220.	granted under the Licensing Regulations.
	Questions whether variances are determined on an individual basis for the provider requesting the variance or simply compared to all other providers who are able to comply without hardship.	**No change:** The regulation states a hardship is unique to the provider.
	Questions whether variances are approved if the provider is unable to comply due to the regulations or laws of other agencies or businesses.	**No change:** Variance requests will be reviewed on a case-by-case basis.
	Questions whether requests for variances sent straight to the commissioner's office, as it states in the regulations. with a cc: to Licensing or directly to Licensing office.	**No change:** **This will be addressed in training.**
Part III--Administrative Services—Article 1—Management and Administration- Licensing Availability **12 VAC 35-105-140**		
✍✍ General Comments	Indicates that the requirement that a license be prominently displayed for public inspection is not feasible in all locations. Suggests the statement be revised to "…or, in the case of facilities with 4 or fewer beds, available for inspection upon request." This provides a more normal environment.	**No change:** Existing provision is reasonable. A license must be displayed to provide information to the public.
Reviews by the Department; Requests for Information **12 VAC 35-105-160**		
✍✍ General Comments	States that the change from 48 hours reporting criteria to 24 hours seems unreasonable — especially on weekends and holidays and there will be no one at the Department's satellite offices to receive the information. The previous 48-hour time line was more realistic.	**No change:** This is consistent with the Human Rights Regulations (see 12 VAC 35 115-230).
✍✍ Item C	**Point 1**: Suggests adding language that would clarify that this refers to abuse or neglect perpetrated by a specific licensee's employees. (see definition in the CHRIS Manual pages 1-2)	**No change:** Item C, Points 1, and 2, are consistent with the Human Rights Regulations (see 12 VAC 35 115-230).

Section	Comment	DMHMRSAS Recommendation
Item C (cont.)	Indicates that this provision lacks clarity regarding investigations of human rights violations. Regulations do not address responding to allegations of rights that not clearly fall within the definitions of "abuse" or "neglect". Suggests the language of 12 VAC 35-105-160 be changed to "allegation of abuse, neglect, or violation of rights. **Point 2:** Indicates that the provision needs a better definition of "deaths and serious injuries" to clarify that this pertains to individuals receiving services. Definition of where and when an event occurs is made complex by the differing levels of contact with individuals in facilities vs. those receiving care in the community. Recommend changing "*serious injury*" to "*injury that threatens life or limb*" to differentiate between life-threatening injuries and less serious injuries that still require medical care. Recommends clarification and **extended** time frames for reporting of deaths and serious injuries. Need to clarify that for non-residential programs, only injuries or death related to the program or occurring at programs sites need to be reported. Questions who grants the exemption for the completion of the investigation within 10 days. Indicates that neither the revised Human Rights Regulations nor the proposed licensing regulations specify to which Office within DMHMRSAS reports of death or serious injury are to be made. Given that the requirement is for a report of every visit to an Emergency Room for a fall from a seizure, a twisted ankle, etc. and the potential occurs for events such as these to happen at night, on the weekend, on holidays. etc. It will be imperative for the Department to assign adequate resources to the receipt and recording of reports both during regular business hours and during off hours.	See response above. **No change:** The Licensing Specialist grants the exemption. **No change:** Reporting procedures will be addressed in training.

Section	Comment	DMHMRSAS Recommendation
Corrective Action Plan **12 VAC 35-105-170**		
✍✍ Item A	Suggests adding the word "substantial" before the word "noncompliance."	**No change:** Any violation may result in a citation of noncompliance**.**
✍✍ Item C	Suggests deleting first "plan" word in the sentence Recommends inserting the word *"Projected"* before "Date *of completion for each action; and "*.	**Delete the first "plan".** The ~~plan~~ corrective action plan shall include a: **No change:** This is the date the provider pledges the completion of corrective action(s). If this date needs to be revised, the provider can request an alternate date.
✍✍ Item D	Indicates that the 10-day turnaround time is too short. Recommends extending this to 15 business days with an additional 10-day extension. Believes that time frames should be imposed on DMHMRSAS for reports of any licensure visits, scheduled or unscheduled; approval or disapproval of a corrective action plan and any revisions requested.	**Change to read:** 15 business days. **No change:** This is not realistic, as responses often involve sources other than the Department; putting a time limit on this provision may not be beneficial to the provider or to the individual receiving the services.
Notification of Changes **12 VAC 35-105-180**		
✍✍ General Comments	Recommends the following provisions be added related to closure of a service: "A provider organization shall notify the Department in writing of its intent to discontinue services thirty days prior to the cessation of services. The provider organization will continue to provide all services that are identified in an individual's Individual Services Plan (ISP) after it has given official notice of its intent to cease operations. The provider organization will further continue to maintain substantial compliance with all applicable regulations as it	**Add as D:** A provider shall notify the Department in writing of its intent to discontinue services thirty days prior to the cessation of services. The provider will continue to provide all services that are identified in every individual's Individual Services Plan (ISP) after it has given official notice of its intent to cease operations and until the individual is appropriately discharged. The provider will further continue to maintain substantial compliance with all applicable regulations as it discontinues its services.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	discontinues its services to consumers." All individuals receiving services shall be notified of a provider organization's intent to cease services in writing thirty days prior to the cessation of services. This written notification will be documented in each consumer's ISP. Indicates that regulations should specify the timeframe for the Office of Licensing to respond and approve the addition, deletion or movement of the "geographic location of the provider or its services," or the "bed capacity for services providing residential or inpatient services."	**Add as E:** All individuals receiving services shall be notified of a provider organization's intent to cease services in writing thirty days prior to the cessation of services. This written notification will be documented in each consumer's ISP. Also refer to Part V. Article 1. Record Management policy. **No change:** This will be addressed as a training issue.
✍✍ Items A and B	Recommends rewording this provision as follows: *A. The provider shall provide a written change notice to the department prior (within the time specified in parentheses in each item below) to implementing changes that affect:* *1. Organizational or administrative structure, including the name of the provider (90 days);* *2. Geographic location of the provider or its services (30 days);* *3. Service description as defined in these regulations (30 days);* *4. Significant changes in employee or contractor qualifications (30 days);* *5. Bed capacity for services providing residential or inpatient services (30 days).* *Each written change notice will include an outline of the circumstances currently licensed and the proposed new circumstances for which approval is being sought, as well as the reason(s) for the change(s) requested.* *B. The department shall review provider submissions of change notices and issue its approval or specific objections in writing to the provider within 30 days of receipt of the provider's change notice*."	**No change:** Recommendation is too prescriptive.

Section	Comment	DMHMRSAS Recommendation
Items A and B (cont.)	Recommends that this section be clarified to require general hospitals to notify the department only of changes in the services licensed under these regulations and not any other services provided in the hospital. **Point 4**: Recommends clarification to require notice only of changes in job descriptions rather than changes in personnel, assuming the former to be the intent.	**No change:** General hospitals are not required to report changes in services not licensed by the Department. **Change A. 4. to read:** 4. Significant changes in ~~employee or contractor~~ qualifications required for a position and/or qualifications of an individual occupying a position.
Fiscal Accountability **12 VAC 35-105-210**		
✍✍ Item B	**Point 2**: Suggests waiving the requirement in the first sentence regarding balance sheet for those licensees that operate as a part of local government.	**Change to read:** Providers operating as a part of a local government agency are excluded from providing a balance sheet; however, they shall provide a financial statement.
Indemnity Coverage **12 VAC 35-105-220**		
✍✍ General Comments	States that though not expressly disallowed, it should be made clear that self-insurance is permissible since this is frequently how those licensees that operate as a part of local government are covered.	**No change:** Self-insurance is permissible.
Deceptive or False Advertising **12 VAC 35-105-250**		
✍✍ Item B	Recommends permitting names that reflect services for which no license is required. For clarity, reword: *"Provider's name and service name shall not include named services for which licensure is required if the provider is not licensed to provide such services."*	**No change:** The regulations generally do not address services that are not required to be licensed.
Article 2—Physical Environment - Building Inspection and Classification **12 VAC 35-105-260**		
✍✍ General Comments	A group of regulations, beginning with this one, includes the statement that "*sponsored residential services will certify compliance of sponsored residential homes with this regulation*." It is not clear how this would be operationalized. This should be	**No change:** Sponsored Residential Placements (SRPs) are not the individual's home, but are the homes of SRP providers. These are residential services. Please refer to definition of home-based.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	deleted, since sponsored residential services are provided in a consumer's own home; it is a direct contradiction of the previous sentence stating that the regulation "*does not apply to...home or non-center based services*." Recommends clarification of this clause. Should a sponsored placement sponsor have to provide certificate of occupancy on sponsored placement home? Many do not have a certificate.	**No change:** Most buildings have a Certificate of Occupancy (CO). If the locality has not issued a CO, the provider should document this.
Building Modifications **12 VAC 35-205-270**		
✍✍ Item A	Questions the basis for the submission of building plans/structural modifications to DMHMRSAS. Does not believe that the Department intends to review these plans. Suggests that the appropriate regulatory authorities should approve such plans and DMHMRSAS be notified of any building modifications. This provision should be reworded to reflect this. Submitting for review and approval could present problems particularly for new structures where structural changes may occur while the modifications are in progress (with no time for licensure review)	**Change to read:** Building plans and specifications for new construction of locations, change in use of existing locations, and any structural modifications or additions to existing locations where services are provided shall be submitted for review by the department ~~and shall be approved by appropriate regulatory authorities~~ to determine compliance with the licensing regulations. This section does not apply to correctional facilities, jails, or home and noncenter-based services.
Physical Environment **12 VAC 35-105-280**		
✍✍ Item A and Item C	Indicates that the meaning of "clear visual perception" is not clear. This may be a problem for existing structures that cannot be easily modified. Recommends that this provision be eliminated and **Item A** be changed as follows: "*The physical environment, design, structure, furnishing and lighting shall be appropriate to the population served and the services provided*."	**Change to read:** The physical environment, design, structure, furnishing and lighting shall be appropriate to the population served and the services provided.
✍✍ Item E	The regulation recommends that "Temperatures shall generally be maintained between 65 and 80 F. However, Virginia has been known to have warmer days and locations which lack central air conditioning may be warmer in some rooms or at some times than the recommended temperatures.	**No change:** Temperatures outside this range are normally not comfortable for anyone. This is consistent with other state regulations.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item F	States that the standard refers to "residents" but does not appear to be exclusive to residential services. Indicates that heating plants in some structures and externally regulated hot water systems may prevent the provider from regulating water temperature within the specified range. Add "If temperatures can not be maintained within the specified range, the provider shall make provisions for protecting individuals from injury due to scalding." Recommends further review of the financial impact of requiring hot water temperature standard to be in the range of 100° to 120° as it may require extensive reworking of some existing hot water systems.	**Change to read:** …~~residents~~ individuals being served… **Change to read:** "If temperatures cannot be maintained within the specified range, the provider shall make provisions for protecting individuals from injury due to scalding."
Food Service Inspections **12 VAC 35-105-290**		
✍✍ General Comments	States that this provision contradicts the Federal Fair Housing Act and the Virginia Code of Virginia governing group homes. States that it would be costly to comply with this requirement and treat homes as restaurants. The rule should govern homes with more than 8 beds (see 12 VAC 35-105-320). It is doubtful that local health inspectors would inspect residential programs. Suggests the following: "*ensure that such premises are maintained within customary food preparation and sanitation practices usual for private residences.*" Indicates that it does not appear appropriate for sponsored placement home as burden would be too onerous. Indicates that it is not clear that such inspections are needed. The additional cost and quality of inspection would make this an unreasonable requirement. Indicates that it is unclear which standards apply to providers "responsible for preparing or serving food" and whether the various local health departments apply the standards consistently across the	**No change:** The federal law and state regulations require food inspections. (See 12 VAC 5-421-10) **Clarify by adding:** This does not apply to sponsored residential services. Sponsored placement homes would not be subject to Virginia Department of Health requirements because they are family dwellings. **No change:** The regulations require the providers to ask for an inspection. The local Department of Health will determine if an inspection is required or appropriate.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	several jurisdictions. Standards applicable to restaurants or institutional kitchens are not appropriate in consumer homes. The greater concern is the inconsistency across jurisdictions and the institutional nature of the regulation.	
Annual Water and Sewer Inspections **12VAC 35-105-300**		
✍✍ Item A	Indicates that local government agencies refuse to conduct these inspections. The additional cost and quality of these inspections by private companies is an unreasonable requirement. Recommends that water to be inspected annually and the sewer every 3 years in sponsored placement homes. Requests that a private vendor be allowed to inspect the sewers.	**Change to read:** A. A location shall either be on ~~city or county~~ public water and sewage systems or the location's water and sewage system shall be inspected and approved by state or local health authorities at the time of its original application and annually thereafter. Documentation of the three most recent inspections and approval shall be kept on file. Sponsored residential home services shall certify compliance of sponsored residential homes with this regulation. B. A location that is not on a public water system shall have a water sample tested annually by an accredited, independent laboratory for the absence of chloroform. The water sample shall also be tested for lead or nitrates if recommended by the local health department. Documentation of the three most recent inspections shall be kept on file.
Weapons **12 VAC 35-105-310**		
✍✍ General Comments	Recommends deleting the phrase: "*Sponsored residential home services shall certify compliance of sponsored residential homes with this regulation*." This conflicts with the phrase that follows. Suggests addition of "sworn law enforcement personnel or…" *States that weapons need to be defined.* Indicates the phrase "to the extent of the law" is too vague. Recommends the use of trigger locks, gun safes and secure separate ammunition storage can accomplish objective of without infringing on 2nd amendment rights	**Change to read:** The facility shall have and implement a written policy governing the use and possession of firearms, pellet guns, air rifles and other weapons on the facility's premises. The policy shall provide that no firearms, pellet guns, air rifles and other weapons on the facility's premises shall be permitted unless the weapons are: 1. In the possession of licensed security or sworn law enforcement personnel 2. Kept securely under lock and key, or 3. Used under the supervision of a responsible adult in accordance with policies and procedures developed by the facility for the weapons' lawful and safe use.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	States that this provision precludes or reduces the opportunity for disabled individuals to engage in safe, appropriate and healthy participation of shooting sports. Indicates that this provision creates significant disincentive for preferred sponsored placements in rural areas where hunting and shooting sports an ingrained multi-generational tradition States that the provisions limits choices available to disabled individuals - where a farm which requires a weapon for varmint control or humane culling, would preclude from offering sponsored residential placements, despite the disabled individual preference.	
Fire Inspections **12 VAC 35-105-320**		
✍✍ General Comment	States that, due to provisions of the Statewide Fire Prevention Code of Virginia, this standard applies only to residential programs of eight beds or more. Makes the potential for Health Department inspections of single occupancy supervised living homes (see 12 VAC 35-105-290) seem even more institutional..	**No change:** The Virginia Department of Health (VDH) regulates these homes.
Condition of Beds **12 VAC 35-105-350**		
✍✍ General Comments	Objects to the requirement that bed linens be changed every seven days. It would be nearly impossible to determine compliance with the requirement. This is too prescriptive. The third sentence implies a passivity on the part of the consumers that is demeaning and suggests that they have no ability to take responsibility for their own actions. Change to read: "Providers shall assist individuals as needed with bathing, clean clothing and linens each time their clothing or bed linen is soiled."	**Change to read:** Beds shall be clean, comfortable and equipped with a mattress, pillow, blankets, and bed linens. ~~Bed linens shall be changed every seven days or more often as needed. Providers shall give individuals a partial bath, clean clothing, and linens each time their clothing or bed linen is soiled.~~ When a bed is soiled, providers shall assist individuals with bathing as needed, and provide clean clothing and bed linen. Sponsored residential home services shall certify compliance of sponsored residential homes with this regulation.

Section	Comment	DMHMRSAS Recommendation
Criminal Background Checks **12 VAC 35-105-400**		
✍✍ Items A and B	Indicates that the Department plays no role in background check process for CSBs. Also states that there is no legal basis to include "pending charges" in this provision. States that these regulations need to conform to the statute that does not require contractors to have background checks and CI'S checks. Proposes requiring providers to have a policy pertaining to the provider's requirement for background checks for contractors and employees of temporary employment agencies.	**Change Heading to read** Criminal History & Registry Checks The regulation states the provider submits information required by the Department. CSBs are not required to submit information. **Change to read:** A. The provider shall develop a policy for the criminal history and registry checks for all employees, contractors, students and volunteers. The policy shall contain, at a minimum, a disclosure statement concerning whether the person has ever been convicted of or is the subject of pending charges for any offense. B. After July 1, 1999, providers shall comply with the background check requirements for direct care positions outlined in § 37.1-183.3 of the Code of Virginia. C. The provider shall submit all information required by the Department to complete the background checks for all employees, and for contractors, students and volunteers if required by policy D. Prior to a new employee ~~or contractor~~ beginning duties, the provider shall obtain the employee's written consent and personal information necessary to obtain a search of the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services. Results of the search of the registry shall be maintained in the employee's personnel record. E. The provider shall maintain the following documentation: 1. The disclosure statement; and 2. Documentation that the provider submitted all information required by the Department to complete the background

Section	Comment	DMHMRSAS Recommendation
Items A and B (cont.)	Concerned that this provision appears to mean that a provider may never hire a person convicted of specified offenses. However, the Code of Virginia indicates that, with the exception of felony offenses related to drug possession, the prohibition on hiring applies only to the five years prior to the application date for employment. Suggests that the provision be clarified to indicate that if the charge was a misdemeanor assault, etc. that occurred many years ago with no additional charges. Is this unfair discrimination and should there be some provision for reasonable accommodation?	and registry checks, and memoranda from the Department transmitting the results to the provider. **No change:** The *Code of Virginia* does not provide reasonable accommodations for barrier crimes.
Qualifications of Employees or Contractors **12 VAC 35-105-420**		
✍✍ General Comments	Recommends that there should currently be educational requirements to hold a license to operate a *facility*. Medicaid requires a QMRP (a bachelors degree in human services and two years to sign reports). Why don't the licensure standards at least require a QMRP status to hold a license.	**No change:** QMRP only pertains to individuals served with MR.
✍✍ Item C	Indicates that the requirements for the program director are too broad. It is not reasonable to have had experience providing services to all of the specific populations/programs that the director may oversee.	**Change to read:** ~~Program~~ Service director …
Employee or Contract Personnel Records **12 VAC 35-105-430**		
✍✍ Item A	Indicates that it is not practical or cost efficient to obtain employment records for all contract personnel.	**No change:** The Department believes that this information is necessary for any individual to work in a direct care position.

Section	Comment	DMHMRSAS Recommendation
Orientation of New Employees, Contractors, Volunteers and Students **12 VAC 35-105-440**		
✍✍ General Comments	Indicates more time is needed to orient contractors, volunteers and students. Frequently, these individuals are not working on a regular basis. The list of items that must be included in the orientation within 14 days will be impossible in some cases. A more reasonable time frame would be 30 to 60 days. The requirement should clearly state that the employee cannot have sole responsibility for clients until orientation is completed.	**Change to read:** …15 business ~~calendar~~ days...
Employee Training and Development **12 VAC 35-105-450**		
✍✍ General Comments	Suggests the provision should be rephrased: *"The provider shall have a policy to provide training, including medication administration, behavior management and emergency preparedness, as well as development opportunities for employees to enable them to perform the responsibilities of their jobs. Training and development shall be documented in the employee personnel records."* Medication training should occur only on initial hiring of staff. Retraining on medication administration is the language currently used. The definition of retraining is unclear. Is this periodically or is this as needed. Can this description be more specific?	**No change:** There are frequent violations in medication administration, behavior management and emergency preparedness. The provider would determine the nature of the retraining.
Emergency Medical or First Aid Training **12 VAC 35-105-460**		
✍✍ General Comments	Indicates that this requirement does not work for supported apartments. Because of the varying work schedules, many people at each site will have to be trained. Not suitable for sites with 4 or fewer beds.	**No change:** The existing provision is reasonable and consistent with the current regulations.

Section	Comment	DMHMRSAS Recommendation
Employee or Contractor Performance Evaluation **12 VAC 35-105-480**		
✍✍ Item C	States that it is unclear which contractors constitute the need for an annual performance evaluation. Questions whether this includes staff who do not work directly with residents. Recommends clarification by adding "those who perform direct care services of 16 hours per week or more."	**No change:** This regulation provides flexibility for the provider to determine the policies and procedures for performance evaluations for contractors.
Students and Volunteers **12 VAC 35-105-500**		
✍✍ Item B	Indicates that the meaning of this provision should be clarified. Suggest restating as follows: *"The provider shall not rely on students or volunteers as formal employees or contractors for the provision of direct care services in any staffing plan required by a service description that mandates an experience or training requirement greater than that of the student or volunteer, nor shall students or volunteers towards(sic) the provider's staffing ratio*." Add the term "solely' so it reads, "Provider shall not rely solely on students or volunteers for the provision of direct care services" (Interns provide direct service with appropriate supervision).	**Change to read:** The provider shall not rely on students or volunteers for the provision of direct care services. <u>The provider staffing plan shall not include volunteers or students</u> .
Tuberculosis Screening **12 VAC 35-105-510**		
✍✍ Item A through Item D	Notes that "it is understood by all that TB is on the rise and precautions need to be taken, although when concerns are placed into regulations, there might be some unforeseen employee rights circumstances. Further, the Federal Government is now suggesting a focused approach to staff screening rather than blanket annual screening for all."	The Department consulted with the Director of TB at Virginia Department of Health who assisted in the revision of this regulation**.** **As recommended by VDH, change to read:** A. Each new employee, contractor, student or volunteer who will have direct contact with individuals being served shall obtain ~~an evaluation~~ <u>a statement of certification by a qualified licensed practitioner</u> indicating the absence of tuberculosis in a communicable form within 30 days of employment or contact with individuals. ~~A statement signed by a qualified licensed practitioner documenting the absence of tuberculosis in a communicable form includes the types of tests administered, dates of the tests, and the results of those tests. An evaluation~~ <u>A statement of certification</u> shall not be required for an employee who has separated from service with another licensed provider with a break in service of six

Section	Comment	DMHMRSAS Recommendation
Item A (cont.)		months or less or is currently working for another licensed provider. The employee must submit a copy of the original screening to the provider. B. All employees, contractors, students or volunteers in substance abuse outpatient or substance abuse residential treatment services shall be certified as tuberculosis free on an annual basis by a qualified licensed practitioner . C. ~~An~~ Any employee, contractor, student or volunteer who comes in contact with a known case of ~~infectious~~ active tuberculosis disease or who develops ~~chronic respiratory~~ symptoms of active tuberculosis disease (including, but not limited to fever, chills, hemoptysis, cough, fatigue, night sweats, weight loss or anorexia) of three weeks duration shall be screened as determined appropriate based on consultation with the local health department. D. An employee, contractor, student or volunteer suspected of having ~~infectious~~ active tuberculosis shall not be permitted to return to work or have contact with employees, contractors, students, volunteers or individuals receiving services until a physician has determined that the person is free of ~~infectious~~ active tuberculosis.
✍✍ Item B	Requiring a TB test to on file within seven (7) days of employment is much too short of a timeframe and has the strong potential to lead to increased cost for emp loyers.	See above response.
✍✍ Items C and D	Indicates that Screening provisions should not apply to contractors that are operating under a provider's license. Suggests the following re-wording of these provisions: *"The provider shall take precautions to protect both staff and individuals receiving services in situations where infectious tuberculosis may be suspected, including screening and treatments*	**No change:** Specific changes were made after consulting with the Director of TB at VDH. See above response.

Section	Comment	DMHMRSAS Recommendation
Items C and D (cont.)	*from the local health department and/or a physician of a type to be determined by the local health department. Efforts should be made to limit risk of infections from the person showing symptoms to other individuals*."	
Article 5—Health Safety and Management -Risk Management **12 VAC 35-105-520**		
✍✍ Item D	Indicates that providers should not duplicate efforts made for Workman's Compensation claims. Providers should not be responsible for documentation that is a contractor's responsibility. Delete the phrase "Recommendations for improvement…" This assumes that there is a need for improvement.	**No change:** The provider will not need to duplicate other documentation to meet this requirement. The Department will accept the Workers' Compensation documentation.
✍✍ Item E	States that this provision needs further defining. Item B covers E. Recommends deleting E.	**No change:** Falls are an important area of risk and need to be addressed when the populations being served are at risk of falls.
Emergency Preparedness and Response Plan **12 VAC 35-105-530**		
✍✍ Item A	Indicates that development of the plan will require a considerable amount of work for all outpatient sites. This should be simplified for group home services. This is an example of regulations that are way out of proportion for outpatient and day programs; they seem designed for facility services. Regulations focus on internal organizational issues, but fail to include coordinating communications and actions with local emergency assistance teams, which is central to disaster management. Suggest changing to: *"The provider shall develop a written emergency preparedness and response plan for all of a provider's inpatient and facility-based services with more than 4 beds, in coordination with local emergency preparedness coordinators and centers."* **Point 4:** Add **h** "How to locate and shut off utilities when necessary."	**No change:** This provision is applicable to the provider, not the individual service. **Add:** **h.** <u>How to locate and shut off utilities when necessary</u>.

Section	Comment	DMHMRSAS Recommendation
Item A (cont.)	**Point 5:** Indicates that the fire department retains information about building and site maps that are necessary to shut off utilities. This provision is excessive.	**No change:** In a mass emergency, reliance upon local authorities would not be practical. Response time could be very long. What is required bythe provider is an immediate action procedure in the event local authorities cannot respond.
✍✍ Item B	Indicates that applying this to natural disasters, workplace violence, and other less frequent emergencies in all settings seems excessive. Suggest changing to: *"The provider shall develop and implement emergency preparedness and training for all of a provider's inpatient and facility-based services with more than 4 beds."*	**No change:** The proposed regulation is applicable to the provider, and the provider will determine the scope of training for various settings.
✍✍ Item D	Questions whether residential facilities would be required to maintain an emergency supply of water and food staples.	Yes. FEMA recommends a three-day supply of non-perishable food and a gallon of water per day, per person.
✍✍ Item F	Indicates that it may not be possible to notify the department of disasters within one business day. Suggests changing to "*as soon as practical."*	**Change to read**: The provider should first respond and stabilize the disaster/emergency. After the disaster/emergency is stabilized, the provider should report the disaster/emergency to the Department, but no later than 72 hours after the incident occurs.
Access to Telephone in an Emergencies; Emergency Telephone Numbers **12 VAC 35-105-540**		
✍✍ Item B	States that the regulation asks for the emergency telephone numbers and location of the listed emergency facilities, but only their telephone numbers are needed, not their locations. You would want to know the location of the nearest hospital/emergency room. With that exception, delete the need for locations of the various types of facilities if 911 is available in the community.	**No substantive change.** The provider cannot not rely on telephone systems working in a disaster/emergency. They may be overwhelmed or inoperative; wireless systems have the same vulnerability. Systems might be inundated. Even during the course of a normal workday, telephone systems might be out. Staff may have to transport. Knowledge of the location of nearest ER services is necessary.

Section	Comment	DMHMRSAS Recommendation
First Aid Kit Accessible **12 VAC 35-105-550**		
✍✍ Item A	Indicates that this provision would not be feasible in supported apartments or standard outpatient settings. The respondent states that the Director of the Poison Control Center at Medical College of Virginia Hospitals has advised that activated charcoal should not be used in community programs. These two items may be kept in first aid kits. Requiring them to be stored in locked areas may limit their accessibility. Recommends deleting B and replacing with: *"A well-stocked first aid kit, including an accessible unexpired 30 cc bottle of Syrup of Ipecac (for use at the direction of Poison Control or a physician), shall be maintained..."* The minimum contents of first aid kit are defined under sobering up/detoxification services in 12 VAC 35 105 1140. Asks whether the same contents should be required here.	This regulation does not apply to apartments in which clients receive supportive in-home services. Accidents can happen in outpatient settings. The Department is retaining the requirement for Ipecac and charcoal after consultation with the Director of Toxicology at MCV. **Change to read:** The minimum requirements of a well-stocked first aid kit that shall be maintained include a thermometer, bandages, saline solution, band-aids, sterile gauze, tweezers, instant ice-pack, adhesive tape, first aid cream, antiseptic soap, an accessible, unexpired 30 cc bottle of Syrup of Ipecac, and activated charcoal (for use at the direction of the Poison Control Center or a physician). A and B have been consolidated and these requirements will be deleted under 12 VAC 35-105-1140.
Part IV—Services and Supports - Article 1—Service Description and Staffing		
Service Description Requirements **12 VAC 35-105-580**		
✍✍ Item B	States that the requirement is too global for many community services. Reword as follows: *"Documentation of structured programs that address care, treatment, training, rehabilitation or other supports provided, and meet the objectives of any required service plan."*	**No change:** The existing provision is reasonable; the provider can define with the scope of services.
✍✍ Item F	Indicates that providers should be concerned about maintaining a safe environment for all. Specifying how or what should be done and for whom is prescriptive. Rephrase: *"The provider shall provide for the safety of children accompanying parents receiving services."*	**Change to read:** "The provider shall ~~develop a plan providing~~ provide for the safety of children accompanying parents receiving services."

Section	Comment	DMHMRSAS Recommendation
✍✍ Item G	Indicates that the mention of pregnant substance abusing women is not appropriate for a licensure document. Goes beyond the scope of licensure.	**No change:** This is necessary to comply with *Code of Virginia* § 37.1-182.1.
Provider Staffing Plan **12 VAC 35-105-590**		
✍✍ Item A	Requiring the number of people served in a staffing plan is not always indicative of an appropriate staffing pattern. Knowledge of intensity of individuals who are served should be considered. Rephrase as follows: *"The provider shall design and implement a staffing plan with a staffing pattern that meets the needs and the capacity of the program, including the type and role of employees and contractors that reflects the…"* Also recommends deleting Point 4.	**No change:** It is impossible to assess the adequacy of a staffing plan without knowing the number of individuals to be served and whether contract services will be relied upon.
✍✍ Item B	Indicates that the provision is unclear. Clarification is needed regarding what constitutes a transitional staffing plan and under what circumstances such a plan would be needed.	**Change to read:** The provider shall develop a transitional staffing plan for new services, <u>added locations, and changes in capacity</u>.
✍✍ Item C	**Point 2** Indicates the requirements in this item are unclear with the last sentence stating experience equivalent to the educational requirement. This needs to be more specific. Also, questions whether the QMHP and QMHP requirements apply to the *clinical* services or all services. In. many services, there may be several levels of supervision in a particular service, i.e. house manager, coordinator and director. Specify at what level does the QMHP and QMRP apply. Clarification is needed about the "supervision" in this section. Questions whether it id only relevant to clinical supervision provided to clinical staff. Would the provider need to describe how contract employees are supervised, including those who provide non-direct care services?	**No change:** This applies to supervision for clinical treatment or habilitative services, and those individuals responsible for approving assessment and individual services. This will be addressed as a training issue. See above response.

Section	Comment	DMHMRSAS Recommendation
Item C (cont.)	States that the requirement for a QMRP to perform assessments should be eliminated in favor of experience and KSA's. **Point 4:** States that this seems to be an unnecessary requirement for licensed professionals who have proven themselves capable of this task through the Department of Professional Regulation's requirements for experience, prior supervision, and a written examination. Recommends adding "*This section is waived for providers of services who are licensed for independent practice, QMHP, QMRP or equivalent."*	**No change:** The proposed regulation allows for equivalent experience. **No change:** Licensed professionals would meet the QMRP and QMHP definitions.
✍✍ Item D	Indicates that this may be beyond the scope of some programs. To avoid potential problems recommends adding: *"appropriate for the scope of services it has contracted to provide to the individual being served."* Many community settings encourage the use of community resources for medical, dental and other related services. These medical providers, chosen frequently chosen by the consumer, are neither employees nor contractors of the provider. To imply otherwise is to eliminate the freedom of choice.	**Change to read:** D. The provider shall employ or contract with persons with appropriate training, as necessary, to ~~serve~~ meet the specialized needs of and to ensure the safety of individuals being served in residential services with medical or nursing needs, speech, language or hearing problems or other needs where specialized training is necessary.

Section	Comment	DMHMRSAS Recommendation
Nutrition **12 VAC 35-105-600**		
✍✍ Item A	**Point 3**: Indicates that this is vague and should be deleted. Any need for assistance should be documented in the individual service plan (ISP).	**No change:** This is an affirmative statement of what a provider should do when an individual requires assistance in feeding.
✍✍ Item B	States that this provision is not needed. Such monitoring should be part of the ISP. Suggests adding the term "as appropriate", so it reads "Providers of residential and inpatient services shall develop and implement a policy to monitor, as appropriate, each person food consumption.."	**No change:** Monitoring food consumption in residential and inpatient services needs to be governed by policy, given the nature for the populations to be served. **No change:** This provision allows for proactive monitoring to protect individuals receiving services.
Community Participation **12 VAC 35-105-610**		
✍✍ General Comments	States this should not be a licensing requirement. If an individual's needs are taken care of through one service, another service may not attend to this. Further, this regulation should also not apply to emergency services, ICT, Intensive Outpatient, Opioid, Partial hospitalization, respite care, residential treatment, and case management.	**Change to read:** This regulation applies to residential ~~services.~~, day support and day treatment services.
Article 2—Screening, Admission, Assessment, Service Planning and Orientation -Policies on Screening, Admission, and Referrals **12 VAC 35-105-630**		
✍✍ Item D	Suggests changing wording to offer suggestions or recommendations for other appropriate services. This provision states that providers shall assist individuals who are not admitted to identify other appropriate services. Assist may not be the appropriate word. Assist is part of what the case manager does for open cases.	**No change:** The use of the word "Assist" includes offering, suggesting, etc.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item E	States that this requires providers to develop a policy on the qualifications of employees or contractors responsible for providing screening, admissions, referrals etc. Asks how this is different from a job description. It is duplicative, unnecessary and should be deleted as the job description is defined elsewhere.	**Change to read**: E. The provider shall develop and implement ~~a policy on the qualifications of employees or contractors responsible~~ procedures for ~~providing~~ screening, ~~admission~~ admitting and ~~referrals~~ referring ~~and resources for consultation~~ individuals to services, to include staff who are designated to perform these activities. ~~F. The provider shall develop procedures for screening, admitting and referring individuals to services.~~
Assessment Policy **12 VAC 35-105-650**		
✍✍ Item B	Indicates that the documentation requirements for episodic care are excessive. Requiring all 11 elements in the assessments for every type of service is too prescriptive and impractical, requiring a provider to conduct an assessment listing 11 items, some of which may not be appropriate for all program assessments. The prescriptive list should be removed and instead the requirement should state that "*the provider shall, as a procedure prior to providing services, conduct an assessment*."	**No change:** Existing provision is reasonable. This is the minimal amount of information required to perform an assessment for a treatment plan.
✍✍ Item D	Indicates that, when the treatment plan is updated and a quarterly report is completed, this is a reassessment of where the individual is and the progress that has been made. It shows both strengths and weaknesses. An additional reassessment should not be required unless there are clinical reasons that necessitate it. This does not specify that "*annually"* means one year in a specific program. It is unnecessary to state and should be deleted.	**No change:** The quarterly review of the treatment plan can meet the annual re-assessment requirement.
Individualized Services Plan **12 VAC 35-105-660**		
✍✍ General Comment	Indicates that this whole section could be much more recovery focused with an emphasis on the consumer having active participation in the creation of his service plan. At a minimum, point 5 under C. "The individualized services plan shall address"	**Change numbering order** # C 5 will become #C 1 and other steps subsequently reordered.

Section	Comment	DMHMRSAS Recommendation
General Comment (cont.)	could be the first point mentioned to emphasize consumer involvement. Also the wording might be changed from "individual's needs and preferences" to "the individual's stated personal rehabilitative and life goals."	**No other change:** This provision is consistent the Human Rights Regulations.
✍✍ Item A	Indicates that it is logistically impossible to complete an ISP within 24 hours for most providers. Believes that documentation of screening for admission and any assessments conducted prior to admission may serve as a service plan upon admission and may continue in effect until the ISP is developed or the individual is discharged—whichever comes first. The requirement that the Individual Service Plans be written only by a QMRP is of concern. Some of these are nondegreed persons, again with many years of experience. It would be a tremendous hardship if Residential Counselors and Supervisor could not write plans. Who would do it?? Second level positions to be degreed and perform the shift work and direct care responsibilities that go along with these positions would greatly reduce the pool of applicants we would get.	**No change:** The operative word is "preliminary." This is not expected to be a full ISP, and requirements in Section C do not apply. This provision is consistent with the Human Rights Regulations that require a plan before services are offered. (See 12 VAC 35-115-60). **No change:** Refer to Section 12 VAC 35-105-590. (C4) states this responsibility may be delegated to an employee or contractor who is a QMHP or QMRP or who has equivalent experience.
✍✍ Item C	**Point 3**: Indicates that this requires a plan when one may not be needed. Goals and objectives should be based on the needs of the individual. This provision should be deleted.	**No change (see General Comment above):** The standard states an ISP shall address: a communication plan for individuals with communication barriers, including language barriers.
✍✍ Item D	States that this does not describe how a provider is supposed to document compliance with human rights regulations on each ISP. This is implicit if it signed by the individual receiving services (Refer to 12 VAC 35-105-670 B).	**Change to read:** The provider shall comply with Human Rights (HR) Regulations…." Section 12 VAC 35-105-670B requires involvement of the individual receiving services or the legally authorized representative (LAR).

Section	Comment	DMHMRSAS Recommendation
✍✍ Item G	Indicates that this provision is duplicative and should be deleted. Policy on personnel qualifications is found in job descriptions.	**Change to read:** The provider shall designate a person who will develop and implement individualized service plans.
✍✍ Item I (E)	States that not all individuals receiving services have family. Add "*if appropriate.*"	**Change: Combine # I with # E to read:** The provider shall involve family members, guardians, or others, if appropriate, at least annually, in developing, reviewing or revising the individualized service plan consistent with laws protecting confidentiality, privacy, the human rights of individuals receiving services (See 12 VAC 35-115-60) and the rights of minors.
Individualized Service Plan Requirements **12 VAC 35-105-670**		
✍✍ Item A	Indicates that an ISP is required by licensure after 30 days:	
	a. Asks what information is expected in this ISP and how does it compare to the DMAS ISP that is developed after a 60 day assessment.	a. This issue will be addressed as a training issue.
Item A (cont.)	b. Does the ISP format for licensure include the service the individual receives such as day support or residential with the level of assistance and monitoring for self help skills as well as any support services from outside the company such as OT and PT, etc., or is it meant to be the same as the DMAS ISP with goals and objectives for treatment?	b. **No change:** Yes, the ISP covers all services.
✍✍ Item C	This provision should not be applicable to respite services.	**No change:** This provision is consistent with Human Rights Regulations. (See 12 VAC 35-115-60). Providers must develop a preliminary plan, as services cannot be delivered without a service plan.

Section	Comment	DMHMRSAS Recommendation
Progress Notes or Other Documentation **12 VAC 35-105-680**		
✍✍ General Comments	This provision should not be applicable to respite services.	**No change:** Consistent with Human Rights Regulations. (See 12 VAC 35-115-60).
Article 4—Medical Management- Health Care Policies **12 VAC 35-105-720**		
✍✍ General Comments	Indicates that the requirement to include a listing of dental providers (*6*) looks like a long-term care requirement, not outpatient medical management. Some of these prescribed elements are not appropriate for all program types. Points A. *3, 5*, and *7* do not apply to all services and are more appropriate for case management and residential. The language should state "*as appropriate*" for other services. Many individuals receiving services are capable and should be encouraged to arrange their own transportation to medical appointments. It appears that licensees are required to provide transportation to non-licensee services. If accurate as currently stated, this is a practical impossibility. It should apply only to residential programs; if designed for any other specific service categories, these categories should be listed either in this regulation or in an applicability matrix. Change to the "*provider facilitates and arranges….*" As written, this section appears to imply that licensees are required either to provide directly, or to pay for, medical services for indigent consumers who lack access to medical services due to lack of ability to pay. This could represent a huge financial burden. Inclusion of a statement that relieves the licensee of a financial responsibility for medical care is indicated: *"The provider is not to be held financially responsible if funding does not exist to provide for the consumer's medical care."*	The provider determines medical policy appropriate to the scope and level of services he or she provides. **Change A to read:** 3**.** Identified medical care needs ~~beyond the scope of services~~ will be ~~met~~ addressed**;** 7. The provider ensures a means for facilitating and arranging, as appropriate, ~~arranges for~~ transportation to medical and dental appointments and medical tests when services cannot be provided on site. **No change:** The intent of this regulation is not to require the licensee to pay for health care, but for providers to have a policy that addresses how health care will be addressed outside the scope and level of services provided.
✍✍ Item B	This Item appears to be an extension of Item A and is therefore not necessary.	**No change:** Item B provides clarification for Item A.

Section	Comment	DMHMRSAS Recommendation
Medical Evaluation **12 VAC 35-105-730**		
✍✍ General Comments	Suggests changing the title of this section to "Medical History" or "Medical Information."	**Change section heading to read:** Medical Information
✍✍ Item A	Indicates that it is not necessary to have a physical exam for admission to case management or outpatient services. Suggests adding: *"except when not required for the provision of services including, but not limited to, case management or outpatient services."* Recommends adding "as appropriate to the scope of services", so it reads, The provider shall develop and implement as appropriate to the scope of services provided, a medical evaluation or document its ability to obtain a medical evaluation that consists of, at a minimum a health history and emergency medical information.	**No change:** A current health history is required for all individuals admitted to a service, though a physical exam is not. See above response.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item B	**Point 9:** States that asking about gynecological history is overly intrusive and inappropriate as well as not pertinent in many services and may deter some women from proceeding with services. Absent a similar category for men, it may also be perceived as sexist. It is not clear what constitutes a gynecological history. Indicates however, that it is reasonable to inquire of female clients if they are currently pregnant because this may provide eligibility for some specialized services and may influence whether psychotropic medications are prescribed. This should be restated: *"A health history shall include whether or not a female client is pregnant."* Recommends a health history should not routinely include "gynecological history, including pregnancies." When appropriate, depending on the scope of the program, it may be useful to ask the date of the most recent PAP exam or gynecological exam. Recommend the inclusion of a statement that relieves the licensee of a financial responsibility for medical care if the funding does not exist to provide medical services.	**Change to read:** Sexual health and reproductive history **No change:** Licensing regulations do not address financial responsibility for health histories.
Physical Examination **12 VAC 35-105-740**		
✍✍ Item A	Indicates that physicals would not generally occur in residential settings. In some programs, physicals should be done within 60 days prior to admission, consistent with Medicaid requirements. Sometimes it is not feasible for individuals to obtain physicals within 30 days due to backlog in public health centers. Suggests change to "*an appointment for a physical is made within 30 days of admission*" and "*request results*" of physicals. We cannot control if we get the results. Also, technically, a client may wish to keep his health issues with his own practitioner confidential. Clarify whether the phrase: "within 30 days of admission" applies to 30 days before or after admission.	**No change:** The intent of this section is to ensure each client has a current physical examination. This means within 30 days after the individual had been admitted.

Section	Comment	DMHMRSAS Recommendation
***Emergency Medical Information* 12 VAC 35-105-750**		
✍✍ Item A	Indicates that for clarity, Items A and B should be in reversed order. The new *A.* should read: *"Current emergency medical information shall be readily available to employees or contractors wherever program services are provided. B does not apply to home and non-center-based services."* Point 8: States that advance directives should not be required. Should be changed to read, "*Advance directive (if one exists)*." or when appropriate	**No change:** Reversing A with B is not substantive. This information should be available in every service setting. **Change to read:** 8. Advance directive, <u>if one exists.</u>
***Medical Equipment* 12 VAC 35-105-760**		
✍✍ General Comments	Indicates that this provision is not clear. Questions what is meant by medical equipment and if the provision applies to all types of services. May already be covered in 12 VAC 35-105-720 C.	**No change:** This concern will be addressed as a training issue.
***Article 5—Medication Management Services- Medication Management* 12 VAC 35-105-770**		
✍✍ Item C	States that this provision, as written, would seem to prevent delivery of medication to a parent, spouse, legal representative, etc. Replace with: "*delivered only to the individual (or a parent, spouse or legal representative) for whom the medications are prescribed*"	**Change to read:** Medications shall be <u>administered</u> only to the individuals for whom the medication are prescribed and shall be administered as prescribed.
✍✍ Item E	Indicates that the provision should be changed to designate a current label on the medication equivalent to a current medication order. Orders cannot generally be obtained individuals for whom self-administration is supervised in the community. Also suggests addition of "*with the exception of over-the-counter medications...*" to the end of the sentence to cover instances in which a medication order typically is not written or required.	**No change:** This section allows the provider to confirm the labeled medication is the current order. The standard does not direct the provider how this verification should be done, thereby allowing the provider to customize procedures. The Board of Nursing education curriculum requires over-the-counter medications to be prescribed or contained in standing

Section	Comment	DMHMRSAS Recommendation
Item E (cont.)		orders. This provision does not apply to self-administered drugs, unless the provider is supervising self-administration.
✍✍ Item F	Indicates that adding "*with the exception of over-the-counter medications*" would be advisable for this provision.	**No change:** These medications need to be reviewed and disposed of if they become outdated.
Medication Errors and Drug Reactions **12 VAC 35-105-780**		
✍✍ General Comments	States that medication errors should be redefined to exclude instances where a client is not in a residential program and misses or gets a late dosage due to their not keeping an appointment, etc.	**No change:** The context of medication administration is an important consideration in determining if there is an error. The reason for the missed dose should be noted on the MAR.
✍✍ Item A	Suggests deleting Item A. Provision is too narrow. Change to "*the provider will have a policy, approved by a licensed physician, about how it will respond to medication errors or adverse drug reactions.*"	**No change:** This is consistent with the Board of Nursing curriculum requirements and other regulations pertaining to medication administration. On the advice of the Office of the Attorney General DMHMRSAS proposes the following revision for clarification**:** n the event of a medication error or adverse drug reaction, A. First aid shall be administered if indicated. . . .
✍✍ Item B	Indicates that this provision is too prescriptive. Suggests changing to like "*...shall have a policy that addresses what actions should be taken in the case of a medication error…*" Same comment for Item C and D.	**No change:** This is consistent with the Board of Nursing curriculum requirements and other regulations pertaining to medication administration.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item E	Recommends deleting the reference to the method of documenting medications, "*The provider shall document any medicine received and refused by each individual*.' This will eliminate the need for double documentation--client's record and a log. Indicates that this provision is very prescriptive. Should be part of the provider's "safe administration" policy. Delete "shall review every quarter."	**Change to read:** The provider shall review all medication errors at least quarterly as part of the quality assurance in Section 12 VAC 35-105-620. Medication errors are violations frequently and repeatedly cited. This is an area related to health and safety that providers need to address.
***Medication Administration and Storage or Pharmacy Operation* 12 VAC 35-105-790**		
✍✍ General Comments	Indicates that there is no clear definition of "storage." Delete this word from the provision.	"Medication Storage" has been added to the definitions section.
✍✍ Item A	**Point 2**: Indicates that community programs follow the medication curriculum by the Virginia Board of Nursing. State facilities follow the Virginia Board of Pharmacy. Community programs follow the Virginia Board of Nursing curriculum so *"/or the Virginia Board of Nursing..."* needs to be added.	**Add as 3:** *3*. The Virginia Board of Nursing Regulations and Medication Administration Curriculum.
***Article 6—Behavior Management- Policies and Procedures on Behavior Management Technique* 12 VAC 35-105-800**		
✍✍ Item B	Believes that "trained in behavior management programming" should be clarified. Is concerned that some providers may have to terminate good programs because they do not meet the "trained" requirement.	**No change:** The provider defines the training required; this regulation is the same as the current regulation.
✍✍ Item D	Indicates restraint should be defined in D.	**No change:** Restraint is defined in the definitions section of the regulations.

Section	Comment	DMHMRSAS Recommendation
***Prohibited Actions* 12 VAC 35-105-820**		
✍✍ General	**Point 6**: States that providers should be able to remove persons from services who are noncompliant or a danger to self/others. Concerned that if there are waiting lists or if there is an "*appropriate*" service, that is not offered, this provision would give individuals the leverage to demand services that are not available. Recommends rewording: *"Deprivation of services and treatment indicated in the individual services plan, except for those persons who must be removed due to noncompliance or because they are a danger to themselves or others."*	**No change:** This language is in the current regulations and is consistent with the Human Rights Regulations. (See 12 VAC 35-115-110)
***Seclusion, Restraint and Time Out* 12 VAC 105-830**		
✍✍ Item C	**Point 1:** These procedures are in compliance with a behavior plan and, for the most part, do not involve a doctor's order. Suggest adding "*if applicable or reference to an approved behavioral plan*."	**No change:** This is consistent with the Human Rights Regulations. (See 12 VAC 35-115-110)
Article 7—Continuity of Service and Discharge		
***Discharge* 12 VAC 35-105-860**		
✍✍ General	Suggests that at the time of dis charge, certain information needed to be provided, ***in writing***. to the client and/or his AR or the provider to who the individual had been referred for future services. These shall include, at the very least, medications and dosages, phone numbers and addresses of any providers to whom the client is referred, an emergency contact and medical issues identified with the identity of the provider of medical services.	**Add as B and renumber following sections:** Discharge instructions shall be provided, in writing**,** to the individual or his LAR or both. Discharge instructions shall include, at a minimum, medications and dosages, phone numbers and addresses of any providers to whom the individual is referred, current medical issues, conditions, and the identity of health care providers. This regulation applies to residential and inpatient services.

Section	Comment	DMHMRSAS Recommendation
Part V—Records Management		
Documentation Policy **12 VAC 35-105-880**		
✍✍ General	Asks whether it is permissible in hospitals, under state and federal law, for a medical record entry to be authenticated by other physicians in the ordering physician's group if the ordering physician is unavailable, with procedures for such authentication to be set forth in hospital policies and procedures (See Va. Code of Virginia, § 32.1-l27 B (11). Requests revision of this section to permit this same practice under these regulations.	**No change:** Yes, it is permissible if done in accordance with Virginia Code § 32.1-l27 (B) (11), regulations promulgated pursuant to that Code section, internal hospital policies and procedures, and medical staff by-laws.
Individual's Service Record **12 VAC 35-105-890**		
✍✍ Item B	**Point 8 & 10**: Recommends adding "if applicable" to the end of each.	**Change to read:** 8. Name of legal guardian or authorized representative, if applicable; 10. Adjudicated legal incompetency or legal incapacity, if applicable; and
✍✍ Item C	**Point 1** "Admission Form". Clarify what is the document this standard refers to.	**Delete Point 1,** "Admission form," and renumber remaining provisions.
Retention of Individual's Records **12 VAC 35-105-910**		
✍✍ Item B	Asks whether *"permanent"* means that this information must be kept indefinitely beyond the 3-year period required by Section A. Recommends that this section be clarified to address this.	**No change:** Yes, this means permanently.
Part VI—Additional Requirements for Selected Services- Article 1—Opioid Treatment Services- Registration, Certification or Accreditation **12 VAC 35-105-930**		
✍✍ General Comments	Recommends that *deemed status* be granted to these programs. They must be accredited by a major national accreditation program for Federal or other state purposes. It creates a substantial burden	**No change:** The *Code of Virginia* requires that all providers be licensed and that the Department conduct annual inspections and investigate all

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	of paperwork at the local level when programs must maintain compliance records to meet multiple and different criteria.	complaints with a focus on preventing specific risks to consumers. There is a public health interest for the state in maintaining direct monitoring of these services. It is unclear why the respondent views the regulations as requiring "a substantial burden of paperwork."
Service Operation Schedule **12 VAC 35-105-950**		
✍✍ Item A	Indicates that it is not clear why the services are required to operate 24 hours a day except for state holidays. Is the intent that there be provisions for necessary access to medication and services within the program at all times? States that the draft regulations requires that programs be open seven days a week, in contrast to the federal regulations which allow programs to be closed on Sundays. This again simply costs the program money and is an unnecessary requirement.	**No change:** The proposed regulation does not require 24-hour- per-day operation**.** The Department believes that comprehensive services and supports must exist for individuals served who are early in their treatment experience. DEA studies have consistently found the highest rate of diversion of medication in areas where programs are closed on Sundays with more liberal policies regarding take home medications.
Counseling Sessions **12 VAC 35-105-970**		
✍✍ General Comment	Indicates that the draft document requires two years of mandatory counseling, which is not required under the federal regulations. Requests clarification.	**No change:** Federal guidelines require participation in two years of treatment before individual can receive methadone outside the program.
Drug Screens **12 VAC 35-105-980**		
✍✍ General Comment	States that the draft regulations require four more urine screens than required in the fed regs. The extra urine screens simply add cost without value to each and every opioid program in Virginia. Requests clarification.	**Change A to read:** A. The provider shall perform ~~random drug screens~~: ~~1. Weekly, during the first 30 days of treatment;~~ at least eight random drug screens during a twelve month period unless the conditions in subdivision B of this subsection apply;

Section	Comment	DMHMRSAS Recommendation
General Comment (cont.)		B. ~~2. Monthly, after the first 30 days of treatment, unless the conditions in subdivision 3 of this subsection apply; and~~ Whenever an individual's drug screen indicates continued illicit drug use or when clinically and environmentally indicated, random drug screens shall be performed weekly. ~~3. Weekly, whenever an individual's drug screen indicates continued illicit drug use or an individual fails to participate in the treatment plan.~~ Renumbered the remaining sections.
Take-Home Medication **12 VAC 35-105-990**		
✍✍ General Comment	Indicates the draft regulations state absence of recent alcohol and other drug USE compared to federal regulations, which state absence of recent ABUSE of drugs, including alcohol. The difference between the words USE and ABUSE is vast, therefore, the draft regulations are very different from the federal regulations. Requests clarification.	**Change to read:** 2. Absence of recent alcohol abuse or other illicit drug use.
Guests **12 VAC 35-105-1010**		
✍✍ General Comments	Suggests adding: "…*if the opioid treatment program is of a nonresidential nature or if clients are permitted to leave the premises."* If the concern is about a client receiving methadone from multiple sites, this concern is not valid for clients who remain in the residential program and do not leave.	**No change:** This regulation applies to guests only.
	States that the proposed regulation calls for opiate treatment providers to contact every other opiate treatment provider within a fifty-mile radius prior to admission. Clarify if this requirement is consistent with proposed HIPAA regulations.	This is covered under confidentiality standards in HIPAA and both the Department's human rights and licensing regulations. Contacting other services may be completed only upon the written, signed consent of the individual served.
	Indicates that, under opiate treatment services, there is no longer a reference to requirements for dealing with doses in excess of 100 mg. Clarify if this is a change in federal regulations**.**	This is no longer required under federal regulations.

Section	Comment	DMHMRSAS Recommendation
Article 2—~~Sobering Up and~~ [Social] Detoxification Services - Criminal Justice Referrals **12 VAC 35-105-1060**		
✍✍ General Comments	Believes the proposal for criminal justice referrals in 1060 to1150 presents some conflicts with/may duplicate the requirement for establishing detoxification facilities and programs in Chapter Article of Title 9.1 of the Code of Virginia. Section § 9.1-163 defines a "detoxification center program [as] any facility, program or procedure for the placement of public inebriates as an alternative to arresting and jailing such persons, for the purposes of monitoring the withdrawal from excessive use of alcohol." This approximates the definition of "sobering up services" in the current and proposed regulations. Believes that "monitoring" of withdrawal may not fit the definition of "care and treatment [as] a set of individually planned interventions.. etc." in the regulations and question the necessity of licensing programs that solely provide monitoring for individuals diverted from the criminal justice system.	12 VAC 35-105-1060 has been deleted from the regulations, as the *Code of Virginia*, §§ 9.1-163 and 9.1-164, specify this service should be governed solely by the regulations of the Department of Criminal Justice. This clarification will result in changes and deletions throughout Article 2-Sobering-up and Detoxification Services-12VAC 35-105-1060 through 12VAC35-105-1150.
Direct-Care Training for Providers of ~~Sobering-Up and~~ Detoxification Services **12 VAC 35-105-~~1090~~ 1080**		
✍✍ General Comments	Indicates that this regulation needs to be modified to be consistent with the existing procedures of the Department's Office of Substance Abuse Services. Suggests deleting the words "and certification" and "Department of Mental Health, Mental Retardation and Substance Abuse Managed Withdraw Training and" and adding or inserting the following so the section would read:*Direct-care staff training shall include:* ✍ Department of Mental Health, Mental Retardation and Substance Abuse Managed Withdraw Manual ✍ First responder training; or ✍ First aid and CPR training	**Change to read:** A. The provider shall document staff training in the areas of: 1. Management of withdrawal; and 2. First responder training; or 3. First aid and CPR training.

Section	Comment	DMHMRSAS Recommendation
Admission Assessments **12 VAC 35-105-~~1120~~ 1110**		
✍✍ Item A	**Point 1:** The term "high risk" should be clearly defined. Suggests re-wording as follows: *"Identify individuals who have a high risk for medical problems or who may pose a danger to themselves or others."*	**Change to read:** 1. Identify individuals with a high-risk ~~profile~~ <u>for medical complications or who may pose a danger to themselves or others</u>;
Article 3—Services in ~~Facilities Operated by the~~ Department of Corrections' Correctional Facilities – Clinical and Security Coordination **12 VAC 35-105-~~1160~~ 1140**		
✍✍ General Comments	Indicates that the provisions disregard the fact that mental health providers are "guests" in correctional facilities. These provisions can be applicable only to correctional facilities seeking licensure-- not outpatient services or other providers who operate in jails. It is beyond the control of the licensed provider to assure the following parts of this section are met: (1) assuring formal and informal means of dispute resolution; (2) assuring cross training; (3) Items E, F, G, H , I and J in this section.	**No change:** These regulations apply only to DOC operated facilities (see definition) and have been in effect since 1995. DOC was required to obtain licensing for its residential mental health services.
Other Requirements for Correctional Facilities **12 VAC 35-~~1170~~ 1150**		
✍✍ General Comments	Recommends deleting this section. Believes the entire section does not make sense and oversteps the bounds of the Department's authority. See comment regarding 12 VAC 35-105-1160 regarding licensing services in a correctional facility.	**No change:** See above response.
Article 4—Sponsored Residential Home Services		
Sponsor Qualification and Approval Process **12 VAC 35-105-~~1200~~ 1180**		
✍✍ General Comments	Indicates that the definition of group residential home is too restrictive.	**No change:** See definition for group home residential service.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item C	**Point 4**: Recommends removing the restriction of financial capability of the sponsor to meet the sponsor's expenses independent of payments received for residents living in the home. This is not required for group homes and places an extra burden on single persons to provide residential supports. Recommends deletion. a. Suggests requiring the provider to ensure up to 3 months operating expenses to be the sponsor in the event of a crisis, placing the onus on the business rather than the individual caregiver **OR** b. Adopt rules for SRPs requiring a budget and resources (including line of credit) to meet 3 months operating expenses prior to allowing placement as is the process for group homes.	**Change to read:** 4. The financial capacity of the sponsor to meet the sponsor's own expenses for <u>up to 90 days</u>, independent of payments received for residents living in the home.
✍✍ Item D	Indicates that there is no legal authority to conduct criminal background checks "*for all adults in the home*." Suggests changing this to "*...those adults in the home who are being retained as service providers."*	**Change to read:** D. The provider shall obtain references, criminal background checks and a search of the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services for all adults in the home <u>who are staff. The provider must develop policies for obtaining references, background and registry checks for all adults in the home who are not staff and not the individuals being served.</u>
✍✍ Item F	Indicates that the regulations removes the foster designation in favor of the term sponsored placement. Tax implications of this change should be studied and made available for comment prior to the change being made. "Sponsored residential homes shall not also operate as group homes or foster homes." Sponsored residential homes are foster homes by definition. If the intent is to restrict this use for both children and adults, the regulation should be clear to state this restriction. Recommends clarification of regulation that a group home cannot be private residence is not clear.	**Change to read**: F. Sponsored residential homes shall not also operate as group homes or <u>department of social services approved foster homes</u>. Note: These homes were not referred to or licensed as foster homes under the current regulations. They were licensed as group homes or sponsored placement homes. **No change:** See definition for group home residential services.

Section	Comment	DMHMRSAS Recommendation
Supervision **12 VAC 35-105-~~1220~~ 1200**		
✍✍ Item A	Suggests clarifying the responsibility of supervision oversight.	**No change:** This is specified in the ISP and in the definition of residential services.
✍✍ Item B	Indicates that this is not done currently and is not observable or enforceable because family members and their vehicles are not under licensee control. Recommends deleting this provision.	This is required by law. **Change to read**: Any member of the sponsor family who transports individuals receiving services must have a valid driver's license and automobile liability insurance.
Sponsored Residential Home Service Records **12 VAC 35-105-~~1230~~ 1210**		
✍✍ General	**Point 2**: Indicates that there is no legal authority for this requirement. Recommends elimination. **Point 4:** Indicates that requiring a log to include the names of all visitors and the purpose of the their visit to the home violates the privacy of individuals being served would resort in fewer visitors and increased isolation for individuals served.	**Change to read:** Criminal background checks and results of the search of the registry of founded complaints of child abuse and neglect on all ~~individuals~~ adults ~~residing~~ who are staff in the home ~~over the age of 21 who are not individuals receiving services.~~ **Change to read:** 4. A log of provider visits to each sponsored residential home including the date, the staff person visiting, the purpose of the visit, and any significant events; and
Maximum Number of Beds or Occupants in Sponsored Residential Home **12 VAC 35-105-~~1250~~ 1230**		
✍✍ General Comments	Suggests removing the restriction that sponsored placement is restricted to two beds. This restriction is not required for group homes. ✍ Would be disruptive to consumers currently living in a situation of more than two beds. ✍ Limits ability to co-locate siblings significant others and /or close friends	**No change:** If more than two individuals are receiving services, the home will be licensed as a group home.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont)	✍ Reduces number of observable relationships and opportunities for incidental programming ✍ Self-determination and autonomy are reduced Limiting the number of occupants in sponsored placement home to two consumers promotes the family atmosphere. Allow 3 clients to live in the same sponsored residential home if there are two care providers in the home.	
Article 5—Case Management Services- Service Requirements for Providers of Case Management Services **12 VAC 35-105-~~1260~~ 1240**		
✍✍ General Comments	States that this whole section does a nice job of recording the many potential functions of a case manager the way they typically function in Virginia MH and MR systems. In general it promotes a model that is beyond brokering and less than ongoing therapy.	
	Suggests that this section could be greatly enhanced to include references to contemporary recovery orientation and inclusion of evidence based services that would promote a higher level of care and promote consumer autonomy with little to no additional cost or burden to a program.	**No change:** Recovery orientation does not include individuals with mental retardation.
	Recommends a detailed cost analysis be done to determine the economic impact of licensing additional service. Expanding licensure to cover case management services will likely impact on the cost of services. Agency background document states, "Licensure will require more administrative documentation and reporting but is not likely to have any effect on quality or quantity of services provided." Additional administrative documentation and reporting requirements may decrease the quality or quantity of services provided as providers redirect employee resources from service delivery to administrative tasks. To maintain quality,	Licensing of case management and other additional services referenced by this respondent has been mandated by the Code of Virginia (§§37.1-184 and 37.1-179)

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	providers may add employee resources to deal with the additional administrative work, resulting in increased cost of services. Increased cost may result in decreased quantity of services as finding sources, operating with no increase in funding to absorb the higher cost, are forced to purchase less services. DMHMRSAS, Office of Licensing will require additional resources to do an effective job administratively; increased burden on providers.	
✍✍ Item A	States that this appears to require case management outreach to potential clients for all licensed providers. This is vague and unclear. If it is included, the case management license will require a lot of increased documentation in a service that is already overburdened and under-funded. With the high caseloads of individuals currently who are receiving services, outreach does not seem practical. This should be deleted or at the very least, reworded: *"Providers of case management services for providers may contact potential individuals to identify needs for services.* Suggests that this provision be reworded to: *Providers of case management services shall* promote recovery and well being in those individuals eligible for case management services. (Integrates the optimism of a recovery model.)	**Change to read:** As part of the intake assessment, the provider of case management services shall identify individuals whose needs may be addressed through case management services. **No change:** This section has been changed to address intake assessment**.**
✍✍ Item B	**Point 2:** Reword to: Encouraging effective engagement with natural support systems such as family and significant others. Includes consultation with and psychoeducation for relevant family members (unless prohibited by the consumer). (Promotes family psychoeducation, a service with much scientific support that is not particularly prevalent in Virginia, without specifically requiring it.) **Point 4:** Reword to: Linking the individual to those community supports that are likely to promote the personal rehabilitative and life goals of the consumer as developed in the ISP. (Consumer empowerment.)	**No change:** Existing language is closely linked to Medicaid regulations for reimbursement. Additionally, the recommendation applies to mental health and substance abuse services, but excludes individuals with mental retardation. **Change to read:** Linking the individual to ~~services and supports specified in the individualized services plan, including primary medical care~~ those

Section	Comment	DMHMRSAS Recommendation
Item B (cont.)	**Point 7:** Reword to: Monitoring service delivery through assessment of consumer satisfaction with services. This would also include contact with and feedback to providers and may also include periodic site and home visits. (Consumer empowerment.) **Point 8:** Reword to: Develop a supportive relationship that assists the consumer in attaining his stated personal and life goals for recovery. (Consumer empowerment.) **Point 10:** Reword to: Developing a crisis plan for an individual that includes the individual's preferences regarding treatment in an emergency situation. This could include the development of a psychiatric advance directive. (Consumer empowerment.)	community supports that are likely to promote the personal habilitative/rehabilitative and life goals of the individual as developed in the individualized service plan (ISP). **Change to read:** Monitoring service delivery through contact with individuals receiving services, with service providers, and periodic site and home visits to assess the quality of care and satisfaction of the individual. **No change:** This language is not applicable to individuals with mental retardation. The language must apply to all populations. **Change to read:** Developing a crisis plan for an individual ~~as needed~~ that includes the individual's preferences regarding treatment in an emergency situation.
Qualifications of Case Management Employees or Contractors **12 VAC 35-105-~~1270~~ 1250**		
✍✍ General Comments	Recommends deleting Points A, B and C of this Section. Suggests replacing with requirements that case managers meet the qualifications of QMHP or QMRP, assuming grandfathering for those already employed and an experience equivalency for both. Believes that the provisions lead to 2 or 3 standards of competency and has many provisions which are not well defined.	**No change:** Existing provision provides flexibility for providers to hire case managers who meet the case management qualifications identified in provision 1270, but not be a QMRP or QMHP.
✍✍ Item A	**Point 6:** Suggests moving this to A. 1. and rewording to: Knowledge in developing a recovery oriented individualized service plan that addresses the stated personal rehabilitation and life goals of a consumer.	**No change:** This language is not applicable to individuals with mental retardation. The language must apply to all populations.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item B	**Point 2:** Suggests rewording to: Using information from assessments, evaluations, observation, and interviews to assist the consumer in the development of an individualized service plan designed to meet the goals of the consumer. **Point 3:** Suggests rewording to: Identifying and documenting how resources, services and natural supports such as family can be utilized to promote achievement of an individual's personal rehabilitative and life goals.	**No change:** This is not a substantive change. **Change to read:** Identifying and documenting how resources, services and natural supports such as family can be utilized to promote achievement of an individual's personal habilitative/rehabilitative and life goals;
~~Screening, Referral and Admission~~ **~~12 VAC 35-105-1280~~**		
✍✍ General Comments	Insert the following to read " . . . *for the purpose of determining the potential need and determining eligibility for…"* States that this does not appear to be a regulation, but a clarification of a definition applicable to screening, referral and admission activities of case management services. Should this be incorporated under the definitions?	This provision has been deleted and the recommendation has been incorporated in the definition of "case management services."
Article 6—Community Gero-Psychiatric Residential Services- Admission Criteria **12 VAC 35-105-~~1290~~ 1260**		
✍✍ General Comments	Indicates that the introductory paragraph refers to these units being for individuals whose needs cannot be met in a traditional nursing home. An alternative wording might be: Gero-Psychiatric Residence programs are designed for individuals who do not have the intensive physical nursing needs of a traditional nursing home, and have intensive behavioral needs related to a mental illness or dementia that render that individual unsafe to live alone or in ordinary domestic housing. Appropriateness for placement into a gero-psychiatric residential setting will be established following medical and psychiatric assessment performed by qualified individuals who have been trained in the level of service available within a gero-psychiatric residential setting.	**No change:** This model may serve individuals with intensive, physical nursing needs who have behavior needs that cannot be meet in a nursing home.

Section	Comment	DMHMRSAS Recommendation
General Comments (cont.)	Believes that is in inadvisable to adopt community gero-psychiatric residential services regulations at this time, pending further in-depth discussion between the long term care profession and the department. Strongly urges the Department to delete this entire article along with the definition of "commununitv' gero—psvchiatric residential services**."**	**No change:** The Department developed these regulations in consultation with many individuals and organizations. Virginia Code §37.1-179 requires providers of this service to be licensed by the Department.
Physical Environment Requirements of Community Gero-Psychiatric Residential Services **12 VAC 35-105-~~1300~~ 1270**		
✍✍ Item B	Suggests adding non-glare.	**No change:** The current provision is reasonable.
Service Requirements for Providers of Gero-Psychiatric Residential Services **12 VAC 35-105-~~1320~~ 1290**		
✍✍ Item B	Indicates that it is not clear to what extent crisis stabilization is to be provided. This may be a bit too wide open. You would want basic behavioral mini crises to be handled "in-house," maybe at the same level as a hospital, i.e. through a RN present and on call doctor, but major problems and physical emergencies should have a pathway for access to higher level of services.	**No change:** 12 VAC 35-105-700 requires providers to have policies on how they will handle crises, which include crisis stabilization services. This does not preclude providers from accessing a higher level of assistance, when applicable.
✍✍ Item C	Indicates that. the way this is written, it is difficult to understand if each individual is to have a unique physical management plan, or if the facility shall "institutionalize" through nursing policy a physical management policy. (A combination of both would be ideal.)	**No change:** Policies are to be written for the facility, but are implemented on an individualized basis.
Staffing Requirements for Community Gero-Psychiatric Residential Services **12 VAC 35-105-~~1330~~-1300**		
✍✍ Item C	Indicates that this section lists Licensed Mental Health Professionals and the specific licenses. It also excludes Licensed Professional Counselors from the definitions. Asks whether it was the intent to exclude this class of providers.	**No change:** A licensed therapist could include a Licensed Professional Counselor (LPC).

Section	Comment	DMHMRSAS Recommendation
Interdisciplinary Services Planning Team **12 VAC 35-105-~~1340~~ 1310**		
✍✍ Item A	This section lists Licensed Mental Health Professionals and the specific licenses. It also excludes Licensed Professional Counselors from the definitions. Asks whether it was the intent to exclude this class of providers.	**No change:** The listing reflects the minimum requirements for team membership.
Physician Services and Medical Care **12 VAC 35-105-~~1370~~ 1340**		
✍✍ Item B	Suggests increasing the timeframe to 72 hours, not 48 hours for conducting a physical examination.	**Change to read:** 72 hours
Article 7-- Intensive Community Treatment and Program of Assertive Community Treatment		
✍✍ General Comments	Believes that Article 7 is overly prescriptive and has too much detail. This reduces flexibility, inhibits effective delivery of services and makes it difficult to change. Licensure staff may have no experience in many of the programs to which they have to apply standards.	**No change:** PACT is a very specific service with highly prescribed methods. Fidelity to the model is correlated with better services and outcomes. A transition plan will be required of PACT teams that will allow for "start-up" when teams are not in full compliance with the PACT model relative to staffing patterns and client capacity.
	Indicates that this is very prescriptive for Intensive Community Treatment (ICT) and Programs of Assertive Community Treatment (PACT) and would create problems for licensees currently providing both services. Suggest rewriting this entire Article with the input of representatives currently providing these services. States that one of the most alarming aspects is the prescriptive ratios for nurses and psychiatrists.	**No change:** Input was received and suggestions incorporated from the PACT Network (i.e., representatives currently providing services) as well as PACT consumers and family members.

Section	Comment	DMHMRSAS Recommendation
Admission and Discharge Criteria **12 VAC 35-105-~~1390~~ 1360**		
✍✍ Item A	**Point 1**: Indicates that this definition should be consistent with the state definition of "Serious Mental Illness" (SMI). Recommends that the following changes are made or the effort to list what diagnoses are eligible should be dropped:	**No change:** PACT is targeted to a subset of SMI consumers.
	Severe and persistent mental illness, predominantly schizophrenia, other psychotic disorder, or mood disorder, <u>and axis II disorders of such severity</u> that seriously impairs functioning in the community. Individuals with a primary diagnosis of a substance abuse disorder or mental retardation are not eligible for services.	**No change:** Axis II disorders are not prohibited conditions. PACT was designed for the identified disorders.
	A1. The Team Leaders support the specificity of this criteria since extensive research over more than 25 years draws the same unequivocal conclusion that PACT is the treatment of choice for this population, i.e., they demonstrate the most need for a continuing PACT level-of-care and gain the most benefit.	**No change:** The Department believes this provision is reasonable.
	A.1…Individuals with a sole diagnosis of substance addiction or abuse or mental retardation are not eligible for services. The original criteria in the PACT manual include the exclusion of sole dementia and other organic diagnoses because of the need for the potential for rehabilitation. We are also wondering about sole diagnoses on Axis II (e.g., Antisocial Personality Disorder or Borderline Personality) if other forms of treatment have not first been attempted and failed.	**No change:** These exclusionary criteria do not appear in the "Recommended PACT Program Standards for New Teams" in the 1998 version of the PACT Manual. Individualized determinations should be made regarding the individual's needs and the PACT Team's ability to meet their needs and promote recovery.
	Point 2: Suggests changing "…to include *one or more of the following*…" *A.2. Significant functional impairments on a continuing or intermittent basis…* suggest we add here "without intensive community support" *…to include:*	**Change to read:** ~~Significant functional~~ 2. Impairments on a continuing or intermittent basis <u>without intensive community support to include one or more of the following…."</u>

Section	Comment	DMHMRSAS Recommendation
Item A (cont.)	**Point 3**: a. Several respondents suggest deleting "*state*" before health facility.	**Change a. to read:** "Residence in a state mental health facility or other psychiatric hospital but clinically assessed to be able to live in a more independent situation if intensive services were provided or anticipated to require extended hospitalization ~~in a state mental health facility~~, if more intensive services are not available."
	a. Since private bed purchase is also a burden on the budget, there is no reason to restrict to state facilities…for that matter, the budget should not matter, but the needs of the consumer should prevail. Recommend to reword: "Reside in a state psychiatric hospital or other psychiatric <u>service</u> but clinically assessed to be able to live in a more independent situation if intensive services are provided, or an individual who is anticipated to require extended hospitalization if more intensives services are not available;"	**No change:** Point a. addresses hospitals. See above response.
	d, e, and g: Believes that these provisions are not good indicators of high service needs and should be deleted	**No change:** Deleting these indicators would make the criteria too restrictive.
	A.3.a. Residence in a state mental health facility or other psychiatric hospital, but clinically assessed to be able to live in a more independent situation suggest we add here "but not requiring 24-hour supervision." If intensive services were provided. We believe this would help clarify the limits of PACT's services, since we are not the next most intensive service outside of the hospital/institutional setting.	**No change:** PACT teams generally do not provide 24-hour supervision, but are available to provide services 24-hours per day. The regulations should not include language that would limit that availability.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item B	**Point 1**: *Moving out of the Service area.* Most Team Leaders leave a case open for three months if the consumer left no forwarding address, because in our experience they frequently return.	**Change to read:** B. PACT individuals should not be discharged for failure to comply with treatment plans or other expectations of the provider, except in certain circumstances as outlined. Individuals must meet at least one of the following criteria to be discharged.
	Point 3: *Incarceration for a period to exceed a year.* Team Leaders would like to add or hospitalized for more than a year – especially, but not exclusively in the case of forensic admissions.	**Change to read:** Incarceration for a period to exceed a year or hospitalization for more than one year.
	Point 4: *Choice of the individual….* Whereas the Team Leaders fully support the human rights issues involved in consumer choice, believes this wording is too restrictive. It does not allow for the fact that most clients turn PACT down on first blush. It may stifle the creativity of the Team to engage clients or water down the quintessential assertive aspect of outreach services. If the responsibility to attempt creatively and repeatedly to engage individuals is diverted from the Team, future PACTs may leave out of their referral prospects the very individuals most in need of PACT services.	**No change:** The current language requires there to be documentation of revision to the ISP " to meet any concerns of the individual leading to the choice of discharge. Such revisions to the ISP must occur prior to a discharge and this requirement is intended to encourage creative outreach and engagement. This is the national standard.
	Point 5: Recommends that this point be deleted since it can be covered under *B.4*, or at minimum, the element be reworded to describe a mutual decision of the individual and treatment provider after at least two years of the PACT/ICT service recipient only needing minimal services.	**Change to read:** Demonstration by the individual of an ability to function in all major role areas with minimal team contact and support for at least ~~one year~~ two years as determined by both the individual and ICT or PACT Team.
	Point 5: Recommends this addition at end to maintain continuity of services: Demonstration by the individual of an ability to function in all major role areas with minimal team contact and support for at least one year and demonstration that the individual is able to obtain and utilize adequate treatment and services, at a lesser level of intensity, for a period of two to three years.	**No change:** If the consumer is in another service, a discharge from PACT would have already occurred.

Section	Comment	DMHMRSAS Recommendation
Item B, Point 5 (cont.)	Concerned that the combination of budget shortfalls, increased demand, and bureaucracy's general discomfort with long-term or permanent services for a limited pool of consumers; will result in pressure on programs to move clients on and make room for more numbers at the expense of quality stabilizing services. Recommend: 1) the length of time be increased to two years, and 2) a statement requiring the mutual decision of provider and consumer with adequate step-down linkage and return plan be added.	**No change:** The current language requires there to be documentation of revision to the ISP to meet any concerns of the individual leading to the choice of discharge. Such revisions to the ISP must occur prior to a discharge and this requirement is intended to encourage creative outreach and engagement.
Treatment and Staffing Plan **12 VAC 35-105-~~1400~~ 1370**		
✍✍ Item A	**Point 1:** Suggests that the regulations specify "adequate support" rather than require a program assistant for ICT and ACT. a. Believes that all credentialing requirements should allow grandfathering for incumbents who served in the position prior to adoption of regulations. Supports the intent to require at least one professional on each team. However, believes that that requirement should not be tied to any particular position--especially the Team Leader. The Team Leader is pivotal for the successful implementation of PACT/ICT and far more important than a license is expertise with the SPMI population and an understanding and commitment to the model. Licensing requirements might exclude more qualified individuals in favor of less experienced and poorly matched individuals. d. Believes that there should be no requirements for peer specialists on ICT teams. **Point 2:** Believes that this is a confusing statement. "If '*in the same proportion'* indicates two Team Leaders, this is hardly wise. If it indicates two Program Assistants, this is hardly necessary; if two Peer Specialists, this is questionably practical in proportion to the other team roles. PACT teams have certainly benefited from the	**No change:** The Program Assistant has a specific role as a team member in accordance with the model. **Change A.1. to read:** 1. The ICT and PACT team shall have employees or contractors, 80% of whom meet the qualifications of QMHP, <u>who are qualified to provide the services described in 12 VAC 35-105-1360, including at least five full-time equivalent clinical employees or contractors on an ICT team and at least ten full-time equivalent clinical employees or contractors on a PACT team, a program assistant, and a full- or part-time psychiatrist. The team shall include the following positions…</u> a. Team leader – one full time equivalent (FTE) ~~LMHP~~ <u>QMHP</u> with three years experience… **No change:** The Peer Specialist has a specific role as a team member in accordance with the model. **Change to read:** <u>2. In addition, a PACT team includes at least three FTE nurses (at least one of whom is an RN) and five or more mental health professionals.</u>

Section	Comment	DMHMRSAS Recommendation
Item A (cont.)	addition of peers and their positions should be written into the licensing regulations, but the proportional requirements should be dropped. "PACT should not be defined in terms of ICT teams. Delete 'are ICT teams that' The requirement that 3 of 10 PACT team members be nurses causes significant problems in the current job market and is not supported by the research, most of which involved a lower ratio. We urge a reduction to 2 nurses. At the very least, the ratio should be related to team caseload size. One nurse for every 40 clients might be a compromise but still does not solve the noncompliance problem during vacancies. "In the 1/17/01 draft of Program Standards from DMHMRSAS, the standard proposed was 2 nurses per team. In the Stein and Santos monograph regarding this model [1998], two nurses are the standard. Licensure regulations should not embody optimal levels of care but acceptable levels. The Dartmouth Fidelity Instrument gives the highest rating to having one nurse per 50 consumers."	The definition has been changed within this regulation. **No change:** The Dartmouth fidelity instrument identifies "between 1.4 and 1.99 FTE" nurses as 80% and "two or more" as 100% compliant with the model. Not all the Dartmouth Fidelity Items are covered in the licensing regulations. The standards can be waived for vacancies during active recruitment.
✍✍ Item C	Believes that the daily meeting requirement for ICT teams is not necessary. Suggests that teams should be required to meet a minimum of four days per week. States that "…(t)his is the highest rating possible in this category on the fidelity review tool often used to evaluate these programs."	**Change to read:** C. ICT and PACT teams shall meet daily Monday through Friday <u>or at least four days per week to</u> review and plan services and to plan for emergency and crisis situations.
✍✍ Item D	Indicates that it is not reasonable for an ICT team to staff seven days per week with five staff. Based on individual needs it might be preferable to do more in the evenings and less on weekends. With this amount of weekend coverage, staff turnover could be a problem. Suggests replacing "*…8 hours per day, 7 days per week, 365 days per year*" with "*…available daily throughout the year.*" Delete: 365 days per year.	**Change to read:** D. ICT teams shall operate a minimum of 8 hours per day, ~~7 days per week, 365 days per year~~ 5 days per week and shall provide services on a case-by-case basis in the evenings and on weekends.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item E	Indicates that the wording of this provision is confusing. Suggests deleting the word "*only*."	**Change to read:** The ICT and PACT team shall make crisis services directly available 24 hours a day but may ~~only~~ arrange coverage through another crisis services if the provider coordinates with the crisis services.
✍✍ Item F	Recommends the following addition: The PACT team shall have an advisory committee that comprises family and consumer members, including those served by the PACT, advocates, and relevant representatives from the community. The committee shall meet regularly, elect its own officers, have operational rules, and consult on policy, program, and personnel matters, and interpret the work of the PACT to the larger community.	**No change**: This recommendation exceeds the PACT model and is an organizational issue, not a service-related issue. Such advisory committees are recommended for support and guidance to the Team, but they are not a licensing requirement.
Contacts **12 VAC 35-105-~~1410~~ 1380**		
✍✍ Item B	States that the aggregate average of three contacts a week needs to permit the team to designate some lower-need clients and exempt them from inclusion in that average to support a no-discharge policy. Loosen up the 75% rule to 50%.	**Change to read:** "Each individual receiving ICT or PACT services shall be seen face-to-face by an employee or contractor~~ a minimum of at least one time per week and 75% of all such contacts should occur in-vivo (i.e., in the community where people live, work, and recreate as opposed to any clinical office settings.)~~]; or the employee or contactor should attempt to make contact as specified in the ISP.
✍✍ Item C	Suggests adding: Contact with support systems shall be made at least three time per month, if appropriate.	**No change:** This recommendation exceeds the PACT model.
ICT Service Daily Operation and Progress Notes **12 VAC 35-105-~~1420~~ 1390**		
✍✍ General Comments	Indicates that this section includes ICT and PACT and should be labeled as such.	**Change heading to read:** 12VAC 35-105-1420. ICT and PACT Service Daily Operation and Progress Notes.

Section	Comment	DMHMRSAS Recommendation
✍✍ Item A	Believes that the daily meeting requirement is not necessary (see comment 12 VAC 35-105-1400.C)	See above response.
✍✍ Item B	Indicates that other forms of documentation, such as electronic records, should be allowed under this provision. This requirement does not allow for rapidly developing information management technology. Suggests rewording as follows: "*ICT and PACT services shall maintain documentation of services provided and contacts made, as well as a roster of individuals currently being served. This information shall be documented and made available so as to facilitate service coordination and continuity*."	**No change:** Current wording allows for electronic records. The daily log is an essential component of the PACT model of operations.
ICT and PACT Assessment **12 VAC 35-105-~~1430~~ 1400**		
✍✍ Comment	Point 6: Suggests replacing "accommodations" with "resources."	**Change to read:** 6. Housing and daily living skills, including the support needed to obtain and maintain decent, affordable housing integrated into the broader community; the current ability to meet basic needs such as personal hygiene, food preparation, housekeeping, shopping, money management and the use of public transportation and other community based ~~accommodations~~ <u>resources.</u>
Service Requirements **12 VAC 35-105-~~1440~~ 1410**		
✍✍ General Comments	States that this section, as written, assumes that all individuals need all of the listed services. Suggests a more general statement as follows: "*…the ISP [individual's services plan] will address identified needs and may include…*" Recommends adding the wording " as appropriate to the scope and services provided.	**No change:** The ISP should be written to be consistent with the assessment.

Section	Comment	DMHMRSAS Recommendation
✍✍ General Comments (cont.)	3. Nursing: Suggests specifying psychiatric nursing or psychiatric nursing and assistance with medical case management to clarify that PACT/ICT does not provide primary in-home health care. 6. Substance abuse assessment and treatment: Indicates that this provision may imply that teams would have to offer groups or be out of compliance. Suggests omitting the modality so that it reads "*…Substance abuse assessment and treatment including therapy for individuals with dual diagnosis of mental illness and substance abuse.*"	**No change:** *The services provided will be consistent with the individualized service plan.* Strike "including individual and group therapy."

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 following discussion details changes to the existing licensing regulations (12 VAC 35-102-10 et seq.) that have been incorporated into the proposed replacement regulations.

The "Introduction" (Part I) of the proposed regulations includes general provisions in Article I ("Authority and Applicability") and Article 3 ("Licensing Process") that are not addressed in the existing regulations. Article 2 ("Definitions") provides definitions of various services and other key words used in the regulation. New services and terms such as, "corrective action plan," "crisis," "individual," "medication error," "neglect," "provider," "restriction," and "serious injury," have been defined in the proposed regulations that are not included in the current regulations and many definitions have been updated and revised. Definitions have also been revised to be consistent with other agency regulations (e.g. Human Rights Regulations).

Parts II-IV of the regulations are requirements that apply to all service providers. Any exemptions or specific applicability are detailed in these sections of the regulations.

Part III is titled "Administrative Services." The substantive changes from the current regulations include:

- ?? Requirements for compliance with § 37.1-197.1 of the Code of Virginia regarding prescreening and predischarge planning;
- ?? Required timeframes for submitting corrective action plans;
- ?? Requirements for annual operating statements and balance sheets;
- ?? More specific requirements for general physical environment, including room temperatures, hot water temperatures, floor surfaces, and lighting;
- ?? A 20-bed limit for new community intermediate care facilities for individuals with mental retardation (ICF/MR). Existing community ICF/MRs would be grandfathered;
- ?? Requirements for clean bedding;
- ?? Provisions to comply with Code requirements for providers to submit criminal background checks and search the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services;
- ?? Clarification that service directors must have experience in working with the population served and in providing the services outlined in the service description;
- ?? Clarification that the knowledge, skills, and abilities, professional qualifications, and experience required for each job description be appropriate to the duties and responsibilities required of the position;
- ?? A requirement that orientation of new employees must be completed within 15 business days;
- ?? Retraining requirements;

- ?? Prohibition on a provider's reliance on students and volunteers for the provision of direct care services;
- ?? Requirements to develop a prevention/management program for populations identified at risk for falls; and
- ?? More detailed requirements for an emergency preparedness and response plan.

Part IV of the proposed regulations is titled "Services and Supports." The "Service Description" and "Staffing" sections were relocated from the "Administrative Services" section from the current regulations. "Medical Management," "Medication Management" and "Behavior Management" sections were moved from the "Specialized Services" in the current regulations. This relocation is intended to indicate that medical management, medication management, and behavior management are considered basic services. Substantive new provisions include:

- ?? A requirement that providers document that each service offers a structured program of care designed to meet the individuals' physical and emotional needs;
- ?? A requirement for the physical separation of children and adults in residential and inpatient services and separate group programming for adults and children;
- ?? A requirement that supervisors for mental health or mental retardation services be a "Qualified Mental Health Professional" or "Qualified Mental Retardation Professional," as defined in the regulations, or an individual with equivalent experience;
- ?? A requirement that providers employ or contract with persons with appropriate training as necessary to serve the needs of individuals with medical or nursing needs, speech or hearing problems, or other needs where specialized training is necessary;
- ?? Requirements for preliminary assessments to determine whether the individual qualifies for admission;
- ?? A requirement that providers develop and implement a preliminary individualized services plan within 24 hours of admission and a complete individualized services plan within 30 days. The plan is to be reviewed and revised quarterly and rewritten annually;
- ?? A requirement that individualized services plans address any medical care needs appropriate to the scope and level of service either by providing medical care, arranging for medical care or referring for medical care; and
- ?? A requirement that residential service providers either administer or obtain results of physical exams within 30 days of admission.

A new Part V has been created that pertains exclusively to "Records Management." This part consists of provisions compiled from other parts of the current regulations, although there are no substantive changes in Part V.

Part VI is titled "Additional Requirements for Selected Services." Part VI in the regulations replaces the section titled "Specialized Services" in the existing regulations and has been renamed to more accurately reflect the content. Providers of these "selected services" must comply with the requirements for all providers in Parts II-IV of the proposed regulations as well as the additional requirements in Part VI. The first three articles "Opioid Treatment Services," "Social Detoxification Services," and "Services in Department of Correction's Correctional Facilities," are revised from the current regulations. In particular, "Opioid Treatment Services"

was revised to be consistent with new federal regulations and "Sobering Up Services" was deleted from the current regulations.

Part VI also includes additional new requirements for licensing for sponsored residential home services, case management services, community gero-psychiatric residential services, and intensive community treatment and program of assertive community treatment services.

There are currently no specific provisions for licensing sponsored residential home services under the current regulations. Licenses are currently issued for sponsored residential home services under existing regulatory provisions for sponsored placement services or group homes. The proposed regulations include specific provisions for licensing sponsored residential home services which will result in greater accountability from providers of sponsored placement services with regard to physical environment, selection and training of the sponsors and the provision of services. The provider is also responsible for providing basic information on the sponsored residential homes to the Department and maintaining written agreements with the sponsors. The maximum number of beds for individuals receiving services in a sponsored residential home is two.

An amendment to the Code of Virginia that was enacted during 2001, authorizes the Department to license case management services and community gero-psychiatric residential services. The proposed regulations outline requirements for licensing case management services and the qualifications for case managers. This will replace the existing certification requirements for case management provided in 12 VAC 35-170. New provisions have also been included for licensing community gero-psychiatric residential services in this section.

The existing regulations do not include specific provisions for licensing intensive community treatment and programs of assertive community treatment services. Such services are now licensed under existing general criteria. The new regulations include criteria for admission, treatment team and staffing plan, contacts, daily operation and progress notes, assessments and services which are intended to address the prescriptive nature of this intensive service model.

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.

This regulation describes the minimum standards that providers of mental health, mental retardation and substance abuse services must meet in delivering services. The minimum standards are designed to protect the health, safety and welfare of individuals receiving services. Such assurance provides peace of mind to many families who have entrusted the care and well-being of their children, parents, brothers, sisters, or other relatives to a service provider.

The regulation does not erode the authority and rights of parents in the education, nurturing and supervision of their children. The regulations require providers to comply with the human rights regulations in regards to participation in individual decision making by the individual or legally authorized representative. The human rights regulations require providers to obtain the consent of at least one parent of a minor before treatment, including medical treatment, begins. It outlines the provisions 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. The licensing regulations also require providers to involve family members in developing or revising the individualized services plan consistent with laws protecting confidentiality, privacy, the human rights of individuals receiving services and the rights of minors.

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. Providers are required to develop and implement individualized services plan that address the relevant psychological, behavioral, medical, rehabilitation and nursing needs as indicated by a complete assessment and that address the individual's needs and preferences.

This regulation has no effect on the marital commitment or on family income.