

**Title 10**  
**MARYLAND DEPARTMENT OF HEALTH**  
**Subtitle 63 COMMUNITY-BASED BEHAVIORAL HEALTH PROGRAMS**  
**AND SERVICES**

**Notice of Proposed Action**  
[25-063-P]

The Acting Secretary of Health proposes to:

- (1) Repeal existing Regulations **.01—.05** and adopt new Regulations **.01—.13** under **COMAR 10.63.01 General Compliance and Reporting Requirements**; .
- (2) Repeal existing Regulations **.01—.04** and adopt new Regulations **.01—.14** under **COMAR 10.63.02 General Staffing Requirements**;
- (3) Repeal existing Regulations **.01—.21** and adopt new Regulations **.01—.10** under **COMAR 10.63.06 Licensure Process**;
- (4) Adopt new Regulations **.01—.10** under a new chapter, **COMAR 10.63.09 Corrective Actions and Sanctions**.

**Statement of Purpose**

The purpose of this action is to repeal existing regulations within COMAR 10.63 (Community Behavioral Health Programs and Services) to align with current statutory requirements and include additional regulatory requirements to support improved quality of services compliance and provide a more equitable and sustainable operating environment for community-based behavioral health programs in the State.

- (1) COMAR 10.63.01 sets forth compliance and reporting requirements for all organizations operating programs to provide community-based behavioral health services;
- (2) COMAR 10.63.02 outlines general staffing requirements;
- (3) COMAR 10.63.06 concerns the application and licensure process; and
- (4) COMAR 10.63.09 provides the regulatory framework for corrective actions and sanctions undertaken by the Behavioral Health Administration for material and egregious non-compliance with federal or State law or regulation.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.** The proposed regulations will have an economic impact for the Department. The proposed regulations update and add requirements for accreditation-based and non-accreditation-based licenses which subsequently add to the review and approval of licensure applications by the Department before licenses are issued. In this manner, the proposed regulations increase expenditures in the required staffing levels, training, and systems support needed to implement the changes to licensure requirements. The amount of these increased expenditures is indeterminable as any method used to project the effect of the proposed regulations on the current volume of licensure applications is speculative.

For organizations operating programs to provide community behavioral health services, the cost of adhering to the proposed regulations that update and clarify application requirements for accreditation-based and non-accreditation-based licenses is indeterminable, as any costs will vary by organization, number of sites and the program type(s) they are seeking licensure for in the State. For certain program types, the proposed regulations update staffing requirements which may include changes to required staff credentials, staffing levels, site requirements, program requirements, and management requirements for licensure. The proposed regulatory package also updates and clarifies program requirements for certain program types, which may also generate regulatory burden and associated compliance costs.

Some local governments functioning as the Local Behavioral Health Authority or the Local Addiction Authority may provide substance-related disorder services, and which may require the local government agencies to be accredited. The amount of agencies that would need to be accredited cannot be determined as it will vary between local governments.

**II. Types of Economic Impact.**

Impacted Entity	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	

A. On issuing agency:		
Maryland Department of Health	(E+)	Indeterminable
B. On other State agencies:		
	NONE	
C. On local governments:		
Local Behavioral Health Authorities/Local Addiction Authorities	(E+)	Unquantifiable
	Benefit (+)	
	Cost (-)	Magnitude
D. On regulated industries or trade groups:		
(1) Licensed Community-Based Behavioral Health Organizations	(-)	Indeterminable
(2) Licensed Community-Based Behavioral Health Organizations	(+)	Indeterminable
(3) Administrative Service Organization	(+)	Unquantifiable
E. On other industries or trade groups:		
(1) Behavioral Health Consultants	(+)	Indeterminable
(2) Community Behavioral Health Trade Groups	(+)	Indeterminable
(3) Accrediting Organizations	(-)	Indeterminable
F. Direct and indirect effects on public:		
(1) Indirect Effects on Quality of Care	(+)	Indeterminable
(2) Indirect Effects on Access to Care	(+)	Unquantifiable
(3) Indirect Effects on Access to Care	(-)	Unquantifiable

### III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. These new requirements add to the review and approval of licensure applications by the Department before licenses are issued. In this manner, the proposed regulations increase expenditures in the required staffing levels, training, and systems support needed to implement the changes to licensure requirements. The amount of these increased expenditures is indeterminable.

C. Additional expenditures may be related to increased audit and compliance activities and any increased regulatory burden. At this time, the impact is unquantifiable.

D(1). The Department anticipates that increased program and compliance activities and increased regulatory burden may result in additional costs for organizations.

D(2). The Department anticipates that a reduction in fraud, waste, and abuse within the provider community may result in benefits for organizations as a whole, but any exact amount of benefit would be indeterminable.

D(3). The Department anticipates that a reduction in fraud, waste, and abuse within the provider community may result in a benefit for the Administrative Service Organization. At this time, the impact is unquantifiable.

E(1). The Department anticipates that Behavioral Health Consultants may have additional opportunities to assist regulated organizations with compliance with these regulations and the new licensure process. Any exact amount of benefit would be indeterminable.

E(2). The Department anticipates that Community Behavioral Health Trade Groups may see an increased need for support among association members to comply with new regulatory requirements. Any exact amount of benefit would be indeterminable.

E(3). The Department understands that as a result of these regulations, accreditation organizations may see less organizations operating programs providing community-based behavioral health services seeking accreditation. Any cost associated with this would be indeterminable.

F(1). The Department strongly believes that these new regulatory requirements will result in better providers and better overall quality of care as a result. Nevertheless, any exact amount of this benefit is indeterminable.

F(2). The Department strongly believes that these new regulatory requirements will result in a higher quality of care and an improved access of care for community-based behavioral health programs.

F(3). The Department appreciates that these new regulatory requirements may result in the closure of some community-based behavioral health programs over time, any exact impact would be unquantifiable.

### Economic Impact on Small Businesses

An analysis of this economic impact follows:

The proposed action has a meaningful economic impact on small businesses. For organizations operating community behavioral health programs, many of which are small businesses, the cost of adhering to the proposed regulations that update and clarify application requirements for accreditation-based and non-accreditation-based licenses is indeterminable, as costs will vary by organization, number of sites, and the program type(s) they are seeking licensure for in the State. For certain program types, the proposed regulations update staffing requirements which may include changes to required staff credentials, staffing levels,

site requirements, program requirements, and management requirements for licensure all of which may increase operating costs, compliance costs and general regulatory burden.

#### **Impact on Individuals with Disabilities**

The proposed action has an impact on individuals with disabilities as follows:

To the extent that individuals with disabilities receive community-based behavioral health services, the Department believes that these regulations will result in better care for individuals receiving these services. Overall, the Department anticipates a positive impact and an improved quality of care.

#### **Opportunity for Public Comment**

Comments may be sent to Jordan Fisher Blotter, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 534, Baltimore, Maryland 21201, or call 410-767-0938, or email to [mdh.regs@maryland.gov](mailto:mdh.regs@maryland.gov). Comments will be accepted through June 16, 2025. A public hearing has not been scheduled.

### **10.63.01 [Requirements for All Licensed Programs] *General Compliance and Reporting Requirements***

Authority: Health-General Article, [§§7.5-204, ] §§7.5-204 (a)(2), [8-402, 8-404,] and [10-901] 7.5-402, Annotated Code of Maryland

#### **.01 Definitions.**

*A. In this chapter, the following terms have the meanings indicated.*

*B. Terms Defined.*

(1) "Accreditation organization" means a private entity that conducts inspections and surveys of health care facilities or health care staff agencies based on nationally recognized and developed standards that is approved by the Secretary in accordance with Health General Article, §19-2302, Annotated Code of Maryland.

(2) "Accreditation" means the approval granted to a program by an accreditation organization.

(3) "Accreditation-based license" means a license which requires that the organization be accredited by an approved accreditation organization.

(4) "Administration" means the Behavioral Health Administration within the Department that provides oversight to organizations that are licensed in accordance with this subtitle.

(5) "Agreement to cooperate" means a written agreement between an organization operating a program and the appropriate local authority that provides for coordination and cooperation in carrying out behavioral health activities in a given jurisdiction.

(6) "Applicant" means the legally authorized individual or entity submitting an application for licensure.

(7) "Behavioral health services" means prevention, screening, early intervention, treatment, recovery, support, wraparound, and rehabilitation services for individuals with substance-related disorders, addictive disorders, mental disorders, or a combination of these disorders.

(8) "Business day" means any day except Saturday, Sunday, or a State holiday.

(9) "Community-based" means a setting of a behavioral health services program that is not located in a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland.

(10) Corporate Officers.

(a) "Corporate officers" means the managing employees or other individuals responsible for the conduct of the affairs of the organization inclusive of the organization's controlling board.

(b) "Corporate officers" includes but is not limited to the organization's:

(i) Chief Executive Officer;

(ii) Chief Financial Officer;

(iii) Chief Medical Officer;

(iv) Chief Information Officer;

(v) Corporate Compliance Officer;

(vi) Board members; and

(vii) Other senior officers of the organization.

(11) "Corrective action" means specific actions undertaken by an organization to address a violation of any local, state, or federal law or regulation.

(12) "Critical incident" means an event that impacts the health, safety, or welfare of a program participant or staff.

(13) "Department" means the Maryland Department of Health.

(14) "Discontinuation plan" means an organization's written plan which is provided to the Administration when the organization intends to discontinue program or licensed service operations.

(15) Experimental Project.

(a) "Experimental project" means a project, irrespective of funding, that if deemed successful, may be considered and adopted as a permanent policy or program.

(b) "Experimental project" includes:

(i) Demonstration projects; or

(ii) Pilot projects.

- (16) "Family support services " has the meaning stated in Health-General Article, §7.5-101, Annotated Code of Maryland.
- (17) "Group practice" has the meaning stated in Health Occupations Article, §1-301, Annotated Code of Maryland.
- (18) "Guardian" has the meaning stated in Estates and Trusts Article, §13-101, Annotated Code of Maryland.
- (19) "Jurisdiction" means Baltimore City or one of the 23 counties in the State.
- (20) "License" means an authorization issued by the Secretary permitting an organization to operate a behavioral health program at a specific site in the State.
- (21) "Licensed mental health professional" means a practitioner authorized under Health Occupations Article, Annotated Code of Maryland, who has specialty in the diagnosis and treatment of mental health, addictive, substance-related, or co-occurring disorders.
- (22) Local Authority.
- (a) "Local authority" means the designated county or multicounty authority responsible for planning, managing, and monitoring publicly funded mental health, substance-related, or addictive disorder services.
- (b) "Local authority" includes the:
- (i) Core service agency as defined in Health General Article, §7.5-101(g), Annotated Code of Maryland;
  - (ii) Local addictions authority as defined in Health General Article, §7.5-101(j), Annotated Code of Maryland; and
  - (iii) Local behavioral health authority as defined in Health General Article, §7.5-101(k), Annotated Code of Maryland.
- (23) "Medically necessary" means a service or benefit that is:
- (a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
  - (b) Consistent with current accepted standards of good medical practice;
  - (c) The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and
  - (d) Not primarily for the convenience of the participant, family, provider, or organization.
- (24) "Organization" means an association, partnership, corporation, unincorporated group, or any other legal entity licensed to operate a program to provide community-based behavioral health services.
- (25) "Participant" means an individual receiving behavioral health services in a community-based program.
- (26) "Peer support services" has the meaning stated in Health-General Article, §7.5-101, Annotated Code of Maryland.
- (27) "Plain language" means language which is easily understandable by program participants and takes into account the various levels of education and understanding of the population.
- (28) Plan of Care.
- (a) "Plan of care" means a medically necessary care plan which is responsive to an individual's goals, values, and preferences while considering the individual's needs respective to their behavioral health condition.
- (b) "Plan of care" includes but is not limited to:
- (i) An individualized treatment plan; and
  - (ii) An individualized rehabilitation plan.
- (29) "Program" means a named set of services operated by an organization inclusive of:
- (a) A substance-related disorders program as defined in Health General Article, §7.5-101(q), Annotated Code of Maryland;
  - (b) A mental health program as defined in Health General Article, §7.5-101(m), Annotated Code of Maryland;
  - (c) An addictive disorders program; and
  - (d) A combination of §B(29)(a)—(c) of this regulation.
- (30) "Public behavioral health system" means the system that provides medically necessary behavioral health services for Medical Assistance participants and certain other uninsured individuals.
- (31) "Recovery residence" means a program certified under this subtitle to provide alcohol and illicit drug-free housing to individuals with substance-related disorders, addictive disorders, or co-occurring mental health and substance-related disorders or addictive disorders.
- (32) "Residential" means the setting of a community-based program in which program participants both reside and receive behavioral health services.
- (33) "Secretary" means the Secretary of the Maryland Department of Health or their designee.
- (34) "Site" means the location where the organization operates the program as detailed on the program's license.
- (35) "Telehealth" means the synchronous delivery of medically necessary services to a participant at an originating site by a distant site provider, through the use of technology-assisted communication in accordance with COMAR 10.09.49.

## **.02 Programs Requiring License.**

A. Except as provided in §C of this regulation, an organization shall have a valid and current license issued by the Secretary in accordance with COMAR 10.63.06 to operate a program which provides community-based behavioral health services in the State.

B. A license issued in accordance with COMAR 10.63.06 may not be transferred.

C. In accordance with Health-General Article, §7.5-401, Annotated Code of Maryland, the following do not fall within any of the program descriptions set forth in this subtitle which require a license in accordance with COMAR 10.63.06:

(1) A health professional in either a solo or group practice, who is:

(a) Licensed under the Health Occupations Article, Annotated Code of Maryland; and

- (b) Providing behavioral health services in accordance with the requirements of the appropriate professional board;
- (2) Alcoholics Anonymous, Narcotics Anonymous, peer support services, family support services, or other similar organizations, if the organization holds meetings or provides support services but does not provide any type of treatment;
- (3) Employees' assistance programs of a business or State entity;
- (4) Outpatient behavioral health treatment and rehabilitation services accredited by an approved accreditation organization provided in regulated space of a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland;
- (5) Federally qualified health center providing primary health services in accordance with 42 USC §254b; and
- (6) Private therapeutic group homes authorized under:
  - (a) Health-General Article, §§10-920—23, Annotated Code of Maryland;
  - (b) COMAR 10.21.07; or
  - (c) COMAR 14.31.05—.07.
- D. Recovery Residences.
  - (1) Recovery residences are exempt from the licensure requirements set forth in §A of this regulation.
  - (2) Recovery residences are required to be certified by the Maryland Certification of Recovery Residences in accordance with the program description set forth in this subtitle.
- E. The Administration may exempt an organization from the requirements of this subtitle if the program:
  - (1) Is an experimental project or does not fall within any of the program descriptions set forth in this subtitle; and
  - (2) At the satisfaction of the Administration, is proved to be subject to contractual provisions, conditions of grant award, or other requirements that are comparable to the requirements of this subtitle.

**.03 Compliance with State and Federal Law and Regulation.**

- A. An organization licensed in accordance with COMAR 10.63.06 to operate a program to provide community-based behavioral health services in the State shall comply with all applicable requirements of this subtitle.
- B. An organization licensed in accordance with COMAR 10.63.06 to operate a program shall comply with all applicable federal and State laws and regulations, including, but not limited to:
  - (1) The Health Insurance Portability and Accountability Act, 42 U.S.C. §§1320d—1320d-9, and implementing regulations at 45 C.F.R. Part 160 and 164;
  - (2) Federal regulations on confidentiality of substance use disorder patient records, 42 CFR Part 2;
  - (3) State confidentiality statutes, including:
    - (a) Health-General Article, §§4-301—4-310, Annotated Code of Maryland;
    - (b) General Provisions Article, §§4-101—4-601 Annotated Code of Maryland; and
    - (c) Current applicable State confidentiality regulations;
  - (4) The Americans With Disabilities Act, 42 U.S.C. §§12101—12213;
  - (5) The federal Fair Housing Act, 42 U.S.C. §3604;
  - (6) The Eliminating Kickbacks in Recovery Act, 18 U.S.C. §220; and
  - (7) Labor and Employment Article, Title 3, Annotated Code of Maryland.
- C. Organizations Advertising or Offering Housing for Program Participants. Any organization advertising or offering housing for program participants shall comply with Real Property Code, Title 8, Annotated Code of Maryland, and any local requirements, regardless of whether housing is provided directly by the organization or program or through a referral to another organization.

**.04 Compliance with Accreditation Standards.**

- An organization operating a program to provide community-based behavioral health services with an accreditation-based license shall:
  - A. Comply with all requirements and standards of the accreditation organization by which it is accredited;
  - B. Provide behavioral health services only to populations for which it is accredited; and
  - C. Notify the Administration in writing within 5 business days of any change in accreditation status.

**.05 Corporate Compliance Requirements.**

- A. An organization shall document and implement a corporate compliance plan covering each program it operates.
- B. An organization's compliance plan shall:
  - (1) Meet the standards established by the applicable accreditation organization for its operated program or services; or
  - (2) For organizations without an applicable accreditation organization compliance standard, meet the standards outlined in §C of this regulation.
- C. Corporate Compliance Standards. A corporate compliance plan shall include the:
  - (1) Implementation of policies and procedures covering compliance in key areas of the organization's provision of behavioral health care services, including, at a minimum:
    - (a) Billing;
    - (b) Coding;
    - (c) Confidentiality;
    - (d) Documentation;
    - (e) Ethical behavior;

- (f) Preventing illegal service and referral incentives; and
- (g) Contingency planning in case of a loss of key staff or capacity to serve program participants;
- (2) Appointment of a corporate compliance officer;
- (3) Implementation of a no-fault reporting system for compliance issues that ensures that whistleblowers are not subject to punitive actions;
- (4) Documentation of a policy statement indicating a prohibition of conflicts of interest between the organization and program participants;
- (5) Implementation of a strategy for risk assessment, auditing, and monitoring which includes:
  - (a) A documented annual review of risk areas in the organization;
  - (b) Succession and contingency plans for the organization; and
  - (c) An audit program with at least four audits a year that is focused on proper documentation, billing, and coding practices in high risk areas;
- (6) A process for documentation of the organization's responses to critical incidents in accordance with Regulation .06 of this chapter and the development of any necessary corrective actions;
- (7) Investigation of any violations of State or federal law or regulation, or organizational policy; and
- (8) Organization's procedure in the event of any violation of State or federal law or regulation, or organizational policy including the:
  - (a) Implementation of any necessary corrective action; and
  - (b) Submission of any required reports to the Administration or other applicable State, local, or federal authority.

#### **.06 Reporting Requirements.**

##### **A. Critical Incident Reporting.**

- (1) An organization operating a community-based behavioral health program shall report the following critical incidents to the Administration:
  - (a) Any death of a program participant;
  - (b) Injuries to program participants that are:
    - (i) Life-threatening; or
    - (ii) The result of interpersonal violence;
  - (c) The following sexual activity:
    - (i) Consensual sexual activity between a current program participant and a member of the organization's staff, including volunteers or consultants associated with the program or the organization operating the program; and
    - (ii) Non-consensual sexual activity between a current or former program participant and a member of the organization's staff including volunteers or consultants associated with the program or the organization operating the program;
  - (d) Any unexpected evacuation of a program site under circumstances that threaten the life, health, or safety of program participants;
  - (e) Any fatal or non-fatal overdose of a program participant;
  - (f) Suspected or alleged abuse, neglect, or exploitation of a program participant;
  - (g) A disease or condition listed in the List of Reportable Diseases or Conditions, as set forth in COMAR 10.06.01.03 in addition to the reporting requirements of COMAR 10.06.01.04 for any program participant or organization staff;
  - (h) Any suicide attempt by either:
    - (i) A current program participant; or
    - (ii) A former program participant within 30 days following discharge;
  - (i) Any credible threat by a program participant determined by the organization to represent a risk to the life, health, or safety of staff, other program participants, targeted individuals, or the general public;
  - (j) A program participant's violation of an order of conditional release from a State psychiatric hospital;
  - (k) From a program that administers, dispenses, monitors or stores medication:
    - (i) Any theft of medication;
    - (ii) Any unexplained loss of medications; and
    - (iii) Any medication error that requires medical intervention;
  - (l) Any disappearance or elopement of one of the following program participants from a residential program site:
    - (i) A child;
    - (ii) A vulnerable adult;
    - (iii) An older adult; or
    - (iv) An adult with a behavioral health or somatic condition that if left unattended or untreated would be life threatening; and
  - (m) Any other serious incident as determined by the Administration that threatens the life, health, or safety of program participants.

(2) An organization shall report all critical incidents to the Administration, or its designee, on the form provided by the Administration within 3 business days of the organization's knowledge of the critical incident.

(3) An organization's failure to report a critical incident in accordance with §A(1)—(2) of this regulation may result in a civil money penalty in accordance with COMAR 10.63.08.

##### **B. Organization Financial Status Reporting.**

*(1) An organization shall notify the Administration of changes in the financial condition of the organization that may affect its ability to operate a program to provide behavioral health services including, at minimum:*

- (a) Filing of bankruptcy;*
- (b) Any wage claim against the organization;*
- (c) Notification of failure to pay State or federal taxes;*
- (d) Any foreclosure action against the organization filed in Circuit Court;*

*(e) Any of the following District Court actions filed against the organization:*

- (i) Failure to pay rent; or*
- (ii) Breach of lease;*
- (f) Any utility shut-off notice due to non-payment;*

*(g) Any legal actions brought against the organization or the organization's owner seeking to recover greater than \$15,000; and*

*(h) Any other action which may affect the organization's ability to operate a program.*

*(2) An organization shall report all changes in the financial condition to the Administration, or its designee, on the form provided by the Administration within 3 business days of the organization's knowledge of the change in the financial condition.*

*(3) An organization's failure to report a change in the financial condition in accordance with §B(1)—(2) of this regulation may result in a civil money penalty in accordance with COMAR 10.63.08.*

**C. Program Outcomes Reporting.**

*(1) The organization shall provide data elements to the Administration at the frequency required by the Administration if:*

*(a) The program's provided behavioral health services are funded by the federal Substance Abuse and Mental Health Services Administration and related federal funding sources; and*

*(b) The organization bills the public behavioral health system for either:*

- (i) Specialty mental health services in accordance with COMAR 10.09.59; or*
- (ii) Community-based substance use disorder services in accordance with COMAR 10.09.80.*

*(2) The data elements provided to the Administration shall be in accordance with federal requirements set forth in:*

- (a) 42 U.S.C. §300x-9;*
- (b) 42 U.S.C. §300x-35;*
- (c) 42 U.S.C. §300x-52(a); and*
- (d) 42 U.S.C. §300x-53(a).*

*D. An organization shall report vacancies in accordance with COMAR 10.63.02.03.*

**.07 Site Requirements.**

**A. Licensed Program Site Location Requirements.**

*(1) An organization's licensed program site shall be located in the State.*

*(2) An organization may not have a licensed program site:*

- (a) In a manner inconsistent with federal, State, or local law, ordinance, or regulation inclusive of zoning requirements;*
- (b) If providing outpatient behavioral health services on the same site as a residential dwelling; or*
- (c) If providing residential behavioral health services on the same site as any other licensed healthcare service.*

*(3) Accessibility.*

*(a) A program shall be accessible to program participants and others involved in their care during its approved operating hours.*

*(b) Accessibility includes but is not limited to:*

- (i) Compliance with the federal Americans with Disabilities Act, 42 U.S.C. §§12101—12213;*
- (ii) The provision of translation services as necessary to meet the needs of program participants; and*
- (iii) The provision of deaf and hard of hearing services necessary to meet the needs of program participants.*

*(4) Regardless of the amount of services provided by telehealth, the organization shall have sufficient space on its licensed program site to:*

- (a) Provide confidential behavioral health services during operating hours; and*
- (b) Provide the behavioral health services which it is licensed to provide, including group services.*

*(5) If an organization utilizes a shared space for a program providing community-based behavioral health services, the organization shall maintain confidentiality in accordance with the requirements of Regulation .03 of this chapter.*

**B. Post-Licensing Inspections.**

*(1) The Administration or its designee may make announced or unannounced visits to inspect an organization at:*

- (a) A licensed program site;*
- (b) An administrative office; or*
- (c) Any other location deemed necessary for the health, safety, or welfare of program participants.*

*(2) The Administration, or its designee, has the authority to inspect, scan, and copy business records of the organization or program, including but not limited to:*

- (a) Financial records;*
- (b) Treatment records;*
- (c) Service records;*

- (d) Staffing records; and
  - (e) Policies and procedures.
- (3) The Administration, or its designee, may inspect an organization operating a program providing behavioral health services to:
- (a) Determine compliance with any accreditation standards;
  - (b) Follow-up on any issue identified by the organization's accreditation organization;
  - (c) Validate the findings of the organization's accreditation organization;
  - (d) Investigate any critical incidents; or
  - (e) Determine compliance with any State or federal law or regulation.

**.08 Documentation Requirements.**

A. Medical Records. An organization shall maintain documentation of all behavioral health services provided to program participants, to include, at minimum, the following:

- (1) The date of service with service start and end times;
- (2) The program participant's primary behavioral health complaint or the reason for the visit;
- (3) A brief description of the service provided, including progress notes and any referrals for additional services;
- (4) The place of service;
- (5) Whether the service is by telehealth, and, if so, the location of both the licensed mental health professional and the program participant;
- (6) A statement indicating that the program participant received copies of:
  - (a) The organization's grievance policy; and
  - (b) Any necessary billing documents; and
- (7) A signature block which may be handwritten or electronic which includes the following for the licensed mental health professional:
  - (a) Printed name;
  - (b) Title;
  - (c) Signature; and
  - (d) Date.

B. Confidentiality. An organization shall maintain program medical records and confidential information:

- (1) According to the requirements of Regulation .03 of this chapter; and
- (2) At the licensed program site in a location that is:
  - (a) Exclusively controlled by the organization; and
  - (b) Locked.

C. Timekeeping. An organization shall maintain timekeeping records in accordance with COMAR 09.32.01.06 for required staff enumerated in COMAR 10.63.02 or in any of the program descriptions set forth in this subtitle and contractors, including physicians and nurse practitioners.

**.09 Telehealth Service Requirements.**

A. Scope. This regulation applies to community-based behavioral health services delivered via synchronous telehealth which are eligible for reimbursement by the Public Behavioral Health System.

B. Covered Services. In accordance with COMAR 10.09.49.03, community-based behavioral health services delivered via telehealth shall be:

- (1) Medically necessary;
- (2) Provided to the same extent and standard of care as services provided in person;
- (3) Within a licensed behavioral health professional's scope of practice; and
- (4) Permitted to be provided via telehealth as set forth in the chapter of this subtitle defining the covered service being rendered.

C. The organization shall ensure that all licensed mental health professionals obtain the program participant's consent to services via telehealth, unless there is an emergency that prevents obtaining consent, which shall be documented in the program participant's medical record.

D. Medical Record Documentation. The organization shall ensure medical records for services rendered via telehealth:

- (1) Maintain documentation in the same manner as during an in-person visit, using either electronic or paper medical records;
- (2) Are retained according to the provisions of Health-General Article, §4-403, Annotated Code of Maryland; and
- (3) Include program participant consent documentation as required in §C of this regulation.

E. Technical Requirements. An organization operating a program providing community-based behavioral health services shall meet all technical requirements described in COMAR 10.09.49.05.

F. Confidentiality. An organization operating a program providing community-based behavioral health services shall meet all requirements described in:

- (1) COMAR 10.09.49.06; and
- (2) Regulation .03 of this chapter.

G. Limitations. An organization operating a program providing community-based behavioral health services is subject to the following limitations on the provision of a service delivered via telehealth:

(1) A service delivered via telehealth is subject to the same program restrictions, preauthorizations, limitations, and coverage requirements that exist for services delivered in person.

(2) A service delivered via telehealth does not include:

(a) An audio-only telephone conversation between a licensed mental health professional and a program participant unless provided on dates of service between July 1, 2021, and June 30, 2023, inclusive;

(b) An electronic mail message between a licensed mental health professional and a program participant;

(c) A facsimile transmission between a licensed mental health professional and a program participant; or

(d) A telephone conversation, electronic mail message, or facsimile transmission between a licensed mental health professional without direct interaction with the program participant.

(3) Program specific limitations as set forth in the chapter of this subtitle defining the covered service being rendered.

#### **.10 Agreement with Local Authorities.**

A. An organization that intends to operate a program to provide community-based behavioral health services in the State shall execute an agreement to cooperate with the applicable local authority in each jurisdiction in which they intend to provide behavioral health services prior to applying for a license for any program licensed under this subtitle.

B. The agreement to cooperate shall provide for coordination and cooperation between the organization and local authority in the jurisdiction that services are to be provided, including, but not limited to, facilitating:

(1) Any site visit, including but not limited to a complaint or critical incident investigation;

(2) The transition of services if:

(a) The organization closes any of its program sites; or

(b) An organization plans to close or discontinue a service;

(3) Program compliance audits; and

(4) The provision of any additional documentation requested by the Administration.

C. The agreement to cooperate may not include a provision that authorizes the local authority to prohibit an organization from offering services at any location.

D. The agreement to cooperate shall be included with the licensure application provided to the Administration in accordance with COMAR 10.63.06.03.

#### **.11 Rights of Program Participants.**

A. An organization may not discriminate in the provision of community-based behavioral health services on the basis of race, creed, color, age, gender, sexual orientation, gender identity, national origin, marital status, disabilities, or any other classification prohibited under State or federal law in accordance with the requirements of Regulation .03 of this chapter.

B. An organization shall protect and promote the exercise of the program participant rights enumerated in §D of this regulation in all aspects of its program operations.

C. Notification of Program Participant Rights. The organization shall inform the program participant, in a language that the participant understands, of:

(1) The rights and responsibilities listed in §D of this regulation; and

(2) The Suicide and Crisis Hotline.

D. Program Participant Rights.

(1) An organization shall provide care for program participants in a manner and in an environment that maintains or enhances each participant's dignity and respect.

(2) A program participant receiving community-based behavioral health services from an organization licensed in accordance with COMAR 10.63.06 has the right to:

(a) Be treated with consideration, respect, and full recognition of the program participant's human dignity and individuality;

(b) Receive treatment, care, and services that are adequate, appropriate, and in compliance with relevant State, local, and federal laws and regulations;

(c) Receive treatment in accordance with their individualized plan of care or rehabilitation plan;

(d) If applicable, receive treatment in accordance with the preferences of their advance directive for mental health services in accordance with Health-General, §10-708, Annotated Code of Maryland;

(e) Consent to or refuse treatment after the possible consequences of refusing treatment are fully explained;

(f) Be free from mistreatment, neglect, and verbal, mental, emotional, sexual, and physical abuse;

(g) Contact at any time:

(i) Personal legal counsel;

(ii) The State protection and advocacy agency;

(iii) The applicable local authority;

(iv) The Administration; and

(v) The Department.

(h) Make suggestions, complaints, or present grievances on behalf of the program participant or others, to the organization, the State protection and advocacy agency, the applicable local authority, the Administration, the Department, or other individuals without threat or fear of retaliation;

(i) Receive a prompt response, through the organization's established complaint or grievance policy, to any complaints, suggestions, or grievances the program participant may have;

(j) Except when prohibited for the health and safety of the program participant or others, keep any identification, insurance information, and public benefits documentation in their possession;

(k) Designate their own representative payee for Social Security;

(l) Authorize advocates, family, or friends to participate in care coordination or the treatment planning and discharge planning process;

(m) Contact emergency services for emergency assistance or transportation to a hospital at any time; and

(n) Not be compelled to perform work for the organization and, if the program participant chooses to perform work for the organization, is monetarily compensated by the organization for any work performed.

E. Addressing Alleged Violations of Participant Rights. An organization licensed to operate a program to provide community-based behavioral health services in accordance with COMAR 10.63.06 shall:

(1) Initiate an investigation within 3 business days into any alleged violations of program participant rights involving anyone furnishing services on behalf of the organization;

(2) Document any actions taken to prevent further violations while the alleged violation is investigated;

(3) Investigate and document all alleged violations in accordance with the organization's written policies as outlined in §F of this regulation;

(4) Take any corrective action required by the local authority or the Administration; and

(5) Report any critical incidents in accordance with Regulation .06 of this chapter.

F. Program Participant Rights Policy. An organization operating a community-based behavioral health program shall have a written policy to investigate and document all alleged violations of participant rights that, at minimum, outlines:

(1) The timeline of the investigation;

(2) The procedure for private interviews with any witnesses;

(3) Any necessary safeguards to ensure that the alleged perpetrator is not involved in conducting the investigation;

(4) The procedure for the review of the program participant's file and other relevant records;

(5) Action taken based on the organization's written policies; and

(6) The procedure for the completion and submission of documentation relevant to the investigative process to the local authority or the Administration.

## **.12 Organization Grievance Policy.**

A. Grievance Policy. An organization operating a community-based behavioral health program shall have a grievance policy.

(1) An organization shall provide program participants with a copy of the grievance policy at the time of admission.

(2) An organization's grievance policy shall include at a minimum:

(a) The right of program participants to grieve program decisions including, but not limited to, decisions concerning:

(i) Treatment;

(ii) Violations of program participant rights;

(iii) Discharge; and

(iv) Change in status or services;

(b) Instructions on how to file a grievance as described in §B of this regulation; and

(c) Procedures for the following:

(i) Review of the initial decision on the grievance by supervisory staff;

(ii) An opportunity to appeal the outcome of the initial decision to senior management; and

(iii) Explicit provisions that allow the program participant at any time to contact the appropriate local authority, the Administration, and if applicable, the accreditation organization.

B. An organization operating a program providing community-based behavioral health services shall provide program participants instructions on how to file a grievance which shall:

(1) Be in plain language;

(2) Be in a language that the program participant understands;

(3) Accommodate individuals who are unable to read print or communicate in writing;

(4) Outline the steps of the grievance process as described in §A(2)(c) of this regulation; and

(5) Contain current contact information for the appropriate local authority, the Administration, and if applicable, the accreditation organization.

C. An organization operating a program providing community-based behavioral health services may not retaliate against a program participant who presents a grievance.

D. An organization operating a program providing community-based behavioral health services shall inform each program participant in writing when revisions are made to the grievance policy and communicate to program participants the nature and extent of the changes.

## **.13 Discontinuation of Program Operations.**

A. Planned Discontinuation of Program Operations.

(1) An organization operating a program providing community-based behavioral health services shall notify the following no less than 60 business days prior to the intended discontinuation date:

(a) The Administration;

(b) The appropriate local authority; and

(c) If applicable, the State Opioid Treatment Authority.

- (2) The notice provided shall include the organization's written plan for:
  - (a) Discontinuation of operations, including relevant dates;
  - (b) Informing program participants or guardians of the planned discontinuation of services;
  - (c) Informing program participants or guardians of other behavioral health service options;
  - (d) Transitioning program participants to other behavioral health services;
  - (e) Storing and protecting all records after the discontinuation of operations for a period of at least 7 years; and
  - (f) Notifying employees, contractors, and consultants of its discontinuation of operations.
- (3) Within 20 business days from receipt of the organization's notification of intention to discontinue program or licensed service operations, the Administration shall:
  - (a) Notify the organization in writing whether the organization's written discontinuation plan is acceptable; and
  - (b) Either:
    - (i) Approve final closure; or
    - (ii) If the organization's plan is unacceptable, meet with the organization and the appropriate local authority to make a plan that protects the health, safety, and welfare of program participants.
- (4) Until the Administration approves final closure, the organization shall:
  - (a) Provide services as appropriate;
  - (b) Make best efforts to refer program participants to alternative services to ensure continuation of care; and
  - (c) Document its efforts to refer program participants to alternative services.
- (5) Upon approval by the Administration of the organization's discontinuation plan, the organization shall implement the discontinuation plan.
- (6) At all times during the discontinuation process, the organization shall cooperate with the Administration and the appropriate local authority.

**B. Unplanned Discontinuation of Program Operations.**

- (1) An organization licensed in accordance with this subtitle that experiences an unexpected discontinuation or interruption of services for more than 1 day at any licensed program site, whether temporary or permanent, shall immediately, but no longer than 24 hours, inform:
  - (a) Program participants or their guardians via:
    - (i) Direct communication; and
    - (ii) Visible signage at the licensed program site;
  - (b) The Administration;
  - (c) The appropriate local authority; and
  - (d) If applicable, the State Opioid Treatment Authority.
- (2) The organization, if requested by the Administration or the local authority, shall provide a proposed written emergency plan that includes:
  - (a) A census of program participants affected by the discontinuation of services;
  - (b) Types of services affected;
  - (c) Expected or estimated duration of closure;
  - (d) How services will be provided in the interim, including any staffing changes;
  - (e) If applicable, the location where interim services will be provided;
  - (f) If applicable, a plan to transition program participants to an alternative program or make other arrangements to ensure continuity of services for the individuals;
  - (g) A plan for storing and protecting all records, ensuring program participant and auditor access upon request; and
  - (h) A plan for notification of employees, contractors, consultants, and consumers.
- (3) In the event of an unplanned discontinuation of program operations, the Administration or its designee may contact program participants to discuss the discontinuation of services and ensure the continuity of care.
- (4) Within 7 business days after receipt of the organization's notification of discontinuation of program operations, the Administration shall:
  - (a) Notify the organization in writing whether the organization's written discontinuation plan is acceptable; and
  - (b) Either:
    - (i) Approve final discontinuation; or
    - (ii) If the organization's plan is unacceptable, meet with the organization and the appropriate local authority, to make a plan that protects the health, safety, and welfare of program participants.
- (5) The organization may not discontinue program operations until the Administration approves the discontinuation plan.
- (6) At all times during the discontinuation process, the organization shall cooperate with the Administration and the appropriate local authority.

**C. Non-Compliance with Discontinuation Requirements.**

- (1) In the event of a planned discontinuation of services, if an organization fails to comply with §A of this regulation, the Secretary may deny any future application for a license submitted by the organization, its corporate officers, or required staff of the organization.
- (2) In the event of an unplanned discontinuation of services, if an organization fails to comply with §B of this regulation, the Secretary may deny any future application for a license submitted by the organization, its corporate officers, or required staff of the organization.

## **10.63.02 [Programs Required to be Accredited in Order to be Licensed to Provide Community-Based Behavioral Health Services] General Staffing Requirements**

Authority: Health-General Article, [§§7.5-204,] §§7.5-204 (a)(2)[8-402, 8-404, 10-901,] and [10-1402] 7.5-402, Annotated Code of Maryland

### **.01 Definitions.**

*A. In this chapter, the following terms have the meanings indicated.*

*B. Terms Defined.*

(1) "Accreditation organization" means a private entity that conducts inspections and surveys of health care facilities or health care staff agencies based on nationally recognized and developed standards that is approved by the Secretary in accordance with Health General Article, §19-2302, Annotated Code of Maryland.

(2) "Administration" means the Behavioral Health Administration within the Department that provides oversight to organizations that are licensed in accordance with this subtitle.

(3) Allied Health Staff.

(a) "Allied health staff" means an individual not licensed in accordance with Health Occupations Title, Annotated Code of Maryland that is utilized by an organization to provide support services or direct care services in the operation of a community-based behavioral health program.

(b) "Allied health staff" includes, but is not limited to:

(i) Rehabilitation workers;

(ii) Direct service staff;

(iii) Non-certified peer recovery specialists;

(iv) Community health workers;

(v) Health educators;

(vi) Counselor aides; and

(vii) Group living workers.

(4) "Applicant" means the legally authorized individual or entity submitting an application for licensure.

(5) "Behavioral health services" means prevention, screening, early intervention, treatment, recovery, support, wraparound, and rehabilitation services for individuals with substance-related disorders, addictive disorders, mental disorders, or a combination of these disorders.

(6) "Business day" means any day except Saturday, Sunday, or a State holiday.

(7) "Community-based" means a setting of a behavioral health services program that is not located in a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland.

(8) Corporate Officers.

(a) "Corporate officers" means the managing employees or other individuals responsible for the conduct of the affairs of the organization inclusive of the organization's controlling board.

(b) "Corporate officers" includes but is not limited to the organization's:

(i) Chief Executive Officer;

(ii) Chief Financial Officer;

(iii) Chief Medical Officer;

(iv) Chief Information Officer;

(v) Corporate Compliance Officer;

(vi) Board members; and

(vii) Other senior officers of the organization.

(9) "Criminal justice information system" has the meaning stated in Criminal Procedure Article, §10-201, Annotated Code of Maryland.

(10) "Critical incident" means an event that impacts the health, safety, or welfare of a program participant or staff.

(11) "Department" means the Maryland Department of Health.

(12) "License" means an authorization issued by the Secretary permitting an organization to operate a behavioral health program at a specific site in the State.

(13) "Licensed mental health professional" means a practitioner authorized under Health Occupations Article, Annotated Code of Maryland, who has specialty in the diagnosis and treatment of mental health, addictive, substance-related, or co-occurring disorders.

(14) Local Authority.

(a) "Local authority" means the designated county or multicounty authority responsible for planning, managing, and monitoring publicly funded mental health, substance-related, or addictive disorder services.

(b) "Local authority" includes the:

(i) Core service agency as defined in Health General Article, §7.5-101(g), Annotated Code of Maryland;

(ii) Local addictions authority as defined in Health General Article, §7.5-101(j), Annotated Code of Maryland; and

(iii) Local behavioral health authority as defined in Health General Article, §7.5-101(k), Annotated Code of Maryland.

(15) "Organization" means an association, partnership, corporation, unincorporated group, or any other legal entity licensed to operate a program to provide community-based behavioral health services.

(16) "Participant" means an individual receiving behavioral health services in a community-based program.

(17) "Peer support services" has the meaning stated in Health-General Article, §7.5-101, Annotated Code of Maryland.

(18) "Professional licensure background check" means a background check conducted into an individual's professional status, history, and credentials.

(19) "Program" means a named set of services operated by an organization inclusive of:

(a) A substance-related disorders program as defined in Health General Article, §7.5-101(q), Annotated Code of Maryland;

(b) A mental health program as defined in Health General Article, §7.5-101(m), Annotated Code of Maryland;

(c) An addictive disorders program; and

(d) A combination of §B(19)(a)–(c) of this regulation.

(20) "Rap Back Program" has the meaning stated in COMAR 12.15.01.03.

(21) "Residential" means the setting of a community-based program in which program participants both reside and receive behavioral health services.

(22) "Site" means the location where the organization operates the program as detailed on the program's license.

(23) "Telehealth" means the synchronous delivery of medically necessary services to a participant at an originating site by a distant site provider, through the use of technology-assisted communication in accordance with COMAR 10.09.49.

(24) "Variance" means an alternate method of meeting the intent of a regulation under this subtitle as approved by the Administration.

## **.02 General Staff Requirements.**

A. *Supervision of Staff.* An organization operating a community-based behavioral health services program shall provide supervision to staff providing direct care services including all requirements of Health Occupations Article, Annotated Code of Maryland.

B. *Dedicated Program Staff.*

(1) Dedicated program staff are individuals who are employed by an organization to perform duties at a single program site at a time.

(2) Dedicated program staff may perform duties at multiple program sites, but may not actively perform duties for multiple programs simultaneously.

(3) Organizations that require dedicated program staff to perform duties at multiple program sites shall ensure that timekeeping records clearly indicate the program site at which the individual performed duties for each hour worked.

(4) For the purposes of determining if a program meets minimum staffing requirements, an organization may only count the number of hours during which the dedicated program staff performs duties at the program in question.

(5) An organization may not count the hours during which a dedicated program staff performs duties at another program site for the purposes of determining if a program meets minimum staffing requirements, regardless of:

(a) The physical proximity of the different programs;

(b) The amount of services provided by telehealth;

(c) The overlap of services provided by the different programs; and

(d) The overlap in program participants served by the different programs.

C. *Organizational Level Staff.* Organizational level staff are individuals who are employed by an organization that may perform duties for multiple program sites simultaneously, provided that:

(1) The programs are managed according to uniform organizational policies and procedures applicable to all programs;

(2) All program participant records may be accessed from any program site;

(3) The individual in the position responds to emergencies, in person or via remote video conference, within 1 hour of being notified;

(4) Staff at each licensed program site have direct access to the individual in the position as needed; and

(5) On a routine basis, and as clinically required, the individual in the position provides on-site consultation at each licensed program site to ensure adequate clinical and administrative oversight.

D. *Organizations who employ a single individual to perform the duties of multiple positions shall:*

(1) When the individual performs an organizational level position and a dedicated program position, consider the individual dedicated program staff for the purposes of determining minimum staffing requirements; and

(2) Meet the requirements of this chapter and any program specific descriptions set forth in this subtitle associated with each of the positions the individual fills.

## **.03 Vacancy Reporting Requirements.**

A. An organization shall follow the requirements of §B of this regulation upon vacancy of any of the following staff:

(1) A corporate officer;

(2) The medical director as specified in Regulation .13 of this chapter;

(3) The program director as specified in Regulation .07 of this chapter;

(4) The clinical director as specified in Regulation .06 of this chapter;

(5) Clinical supervisors as specified in Regulations .09 and .14 of this chapter;

(6) A rehabilitation specialist as specified in Regulation .10 of this chapter; and

(7) Any other required staff as specified within any of the program descriptions set forth in this subtitle.

B. Upon vacancy of any staff specified in §A of this regulation, the organization shall:

- (1) Immediately implement a good-faith effort to fill the vacancy;
- (2) Seek a variance in accordance with COMAR 10.63.06.10B, if applicable;
- (3) Notify the Administration and the appropriate local authority within 40 business days of the vacancy in the manner specified by the Administration; and
- (4) Notify the Administration and the appropriate local authority immediately upon hire of the individual filling the vacancy in the manner specified by the Administration to include at minimum the individual's:
  - (a) Name;
  - (b) Credentials, including a copy of any applicable licenses or certifications, and a resume or curriculum vitae; and
  - (c) Actual start date.

C. Notwithstanding the requirements of §A of this regulation, an organization shall immediately, but in no event longer than 48 hours, report to the Administration any vacancy that causes a significant impact to a licensed program's operations or the health, safety, or welfare of program participants.

#### **.04 Staff Training and Competency Plans.**

A. An organization operating a community-based behavioral health services program shall develop and implement a training plan that covers each staff member which includes at a minimum policies and procedures related to:

- (1) Onboarding;
- (2) Orientation;
- (3) Annual training;
- (4) Performance standards; and
- (5) Competency development plan.

B. Within 60 business days of hire, at a minimum, all staff shall receive training from the organization in, at minimum, the following:

- (1) Role and responsibilities;
- (2) Corporate compliance;
- (3) Confidentiality and communication with program participants and others, including participant consent;
- (4) Building caring and collaborative relationships with program participants;
- (5) Setting and maintaining safe boundaries with program participants;
- (6) Confidentiality and communication with program participants and others, including participant consent;
- (7) Any other training as specified within the program descriptions set forth in this subtitle; and
- (8) Any other training required by the organization's accreditation organization.

C. Staff Training Records. An organization shall maintain all staff training in accordance with the employment records requirements contained in COMAR 09.32.01.06.

#### **.05 Background Checks for All Programs.**

A. Criminal Background Checks.

(1) An organization shall, at minimum, perform a criminal background check, at the organization's expense, for each employee and contractor:

- (a) Prior to employment; and
  - (b) Every 3 years.
- (2) The pre-employment criminal background check shall, at minimum, include:
- (a) The individual's criminal history in any state in which they have lived or worked in the past 10 years; and
  - (b) If their scope of work for the organization includes transporting program participants, the individual's driving record in any state in which they have lived or worked in the past 10 years.
- (3) Any subsequent criminal background checks conducted while the individual is employed by the organization shall, at minimum, include the State, and, if the individual resides out of State, the state in which the individual resides.
- (4) Any organization providing licensed behavioral health services to minors shall comply with the criminal background check requirements set forth in Family Law Article, §5-551, Annotated Code of Maryland.
- (5) A criminal background check through the Criminal Justice Information System will satisfy the requirements of:
- (a) The initial pre-employment criminal background check; or
  - (b) Any subsequent criminal background checks.
- (6) An organization participating in the Department of Public Safety and Correctional Services Rap Back Program is exempt from the requirements of §A(1)(b) of this regulation.

B. Professional Licensure Background Check.

(1) An organization shall perform a professional licensure background check for each employee and contractor who holds professional licensure:

- (a) Prior to employment; and
  - (b) Every 2 years.
- (2) Each professional licensure background check shall include the State and any state in which the individual has held professional licensure in the past 10 years.

C. Continuous Monitoring for Exclusion.

(1) Each organization shall continuously monitor the following resources to ensure they are not employing individuals who have been excluded from providing services:

- (a) Maryland Medicaid's sanctioned providers list;
- (b) The Department's Office of the Inspector General's exclusion list; and
- (c) The federal Department of Health and Human Services, Office of the Inspector General's List of Excluded Individuals/Entities database.

(2) An organization shall, at minimum, check all employees for exclusion in the resources enumerated in §C(1) of this regulation quarterly.

**D. Background Check Policy.**

(1) An organization shall have a background check policy covering each program it operates regarding the criminal history and professional licensure history of employees and contractors.

(2) The background check policy, at a minimum, shall:

(a) Outline the criteria to be used to determine if an individual with a criminal history can be employed by the organization, including the following considerations:

- (i) The age at which the individual committed the crime;
- (ii) The circumstances surrounding the crime;
- (iii) Any punishment imposed for the crime, including any subsequent court actions regarding that punishment;
- (iv) The length of time that has passed since the crime;
- (v) Subsequent work history;
- (vi) Employment and character references; and
- (vii) Other evidence that demonstrates whether the employee, contractor, or volunteer poses a threat to the health or safety of program participants, program staff, or members of the public;

(b) Outline the criteria to be used to determine if an individual with a license not in good standing in the past 10 years can be employed by the organization; and

(c) Require employees and contractors to report the following:

- (i) All arrests or pending criminal charges except for minor traffic violations that occur during employment; and
- (ii) Any change in professional license or certificate status.

(3) The background check policy may contain exclusionary criteria stricter than required by §E of this regulation, as appropriate, to protect program participants.

**E. Exclusionary Criteria.**

(1) The organization may not employ an employee or contractor if the organization does not complete the criminal background check and professional licensure check as required by §§A and B of this regulation.

(2) The organization may not employ an employee or contractor if the individual is excluded from providing services by:

- (a) Maryland Medicaid;
- (b) The Department's Office of the Inspector General; or
- (c) The federal Department of Health and Human Services.

(3) An organization may not employ an employee or contractor if the individual has been convicted at any time of:

- (a) Child abuse;
- (b) Abuse or neglect of a vulnerable adult; or
- (c) Sexual abuse.

**F. Documentation Requirements.**

(1) An organization shall document the organization's:

- (a) Review of criminal history and professional licensure records of potential employees and contractors;
- (b) Decisions regarding the impact of the criminal history or professional licensure history on the employability of each applicant for employment and on each employee and contractor; and
- (c) Implementation of the policy required by §D of this regulation.

(2) An organization shall maintain the documentation required by §F(1) of this regulation for 3 years after the individual either:

- (a) Is not hired; or
- (b) If hired, leaves employment with the organization.

G. An organization seeking to utilize volunteers shall ensure current and prospective volunteers are subject to the background check requirements as described in §§A—F of this regulation.

**.06 Clinical Director.**

A. A clinical director is an organizational level staff member and may perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

B. A clinical director shall possess, at minimum, the following qualifications:

(1) An active professional behavioral health license at the independent practice level in accordance with the applicable Health Occupations Board; and

(2) At least 5 years of documented experience in human services, 2 years of which include providing administrative or clinical supervision.

C. A clinical director shall:

- (1) Be an employee of the organization which operates the program which they direct;
- (2) Be available in person at each program site a sufficient number of hours in order to effectively direct the clinical aspects of the program in accordance with §D of this regulation; and
- (3) Arrange for an appropriate clinical supervisor in accordance with Health Occupations Article, Annotated Code of Maryland.

D. A clinical director is responsible for the following functions:

- (1) Leading and approving the development of clinical program policies and procedures;
- (2) Providing clinical supervision and oversight of the clinical quality of the organization;
- (3) Managing clinical crises; and
- (4) Ensuring the organization follows appropriate discontinuation of service procedures including transition of care in accordance with COMAR 10.63.01.13.

E. A clinical director may be a clinical supervisor in accordance with Health Occupations Article, Annotated Code of Maryland.

#### **.07 Program Director.**

A. A program director is an organizational level staff member and may perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

B. A program director shall possess, at minimum, the following qualifications:

- (1) A bachelor's degree from an accredited educational institution; and
- (2) Five years of documented experience in human services, 2 years of which include providing administrative or clinical supervision.

C. The program director shall:

- (1) Be an employee of the organization that operates the program which they direct; and
- (2) Be available in person at each program site for a sufficient number of hours in order to effectively direct the program in accordance with §D of this regulation.

D. The program director is responsible for the following functions:

- (1) Leading and approving the development of program policies and procedures;
- (2) Administrative oversight;
- (3) Program supervision and oversight;
- (4) Ensuring the implementation and safety of the therapeutic and treatment environment;
- (5) Ensuring the organization's program license is posted in accordance with COMAR 10.63.06.04D; and
- (6) Ensuring the organization follows appropriate discontinuation of service procedures including the transition of care in accordance with COMAR 10.63.01.13.

E. The program director may delegate the responsibilities enumerated in §D of this regulation through a formal delegation agreement.

#### **.08 Corporate Compliance Officer.**

A. A corporate compliance officer is an organizational level staff member and may perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

B. A corporate compliance officer shall meet all minimum qualifications as set forth by the organization.

C. The corporate compliance officer shall:

- (1) Be an employee of the organization that operates the program which they oversee; and
- (2) Be available in person at each program site for a sufficient number of hours in order to effectively oversee the program in accordance with §D of this regulation.

D. The corporate compliance officer shall:

- (1) Have direct access to the organization's corporate officers;
- (2) Educate the organization on necessary compliance requirements;
- (3) Develop and oversee compliance with the corporate compliance plan in accordance with COMAR 10.63.01.05; and
- (4) Address noncompliance within the organization and, if necessary, report noncompliance in accordance with COMAR 10.63.01.05C(8).

#### **.09 Licensed Mental Health Professionals and Clinical Supervisors.**

A. Licensed Mental Health Professionals.

(1) A licensed mental health professional is dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

(2) A licensed mental health professional shall possess active licensure in accordance with Health Occupations Article, Annotated Code of Maryland and may include the following:

- (a) Psychiatrist;
- (b) Licensed psychologist;
- (c) Psychiatric nurse practitioner;
- (d) Clinical nurse specialist in psychiatric and mental health nursing;
- (e) Licensed certified social worker-clinical;
- (f) Licensed clinical alcohol and drug counselor;

- (g) Licensed clinical marriage and family therapist;
- (h) Licensed clinical professional art therapist;
- (i) Licensed clinical professional counselor; or
- (j) An individual properly supervised under a formal supervision agreement who is either a:
  - (i) Licensed master social worker;
  - (ii) Licensed graduate alcohol and drug counselor;
  - (iii) Licensed graduate marriage and family therapist;
  - (iv) Licensed graduate professional art therapist;
  - (v) Licensed graduate professional counselor;
  - (vi) Licensed certified social worker; or
  - (vii) Registered psychology associate.

**B. Clinical Supervisors.**

(1) Clinical supervisors are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

(2) A clinical supervisor shall:

(a) Only provide clinical supervision if actively licensed to do so in accordance with Health Occupations Article, Annotated Code of Maryland; and

(b) If providing supervision to alcohol and drug counselors have written approval from the Board of Professional Counselors as required by COMAR 10.58.07.13—15.

(3) If a clinical supervisor is not an employee of the organization, the clinical supervisor shall execute the following agreements:

(a) A Business Associates Agreement between the clinical supervisor and the organization in accordance with 45 CFR §164.502; and

(b) A formal supervision agreement between the clinical supervisor and the individual they supervise.

**C. Clinical Interns.** An organization may utilize clinical interns within the scope of service limits established by State law and regulation.

**D.** An organization may not allow a licensed mental health professional to provide behavioral health services to program participants when the mental health professional is located outside the United States or its territories.

**.10 Rehabilitation Specialists.**

**A.** Rehabilitation specialists are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

**B.** A rehabilitation specialist shall, at minimum, have the following qualifications:

(1) Have a minimum of 2 years of direct care experience working with:

(a) Adults that have a serious mental disorder; or

(b) Minors who have serious emotional or behavioral difficulties;

(2) Be licensed or certified as one of the following in accordance with Health Occupations Article, Annotated Code of Maryland:

(a) A licensed mental health professional as defined in this chapter, certified at the independent practice level;

(b) A licensed mental health professional certified at the graduate level, receiving formal, documented supervision, in accordance with licensing board requirements, by a licensed mental health professional who is an employee of the organization;

(c) A licensed mental health professional certified at the graduate level, receiving formal, documented supervision, in accordance with licensing board requirements, by a licensed mental health professional who has a Business Associate Agreement with the organization in accordance with 45 CFR §164.502;

(d) A licensed occupational therapist;

(e) A registered nurse who:

(i) Is licensed and in good standing holds a psychiatric mental health nursing certification in accordance with the American Nurses Credentialing Center; or

(ii) Has, at minimum, a bachelor's degree in social work, counseling, rehabilitation, psychology, nursing, or a related field; or

(f) A master's prepared rehabilitation counselor certified in the practice of rehabilitation counseling by the Commission on Rehabilitation Counselor Certification.

**C.** A rehabilitation specialist shall:

(1) Be an employee of the organization that operates the program; and

(2) Be available in person at each program site for a sufficient number of hours in order to effectively direct the program in accordance with §D of this regulation.

**D.** Rehabilitation specialists shall perform the following duties:

(1) Patient assessments;

(2) Person-centered treatment planning;

(3) Psycho-social skill training;

(4) Clinical documentation; and

(5) Other services as informed by the needs of the program participant.

**.11 Certified Peer Recovery Specialists.**

A. Certified peer recovery specialists are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

B. An organization shall ensure that a certified peer recovery specialist has the following qualifications:

- (1) A high school diploma or high school equivalency certificate; and
- (2) A current certification as a peer recovery specialist from the Board approved by the Department.

C. A certified peer recovery specialist shall adhere to all requirements of the Board, including at a minimum:

- (1) Formal training and education of the knowledge, skills and abilities in each of the four domains identified by the Board; and
- (2) Adherence to the Ethics Code of Conduct, Principles and Service Guidelines established by the Board.

D. A certified peer recovery specialist may not perform any clinical treatment services or functions unless otherwise licensed in accordance with Health Occupations Article, Annotated Code of Maryland.

**.12 Allied Health Staff.**

A. An organization operating a community-based behavioral health services program may utilize allied health staff in the operation of the program to provide:

- (1) Support services; or
- (2) Direct care services which are not within the scope of practice of a licensed clinical professional in accordance with Health Occupations Title, Annotated Code of Maryland.

B. Qualifications. An organization shall have policies and procedures for the employment of allied health staff which specifies:

- (1) Minimum qualifications; and
- (2) Any prevailing professional standards in accordance with the program descriptions set forth in this subtitle.

C. A corporate officer may not serve as allied health staff in the course of their regular duties.

**.13 Medical Directors.**

A. Medical directors are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

B. Effective January 1, 2026, the medical director of a program shall:

- (1) Be licensed in the State as required by Health Occupations Article, §14-301, Annotated Code of Maryland; and
- (2) Be an employee of the organization which operates the program which they direct.

C. The medical director, either directly or through formal delegation, shall:

- (1) Approve and regularly review the program's:
  - (a) Admission criteria;
  - (b) Discharge criteria; and
  - (c) Medical policies, procedures, and protocols;
- (2) Direct patient care;
- (3) Ensure the adequacy of individualized treatment plans;
- (4) Ensure daily medical coverage to meet program participant needs;
- (5) Determine the credentials required of other licensed clinical staff who serve the program;
- (6) Monitor the care delivered by other staff who serve the program;
- (7) Review all critical incidents; and
- (8) Oversee the quality of care delivered by all programs for which the individual is serving as medical director.

D. In addition to the requirements of this regulation, a medical director shall meet any applicable additional program specific qualifications or requirements set forth in this subtitle.

**.14 Substance Use Disorder Program Specific Staff.**

A. Substance Related Disorder Clinical Supervisor:

(1) Substance related disorder clinical supervisors are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.

(2) A substance related disorder clinical supervisor shall have, at minimum, the following qualifications:

- (a) Be employed as a clinical supervisor before October 1, 2002 or, at minimum, licensed as one of the following:
  - (i) A licensed clinical professional counselor;
  - (ii) A licensed certified social worker—clinical; or
  - (iii) A licensed alcohol and drug counselor; and
- (b) Be approved to supervise from the Board of Professional Counselors and Therapists as required by COMAR 10.58.07.13—15.

(3) A clinical supervisor shall provide, in person or via audio visual teleconference, supervision to staff, maintaining a staff to supervisor ratio of no greater than one supervisor to 15 staff.

(4) A Certified Associate Alcohol and Drug Counselor who is approved by the Board of Professional Counselors and Therapists to supervise shall themselves be supervised by a Board approved supervisor in accordance with COMAR 10.58.07.07.

(5) A clinical supervisor may carry a caseload so long as the supervisor's caseload does not impede the clinical supervisor's ability to supervise.

B. Facility Coordinator:

- (1) Facility coordinators for residential substance use disorder programs are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.
- (2) A facility coordinator shall have, at minimum, the following qualifications:
  - (a) A high school diploma or high school equivalency certificate; and
  - (b) Two years of experience as an allied health staff member in a substance related disorder treatment program.
- (3) The responsibilities of a facility coordinator include:
  - (a) Overseeing the daily operations of the licensed program site; and
  - (b) Ensuring the program site is sufficiently maintained to meet the needs of the program.
- C. Substance Related Disorder Clinical Staff.
  - (1) Substance related disorder clinical staff are dedicated program staff and may not perform duties at multiple program sites simultaneously in accordance with Regulation .02 of this chapter.
  - (2) Substance related disorder clinical staff shall, at minimum, be:
    - (a) Licensed or certified as an alcohol and drug counselor by the Board of Professional Counselors and Therapists; or
    - (b) Licensed, certified, or permitted under Health Occupations Article, Annotated Code of Maryland to provide substance abuse treatment.
  - (3) Substance related disorder clinical staff are responsible for the following:
    - (a) Providing substance related disorder assessment and treatment services;
    - (b) Documenting services accurately;
    - (c) Maintaining confidentiality;
    - (d) Ensuring services are provided in accordance with applicable supervision requirements; and
    - (e) Ensuring program participant rights are respected.

## **10.63.06 [Application and] Licensure Process**

Authority: Health-General Article, [§§7.5-204,] §§7.5-204 (a)(2)[8-402, 8-404,] and [10-901] 7.5-402, Annotated Code of Maryland

### **.01 Definitions.**

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
  - (1) "Accreditation organization" means a private entity that conducts inspections and surveys of health care facilities or health care staff agencies based on nationally recognized and developed standards that is approved by the Secretary in accordance with Health General Article, §19-2302, Annotated Code of Maryland.
  - (2) "Accreditation" means the approval granted to a program by an accreditation organization.
  - (3) "Accreditation-based license" means a license which requires that the organization be accredited by an approved accreditation organization.
  - (4) "Administration" means the Behavioral Health Administration within the Department that provides oversight to organizations that are licensed in accordance with this subtitle.
  - (5) "Administrative withdrawal" means the Administration's cancellation of an organization's application for licensure.
  - (6) "Agreement to cooperate" means a written agreement between an organization operating a program and the appropriate local authority that provides for coordination and cooperation in carrying out behavioral health activities in a given jurisdiction.
  - (7) "Applicant" means the legally authorized individual or entity submitting an application for licensure.
  - (8) "Behavioral health services" means prevention, screening, early intervention, treatment, recovery, support, wraparound, and rehabilitation services for individuals with substance-related disorders, addictive disorders, mental disorders, or a combination of these disorders.
  - (9) "Business day" means any day except Saturday, Sunday, or a State holiday.
  - (10) "Community-based" means a setting of a behavioral health services program that is not located in a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland.
  - (11) Corporate Officers.
    - (a) "Corporate officers" means the managing employees or other individuals responsible for the conduct of the affairs of the organization inclusive of the organization's controlling board.
    - (b) "Corporate officers" includes but is not limited to the organization's:
      - (i) Chief Executive Officer;
      - (ii) Chief Financial Officer;
      - (iii) Chief Medical Officer;
      - (iv) Chief Information Officer;
      - (v) Corporate Compliance Officer;
      - (vi) Board members; and
      - (vii) Other senior officers of the organization.
  - (12) "Corrective Action" means specific actions undertaken by an organization to address a violation of any local, state, or federal law or regulation.
  - (13) "Deficiency" means a failure to meet an accreditation, licensure, or certification standard, or a relevant federal, State, or local ordinance, law, regulation, or building code, as applicable.

- (14) "Department" means the Maryland Department of Health.
- (15) "Jurisdiction" means Baltimore City or one of the 23 counties in the State.
- (16) "License" means an authorization issued by the Secretary permitting an organization to operate a behavioral health program at a specific site in the State.
- (17) Local Authority.
- (a) "Local authority" means the designated county or multicounty authority responsible for planning, managing, and monitoring publicly funded mental health, substance-related, or addictive disorder services.
- (b) "Local authority" includes the:
- (i) Core service agency as defined in Health General Article, §7.5-101(g), Annotated Code of Maryland;
- (ii) Local addictions authority as defined in Health General Article, §7.5-101(j), Annotated Code of Maryland; and
- (iii) Local behavioral health authority as defined in Health General Article, §7.5-101(k), Annotated Code of Maryland.
- (18) "Organization" means an association, partnership, corporation, unincorporated group, or any other legal entity licensed to operate a program to provide community-based behavioral health services.
- (19) "Participant" means an individual receiving behavioral health services in a community-based program.
- (20) "Plan of correction" means an organization's written plan of corrective actions to address program deficiencies.
- (21) "Program" means a named set of services operated by an organization inclusive of:
- (a) A substance-related disorders program as defined in Health General Article, §7.5-101(q), Annotated Code of Maryland;
- (b) A mental health program as defined in Health General Article, §7.5-101(m), Annotated Code of Maryland;
- (c) An addictive disorders program; and
- (d) A combination of §B.(21)(a)—(c) of this regulation.
- (22) "Resident agent" has the meaning stated in Corporations and Associations Article, §1-101, Annotated Code of Maryland.
- (23) "Residential" means the setting of a community-based program in which program participants both reside and receive behavioral health services.
- (24) "Secretary" means the Secretary of the Maryland Department of Health or their designee.
- (25) "Site" means the location where the organization operates the program as detailed on the program's license.
- (26) "Variance" means an alternate method of meeting the intent of a regulation under this subtitle as approved by the Administration.

## **.02 License Application Process for All Community-Based Behavioral Health Programs.**

A. An organization seeking to operate a program to provide community-based behavioral health services shall submit an application for licensure to the Administration or its designee in the manner specified by the Administration.

B. The application shall, at minimum, provide the following information:

- (1) The services the organization intends to provide at the program site;
- (2) Verification of the organization's compliance with all applicable requirements for the program under this subtitle; and
- (3) Attestation of the organization's compliance with relevant federal, State, or local ordinances, laws, regulations, and orders governing the program.

C. The applicant shall report the following information regarding the organization seeking licensure:

- (1) A listing of all individuals or entities with an ownership stake in the organization;
- (2) A listing of the names and contact information of all corporate officers of the organization, including board members;
- (3) Contact information including:
  - (a) The name and email address of a designated point of contact;
  - (b) A mailing address; and
  - (c) The contact information for the organization's resident agent; and
- (4) A copy of any program license or certification currently or previously held by the organization.

D. The applicant shall complete a disclosure form in the manner specified by the Administration that discloses, at minimum, the following information for individuals or entities with an ownership stake, corporate officers, key staff, or any additional individuals specified by the Administration:

- (1) Any deficiencies or compliance violations issued by an accreditation organization or licensing entity;
- (2) Any suspension, revocation, or termination of a license;
- (3) Any criminal convictions other than minor traffic violations;
- (4) Any settlements with the Department's Office of the Inspector General; and
- (5) Any money owed to the Department.

E. The applicant shall include with the application all documentation required in §§B—D of this regulation and any additional program specific documentation as set forth in the chapter of this subtitle outlining the program description.

F. Additional Application Requirements for Organizations Requiring Accreditation.

- (1) An applicant applying for an accreditation-based license shall submit the following with the organization's application:
  - (a) The program's most recent behavioral health accreditation survey report;
  - (b) The final letter or certificate issuing accreditation to the organization; and

(c) The findings, reports, and program improvement plans arising from any accreditation survey or decision by any behavioral health accreditation organization during the previous 3 years.

(2) An organization currently operating a program with a plan of correction approved by an approved accreditation organization shall provide:

(a) A copy of the plan of correction; and

(b) Documentation demonstrating that the organization's program currently complies with the plan of correction.

G. As part of the license application process, the Administration may request that an organization submit to an inspection of the program site prior to issuing a license.

#### **.03 Documentation to Accompany License Application.**

A. Applicants shall include the following documentation with their application for licensure to operate a program to provide community-based behavioral health services:

(1) A copy of the agreement to cooperate between the organization and the appropriate local authority as described in COMAR 10.63.01.10;

(2) Copies of all applicable permits required by local jurisdictions and the Administration, including, at a minimum:

(a) Fire permits; and

(b) Use and occupancy permits;

(3) A copy of the organization's current by-laws and articles of incorporation;

(4) A copy of the organization's certificate of status from the State Department of Assessments and Taxation, verifying the organization is in good standing, issued within the current tax year of the application;

(5) A copy of the organizational chart for the organization and program showing the supervisory structure which includes the names, roles, professional titles, and credentials of all required management staff and other required staff;

(6) Documented verification that the program site is:

(a) Owned or leased by the organization;

(b) Under the sole control of the organization; and

(c) Not prohibited from providing behavioral health services on the site;

(7) A copy of the organization's business plan and 1 year operating budget; and

(8) A copy of the organization's plan for continuity of operations in the event of:

(9) Loss of key staff;

(a) Loss of ability to provide services for any reason; or

(b) Loss of facility.

B. Any organization currently operating a community-based behavioral health program with a plan of correction approved by the Administration or local authority shall provide documentation demonstrating the organization's compliance with the plan of correction.

C. Any organization seeking licensure for a program that will prepare or serve food shall provide a copy of its commercial kitchen license for the program or the caterer that is providing food.

D. Additional Documentation.

(1) The Administration may determine additional documentation is necessary to evaluate a license application.

(2) Upon request, the organization shall provide any additional documentation requested by the Administration.

#### **.04 Issuance of License.**

A. The Administration or its designee shall review all completed applications for licensure.

B. If the Administration or its designee determines that the application meets the requirements of this subtitle to provide community-based behavioral health services, the Secretary shall issue a license to the organization to operate a program to provide community-based behavioral health services that specifies the:

(1) Programs that the applicant is licensed to provide, including the addresses of all licensed program sites;

(2) Duration of the licensure period;

(3) If applicable, the name of the accreditation organization; and

(4) Date of issue.

C. Notifications of Licensure.

(1) The Administration shall notify the applicable local authority when an organization has been issued a license to operate a program to provide community-behavioral health services.

(2) The Administration shall post a license listing on its website that describes the following for each licensed program:

(a) The name of the organization operating the program;

(b) The licensed program type;

(c) The effective dates of licensure; and

(d) Contact information:

(i) For non-residential programs, the licensed program site address; or

(ii) For residential programs, the contact address which is provided by the organization.

D. Each organization shall ensure that the license is posted in a public area at the licensed program site.

#### **.05 Duration of License.**

*A. A license is effective on the date issued as it appears on the license and remains in effect for the duration of the license period.*

*B. Unless modified by the Secretary for good cause, the license period is:*

*(1) For an accreditation-based license, the duration of the accreditation period plus 3 months; or*

*(2) For all other licenses, the period established by the Administration at the time the license was issued, which is not to exceed 3 years.*

*C. The Secretary may, at the Secretary's discretion and with notice to the organization, issue an extension or modify a license expiration date.*

#### ***.06 License Renewal.***

*A. An organization seeking to continue operating a program beyond the program's current license period shall submit a new application in accordance with Regulation .02 of this chapter.*

*B. The application shall be received by the Administration or its designee at least 40 business days, but no more than 120 business days, before the expiration of the organization's current license.*

*C. Failure to Submit a Timely Application.*

*(1) If the organization does not submit a new application in a timely manner, as described in §B of this regulation, the Secretary may suspend the organization's license at the end of the current license period.*

*(2) If an organization's license is suspended, the organization shall proceed with enacting an unplanned discontinuation of services as outlined in COMAR 10.63.01.13.*

*D. License Renewal for Organizations with Sanctions.*

*(1) For any organization that is subject to a plan of correction or sanctions under COMAR 10.63.09 the organization may request a temporary license extension to address any deficiencies at least 40 business days prior to the expiration of the organization's current license.*

*(2) The Secretary may grant a temporary license extension, not to exceed 60 business days, to allow the program to perform any corrective actions to address deficiencies or sanctions.*

*(3) An organization operating under a temporarily extended license may submit a new license application in accordance with §A of this regulation once they have addressed all deficiencies or sanctions.*

*(4) The Secretary may deny a license for any organization that has:*

*(a) Failed to address program deficiencies which present a risk to the health and safety of program participants; or*

*(b) Failed to comply with a plan of correction, directed plan of correction, or sanction in accordance with COMAR 10.63.09.*

*E. The effective date and duration period for the license is established in accordance with Regulation .05 of this chapter.*

*F. An organization's previously issued license expires the day prior to the effective date of the newly issued license.*

#### ***.07 Administrative Withdrawal.***

*A. The Administration may withdraw an application for licensure submitted to the Administration when:*

*(1) The Administration cannot make a determination on the application due to incomplete information or missing required documentation;*

*(2) The Administration has attempted to contact the applicant using the contact information provided in accordance with Regulation .02C(3) of this chapter to complete the application or obtain the missing documentation; and*

*(3) The applicant has not supplied the Administration with completed information within 30 business days of notification that the application is incomplete or that additional documentation is required.*

*B. The Administration shall notify the organization when an application for licensure has been administratively withdrawn.*

*C. An applicant whose application is withdrawn in accordance with this regulation may submit a new application in accordance with Regulation .02 of this chapter.*

*D. An applicant whose application is withdrawn in accordance with this regulation may not submit more than two applications for the same program in one calendar year.*

*E. An administrative withdrawal of an application is not a denial as described in Regulation .08 of this chapter and may not be appealed in accordance with COMAR 10.63.09.09.*

#### ***.08 Denial of License to Provide Community-Based Behavioral Health Services.***

*A. The Secretary may deny a license to any applicant that does not sufficiently demonstrate its ability to meet the requirements of this subtitle to provide community-based behavioral health services.*

*B. When determining the applicant's capacity to operate a program in accordance with the requirements of this subtitle, the Secretary shall consider, at minimum, the following:*

*(1) If the applicant or any of the individuals listed under COMAR 10.63.06.02C(1) and (2) have:*

*(a) Had a previous license revoked by the Administration or other licensing authority, or has surrendered or defaulted on a license for disciplinary related reasons; or*

*(b) Discontinued operations of another program without complying with the requirements of COMAR 10.63.01.13;*

*(2) If the information the applicant disclosed in accordance with COMAR 10.63.06.02D would indicate an inability of the applicant to safely operate a program;*

*(3) Any loss or denial of accreditation status by an accreditation organization;*

*(4) Any outstanding debts or financial obligations of the organization; and*

(5) Any criminal convictions of the applicant or any of the individuals listed under COMAR 10.63.06.02C(1) and (2), in accordance with §D of this regulation.

C. The Secretary shall deny any application that meets one or more of the following criteria:

- (1) The applicant failed to disclose information in accordance with COMAR 10.63.06.02D;
- (2) The applicant intentionally falsified information provided in connection with any application to the Department;
- (3) A continuing course of conduct of material non-compliance with applicable statutes and regulations; or
- (4) A pattern of submission of false information to the State or its designees in order to:
  - (a) Obtain medical necessity authorizations for service; or
  - (b) Obtain payment.

D. In making a determination about a license application from an applicant with a criminal record, the Secretary shall consider the following factors:

- (1) The age at which the crime was committed;
- (2) The circumstances surrounding the crime;
- (3) The length of time that has passed since the crime;
- (4) Subsequent work history;
- (5) Employment and character references; and
- (6) Other evidence that demonstrates whether the applicant poses a threat to the health or safety of program participants.

E. If the Secretary denies licensure, the Administration shall give written notice of the denial to the applicant.

F. The notice of the denial of an application for a license shall include:

- (1) The reason for the denial of licensure;
- (2) The effective date of the denial; and
- (3) Notice that the program has a right to a hearing in accordance with COMAR 10.63.09.09.

#### **.09 License Modification.**

A. An organization shall submit a written request to the Administration, in the manner required by the Administration, before adding or closing a program site, or otherwise altering the services provided at a licensed program site.

B. A written request for program modification shall, at minimum, include the following:

- (1) An application for program modification in the manner required by the Administration;
- (2) Documentation indicating that the organization has notified the appropriate local authority of the proposed program modification;
- (3) Documentation indicating that the organization has notified any program participants of the proposed change in program site; and
- (4) If the program operates in accordance with an accreditation-based license, documentation indicating that the organization has notified the appropriate accreditation organization of the proposed program modification.

C. Prior to approval for any modification described in this regulation, an organization's program site may be inspected by the Administration or its designee.

D. Relocation.

- (1) A license modification does not include the relocation of a licensed program to a new program site.
- (2) An organization seeking to relocate operations of a licensed program to a new program site shall:
  - (a) Initiate a discontinuation of program operations in accordance with COMAR 10.63.01.13; and
  - (b) Submit a new license application in accordance with Regulation .02 of this chapter.

E. If an organization adds or closes a program site, or otherwise alters the services provided at a licensed program site without prior approval from the Administration, the Secretary may suspend the organization's license in accordance with COMAR 10.63.09.05.

#### **.10 Variances.**

A. An organization shall request a variance from the Administration if:

- (1) The organization is unable to meet the requirements of any regulation under this subtitle for any program it operates; and
- (2) The organization intends to request the Administration to temporarily exempt an organization from the requirements of any regulation under this subtitle.

B. An organization seeking a variance shall request the variance from the Administration within 40 business days unless the timeline for reporting the occurrence to the Administration as required by this subtitle is sooner.

C. The Administration may grant a variance to any organization operating a program providing community-based behavioral health services licensed in accordance with this chapter for any regulation under this subtitle.

D. The organization shall submit a written request for a variance in the manner determined by the Administration.

E. Granting Variances.

- (1) The Administration shall review completed variance requests and determine if the intent of the regulation to which a variance is sought is met by the alternative proposed by the organization.
- (2) The Administration shall respond to all variance requests with a written notice that:
  - (a) Provides the organization with the decision on the request for a variance, including the justification the Administration used to reach the decision;
  - (b) Provides the timeframe for which the variance is granted; and

- (c) Is shared with the relevant local authority.
- F. A variance is applicable to a single licensed program site and is non-transferable.
- G. Failure to comply with any conditions under which the variance is granted may result in revocation of the variance.
- H The Administration may not grant a variance:
  - (1) That would endanger the health or safety of the individuals served;
  - (2) For any accreditation standard; or
  - (3) For any State, local, and federal laws and regulations other than those governed under this subtitle.
- I. Variances are granted at the Administration's discretion and may not be appealed.

## **10.63.09 Corrective Actions and Sanctions**

Authority: Health-General Article, §§7.5-205(a)(2), 7.5-402, and 19-333—19-339 Annotated Code of Maryland.

### **.01 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) "Accreditation organization" means a private entity that conducts inspections and surveys of health care facilities or health care staff agencies based on nationally recognized and developed standards that is approved by the Secretary in accordance with Health General Article, §19-2302, Annotated Code of Maryland.
- (2) "Accreditation" means the approval granted to a program by an accreditation organization.
- (3) "Accreditation-based license" means a license which requires that the organization be accredited by an approved accreditation organization.
- (4) "Administration" means the Behavioral Health Administration within the Department that provides oversight to organizations that are licensed in accordance with this subtitle.
- (5) "Behavioral health services" means prevention, screening, early intervention, treatment, recovery, support, wraparound, and rehabilitation services for individuals with substance-related disorders, addictive disorders, mental disorders, or a combination of these disorders.
- (6) "Business day" means any day except Saturday, Sunday, or a State holiday.
- (7) "Community-based" means a setting of a behavioral health services program that is not located in a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland.
- (8) "Corrective Action" means specific actions undertaken by an organization to address a violation of any local, state, or federal law or regulation.
- (9) "Deficiency" means a failure to meet an accreditation, licensure, or certification standard, or a relevant federal, State, or local ordinance, law, regulation, or building code, as applicable.
- (10) "Department" means the Maryland Department of Health.
- (11) "Guardian" has the meaning stated in Estates and Trusts Article, §13-101, Annotated Code of Maryland.
- (12) "License" means an authorization issued by the Secretary permitting an organization to operate a behavioral health program at a specific site in the State.
- (13) Local Authority.
  - (a) "Local authority" means the designated county or multicounty authority responsible for planning, managing, and monitoring publicly funded mental health, substance-related, or addictive disorder services.
  - (b) "Local authority" includes the:
    - (i) Core service agency as defined in Health General Article, §7.5-101(g), Annotated Code of Maryland;
    - (ii) Local addictions authority as defined in Health General Article, §7.5-101(j), Annotated Code of Maryland; and
    - (iii) Local behavioral health authority as defined in Health General Article, §7.5-101(k), Annotated Code of Maryland.
- (14) Material and Egregious Violation.
  - (a) "Material and egregious violation" means any course of conduct, including a single incident, that may cause a program, individual, or organization to fail to comply with any statutory, regulatory, or contractual requirement.
  - (b) "Material and egregious violation" includes but is not limited to:
    - (i) Fraudulent or other behavior which influences or may influence the payment or receipt of money or other property;
    - (ii) Practices which affect or may affect the health or safety of any individual; or
    - (iii) Practices which violate or may violate participant rights.
- (15) "Notice of deficiencies" means the notice provided by the Administration to an organization regarding any deficiencies, including a violation of any local, State, or federal law or regulation.
- (16) "Organization" means an association, partnership, corporation, unincorporated group, or any other legal entity licensed to operate a program to provide community-based behavioral health services.
- (17) "Participant" means an individual receiving behavioral health services in a community-based program.
- (18) "Plain language" means language which is easily understandable by program participants and takes into account the various levels of education and understanding of the population.

- (19) "Plan of Correction" means an organization's written plan of corrective actions to address program deficiencies.
- (20) "Program" means a named set of services operated by an organization inclusive of:
- (a) A substance-related disorders program as defined in Health General Article, §7.5-101(q), Annotated Code of Maryland;
  - (b) A mental health program as defined in Health General Article, §7.5-101(m), Annotated Code of Maryland;
  - (c) An addictive disorders program; and
  - (d) A combination of §B.(20)(a)—(c) of this regulation.
- (21) "Secretary" means the Secretary of the Maryland Department of Health or their designee.
- (22) "Site" means the location where the organization operates the program as detailed on the program's license.
- (23) "Summary suspension" means the indefinite suspension of an organization's license taken if the Secretary believes emergency action is necessary to protect the public health, safety, or welfare.

### **.02 Notice of Deficiencies.**

A. If the Administration intends to take action after a determination that an organization licensed to operate a program that provides community-based behavioral health services has violated any provision of this subtitle, including any material and egregious violation of local, State, or federal law or regulation or any accreditation standard, the Administration shall provide the organization with a notice of deficiencies.

B. The Administration's notice of deficiencies provided to the organization shall include:

- (1) A citation to each statute, regulation, or ordinance violated;
- (2) The basis for determining the violation; and
- (3) Any intermediate sanctions imposed due to the deficiencies.

C. Plan of Correction.

(1) The organization shall submit a plan of correction to the Administration within 10 business days of receipt of the notice of deficiencies, stating:

- (a) The corrective action which will be undertaken to address the deficiency;
- (b) The individuals in the organization responsible for the corrective action;
- (c) The timeline for the corrective action, including a date of resolution; and
- (d) How a recurrence will be prevented.

(2) If the Administration determines the nature of the deficiency warrants a more immediate response, the Administration may require that the plan of correction be submitted sooner than 10 business days after receipt of the notice of deficiencies.

(3) The Administration may grant an extension, not to exceed 20 business days, for the submission of the plan of correction.

D. Notification Requirements. If the Administration issues a notice of deficiencies to an organization in accordance with §A of this regulation, the organization shall, within 10 business days of receipt of the notice:

- (1) Provide program participants or their guardians with a written plain language summary of the notice of deficiencies;
- (2) Provide the Administration with a copy of the notice which was provided to program participants; and
- (3) If applicable, provide a copy of the notice of deficiencies to the organization's accreditation organization.

### **.03 Directed Plan of Correction.**

A. If the Administration determines that an organization licensed to operate a program that provides community-based behavioral health services has violated any provision of this subtitle, including any material and egregious violation of local, State, or federal law or regulation, the Administration may impose a directed plan of correction on the organization, in addition to any intermediate sanctions imposed in accordance with Regulation .04 of this chapter.

B. A directed plan of correction may include the following:

- (1) Mandated staffing patterns which may specify the number of personnel and personnel qualifications;
- (2) Imposition of a site monitor; by which the Administration, or its designee, maintains an ongoing physical presence to provide assistance and evaluate the extent of the organization's progress in correcting violations;
- (3) Submission of reports at the frequency stated by the Administration outlining the organization's progress in correcting violations; or
- (4) Other requirements at the discretion of the Administration to ensure the health, safety, or welfare of program participants.

C. Termination of Directed Plan of Correction. A directed plan of correction may be terminated when:

- (1) All conditions of the directed plan of correction are met at the satisfaction of the Administration; or
- (2) The Administration determines that progressive disciplinary action is warranted in accordance with Regulations .04–.06 of this chapter and revokes or amends the directed plan of correction.

D. Notification Requirements. If the Administration issues a directed plan of correction to an organization in accordance with §A of this regulation, the organization shall, within 10 business days of receipt of the directed plan of correction:

- (1) Provide program participants or their guardians with a written plain language summary of the directed plan of correction;
- (2) Provide the Administration with proof of the notice which was provided to program participants; and
- (3) If applicable, provide notice of the directed plan of correction to the organization's accreditation organization.

### **.04 Intermediate Sanctions.**

A. If the Administration determines that an organization licensed to operate a program that provides community-based behavioral health services has violated any provision of this subtitle, including any material and egregious violation of local, State, or federal law or regulation, the Administration may take one or more of the following actions as an intermediate sanction:

(1) Prohibit the organization from providing community-based behavioral health services to any additional individuals not currently receiving services with the organization's licensed program;

(2) Require the organization to reduce the number of program participants currently receiving behavioral health services;

(3) Restrict the organization's operated program to specified behavioral health services;

(4) Require the organization or any of its staff to receive mandatory training in identified areas within specific timeframes at the organization's expense;

(5) Require the organization to use the services of an Administration approved consultant at the organization's expense;

(6) Require the establishment of an escrow account that shall be utilized for specific, identified purposes at the direction of the Administration;

(7) Impose a civil money penalty in accordance with COMAR 10.63.08; or

(8) Require the organization to take any other intermediate action determined necessary by the Administration.

B. The Administration may impose an intermediate sanction in lieu of or in addition to:

(1) A notice of deficiencies in accordance with Regulation .02 of this chapter; or

(2) A directed plan of correction in accordance with Regulation .03 of this chapter.

C. Notification Requirements. If the Administration issues a directed plan of correction to an organization in accordance with §A of this regulation, the organization shall, within 10 business days of receipt of the notice of the intermediate sanction:

(1) Provide program participants or their guardians with a written plain language summary of the intermediate sanction;

(2) Provide the Administration with a copy of the notice which was provided to program participants; and

(3) If applicable, provide notice of the intermediate sanction to the organization's accreditation organization.

D. If an intermediate sanction requires a program to discontinue services to current or new program participants, an organization shall discontinue operations in accordance with COMAR 10.63.01.13B.

#### **.05 Summary Suspension.**

A. The Secretary may order a summary suspension of an organization's license to operate a program providing community-based behavioral health services if:

(1) The organization violated any provision of this subtitle, including any material and egregious violation of local, State, or federal law or regulation; and

(2) The public health, safety, or welfare imperative requires emergency action.

B. If the Secretary summarily suspends an organization's license to operate a program providing community-based behavioral health services, the organization shall immediately, but no greater than 24 hours after receipt:

(1) Stop providing services to program participants;

(2) Discontinue any enrollment of any new program participants;

(3) Follow the requirements for an unplanned discontinuation of program operations as outlined in COMAR 10.63.01.13B; and

(4) Cooperate with the Administration and local authority regarding any necessary coordination of care.

C. Following the summary suspension of the license of the organization, the Administration shall follow the requirements of State Government Article, §10-226, Annotated Code of Maryland.

D. The organization may request a hearing on the summary suspension in accordance with Regulation .09 of this chapter.

#### **.06 License Revocation.**

A. If the Administration determines that an organization licensed to operate a program that provides community-based behavioral health services has violated any provision of this subtitle, including any material and egregious violation of local, State, or federal law or regulation, the Secretary may revoke the organization's license.

B. If the Administration determines that the organization has failed to adhere to a plan of correction or sanction imposed under Regulations .02—.04 of this chapter, the Secretary may revoke the license.

C. The Secretary shall revoke the license of any organization whose accreditation is terminated, not renewed, or otherwise lost.

D. An organization whose license is revoked may not provide community-based behavioral health services which were covered under the revoked license.

E. If the Secretary revokes a license under this chapter, the Administration shall give written notice of the revocation to the organization.

F. An organization may appeal a revocation in accordance with Regulation .09 of this chapter.

G. The notice of the revocation shall include:

(1) The program site, license number, and program which is being revoked;

(2) The facts that warrant the revocation of licensure;

(3) Notice that the organization has a right to a hearing in accordance with Regulation .09 of this chapter; and

(4) The date upon which the program must cease providing services.

H. Notification Requirements. If the Secretary revokes an organization's license to operate a community-based behavioral health program in accordance with §A of this regulation, the organization shall, within 24 hours of the notice of revocation:

(1) Provide program participants or their guardians with a written plain language notice of the revocation;

- (2) Provide the Administration with proof of the notice which was provided to program participants; and
- (3) If applicable, provide notice of the revocation to the organization's accreditation organization.

I. If the Secretary revokes an organization's license to operate a program providing community-based behavioral health services, the organization shall, by the termination date specified in the notice:

- (1) Stop providing services to program participants;
- (2) Discontinue enrollment of any new program participants; and
- (3) Proceed with an unplanned discontinuation of program operations in accordance with the requirements of COMAR 10.63.01.13B.

#### **.07 Settlement Agreement.**

A. An organization that is licensed to operate a program that provides community-based behavioral health services that has violated a requirement of this subtitle may enter into a settlement agreement with the Department.

B. A settlement agreement between an organization and the Department shall be approved by the Secretary.

C. A settlement agreement is considered a public document and may be disseminated in accordance with General Provisions Article, Title 4, Annotated Code of Maryland.

D. Notification Requirements. Upon execution of a settlement agreement with the Department, the organization shall, within 10 business days of settlement:

- (1) Provide program participants or their guardians with a written plain language summary of the settlement agreement;
- (2) Provide the Administration with proof of the notice which was provided to program participants;
- (3) If applicable, provide notice of the settlement to the organization's accreditation organization; and
- (4) Post the settlement agreement:
  - (a) In a public location at the licensed program site; and
  - (b) On the program's website.

#### **.08 Initiation of Receivership.**

The Secretary may take action to initiate receivership of an organization licensed to operate a program that provides community-based behavioral health services in accordance with the requirements outlined in Health-General Article, §§19-333—19-339, Annotated Code of Maryland.

#### **.09 Right to a Hearing on Proposed Sanctions.**

An organization licensed to operate a program that provides community-based behavioral health services in accordance with COMAR 10.63.06 which is aggrieved by any of the following actions may appeal the determination by filing a request for an administrative hearing in accordance with Regulation .10 of this chapter:

- A. The denial of an application for a license under COMAR 10.63.06.08;
- B. The summary suspension of a license in accordance with Regulation .05 of this chapter;
- C. The denial of a request for a modification of a license in accordance with COMAR 10.63.06.09;
- D. The denial of a request to discontinue program operations in accordance with COMAR 10.63.01.13;
- E. The revocation of a license for any reason other than loss of accreditation in accordance with Regulation .06 of this chapter;
- F. The imposition of an intermediate sanction in accordance with Regulation .04 of this chapter;
- G. The imposition of a civil money penalty in accordance with COMAR 10.63.08; or
- H. The suspension of a license in accordance with COMAR 10.63.06.06.

#### **.10 Hearing Procedures.**

A. If the Secretary, Administration, or Department proposes to take an action listed in Regulation .09A—H of this chapter, the Administration shall deliver a written notice of the proposed action to the organization's program director for the community-based behavioral health program in accordance with the provisions of COMAR 10.01.03.08.

B. Within 10 business days after receipt of the notice of the proposed action, the organization shall submit to the Administration, at the address identified in the notice provided in §A of this regulation, a written request for a hearing.

C. The organization's request for a hearing shall comply with the provisions of COMAR 10.01.03.06.

D. If the organization does not submit to the Administration a hearing request that is postmarked within 10 business days after the date of the notice provided in §A of this regulation:

- (1) The organization's right to a hearing on the action is waived; and
- (2) The Administration's action shall become final.

E. The Administration may offer the program the opportunity for an informal case resolution conference to attempt to resolve all or some of the deficiencies listed in the notice provided in accordance with Regulation .02 of this chapter.

F. If the organization submits a request for a hearing on a summary suspension in accordance with Regulation .05 of this chapter, the hearing shall take place in accordance with the requirements of State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.

RYAN B. MORAN, DRPH, MHSA  
Acting Secretary of Health