



Board of Directors

Suanne Blumberg, President
Upper Bay

Joanie Clement, Treasurer
La Clinica del Pueblo

Karen Carloni, Secretary
So. MD Community Network

Sheldon Bienstock
Mosaic Community Services

Avi Burstein
Behavioral Health Partners of Frederick

Dimitri Cavathas
Lower Shore Clinic

Johnnie Fielding
Leading by Example

Arthur Ginsberg
Community Residences

Kevin Keegan
Catholic Charities

Maxine Klane
University of Maryland

Kylie McCleaf
Jewish Social Services Agency

Sheryl Neverson
Volunteers of America

Anne Peyer
Cornerstone Montgomery

John Plaskon
Crossroads Community

Gordon Raley
Family Service Foundation

Scott Rose
Way Station

Karishma Sheth
EveryMind

Sondra Tranen
PDG Rehabilitation Services

July 30, 2020

Behavioral Health Administration
Maryland Department of Health
201 West Preston Street
Baltimore, MD 21201

VIA Email: bha.regulations@maryland.gov

To Whom It May Concern:

The Community Behavioral Health Association (CBH) of Maryland is the professional association for Maryland's public community behavioral health providers. We are comprised of 75 organizations that support CBH's mission to promote a high-quality system of public behavioral health care for individuals and families in Maryland.

Our 75 members are licensed to provide virtually every covered service in the public behavioral health system and operate in every jurisdiction in the state. Our members serve over 180,000 individuals every year receiving services via the public behavioral health system.

We appreciate the opportunity to comment on the Behavioral Health Association's (BHA) draft revisions to COMAR 10.63 addressing Community-Based Behavioral Health Programs and Services. Given the significant amount of proposed changes and our substantial concerns, we respectfully request that we be able to discuss these comments and your next draft revision before the BHA takes any further steps to promulgate these, or other regulations.

We must however strongly object to the timing of this regulatory rewrite. Like all healthcare entities, behavioral health providers are struggling with the impact of COVID-19 on clients, staff, and the provision of services. Added to that significant burden is the incredible amount of provider time being consumed by problems associated with the administrative services organization transition. At a time when MDH departments are looking for ways to support and ease the burden on hospitals, long-term care, and developmental disabilities providers, there appears to be no recognition of the substantial challenges behavioral health providers now face.



Overall Comments

CBH Supported Accreditation in Lieu of Regulation

When CBH was first approached by MDH with the idea of requiring behavioral health providers to become nationally accredited as part of the licensure process, we were very concerned about the costs – both financial and in terms of staff time – of accreditation. Many of our members were opposed to the accreditation proposal. Some providers, external to CBH, took their opposition to the MD General Assembly. BHA assured us that in exchange for our support, providers would be given more flexibility and the onerous provisions that existed in 10.21 would be eliminated. Based on these representations from BHA, CBH supported the adoption of accreditation-based standards to its membership and to the General Assembly.

A broad stakeholder group met many times to create the new 10.63 regs, which are now subject to this rewrite. Much of MDH's proposed language not only recreates the eliminated provisions under 10.21, but actually goes beyond the old regulations in scope. This certainly constitutes a breach of the agreement between MDH and the provider community.

BHA Should Exercise Existing Sub-regulatory Authority

We begin by acknowledging that BHA is struggling to manage a sharp increase in utilization for psychiatric rehabilitation program (PRP) services. Although a DLS analysis suggests that the majority of Maryland counties have seen a decrease in PRP providers, three counties have recently seen a sharp increase in the number of new PRP programs.

As a 501(c)(3), CBH's mission seeks to improve the quality of care and improve access to it. CBH shares BHA's interest in ensuring that PRP services are delivered only to those eligible to receive the services, and that services are delivered by providers with the infrastructure, knowledge and skill to ensure that their work is high quality.

To the extent that a targeted increase in PRP utilization and targeted growth in providers has occurred in three counties, CBH has previously offered suggestions to BHA for narrowly tailored, sub-regulatory approaches to improve system oversight. Our suggestions included:

- Enforcement of existing medical necessity criteria by ASO vendor;
- Accountability to ensure that LDAs, particularly those in areas with documented provider growth, are adequately performing all required activities, including site visits;
- For providers identified as engaging in questionable behavior, scrutiny of compliance with authorization standards and corporate performance standards for providers identified as engaging in questionable practice;

Given that the state's concerns of rising utilization and provider growth are concentrated in a limited number of jurisdictions and limited provider types, we strongly believe that a targeted enforcement approach may yield faster, more effective benefits.



Overall Comments (Applicable to All Sections)

Our main concern with the draft changes to COMAR 10.63 is that the behavioral health providers involved are already heavily regulated and required to meet detailed licensure and accreditation standards. *See, e.g.,* COMAR 10.09.36.02 and 10.09.36.03 (further discussed below). As opposed to targeting any specific gaps, what the proposed changes to COMAR 10.63 do is layer a completely new set of requirements often quite detailed to the point of micro-management. Under the proposed changes, a violation of even the most minor requirement can lead to loss of licensure or the imposition of civil monetary penalties without any consideration as to the materiality of the supposed violation. The additional layer of requirements the BHA seeks to impose is burdensome and not directly focused on the goals we believe that the BHA is seeking to further. If there is a particular concern that the BHA has, its regulatory efforts should be targeted directly at those particular concerns as opposed to scaffolding another set of regulatory requirements onto a pre-existing and quite detailed regulatory regime.

Excessive Regulations Implicates Parity's Limitations on NQTLs

Another complication stems from mental health parity concerns. As you know, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the Affordable Care Act and the 21st Century Cures Act (Cures Act), now applies to the Medicaid program. In general terms, the MHPAEA requires that the financial requirements and treatment limitations imposed on mental health and substance use disorder (MH/SUD) benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical and surgical benefits. The purpose of MHPAEA is to allow Medicaid enrollees to access these important mental health and substance use services in the same manner as medical benefits. Mental health parity requires that both quantitative limitations (e.g., dollar and visit limits) and non-quantitative treatment limitations (NQTLs) such as medical management techniques applied to mental health and substance abuse benefits must be in parity with the predominant limitations applied to substantially all medical and surgical benefits. In our view, much of the new, proposed changes to COMAR 10.63 implicate NQTL concerns because they impose an additional layer of requirements on behavioral health services.

Nexus Between Purpose and Proposed Regulations

Finally, we also wish to point out that under Maryland law, the BHA has to ensure that the proposed regulations will be effective in accomplishing their intended purpose. Regulatory Review and Evaluation Act (RREA), created by Executive Order and State Government Article, §§10-130 -- 10-139, Annotated Code of Maryland. We believe that the BHA has failed to establish the requisite nexus between the intended purpose of its proposed regulatory changes and the actual changes proposed. To do so effectively, there must be an examination of the requirements already applicable to the affected providers and an analysis of where any gaps exist - - the proposed changes should be specifically targeted toward those gaps in order to ensure that providers do not encounter undue regulatory burdens.



In short, the BHA already has a number of tools at its disposal in the form of regulations already extant and on the books that it could use to promote quality of care and program integrity. If used, we believe that those tools are sufficient and the draft regulations are not needed, overly broad, and improperly burden and target behavioral health providers.

Comments as to Specific Sections

10.63.01 – Requirements for All Licensed Programs

10.63.01.02 – Definitions

Subsection (B)(16) defines a behavioral health professional as a psychiatrist, CRNP-PMH, APRN-PMH, LCSW-C, LCPC, LCADC, or properly supervised LGPC, LMSW, LGADC. This is a significant restriction from the current definition in COMAR 10.21.17.02B(42), which defines a mental health professional as an individual who is licensed, certified or otherwise legally authorized to provide the mental health service under Health Occupations Article, Annotated Code of Maryland. We are concerned that the proposed regulation is overly restrictive and may introduce barriers to care, particularly in areas with professional shortages. We believe that any health professional who can prescribe psychotropic medications should be included in the definition of a behavioral health professional so that they can make referrals to psychiatric rehabilitation programs. This may include, for example, other types of nurse practitioners, higher levels of NPs such as those with doctorates, and primary care professionals to the extent that they are able to prescribe psychotropic medication within the scope of their practice.

Subsection (B)(48) introduces the term “key staff.” This term appears to reference four subsets of individuals: “members of the governing body,” “required staff,” “other staff ... who have significant leadership roles,” and “required management staff.” It is not clear who BHA intends to be defined as “required staff.” Nor is it clear how “required staff” are different from “required management staff,” and who the later term encompasses. It is not clear which staff have “significant leadership roles” that would bring them under the scope of this definition.

“Required management staff” are subject to reporting on vacancy, recruitment, and variance requests in 10.63.01.02I. Later subsections indicate that this definition includes certain positions described in 10.63.03. Beyond those enumerated positions, it is not clear who the Department defines as “required management staff.”

“Key staff” are subject to the provider notifying BHA of their departure in 10.63.01.02J. To the degree that this provision is intended to capture anything beyond the required positions enumerated in 10.63.03, we are separately concerned that it is overbroad. The reporting of any



vacancy of any key staff is simply too broad, too burdensome, and not tied to a concrete policy rationale.

“Key staff,” with “governing body members” and “required management staff” are all separately enumerated to be included in notice with license application if affiliated with any program closure in the previous ten years, per 10.63.06.02A(2)(c)(ii), or if any owe the Department money per 10.63.06.02A(2)(c)(v). Beyond our policy disagreements with these provisions, the terminology is confusing. If the term “key staff” encompasses the latter, it’s unclear why they are listed separately.

The draft language (.02 at (64)) amends the definition of “Program” to mean “the site and service combination which is recognized through licensure to offer an organized system of activities performed for the benefit of persons served.” This “site and service combination” language is vague and confusing, and it is unclear how both the site and service combined, comprising the “Program,” will actually be implemented. The implications of the new definition are unclear because the use of the term “Program” throughout the regulations is not consistent.

10.63.01.05 – Requirements for Licensed Community Behavioral Health Programs

Subsection (C) requires a criminal background check for each employee, contractor, or volunteer every three years for licensure. Criminal background checks are already conducted in the context of other requirements. For example, in the context of Medicaid enrollment requirements federal law requires revalidation to take place at least every five years. 42 C.F.R. § 455.414. That revalidation typically includes criminal background checks. Furthermore, it is not clear from the proposed wording that the regulation would be satisfied by fingerprinting with automatic dynamic reporting to the organization should crimes occur in interim periods between manual checks. Another example of the negative consequences of additional regulation is that often the directives don’t keep current with emerging technology.

Subsection (E) requiring supervision of all staff in accordance with the Health Occupations Code is superfluous. Supervision is typically a function of licensure as this provision acknowledges by referring to the Health Occupations Code. There is no need to reiterate the supervision requirement here.

Subsection 10.63.01.05K restates the existing documentation requirements of COMAR 10.09.59.03D, with subtle word variations. In 10.09.59.03D, for example, documentation must contain the title of the individual providing care. Meanwhile the proposed regulations require the individual’s credentials instead. To avoid redundancy and conflict, documentation requirements should only appear in one section governing the specialty behavioral health sector.

Subsections (I) and (J) as to the requirement of reporting Board, management and staff vacancies is nothing other than micromanagement and interference with a provider’s operations. The language does not align with the realities of fluctuating employment market and the low salaries paid. For example, currently, retention and recruitment is so difficult that this reg would result in almost every provider requesting variances for every vacancy because every vacancy “may remain vacant more than 60 days.” The proposed timeframe does not allow sufficient time to advertise openings,



recruit and interview applicants, make an offer and have an applicant provide notice at their current employment. Without sufficient time to capture replacement of routine turnover, the regulation will not capture extended vacancies that could have a negative impact on provider operations. Furthermore, this penalizes all providers acting in good faith to fill vacancies during a workforce shortage, rather than targeting those who may leave vacancies unfilled for extended periods.

Subsection (K) which requires certain documentation and medical record standards is also redundant. The conditions for participation in the Medicaid program applicable to all Medical Assistance providers set forth at COMAR 10.09.36.03 (A)(9) already requires providers to “[m]aintain adequate records for a minimum of 6 years and make them available, upon request to the Department or its designee.” While providers must maintain documentation of billable encounters, the proposed regulation requires documentation of each contact, regardless of whether it was billable or not. It is unclear what this expanded policy is intended to achieve.

Requirements for electronic signatures under subsection (K)(5)(b) are incompatible with the current functionality of providers’ electronic medical records. In addition, some of the proposed change is infeasible. For example, many EMRs do not have the capacity to implement K(5)(b) (linking the electronic signature to the data “in such a manner that, if the data are changed, the electronic signature) is invalidated”). This requirement, which is technologically infeasible for many appropriate EMRs is not necessary in light of K(5)(a) which ensures integrity through an audit record. We would welcome the opportunity to work with the Department to develop language that is compatible with existing EMR functionality and controls for signature security.

Other examples of micromanagement and redundant requirements are set forth in Sections (L) and (M). Section L requires that unlicensed staff be W-2 payroll employees of the organizations (presumably as opposed to Form 1099 contractors) and that adequate timekeeping records are maintained and made available to the BHA. It is unclear why a provider could not hire temporary staff in the form of 1099 contractors provided that Internal Revenue Service (IRS) rules were being met. This regulation removes a provider’s discretion to make that choice where available. Taking away a provider’s discretion to meet staffing needs as appropriate does not further quality of care or program integrity considerations, and does threaten the ability to fill vacant positions amid known workforce shortages.

Section (M) also requires timekeeping records to be maintained and made available. The BHA and its lawful agents already have the right to review a provider’s records and a number of other laws require providers to keep accurate time records. It is unclear why those requirements need to be reiterated as part of the licensure requirements.

10.63.02 – Programs Required To Be Accredited

COMAR 10.63.02.03(C) includes new language specifying that a program with an accreditation-based license may only serve the population for which it is accredited. In our view this would limit programs with such accreditation-based licenses from operating non-accredited programs such as targeted case management or capitation programs. We do not believe that to be the BHA’s intent. We believe clarification of the proposed language is in order.



10.63.03 – Criteria for Programs Required to Have Accreditation-Based License

Several subsections within 10.63.03 require programs to have a clinical director approved by the Board of Professional Counselors and Therapists to supervise alcohol and drug counselors. *See, e.g.,* 10.63.03.03(D) (for IOP), 10.63.03.06(D) (for Level 1), 10.63.07(D) (for partial hospitalization), 10.63.02.11(F) (residential programs). We recommend instead that the language reflect that the clinical director be authorized under the Health Occupations article to oversee substance use program services.

We note that the Board of Social Work Examiners takes the position that LCSW-C may oversee and provide SUD treatment. Stanley E. Weinstein, Ph.D., LCSW-C, Executive Director, Maryland Board of Social Work Examiners, noted in a March 20, 2020, communication, “The LCSW-C is the highest level of licensure for social work and enables the social worker to practice clinical social work at the independent level. We do not credential specific areas of practice, but we state that one should only practice in areas they have been properly trained. So using your question to me, an LCSW-C social worker properly trained can oversee and provide services in a Level 1 Outpatient Substance Abuse Program.”

10.63.03.04 Mobile treatment services program

Subsection .04 for mobile treatment services raises several concerns. First, (A)(2) is already required by both accreditation standards and fidelity standards, so its incorporation here is redundant. incorporate elements of the fidelity standards without increasing reimbursement for the services to the fidelity level.

Subsection (C) is vague and, without additional detail, cannot be evaluated. It is unclear if the state is referring to the TMACT, DLA or other anticipated tool or tools to be required of providers.

Subsection (E) appears to re-state regulatory standards at COMAR 10.09.59.04B(3)(b). It has not been modified to conform to this subsection. Its replication here is redundant.

Subsection (I) requires a provider to report to BHA if the provider is not meeting fidelity standard. Providers disagree often with BHA’s determination that they may not be meeting the fidelity standard. Given the difference in training, experience, and subjectivity, the state’s and provider’s fidelity scoring is rarely in alignment. As a result, is unclear what is intended and how this would be enforced.

10.63.03.05 Outpatient mental health center

Subsection (D) appears to place the medical director in the role of ensuring regulatory compliance, a role more often assigned to clinical directors. The existing language, tasking the medical director



with responsibility for clinical services, is in line with the job description and functions of medical directors employed by CBH members.

Subsection (D)(3) requires the medical director to be onsite for compliance purposes, while allowing the director to conduct clinical oversight via telehealth in (D)(5). We believe that this is an inappropriate narrowing of the statute, which requires the Department to allow medical directors to perform functions via telehealth.

The onsite requirement in subsection (D)(3) is a significant change in scope from existing practice. Currently, the medical director's commitment is only to the organization as a whole; this appears to expect the medical director to be onsite at each program location. Given the role of the medical director and the availability of telehealth, this is unnecessary. It is also too vague to know how BHA will interpret a standard for sufficiency to ensure compliance.

10.63.03.09 Psychiatric rehabilitation program for adults

Subsection (B)(1) is impractical for several reasons. First, it requires an external Mental Health Professional, probably paid via a fee-for-service system, to perform and document a special clinical assessment of the medical necessity for continued PRP services. That is very different from rendering a professional opinion regarding the need. Adding this burden to MHPs will likely mean that more MHPs don't respond to requests for referrals, and then PRPs will need to abandon individuals in need of PRP services simply because an MHP did not respond either way.

Second, it is unclear what it means to "not work in or receive a remuneration in any form from the PRP." While we support the underlying principle at issue here, CBH would like to work with the Department on language that meets the Department's goals with greater clarity.

Subsection (B)(2) requires mental health professional to reassess and certify ongoing need for services every six months. Past practice allowed either signed referrals or attestations documenting the collaboration between the PRP and the referring clinician. Given the impact of COVID we urge that continued flexibility be allowed.

Subsection (D)(1)(b) limits supervision to only individuals who are employees of the organizations. In rural areas of the state where there are documented health professional shortages, such limitations may have the result of reducing access to care. As long as supervision occurs within the parameters of the Health Occupations Act, it is not appropriate for BHA to limit who has the ability to supervise. Adding the BA requirement for Rehabilitation Specialist in subsection (D)(2) is new so should have a two-year grandfather allowance to allow providers to come into compliance.

We note that subsection D(3)(c) allows an occupational therapist to be a rehabilitation specialist for a PRP program. We support the inclusion of OTs in this capacity. However, we note that in 2018, Medicaid deleted occupational therapists from the Medicaid state plan and from the list of practitioners in COMAR 10.09.59.04A(2)(e). Although occupational therapists are not independently reimbursed, we are concerned that deleting reference to them from 10.09.59 raises the potential



for excluding these individuals from employment in community behavioral health settings, particularly as adult services are not duplicative of the EPSDT regulations. We encourage BHA to ensure that the work of occupational therapists in rehabilitation settings is clearly authorized by the Medicaid state plan and COMAR regulations.

Subsection (H) requires a licensed site in every jurisdiction from which a PRP draws more than 10 clients. Providers with locations near county lines can't be expected to establish a site across the line merely because 10 clients live two miles on the other side of the line. A feasible solution would be to require contiguous jurisdictions or mile radiuses.

10.63.03.16 Supported employment program

Adding the BA requirement for Supported Employment Director in subsection (D)(1) is new so should have the same two-year grandfather allowance as Rehabilitation Specialist.

10.63.03.10 Psychiatric rehabilitation program for children

We echo our concerns expressed for adult PRP as outlined above.

10.63.04 – Additional Requirements for Accreditation-Based Licenses for Specific Residential Community-Based Behavioral Health Services

This section 10.63.04.2 A needs to be changed to align with the state group home statute (Health General Article 10-514) that was amended in 2017 to allow small group homes to serve up to nine individuals (as opposed to eight) and large group homes to serve 10-16 (as opposed to 9-16).

According to subsection (M) of proposed COMAR 10.63.04.05 providers must render a disposition within five days of receipt of a completed referral. This short timeframe is impracticable and not in the best interest of either the provider or the individual involved. It allows insufficient time for the RRP provider to consult with the appropriate individuals and does not promote quality of care.

Subsection (N) limits the RRP's discretion in rejecting referrals as it requires that denials of admissions "must be based on reasons approved by the [BHA]. The proposed regulation, however, does not adjust an RRP's reimbursement to compensate for the additional liability or expanded clinical staffing that both the shorter referral timeframe and removal of an RRP's discretion in not accepting a referral would require. RRP's are operated by private entities that hold the potential liability for situations that arise involving clients under their care or supervision. As such providers must decide who they can safely serve. We strongly oppose any attempt to restrict providers' autonomy regarding client admissions or discharges.

10.63.04.07 is infeasible because most RRP homes do not have "private space for counseling staff to perform clinical services," and is not practical to expect providers to buy new properties or construction additions.



The new language in COMAR 10.63.04.07(H) addresses dietary services which redundantly require a program to comply with applicable laws. The new language also requires RRP to have a licensed dietician develop and implement the dietary service plan. However, as part of its services, the RRP coaches and supports clients in developing their own meal plans – an important life skill. Requiring a licensed dietician to both develop and implement (whatever that may mean) the dietary service plan is unnecessary and a needless expense (for which the BHA is not compensating the RRP).

10.63.05 – Criteria for Programs Not Required to Have Accreditation-Based License

10.63.05.05(E) requires DUI education instructors to be “supervised as required by law.” This is yet another example of a redundant requirement. Supervision requirements are already built into service providers’ respective licensing requirements.

While DUI Education programs may be conducted online according to the proposed language in subsection (H), the program does require an initial face-to-face meeting between the instructor and the client. Subsection (H)(1)(b). As a result of the COVID-19 pandemic, many states are providing flexibilities with respect to the provision of healthcare and have accordingly permitted telehealth and reimbursement for services provided through a telehealth modality. We ask that the BHA similarly move away from the requirement of a face to face meeting for the initial meeting.

10.63.06 Application and Licensure Process for All Community-Based Behavioral Health Programs

10.63.06.02 License Application Process

CBH has strong concerns with many provisions in this subsection. We note that COMAR Title 10, Chapter 36 is entitled “General Medical Assistance Provider Participation Criteria Authority” and already sets forth the general criteria with which Maryland Medicaid providers must comply in order to participate in the Medicaid program. For example, COMAR 10.09.36.02 already requires that “Providers of Medical Assistance Program services shall, to the extent required by law, be licensed and legally authorized to practice or deliver services in the state in which the service is provided.” COMAR 10.09.36.03 lists the “Conditions for Participation” in the Medicaid program. These conditions include such important and fundamental requirements as:

A. To participate in the Program, the provider shall:

(1) Ensure compliance with all the Medical Assistance provisions listed in the Code of Maryland Regulations (COMAR) designated for their provider type;

(2) Apply for participation in the Program using the application form designated by the Department;



(3) Be approved for participation by the Department;

(4) Allow the Department or its agents to conduct unannounced on-site inspections of any and all provider locations;

(5) Allow the Department or its agents to require all providers to consent to criminal background checks, including fingerprinting;

(6) Have a current provider agreement with the Program in effect . . .

(7) Comply with all standards of practice, professional standards and levels of service as set forth in all applicable federal and State laws, statues, rules, and regulations as well as all administrative policies, procedures, transmittals, and guidelines issued by the Department . . .

COMAR 10.09.36.03(A). Other important requirements in the same regulation pertain to non-discrimination, recordkeeping and billing requirements.

In addition, COMAR 10.09.36.08 which already applies to Medicaid providers is entitled “Cause for Cause for Suspension or Removal and Imposition of Sanctions.” It already authorizes the Department of Health to take certain actions if it “determines that a provider, any agent or employee of the provider, or any person with an ownership interest in the provider or related party of the provider has failed to comply with applicable federal or State laws or regulations . . .” Those actions include suspension, withholding of payment, removal from the program and disqualification from future participation in the Medicaid program.

Other providers are not subject to the multiple layers of regulation that the BHA is proposing here. By contrast, the COMAR provision relevant to Federally qualified health centers (FQHCs), for example, COMAR 10.09.08.03 simply requires FQHCs to meet the general Medical Assistance Provider Participation Criteria in COMAR 10.09.36.03 and the license requirement set forth in COMAR 10.09.36.02. In a very straightforward and direct manner, FQHCs are made subject to the applicable conditions for participation in Medicaid and licensure.

Specifically, with 10.63.06.02(A)(2)(c)(ii) and (iii) requires organizations to report at every program or site closure within the past ten years. Providers close programs and sites often, for reasons related to finances, capacity, and many other reasons. There is no policy rationale achieved from reporting every single program or site closure in the past decade with every application. This provision is broad, burdensome, and hard to imagine achieving any policy objective.

It is similarly unclear what is achieved with 10.63.06.02(A)(2)(c)(v). All provider organizations likely owe money to the Department at given points throughout the year. Whether an individual staff is late on their professional fees hardly rises to the level of reporting and license suspension for the organization as a whole.



The information required to report for nonprofits in 10.63.06.02(A)(2)(c)(vi) is already publicly available in nonprofits' Form 990s. Similarly, an organization's standing with the Department of Assessments and Taxation is also publicly available.

Organizational charts do not traditionally include **all** staff. To create one as required under 10.63.06.02(A)(2)(e) is unnecessary and, frankly, absurd.

For subsection (E), we recommend that the Department modify the training requirement to limit its application to only organizations applying for any license for the first time, not to an organization with existing licensed programs who adds new programs.

Other examples of the micro-management and redundant requirements include:

(d) A policy statement and attestation prohibiting a conflict of interest between the interests of the provider and those of the individual receiving services;

(c) Verification that the site is owned, leased, or otherwise under the control of the applicant or that, if the site is sub-leased, that this arrangement is allowed under lease terms;

These requirements do not promote quality of care and are redundant and overly burdensome. They also contravene mental health parity principles.

10.63.06 – Denial of a License

For clarity, we encourage the Department to include “or Revocation” in the title of this section.

Subsection (A)(6) allows the Department to revoke the license of program whose leadership discontinued another program's service in the preceding ten years without complying with the current regulations. Because the current regulations contain many new provisions that weren't in effect during the past decade – such as reporting anticipated program closures to the Department – this means that every single current organization who ever closed a program is subject to license revocation. Providers should not be held retroactively to current standards.

Subsection (A)(8) is similarly overbroad. It allows the Department to revoke the license of any provider who owes money to the Department. Due to the failed ASO transition, this is potentially applicable to the overwhelming majority of behavioral health providers. A more targeted approach is warranted.

Subsection (A)(10) standards are too vague to put providers on notice as to what behaviors may warrant a license revocation. The Department's “opinion” is not a compliance standard. There is no differentiation of minimal/administrative versus material ones.



10.63.07 – License Modification

Subsection A is overbroad. By changing the definition of “program” from the organization as a whole to a specific provider-type/site combination, the scope of this requirement is dramatically expanded. The definition of program was of grave concern to us at the time the 10.63 regs were drafted. It was clarified at the time that “program” had been intended to apply to the organization as a whole, not individual service lines, and that requirements to provide notice and get approval for closure applied to whole organizations, not service lines. As a result, 10.63.01.02 uses the following definition: (47) “Program” means an organization that provides or seeks a license to provide community-based behavioral health services. The proposed regs use program to define both organizations and service lines. Further the intent seems to be to require upfront notice and approval before organizations can close service lines. This would have the ultimate effect of holding providers responsible for the gaps in the behavioral health system caused by inadequate reimbursement, since approval to close a service line could be predicated on the fact that there are no viable alternatives for clients receiving those services. While providers should always give at least 30-day notice (if possible) to clients served and recommend alternative services, they cannot and should not be held responsible if alternatives don’t exist. Requiring providers to wait for prior approval could lead to organizational destabilization cause by ongoing financial losses attributed to a service line that is unable to be shut down.

Subsection (F) is a serious concern to CBH. Members need to shut down sites and programs for a variety of reasons, including to maintain the financial viability of the organization as a whole. Providers must control the business operations needed to ensure their sustainability and viability. We have very strong concerns with the Department exercising authority to withhold approval from a provider closing a money-losing service.

10.63.06.08 – Waivers and Variance

We note that while the regulations require providers to apply for a variance within 30 days (see 10.10.63.01.05(I)), the proposed regulations give the Department under (B)(4)(a) six months to respond to a variance request. When a variance is needed to support ongoing business operations, six months is too long to wait. We encourage a more even-handed approach to these timeframes.

10.63.06.10 – Discontinuation of Program Operations

When closing a site or program, providers must notify all clients in a timely manner and offer alternatives to continue treatment, if such alternatives are available. It is unclear what additional obligations and planning the Department contemplates with the proposed regulations. With health professional shortages and inadequate service array in many jurisdictions across the state, it is important to recognize that all services needed by clients during a program closure may simply not be available. In such circumstances, it is unclear what the regulations would require.



10.63.06.11 – Unplanned Discontinuation of Program Operations

This section does not define the difference between a planned and unplanned discontinuation of services. The language seems to suggest that an unplanned discontinuation is an emergency. In emergency circumstances, providers and the clients they serve may be better served by implementing the emergency planning requirements already required under accreditation, rather than engaging in the extending process required by the proposed regulations.

With regard to subsection (E), we note that in many emergencies, waiting seven days or more for the Department's approval may jeopardize clients' health and safety. The proposed regulation does not appear to recognize the variety of emergency situations that would require an immediate program closure.

We object to subsection (C)(1)-(5). Providers cannot plan to transition to services only subject to other service availability.

For reasons previously described, we object to subsection (F) and (I).

Proposed COMAR 10.63.XX – Imposition of Civil Money Remedies

According to the proposed regulatory language, the BHA seeks to impose civil money remedies against a Program that violates COMAR 10.63. COMAR 10.63.XX.01. The proposed language in COMAR 10.63.XX.02 is overbroad and fails to afford providers with meaningful standards by asserting simply that a "civil money penalty may be imposed against a program for violation of a State or federal law or accreditation standard governing a program." Apparently, any violation could trigger a civil money penalty and there is no concept of materiality built into the proposed regulation. At a minimum, there should be some expression of a materiality standard in order to ensure that the imposition of a civil money penalty is fundamentally fair and in line with the alleged violation – especially since under proposed .02(B) a "civil money penalty may be imposed regardless of whether any other civil, criminal, or administrative action is taken against the program by any State, federal, or Departmental agency for the same covered period or violation." Under this proposed .02(B), nothing would prevent the BHA essentially from "piling on" with its own imposition of penalties in the wake of another agency action. This appears punitive to us and does not seem designed to serve a legitimate regulatory interest.

We have serious concerns about a set of regulations that seek to impose penalties on behavioral health providers at a different level than other health care providers. We have reviewed COMAR Title, 10 Subtitle 9 Medical Care Programs, Chapter 36, General Medical Assistance Provider Participation Criteria Authority to determine whether other provisions of COMAR purport to impose additional sanctions by provider type. They do not. The only regulation we noted was COMAR 10.09.36.08 entitled "Cause for Suspension or Removal and Imposition of Sanctions." This provision applies to all Medicaid provider types and does not single a specific provider type. It allows the Maryland Department of Health to take certain actions with respect to "a provider, any agent or

employee of the provider, or any person with an ownership interest in the provider or related party” if there has been a failure to comply with applicable federal or State laws or regulations. The actions include: suspension from the Medicaid program, withholding of payment, removal from the Program and disqualification from future Program participation. COMAR 10.09.36.08(A).

COMAR 10.66.01 also gives the Office of Inspector General the authority to levy civil money penalties on healthcare providers who violate their conditions of payment. Proposed section 10.63.XX creates civil money penalties specific to behavioral health programs. The proposed regulations impose a different standard for civil monetary penalties on behavioral health providers than the standard for other healthcare providers reflected in COMAR 10.66. These include:

- Health care providers under 10.66 are subject to civil monetary penalties that may not exceed the value of the claims at issue (COMAR 10.66.03(D)(3)). There is no limit on the value of the penalty in the 10.63.XX proposed regulations.
- Health care providers under 10.66 are subject to civil monetary penalties only if the claims at issue have not otherwise been subject to penalty, extrapolation audit, false claims act or criminal action (COMAR 10.66.03(D)(4), (5)). There are no similar limits on the penalty in the 10.63.XX proposed regulations.

Finally, we also believe it is important to point out that the federal government possesses significant authority to impose civil monetary penalties against health care providers. 42 U.S.C. § 1320a-7a; 1395nn(g)(3) and (4). Between the authority already present in COMAR 10.09.36.08(A) and in federal law, it is unclear why behavioral health providers should be singled out. The proposed regulations are redundant and punitive. They do not further quality of care considerations and are inconsistent with mental health parity requirements.

Thank you for consideration of our request. If you need any additional information, please do not hesitate to contact me at shannon@mdcbh.org.

Sincerely,



Shannon Hall
Executive Director

cc: Lori Doyle, Public Policy Director
Kathy Ghiladi, Feldesman Tucker Leifer Fidell LLP