

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 15-223)**

Overview and Legal and Fiscal Impact

The regulations establish new licensing and accreditation requirements for providers of community-based behavioral health services.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy notes for Chapter 460 of 2014 and Chapter 469 of 2015.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Community-Based Behavioral Health Programs and Services:

Requirements for All Licensed Programs: COMAR 10.63.01.01-.05

Programs Required to be Accredited in Order to be Licensed to Provide Community-Based Behavioral Health: COMAR 10.63.02.01-.04

Descriptions and Criteria for Programs and Services Required to have an Accreditation-Based License: COMAR 10.63.03.01-.19

Additional Requirements for Accreditation-Based Licenses for Specific Residential Community-Based Behavioral Health Services: COMAR 10.63.04.01-.07

Descriptions and Criteria for Programs Requiring a Non-Accreditation-Based License: COMAR 10.63.05.01-.07

Application and Licensure Process: COMAR 10.63.06.01-.21

Legal Analysis

Background

Chapter 460 of 2014 merged the Alcohol and Drug Abuse Administration (ADAA) and Mental Hygiene Administration (MHA) to establish the Behavioral Health Administration (BHA) in the Department of Health and Mental Hygiene. The 2014 legislation also modified and replaced then-existing certification and approval provisions for alcohol abuse and drug abuse treatment programs and mental health programs to establish licensing provisions for substance use disorder programs and mental health programs. In addition, the legislation authorized the Secretary of Health and Mental Hygiene to require the programs to be granted accreditation by an approved accreditation organization as a condition of licensure.

Under the 2014 legislation, the Secretary must adopt regulations for establishing, operating, and licensing both substance use disorder programs and mental health programs. The legislation further required the department to convene a stakeholder workgroup to review and provide feedback on proposed regulations.

Regarding accreditation, the workgroup looked to existing accredited providers to determine the role accreditation plays in quality of care and met with two accreditation entities approved by Maryland: The Joint Commission and The Council on Accreditation of Healthcare Facilities. According to the department, this inquiry revealed that most requirements and standards in existing regulations were covered by existing accreditation standards. The department indicates that accreditation requires adherence to a single set of behavioral health standards for mental health and substance use disorder treatment programs, thereby eliminating a previous problem of contradictory and duplicative regulations that are diagnosis driven and promoting integrated care for those with both mental health and substance use disorders. Accreditation standards are reviewed and updated annually to reflect changes in quality-of-care expectations.

The workgroup recommended that the department require community-based treatment programs currently covered under COMAR 10.21 (mental hygiene regulations) and COMAR 10.47 (ADAA regulations) to become accredited by a State-approved accrediting organization. The program must be licensed by the department and the license application must include submission of proof of accreditation. The workgroup recommended, however, that there be the following exceptions to this requirement:

- Services not covered by accreditation standards should be covered by regulations only;
- Except for DUI (Driving Under the Influence) and residential services, individuals practicing under their board-approved license will not be required to be licensed as a program to provide behavioral health services; and
- Recovery services, including self-help programs, as they are not treatment services.

Chapter 469 of 2015 (effective October 1, 2015), among other things, required the Director of BHA to do anything necessary or proper to carry out the scope of Title 7.5 (Behavioral Health Administration), Title 8 (Substance Use Disorders Law), and Title 10 (Mental Health Law) of the Health – General Article. In addition, Chapter 469 repealed a provision requiring the Director of BHA to adopt regulations to carry out provisions of law governing BHA and, instead, required the Secretary to adopt regulations to carry out the provisions of Title 7.5, Title 8, and Title 10 of the Health – General Article.

The 2015 legislation also included provisions requiring behavioral health programs to be licensed, authorizing the Secretary to exempt certain persons from licensure requirements for behavioral health programs, requiring regulations governing licensure of such programs to include certain provisions, and authorizing the Secretary to require such programs to be granted accreditation by an accreditation organization approved by the Secretary as a condition of licensure.

Summary of Regulations

The regulations establish new licensing and accreditation requirements for providers of community behavioral health treatment, care, or rehabilitative services. Specific and noteworthy provisions are summarized below.

Requirements for All Licensed Programs

The regulations define terms used in the regulations and establish the requirement that a program be licensed to provide community behavioral health treatment, care or rehabilitation services.

- **Definitions:** Among other terms, “American Society of Addiction Medicine (ASAM) Criteria” is defined to mean an instrument designed to indicate placement guidelines for admission, continued stay, and discharge of individuals with a substance-related disorder. “Behavioral health program” means a substance-related disorders program, a mental health disorders program, an addictive disorder program, or a program that consists of a combination of disorder programs listed above. “Maintenance” means medically supervised continuation of the administration of methadone, LAAM, or other drugs approved by the BHA.
- **License Requirement and Exempt Providers:** An individual or entity must have a valid and current license issued by the department to provide community-based behavioral health services in the State, including providers of DUI education programs and specified substance-related disorder residential services. However, specified providers are exempt from licensure, including a health professional who is licensed under the Health Occupations Article and that is providing services in accordance with the requirements of the appropriate professional board; Alcoholics Anonymous; and outpatient behavioral health treatment and rehabilitation services provided in a regulated space of a hospital if the hospital is accredited by an approved accreditation organization.
- **Requirements for Licensed Community-Based Behavioral Health Programs:** Under the regulations, the department may make announced or unannounced visits to inspect a program for compliance with standards required under the regulations or to investigate a complaint. Among other requirements, a program must have and follow a written policy meeting specified standards regarding the criminal history of the program’s employees, contractors, and volunteers. The regulations also require programs to comply with specified confidentiality provisions of federal and State law; enter into an agreement to cooperate with the core service agency (CSA), local addictions authority (LAA), or local behavioral health authority (LBHA) that operates in the relevant county or Baltimore City before applying for licensure; and submit critical incident reports following certain incidents, such as the death of a program participant.

Programs Requiring Accreditation

The regulations identify programs that are required to be accredited to receive a license to provide community-based behavioral health services, such as group homes for adults with mental illness programs, integrated behavioral health programs, and residential programs at various specified levels of intensity. Specified programs may provide withdrawal management and opioid treatment services as long as the program's license specifically authorizes the service.

A program with an accreditation-based license must comply with the requirements and meet the standards of the accreditation organization by which it is accredited and the department or its designee may enforce such requirements and standards through inspections. The regulations also include requirements that specifically apply to halfway house and group home sites.

Descriptions and Criteria for Accreditation-Based Licensed Programs and Services

The regulations set forth the descriptions of and criteria for community-based programs that are permitted to operate in Maryland if they have valid and current accreditation-based licenses. The programs for which descriptions and criteria are provided are as follows: integrated behavioral health programs, intensive outpatient treatment level 2.1 programs, mobile treatment services programs, outpatient mental health centers, outpatient treatment level 1 programs, partial hospitalization treatment level 2.5 programs, psychiatric day treatment programs, psychiatric rehabilitation programs for adults, psychiatric rehabilitation programs for minors, residential-low intensity level 3.1 programs, residential-medium intensity level 3.3 programs, residential-high intensity level 3.5 programs, residential-intensive level 3.7 programs, respite care services programs, supported employment programs, substance-related disorder treatment programs in correctional facilities, withdrawal management services, and opioid treatment services.

Requirements for Residential Community-Based Behavioral Health Services

In addition, the regulations set forth descriptions of, criteria for, and licensing requirements for group homes for adults with mental illness, residential crisis services programs, and residential rehabilitation programs. The regulations also establish application requirements for approval of a residence to be operated by a community-based behavioral health program and residential site requirements. Among other requirements, all areas of a residence must be safe, clean, free of hazards and clutter, and comply with the requirements of the Americans with Disabilities Act.

Descriptions and Criteria for Non-Accreditation-Based Licensed Programs and Services

The regulations also set forth descriptions of, and the criteria for, the following community behavioral health programs that are permitted to operate in the State if they have valid and current non-accreditation-based licenses: substance-related disorder assessment and referral programs, DUI education programs, and early intervention level 0.5 programs. Among

other requirements, these programs must generally provide a comprehensive assessment of an individual covering specified areas, such as alcohol, tobacco, and other drug use.

Programs with a community-based behavioral health license that does not require accreditation must uphold specified rights of participants, such as treating each participant with consideration, respect, and full recognition of the participant's human dignity and individuality. Such programs must post in a conspicuous area and provide to each participant a statement of participants' rights. The regulations also establish grievance procedures and prohibit discrimination in the provision of services on the basis of race, creed, color, age, gender, sexual orientation, gender identity, national origin, marital status, disabilities, and any other classification prohibited under State or federal law.

Application and Licensure Process

The regulations establish the processes governing application for accreditation-based and non-accreditation-based licenses to provide community-based behavioral health services, issuance and parameters of the license, and sanctioning of licenses.

- ***Application Process for All Programs:*** Among other requirements, an applicant for a license, whether accreditation or non-accreditation-based, must disclose any revocation of a license, certificate, or approval issued within the previous 10 years from any in-State or out-of-State provider previously or currently associated with the applicant, as well as any criminal conviction of the applicant, or the owner, program director, or other staff of the applicant.
- ***Requirements for Licenses Requiring Accreditation:*** Applicants for an accreditation-based license must submit with an application the program's most recent behavioral health accreditation survey report, any corrective action plans required by the report, and the final letter or certificate issuing accreditation for the program.
- ***Requirements for Licenses Not Requiring Accreditation:*** A program applying for a non-accreditation-based license must pass an inspection by the Department, or its designee, of all of the program's sites before issuance of the license.
- ***Issuance and Duration of Licenses:*** The duration of an accreditation-based license equals the accreditation period plus three months. For a non-accreditation-based license, the duration of the license may not exceed three years. To be approved, an application for renewal of a license and supporting documentation must be received by the department or its designee at least 60 days before the expiration of the program's current license.
- ***Denial of Licenses:*** Among other specified reasons, the department may deny a license to provide community-based behavioral health services to an applicant that has had a license or approval revoked by the department or other licensing agency, or has surrendered or defaulted on its license or other approval for reasons related to

disciplinary action, within the previous 10 years. The regulations specify that the department must give written notice of a proposed denial of licensure to the program that includes the facts that warrant the proposed denial and notice that the program has a right to a hearing in accordance with specified regulations.

- ***License Modification:*** Under the regulations, a program may not change its program sites by adding, closing, or moving locations without prior approval from the department's designated approval unit. To request a change in its service array, a program must submit to the department's designated approval unit, if applicable, evidence that the program has received accreditation for the proposed additional program type and evidence that the program has notified the appropriate CSA, LAA, or LBHA of the proposed program modification.
- ***Waivers and Variances:*** The regulations prohibit the BHA from granting waivers of any regulation under the subtitle governing community-based behavioral health programs and services or any accreditation standard. BHA may, however, grant a variance for a regulation if a program is licensed and BHA finds that the intent of the regulation to which a variance is sought is met by the alternative proposed by the program. BHA is prohibited from granting a variance that would endanger the health or safety of the individuals served or for any accreditation standard.
- ***Sale or Transfer of Licenses:*** The license of a program is valid only for the program and address for which the license is issued. If the sale or transfer of a program causes a change in ownership, the program may not sell, assign, or transfer its license and must apply for and receive a new license to operate in the State.
- ***Discontinuation of Program Operations:*** If a program licensed to provide community-based behavioral health services intends to discontinue operations, the program director must submit to the department's licensure unit, the BHA, and the CSA, LAA, or LBHA, as appropriate, a written plan for cessation of operations and other specified actions associated with discontinuation of operations. A program may not discontinue operations until the department's designated approval unit authorizes the discontinuation.
- ***Summary Suspension:*** The regulations authorize the department to order the immediate suspension of the license of a program and the immediate cessation of the program's operation upon a finding that a program licensed under the regulations has violated a regulation and that the public health, safety, or welfare imperatively requires emergency action.
- ***Notice of Deficiencies:*** If the department determines that a licensed program has violated any provision of the regulations, but does not summarily suspend the program, the department's designated approval unit must provide the program with a notice of deficiencies. The program must submit a plan of correction within a specified period stating how and when each failure to comply shall be corrected.

- ***Disciplinary Action:*** The regulations authorize the department to take specified action if it determines that a licensed program has violated a requirement of the regulations. Authorized actions include license revocation; intermediate sanctions, such as prohibiting the program from providing specific services or restricting the program to providing only specified services; imposition of a directed plan of correction; entering into a settlement agreement establishing specific conditions for continued operation; initiating receivership; and imposing civil monetary penalties.
- ***Hearing on Proposed Sanctions:*** A licensed program that is aggrieved by a proposed disciplinary action by the department may appeal the department's decision by filing a request for an administrative hearing. The regulations establish hearing procedures that specify, among other things, how a program may request a hearing and that the right to a hearing is waived if a request for hearing is not submitted to the department within 10 working days after the date on the notice of the department's proposed action.
- ***Deadlines and Effective Dates:*** The regulations specify when certain provisions of the regulations go into effect and dates by which a program must apply to obtain a license. Programs for which a license is required under the regulations may not operate without a license on or after June 1, 2017.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites §§ 7.5-204, 8-402, and 10-901 of the Health – General Article as statutory authority for the regulations. Section 7.5-204 of the Health – General Article establishes the powers, duties, and responsibilities of the BHA, and requires the Director of the BHA to do anything necessary or proper to carry out the scope of Title 7.5 (Behavioral Health Administration), Title 8 (Substance Use Disorders Law), and Title 10 (Mental Health Law) of the Health – General Article.

Section 8-402 requires the Secretary to adopt regulations setting standards for treatment, care, and rehabilitation of individuals with a substance use disorder. Section 10-901 requires a mental health program to be licensed by the Secretary before the program services may be provided in the State. The section also prohibits the Secretary from requiring that specified persons obtain a license to provide mental health services in the State, such as a health professional who is licensed under the Health Occupations Article and who is providing mental health services according to the requirements of the appropriate professional board.

In addition, § 10-901 requires the Secretary to adopt regulations for establishing, operating, and licensing a mental health program. The section also authorizes the Secretary to require a mental health program to be granted accreditation by an accreditation organization approved by the Secretary as a condition of licensure. Regulations adopted must include the

requirements for licensure of a mental health program; the process for a program to apply for a license; a description of the programs that are required to be licensed; any requirements for the governance of a program; provisions for inspections of a program; and provisions for denials, suspensions, and revocations of licenses.

Although not cited by the department, § 7.5-205 of the Health – General Article requires the Secretary to adopt regulations to carry out the provisions of Title 7.5 (Behavioral Health Administration), Title 8 (Substance Use Disorders Law), and Title 10 (Mental Health Law) of the Health – General Article. Section 7.5-301 of the Health – General Article requires a behavioral health program to be licensed by the Secretary before program service may be provided in the State. The section authorizes the Secretary to exempt specified persons from the licensure requirements, such as a health professional who is licensed under the Health Occupations Article and who is providing mental health or substance-related disorder services according to the requirements of the appropriate professional board, Alcoholics Anonymous, and a private therapeutic group home.

Section 7.5-302 of the Health – General Article specifies that regulations adopted under provisions of law governing behavioral health programs must include requirements for licensure of a behavioral health program; the process for a program to apply for a license; a description of the programs that are required to be licensed; any requirements for the governance of a program; provisions for inspections of a program; and provisions for denials, suspensions, and revocations of licenses. In addition, § 7.5-302 authorizes the Secretary to require a behavioral health program to be granted accreditation by an accreditation organization approved by the Secretary as a condition of licensure.

Section 8-403 of the Health – General Article requires that a substance use disorder program be licensed by the Secretary before program services may be provided in the State. The section prohibits the Secretary from requiring certain persons to be licensed to provide substance use disorder services, such as a health professional who is licensed under the Health Occupations Article and who is providing substance use disorder services according to the requirements of the appropriate professional board and Alcoholics Anonymous.

Section 8-404 of the Health – General Article requires the Secretary to adopt regulations for establishing, operating, and licensing a substance use disorder program. Regulations must include requirements for licensure of a substance use disorder program; the process for a program to apply for a license; a description of the programs that are required to be licensed; any requirements for the governance of a program; provisions for inspections of a program; and provisions for denials, suspensions, and revocations of licenses. In addition, § 8-404 authorizes the Secretary to require a substance use disorder program to be granted accreditation by an accreditation organization approved by the Secretary as a condition of licensure.

With the addition of §§ 7.5-205, 7.5-301, 7.5-302, 8-403, and 8-404 of the Health - General Article, the authority cited by the department is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy notes for Chapter 460 of 2014 and Chapter 469 of 2015.

Agency Estimate of Projected Fiscal Impact

The regulations implement provisions of Chapter 460 of 2014 (House Bill 1510), which replaced certification and approval provisions for alcohol abuse and drug abuse treatment programs and mental health programs with licensing provisions for substance use disorder programs and mental health programs and authorized the Secretary of Health and Mental Hygiene to require accreditation as a condition of licensure. The regulations also implement provisions of Chapter 469 of 2015 (House Bill 1109), which clarified and improved consistency among various statutes related to behavioral health services by establishing licensing provisions for behavioral health programs and halfway houses.

The department advises that the regulations have no impact on State government but have an indeterminate impact on those local governments that provide substance-related disorder services and will need to become accredited. The Department of Legislative Services concurs, but notes that this impact has already been assumed under the fiscal and policy note for House Bill 1510 of 2014, which noted that State finances were not anticipated to be affected, but expenditures for at least 12 local governments could increase due to costs associated with accreditation. The fiscal and policy note for House Bill 1109 of 2015 noted that State and local government finances were not anticipated to be affected.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have a meaningful impact on small businesses in the State as community behavioral health programs that are small businesses, and that are not already accredited, must obtain accreditation as a condition of licensure. The Department of Legislative Services disagrees as this impact has already been assumed under the fiscal and policy note for House Bill 1510 of 2014.

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