March 27, 2023

Via mdh.regs@maryland.gov

Jourdan Green
Director
Office of Regulation and Policy Coordination
Maryland Department of Health
201 West Preston Street, Room 512
Baltimore, MD 21201

Re: Comments on Notice 22-334-P (10.63) and Notice 22-351-P (10.09.16)

Dear Ms. Green:

Please accept this letter as the formal comments of the Community Behavioral Health Association of Maryland (CBH) on proposed regulations governing the licensing of crisis programs (No. 22-334-P and No. 22-351-P).

CBH is the leading voice for community-based providers serving the mental health and addiction needs of vulnerable Marylanders. Our 110 members serve the majority of those accessing care through the public behavioral health system. CBH members provide outpatient and residential treatment for mental health and addiction-related disorders, day programs, case management, Assertive Community Treatment (ACT), employment supports, and crisis intervention.

Crisis services are a critical component of the state's continuum of care. Crisis care should help individuals facing a mental health or addiction-related crisis to bridge from 988 or emergency rooms into community and/or residential programs in order to help them find stability and, ultimately, recovery and resilience.

CBH is concerned that the proposed regulations will not allow crisis services to effectively function in Maryland's behavioral health continuum of care.

- For crisis stabilization centers, the regulations describe a staffing and facility model that is an "Emergency Department-lite," rather than a community-based stabilization center, and is not supported by the reimbursement rate;
- For mobile crisis teams, the regulations require staffing and response times that will not work in many jurisdictions across the state and are not supported by the reimbursement rate;
- Changes proposed for all licensed programs in 10.63.01 are at odds with the Department's statutory authority, with legislative intent for telehealth and staffing, and are so incomplete that we cannot effectively comment on them.

As detailed in our comments below, CBH asks the Department to sever and withdraw proposed changes to 10.63.01. We offer amendments to the mobile crisis regulations to promote a more flexible approach that aligns with the reimbursement rate, and offer considerations if the Department wishes to proceed with crisis stabilization as proposed in the regulations. Our comments below are divided into following sections:

- 10.63.01 (Requirements for All Licensed Programs)
- 10.09.16 (Conditions for Medicaid Participation for Crisis Programs)
- 10.63.03 (Criteria for Programs Required to Have a License)

Comments on 10.63.01

CBH urges the Department to sever and withdraw proposed changes to the requirements for all licensed programs, reflected in proposed changes to 10.63.01.02 and 10.63.01.05. The proposed changes are not promulgated in their entirety and contain errors whose corrections constitute material changes that will require re-promulgation of the proposed regulations.

CBH and other stakeholders have asked the Joint Committee on Administrative, Executive, and Legislative Review (AELR) to sever proposed changes to 10.63.01 from the remainder of the proposed changes in Notice 22-334-P, and either hold that section pending revision or withdraw it altogether. We incorporate that request and concerns in these comments as well, appended in these comments as Appendix A.

In addition to the concerns and errors articulated in the letter, we ask you to include the following clarifications in your revision of 10.63.01:

Recommendation: Correct or clarify "informed choice"
The proposed regulations define "informed choice," a term that is not subsequently used in the proposed regulations nor in existing regulations. It is unclear if this intended to address the lack of a definition of "informed consent," a term used throughout 10.63, or whether BHA intends to promulgate future regulations applying "informed choice." It is unclear whether the two terms are meant to be interchangeable or have distinct and different applications. Without clarity about the intended application of the term "informed choice," CBH is unable to offer comment

Recommendation: Revise definition of "medications for opioid use disorder""
Similarly, the regulations propose a definition for "medications for opioid use disorder." The definition is confusing. It states that the term "means the use of medications, in combination with counseling and behavioral therapies as defined in Health-General Article, §21-2A-01." That section of code does not contain a definition of medication, counseling or behavioral therapies, so it is unclear what exactly is intended for reference. Moreover, CBH recommends that the Department adopt a plain language standard for regulatory definitions, such that medication means medication,

while medication in combination with other things is defined with separate terminology. Because some participants in treatment choose to pursue medication only, rather than medication in combination with counseling and therapy, it is important to have language that clearly differentiates between the two treatment modalities.

Comments on 10.09.16

The proposed regulations for crisis services require providers to adopt an expensive staffing model with significant built-in costs. The expense of the crisis models outlined in the proposed regulations cannot be sustained by the proposed reimbursement rate. We urge the Department to consider CBH's suggested changes to the regulations described below in order to permit more flexibility and re-evaluate its rate assumptions through more dialogue with the provider community.

A. Recommendation: Reduce assumed mobile crisis productivity of 6 dispatches/day, which is not sustainable in non-metropolitan jurisdictions.

The reimbursement rate reflected in the proposed regulations is not in line with most mobile crisis providers' actual productivity. The fiscal assumptions indicate that each team is assumed to have $1,115,257 in annual revenue; at the proposed hourly rate of $135.80, each mobile crisis team would need to have 22.5 hours billed daily to achieve the projected annual revenue. To achieve this number of billed hours daily, a mobile crisis team would require six dispatches a day (see Table 1).[1]

Table 1 - Mobile Crisis Rate Assumptions

Amount	Assumption
$ 1,115,257	Assumed annual revenue for each mobile crisis team
$ 3,055.50	Daily revenue assumed for each team
$135.80	Proposed hourly rate
22.5	Billed hours needed daily for each team to achieve daily revenue
4	Hours assumed for average mobile crisis intervention
6	Daily client capacity required to achieve hourly revenue

Few mobile crisis teams among CBH member organizations report approaching such productivity, with rural teams reporting significantly less billable interventions. While a mobile crisis team in Baltimore City averaged seven to ten dispatches per day, teams in Frederick, Carroll, Washington counties and an 8-county region on the Eastern Shore each averaged three to four dispatches per

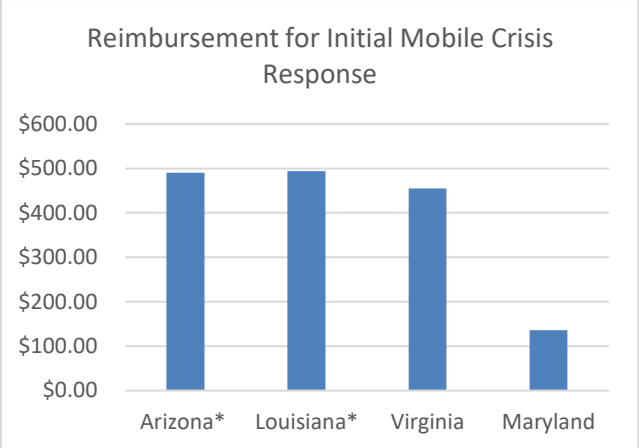
[1] *See* also Mobile Crisis System Work Group minutes at page 5 (Dec. 20, 2022) ("assumption for dispatches per 8-hour shift is two, times three shifts a day times seven days a week. Rolling that up to a weekly amount the assumption is 42").

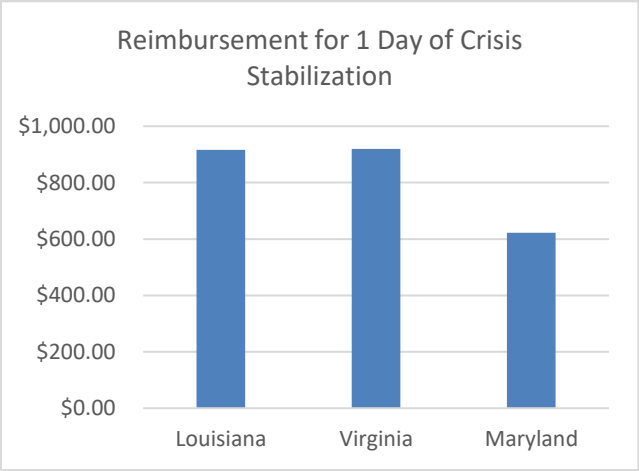
day. This suggests that non-metropolitan areas of the state will not be able to meet the productivity assumptions required to make the rate sustainable.

Overnight productivity is a particular challenge. Calvert County Behavioral Health reported that they averaged 0.6 overnight dispatches, while an eight-county area of the Eastern Shore averaged 0.06 overnight dispatches, translating to a total 21 overnight dispatches *in an entire year*. This is far short of the 22.5 hours needed daily in order to sustain the projected reimbursement rate.[2]

B. Recommendation: Revisit reimbursement and staffing models to ensure sustainable fee-for-service model, or explore other financing models

While there is great variation across states in the staffing and financing model associated with mobile crisis teams, Maryland's proposed rate for the initial hour of response appears much lower than other states that share a 2:1 staffing model for the initial mobile crisis response. Arizona and Louisiana each have a per diem rate in excess of $490, while Virginia's 15-minute increments translate into an hourly rate that is 70% higher than Maryland's proposed rate.[3]





Similarly, Virginia's and Louisiana's per diem rates for crisis stabilization are roughly one-third higher than Maryland's proposed rate, yet appear to have fewer staffing requirements. For example, both Maryland and Virginia require round-the-clock nursing, but Virginia allows nursing staff to be co-

[2] *Id.* at page 8 ("("Paul Galdys: I have been doing this work around the country and … I am concerned. I have not seen anywhere that mobile teams average, three and a half hours per intervention. I agree that they have the downtime and so they probably are serving two or three people a day as they must get to locations and do other things. If you switch that over to the 15-minute increments, I think mobile providers are going to have a difficult time surviving").

[3] *See, e.g.,* Arizona Health Care Cost Commission, "FFS Fee Schedule" (Feb. 1, 2021 effective date); Louisiana Medicaid, "Specialty Behavioral Health Fee Schedule" (undated); Magellan, "VA Medicaid DMAS Rates" (Dec 1, 2021 effective date).

located with other programs,[4] while Maryland requires a minimum of two nurses per shift.[5] Virginia allows the psychiatric evaluation to be completed by a physician assistant,[6] while Maryland requires the evaluation to be completed by a psychiatrist or nurse practitioner.[7] Each of these staffing choices adds cost and reduces flexibility to the crisis model.

A comparison of reimbursement rates for crisis services delivered with similar models in other states suggests that Maryland needs to consider reducing costs through more flexible staffing requirements and/or increasing the rate to support a high-cost and low-productivity service model.

We note that alternative financing models for crisis services exist, such as Certified Community Behavioral Health Clinics (CCBHCs). Under a CCBHC model, existing mobile crisis service providers could partner with a CCBHC as a subcontractor (known as a DCO), and the mobile crisis program's costs can be built into each CCBHC's financing as an administrative cost. The advantage of this approach is that the cost of each mobile crisis team can be customized to the needs of the geographic area and the volumes and response times that their communities need. The CCBHC model thus allows the design and financing of crisis services to differ based on community needs – as Cumberland's needs are very different from Catonsville's. The CCBHC model also builds in care coordination expectations that allow a successful stepdown from crisis care and help prevent a future crisis episode.

C. Recommendation: Allow more flexibility in staffing requirements for crisis services.

In 10.09.16.03, we encourage the Department to consider greater staffing flexibility in crisis programs through a number of changes.

For mobile crisis teams, we recommend the following regulatory changes to improve staffing flexibility:

- Delete the requirement that peer specialists must be certified (COMAR 10.09.16.03C(3)(b)). There are not sufficient certified peers to support staffing mobile crisis teams solely with certified peers. Requiring certification raises the costs and reduces the flexibility of crisis services.
- Delete the provision of the proposed regulations requiring that provider staff must be "pre-approved by the Department" (COMAR 10.09.16.03C(3)(c)). Providers can demonstrate compliance with staff training requirements through mechanisms that do not raise the cost, reduce the flexibility of crisis services, and create potential service delays in ways that a pre-approval process would require.

[4] *See* Virginia, Department of Medical Assistance Services, "Mental Health Services Manual: Appendix G," at p. 29 (Sept. 2022).
[5] COMAR 10.63.03.21F(6).
[6] *Id*. at p. 27.
[7] COMAR 10.63.03.21E(4).

- Amend supervisory requirements to comply with Health Occupations regulations (COMAR 10.0916.03C(4)). The proposed regulations require a mobile crisis team to employ a Board-approved supervisor eligible to supervise all members of the team, and to be available "at all times." Health occupation regulations require supervisors to have the same degree as supervisees, and ensuring round-the-clock coverage of a supervisor adds staffing cost to the proposed model. We recommend deleting "board-approved" and changing "supervise" to "oversee" is order to allow more flexible oversight of the mobile crisis team. We recommend modifying supervisor availability as follows: "Available ~~at all times~~ *during regular business hours* either face-to-face or through telehealth."

We encourage the Department to consider greater staffing flexibility for crisis stabilization centers with the following recommended regulatory changes:

- Allow psychiatric NPs, not just psychiatrists, to serve as medical directors (COMAR 10.09.16.03D(3)(b)). There are not a sufficient number of psychiatrists available in Maryland to serve as medical directors without increasing costs or reducing capacity. This would also be congruent with current statute allowing NPs to function as medical directors of OMHCs.
- In addition to the medical director, the crisis stabilization center is required to have at least three nurses on staff: an NP, a nursing supervisor, and two RNs per shift (COMAR 10.09.16.03(D)(3)). Providers indicate that this level of nursing staff is cost prohibitive with the proposed rates.

D. Recommendation: Allow great flexibility in covered services to reduce costs

CBH recommends that the Department amend the covered services in 10.09.16.05 subsection B and C to incorporate changes supporting three themes:

- Permit greater telehealth flexibility;
- Expand the individuals authorized to complete an initial assessment, such as licensed mental health professionals, doctors, paraprofessionals and peers, as permitted by the evidence-based practice of MRSS; and
- Modify the two-person team response requirement on overnight shifts.

In subsection C for crisis stabilization, we encourage the Department to allow initial assessment to be completed by a broader range of professionals.

These recommended changes are discussed in greater detail in our comments on 10.63.03 below.

E. Recommendation: Delete authorization requirements for crisis services in 10.09.16.07

We encourage the Department to delete subsection .07 in its entirety. The preceding subsection .06 already describes "medical necessity" as one of the limitations for crisis services. Requiring prior

authorization for mobile crisis creates a barrier to the delivery of the service, as participants may be unable to offer the consent and related information necessary to complete an authorization request while in the midst of a crisis. Conducting a *post hoc* authorization for an already-delivered crisis service leaves providers at risk for payment.

Moreover, an authorization standard based on "expected results and cost-effectiveness" is vague and suggests that a mobile crisis team's response may be subject to after-the-fact second guessing. Providers who deliver a medically necessary response in compliance with the regulatory standards should have the assurance that they will be paid.

Comments on 10.63.03

In 10.63.03, the Department proposes new regulations governing mobile crisis teams and crisis stabilization centers. CBH members currently provide grant-funded mobile crisis teams in a majority of Maryland counties, as well as several organizations planning to develop crisis stabilization centers. The feedback from these organizations is that the regulatory framework for both mobile crisis and crisis stabilization is too inflexible, too heavy on staffing and infrastructure, and unsupported by the reimbursement rate. Without a significant rethinking of the regulatory approach to crisis services to resolve these concerns, CBH's members indicate that they would be unable to sustain existing programs once under a Medicaid framework.

A. Overall Comments on Crisis Services

1. Recommendation: Braided funding for uninsured.

Provider experience is consistent with the Department's assumption that only 35% of the individual utilizing crisis services will be Medicaid beneficiaries. For this reason, crisis providers seek to affirm the Department's ongoing commitment to the use of grant funds to deliver crisis services to non-Medicaid beneficiaries. We encourage the Department to provide grant funds to providers up front and reconcile at the end of the year. The volume of Medicaid participant volume and demand will fluctuate, introducing revenue fluctuations and uncertainty into the fixed staffing model of mobile crisis. Upfront grant funding, with reconciliation at the end of the year, can help providers ensure predictable staffing for their mobile crisis programs.

2. Recommendation: Delete vacancy reporting requirements of required staff.

The proposed regulation requires crisis services to report the vacancy of any "required staff," including "licensed mental health professionals" for mobile crisis (COMAR 10.63.03.20I) and a program director, medical director, and nurse manager for crisis stabilization (COMAR 10.63.03.21S). Required staff is defined in COMAR 10.63.02.B(77) as any "staff required to provide

behavioral health services," and must be reported to the Department within 14 days and request a variance within 30 days (COMAR 10.63.01.02I).

CBH incorporates the concerns expressed in the stakeholder letter to AELR about this provision (Appendix A). For the reasons described in that letter, we urge the Department to strike this provision and work with the provider community to develop an alternative approach that meets the Department's policy objectives while balancing the workforce climate facing the provider community.

B. Comments on 10.63.03.20 Mobile Crisis Team Services

1. Recommendation: Expand use of telehealth to improve team flexibility

Under the staffing and response requirements of the proposed regulations, mobile crisis teams may have insufficient staffing at peak hours while being required to maintain excess staffing overnight. Improving flexibility of the staffing model through telehealth gives providers better options for meeting the needs of their community while remaining financially sustainable.

- The proposed regulations indicate that mobile crisis team response shall be in-person (10.63.03.20C(1)). We recommend that this be modified to permit telehealth capabilities under circumstances developed through dialogue with the provider community, as well as the use of paraprofessionals. The reality of mobile crisis is that teams will be stretched by simultaneous calls throughout the day and few calls at night. We recommend modifying 10.63.03.20C(1) as follows: "~~In-person c~~*[C]*ommunity-based professional*, paraprofessional*, and peer intervention services which shall:…"

- The proposed regulations indicate that an assessment shall be conducted "through the use of a telemedicine-assisted assessment" (COMAR 10.63.0.20C(4)(a)). We recommend that the regulations allow telehealth with both audio-only and audio-visual components, subject to the following limitations: "Be conducted in person or through ~~the use of a telemedicine-assisted assessment~~ *telehealth. The mobile crisis team shall have the capability to provide two-way audio/visual communication but may use audio-only if there are broadband or other technology challenges that preclude the use of audio/visual or the participant is not capable of using or does not consent to using a two-way audio/visual communication device*."

2. Recommendation: Expand staffing options to improve team flexibility

In order to bring provider capacity, staffing capabilities and the reimbursement rate into alignment, we offer the recommendations below increase flexible staffing:

- The proposed regulations indicate that the mobile crisis team's assessment must be completed by a licensed mental health professional (10.63.03.20C(4). We recommend that a trained paraprofessional or peer be authorized to conduct the immediate assessment required in the regulations, as allows in the MRSS model: "Assessment: A ~~licensed mental health professional~~ *community-based paraprofessional or peer meeting the training requirements of subsection E below* shall conduct an immediate assessment to determine whether the service is appropriate for the individual. …"

- The proposed regulation indicates that peer and family recovery support specialists must be certified (COMAR 10.63.03.20D(3)(b). Providers currently employ peer and family specialists who are not certified and report difficulty locating specialists with certification. In order to avoid constricting the availability of mobile crisis, we recommend amending this provision by striking the word "certified."

- The proposed regulations indicate that a licensed mental health professional be available to supervise the team (COMAR 10.63.03.20D(2)(b). Under the Health Occupation regulations, professionals can only be supervised by professionals within their same occupational discipline. In order to allow a single professional to manage a team, we recommend amending this provision as follows: "Eligible to ~~supervise~~ *oversee* the member of the team."

- The proposed regulations indicate a response will occur with a two-person team in person (COMAR 10.63.03.20D(1)(a)). In order to promote cost-saving flexibilities, we recommend modifying 10.63.03.20D(1)(a) to allow a single person to respond overnight shifts. Providers can work with the resources available in their communities to ensure adequate safety protocols are in place to support their overnight shifts.

- The proposed regulations indicate that other team staff must be "pre-approved by the Department" (COMAR 10.63.03.20D(3)(c). We recommend deleting this element of the provision as its purpose, standards, and timeframes are not articulated, while creating uncertainty and potential cost implications for providers: "Other staff ~~pre-approved by the Department~~ who shall have completed the training requirements in Regulation .05D of this chapter." We are also uncertain what Regulation .05D is referenced and believe that the proposed regulations may intend to refer the training outlined in COMAR 10.63.03.20E, as no training is referenced COMAR 10.63.03.05D; it would be helpful to clarify what training is referenced.

3. Recommendation: Amend regulations to reflect capacity limitations and participant choice constraints on mobile crisis team deployment.

The proposed regulations incorporate service standards that providers may be unable to meet in all circumstances given real-world constraints. We recommend that the regulations be revised as follows:

- The proposed regulations indicate that mobile crisis teams should be deployed real-time (10.63.03.20C(1)(c)). When a team receives multiple calls at or near the same time, the calls are triaged and response occurs in order of severity. Mobile crisis teams cannot control call volume and cannot ensure real-time deployment if the team is otherwise deployed. We recommend that 10.63.03.20C(1)(c) be amended as follows: "Be deployed in real-time*, or triaged to be deployed at the earliest opportunity,* to the location of an individual in crisis."

- The proposed regulations indicate that mobile crisis teams should be delivered within 60 minutes of determining an individual is in crisis (10.63.03.20C(1)(e)). It is unclear when the determination that an individual is in crisis occurs; is the determination triggered by the call to mobile crisis, the deployment of the team, the team's arrival at the individual's location, or the completion of the assessment? We recommend that the regulation be clarified to exclude travel time and account for a longer response time if a crisis team is already deployed: "Be delivered within 60 minutes of ~~determining~~ *the team's arrival in-person or via telehealth to the location of* an individual in crisis."

- The proposed regulations indicate that follow-up services shall include warm hand-offs (10.63.03.20C(11)(b)(i)), which are defined as ensuring that "the participant has engaged in the services or accessed the resources to which an individual has been referred prior to the referring provider discharging the participation (COMAR 10.63.01.02B(87)). A warm hand-off is not possible in some circumstances. Providers must always be guided by client choice; should a client choose not to avail himself of a referral or resource, the mobile crisis team cannot and should not override that choice. Moreover, mental health services are not always readily available. Waitlists for therapy can extend to three or more months in some areas of the state, while waitlists for specialty services can be even longer. We recommend amending (10.63.03.20C(11)(b)(i) as follows: "Coordination and*, if appropriate and available,* warm hand-off with other service providers."

4. Recommendation: Delete case management if duplication of service is a potential barrier to care.

The proposed regulations incorporate "case management" as a required service for mobile crisis teams (COMAR 10.63.03.20C(6)). Numerous other Medicaid programs with the Department of Health draw down Medicaid dollars for case management services, including Targeted Case Management for adults and children in the public behavioral health system, as well as Medicaid MOM case management and case management with DDA functions. It is our understanding that Medicaid will not pay two different providers to deliver case management to the same individual. If

this rule applies to mobile crisis, we encourage the Department to delete case management from the proposed regulations in order to avoid providers having delivered a service that will not be reimbursable.

C. Comments on 10.63.03.21 Behavioral Health Crisis Stabilization Centers

The proposed regulations for crisis stabilization centers enumerate facility, staffing, and required activities in great detail. They don't clearly describe the qualifying or exclusionary criteria for participants, the purpose, or the result of a crisis stabilization intervention. Possible exclusions may include regulations indicating that crisis stabilization is not appropriate if there is a presence of any condition of sufficient severity to require acute psychiatric inpatient, medical, or surgical care.[8]

The costs associated with the staffing, facility and activities required under the regulations substantially exceed the reimbursement rate. No CBH member who had been planning to pursue licensing as a crisis stabilization center plans to do so without substantial revision to the requirements reflected in the proposed regulations. As one member said, "Our crisis stabilization center is intended to be an alternative to the Emergency Department, not a replacement for it." Providers cited the requirements for four nursing staff and having six staff on-site at all times as among the requirements unsupported by the reimbursement rate.

It is worth noting that the proposed regulations impose requirements in excess of SAMHSA's guidelines:

- SAMHSA's best practice guidelines encourage the use of psychiatrists or nurse practitioners,[9] while the Department requires the use of a psychiatrist as a medical director (COMAR 10.63.03.21F(4));
- While SAMHSA indicates that psychiatrists and NPs may use telehealth, the Department allows telehealth only subject to a staffing plan pre-approved by the Department (COMAR 10.63.03.21E(4), F(2), F(3)).

CBH encourages the Department to create more dialogue with providers about their broad concerns with the crisis stabilization model reflected in the proposed regulations and considering an alternative approach.

Thank you for the opportunity comment on the proposed regulations. If you have any questions or need additional clarification, please do not hesitate to reach out to me. I can be reached at (410) 788-1865 or shannon@mdcbh.org.

[8] *See* Virginia, Department of Medical Assistance Services, "Mental Health Services Manual: Appendix G," at pp. 27-29 (Sept. 2022).
[9] SAMHSA, "National Guidelines for Behavioral Health Crisis Care: A Best Practice Toolkit," at p. 22.

Sincerely,

Shannon Hall
Executive Director

Appendix A: Stakeholder Letter to AELR

March 27, 2023

Joint Committee on Administrative, Executive, and Legislative Review
Annapolis, MD 21401

To Whom It May Concern:

The undersigned organizations respectfully request that the Joint Committee on Administrative, Executive and Legislative Review (AELR) exercise its authority to sever and delay a portion of proposed regulations contained in Notice of Proposed Action No. 22-334-P. If it is not possible to hold the proposed rule, we recommend AELR oppose the rule in its current form and withdraw it. We ask you to take this action because a portion of the proposed regulations is not in conformity with the Department's statutory authority, defeats the legislative intent of the Administrative Procedure Act and the Preserve Telehealth Access Act, and contains other errors warranting substantive correction.

The previous Administration created an environment of regulatory, policy, and operational chaos for Maryland's behavioral health programs. The proposed regulations reflect and exacerbate those challenges in ways that will have negative implications for providers, patients, and other stakeholders. We urge AELR to delay the proposed regulations in order to prevent these harms and to give the incoming Administration adequate time to remedy the problems reflected in this letter.

In Notice of Proposed Action No. 22-334-P, the Behavioral Health Administration has proposed changes to 10.63.01 (requirements for all licensed programs), 10.63.02 (programs required to be accredited), and 10.63.03 (criteria for programs). Although stakeholders plan to submit formal comments on the proposed changes to 10.63.02 and 10.63.03, we have serious concerns about the proposed changes to 10.63.01. Under State Government, § 10-118, the Committee may exercise power to sever a "specific, distinct" provision of a proposed regulation. For the reasons outlined below, we urge the Committee to sever the proposed changes to 10.63.01 from the remaining proposed regulations contained in No. 22-334-P, and delay the adoption of any proposed changes to 10.63.01 until the concerns outlined in this letter are resolved through the promulgation of corrected, complete proposed regulations.

Under State Government, § 10-111.1(b), the AELR Committee's evaluation of a proposed regulation shall include whether the regulation is in conformity with the statutory authority of the promulgating unit, and whether the proposed regulation reasonably complies with the legislative

intent of the statute under which the regulation was promulgated. Proposed changes to 10.63.01 fail both prongs of this standard.

1. **The proposed regulations are not in conformity with BHA's statutory authority.**

Under Health - General, § 7.5-401, the Behavioral Health Administration has statutory authority to regulate a "behavioral health program." The proposed regulations delete the definition of program from the 10.63 definition section.[10] The deletion of a program from 10.63.01.02 leaves the architecture of the entire 10.63 section unmoored.

Programs are the entities required by the existing 10.63 regulations to get licenses, accreditation, conduct employee background checks, adhere to costly staffing standards, and engage in a variety of other critical regulatory activities. As a result, any correction that restores or modifies a definition of program to the proposed regulations will be a substantive change in scope requiring republication of the proposed regulations under State Government, § 10-113(b).

Under MD Code, State Government, § 10-111.1(b), the AELR Committee's evaluation of a proposed regulation shall include whether the regulation is in conformity with the statutory authority of the promulgating unit. Here, BHA has proposed deleting the very term it has statutory authority to regulate, and our request to delay these proposed regulation falls squarely within the Administrative Procedure Act's intended purpose of the Committee's oversight.

2. **The proposed regulations do not reasonably comply with legislative intent and enacted legislation.**

The Preserve Telehealth Access Act of 2021 codified changes to Health General § 15-141.2 to extend the use and payment of telehealth interventions by Maryland health care providers pending further study by the Maryland Health Care Commission. The legislation specifically codified the preservation of telehealth by behavioral health programs licensed by BHA in Health General § 15-141.2(a)(4)(ii). Similarly, HB 1122 passed in 2019, codifying changes that allowed medical directors to fulfill their functions via telehealth. The proposed regulations comply with neither statutory standard.

The proposed regulations limit the definition of "medication monitoring" to "in-person assistance." Medication monitoring involves addressing a client's motivation for medication adherence, addressing medication side-effects, and ensuring medications are taken correctly and timely. Medication monitoring may be effectively delivered through telehealth for some clients. Given expanded coverage of remote patient monitoring, it is possible that components of medication monitoring may also be effectively delivered through new technology. Research supports the

[10] *See* 10.63.01.02B.

efficacy of telehealth in medication management and monitoring,[11] and the Department has offered no rationale for the wholesale elimination of telehealth for medication monitoring.

In addition, the proposed regulations contain a new definition describing "on-site" as presence at a physical location. Applied to existing use of the term in current regulations, this new definition results in a de facto exclusion of telehealth for individuals serving as program directors, medical directors, and in multidisciplinary teams across a variety of programs.[12] The proposed regulations thus appear to violate Health General § 7.5-402(a)(4), which require the Department to promulgate regulations allowing medical directors to meet their onsite requirements via telehealth, as well as the Preserve Telehealth Access Act of 2021.

By eliminating the use of telehealth for medication monitoring in all circumstances and defining "on-site" as physical presence, the proposed regulations do not reasonably comply with the legislative intent of Preserve Telehealth Access Act of 2021 and Health General §§ 7.5-402(a)(4), 15-141.2. Under MD Code, State Government, § 10-111.1(b), the AELR Committee's evaluation of a proposed regulation shall include whether the regulation reasonably complies with the legislative intent of the statute under which the regulation was promulgated.

3. The proposed 10.63.01 regulations require burdensome, vaguely defined reporting requirements that are not rationally tied to a policy objective.

The proposed changes to 10.63.01 include vacancy reporting requirements that are not clearly defined and not tied to an effective oversight framework. The proposed regulations contain new definitions for "required management staff" (including supervisors) and "required staff" (inclusive of anyone required to deliver a service). The proposed regulations require providers to report vacancies for "required management staff" to BHA within 14 days, and request a regulatory variance if the position remains vacant for 30 days. It appears that BHA may intend to further require a program-by-program approach to defining "required staff" subject to the same reporting requirements. Thus, the definitions suggest that potentially *any* vacancy for a supervisory and frontline staff position may be subject to the vacancy reporting requirements and request for a variance from regulations.

Further, it is silent on the status of the provider while awaiting the outcome of the variance request. Given that variance requests for other purposes are already backed up – often for months - we would anticipate a greater backlog given the number of variance requests the new rule would engender. The regulation does not specify whether a provider can continue to operate while

[11] *See* SAMHSA, "Evidence-Based Resource Guide Series: Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders," at p. 19 (2021).
[12] *See* COMAR 10.09.59.04B(5) (requiring program directors to be on-site for 20 hours per week and licensed mental health professionals in outpatient clinics to be on-site 50% of OMHC's regular hours); COMAR 10.63.03.05C (requiring medical director to be on-site for 20 hours per week).

awaiting a variance decision or whose responsibility it would be to find alternative placements for those served by a provider if the request is denied. The proposed rule is silent on the Department's criteria for denying a variance request and depriving a provider of a license based on the scale or duration of its vacancies.

The reporting requirement is set at far less time it takes to fill a vacancy. Vacancies are not filled within 14 days. Some behavioral health positions are subject to nationwide shortages, many areas of Maryland are federally designated as mental health professional shortage areas, and behavioral health providers are facing a workforce crisis. Data from Maryland providers for FY2023 suggests it takes on average:

- 252 days to fill a psychiatric position;
- 90 days to fill a nursing position;
- 100 days to fill a clinic director position;
- 274 days to fill a licensed clinical social worker position; and
- 125 days to fill a therapy position;
- Up to 46% longer to fill vacancies in federally designated mental health professional shortage areas.

It is unclear what policy goals are advanced by providers reporting vacancies at 14 days when the average vacancy is open 12 times longer. The proposed regulation will pose an undue hardship on behavioral health programs given the current workforce challenges and industry standards.

Because the proposed regulation requiring variance requests is not limited to a clearly defined set of job position required by regulation, is not reasonably related to achieving a policy goal, and defines routine industry standards as out of compliance with the regulations, we seek the Committee's support in delaying this provision pending development of a more workable framework by the Department.

4. **Proposed changes to 10.63 have not been promulgated in their entirety.**

The proposed changes to 10.63.01 are materially incomplete, and we are concerned that a piecemeal approach to the promulgation of regulations defeats stakeholders' ability to effective exercise their right to notice and comment.

The proposed regulations contain several new definitions that are not applied and do not appear the existing 10.63 regulations. Newly defined terms with no application include:

- Active treatment;
- Culturally and linguistically appropriate services;
- Cultural and linguistic competency;
- Key staff; and

- On-site in the context of PRP and OMHC programs.

Without concurrent promulgation of any accompanying regulatory changes that apply the new definitions, stakeholders are unable to effectively avail the notice and comments provisions of the Administrative Procedures Act.

In April 2021, BHA licensing staff indicated in writing their intent to change the current regulatory definition of program as an organization to program being a single site. In December 2022, the Department indicated again its intent to promulgate regulations changing the definition of program from organization to site. The regulatory changes described by BHA over the last two years are not reflected in the proposed regulations. And yet, as of March 2023, providers report experiencing licensing challenges and even audit failures that appear to be based on their failure to adhere to a site-based definition of program – *yet no such definition has been promulgated by the Department despite two years of stated intentions*. It is impossible for providers to achieve compliance with unpublished standards.

As published, the proposed regulations do not reflect the scale of changes described by BHA, suggesting that the regulations have not been promulgated in their entirety. Based on the regulations as proposed, it appears that BHA intends to define the scope of telehealth, staff vacancy reporting, and the very definition of program itself individually for each of the 19 different programs regulated under 10.63.

A piecemeal approach to the proposed regulatory changes is insufficient. Stakeholders are unable to comment on the proposed definitions above without understanding how they are applied. In order to promote the ability of stakeholders to effectively exercise their right to notice and comment, we ask the Committee to seek the full promulgation of all proposed changes to the 10.63 regulations.

A sound system of compliance is based on clearly defined and commonly understood rules of the road. The Administrative Procedure Act ensures that the promulgation of regulations that allow providers, patients and other stakeholders of the behavioral health system to promote a culture of compliance.

We seek the Committee's support to sever the proposed changes to 10.63.01 from the remainder of the proposed regulations in order to address the critical concerns raised in this letter. If it is not possible to hold the proposed rule, we recommend AELR oppose the rule in its current form and withdraw it.

Sincerely,

Community Behavioral Health Association of Maryland
Maryland Association for the Treatment of Opioid Dependence
Maryland Addiction Directors Council