LEGAL ACTION CENTER

August 30, 2024

Secretary Herrera Scott
Maryland Department of Health
201 W. Preston Street
Baltimore, MD 21201

RE: COMAR 10.63 Draft Proposed Regulations

Dear Secretary Herrera Scott,

Thank you for the opportunity to provide comments on the draft COMAR § 10.63 regulations. The Legal Action Center (LAC) is a non-profit law and policy organization that fights discrimination, builds health equity, and restores opportunities for people with substance use disorders, arrest and conviction records, and HIV/AIDS. LAC convenes the Maryland Parity Coalition, and works to ensure that people with mental health (MH) substance use disorders (SUD) have access to the comprehensive and equitable treatment they need. LAC, and the 13 undersigned organizations, offer the following comments on the Maryland Department of Health's (MDH) proposal.

1. Medicaid Reimbursement

We appreciate that the Department is thinking proactively about the MH and SUD services that are needed for effective care in the State, and we agree that these services will make a significant difference in improving the lives of Marylanders. However, we have concerns that some of the new requirements and standards for programs are not currently reimbursed by Maryland Medicaid, such as case management and family services in substance use disorder intensive outpatient (IOP) and partial hospitalization (PHP) programs. §§ 10.63.03.03(B)(4), (8); 10.63.03.07(B). That being said, we agree that these services are critical components of IOP and PHP, as well as across the full continuum of SUD treatment, and we encourage the Department to provide reimbursement for these services in all of the ASAM levels of care, both including them in the reimbursement rate for bundled levels of care as well as providing separate reimbursement for such services so that they are meaningfully available in all settings of care including outpatient settings other than health homes.

More broadly, we encourage the Department to ensure that any requirements and standards for programs are consistent with Medicaid reimbursement to ensure it is financially feasible for programs to deliver all of these services, in the manner prescribed.

2. Terminology & Definitions

The term "behavioral health" is used in various places throughout the regulations, such as "behavioral health disorders" in § 10.63.05 and "behavioral health services" in § 10.63.06, but never separately defined. We encourage the Department to review the provisions in which "behavioral health" is used and consider replacing this term with "mental health and substance use disorder" for clarity and consistency. We note that "alcohol, tobacco, and other drugs" is used in § 10.63.05, and we encourage the Department to change this language to "substance" (i.e. "substance use" instead of "ATOD use") for consistency throughout the regulations. We also request that the Department change to word "abuse" in § 10.63.03.03(C)(2)(b).

We commend the Department for including "warm hand-offs" throughout the regulations to ensure that Marylanders have access to the full range of MH and SUD, as well as medical, services and supports that they need. We encourage MDH to amend the definition of warm hand-off at § 10.63.01.02(B)(120) to ensure that these facilitated referrals sufficiently meet the needs of individuals. Specifically, the referring provider should ensure that the receiving provider (1) accepts the patient's insurance (that is, a Medicaid provider and/or contracted with the Medicaid managed care organization, as appropriate, (2) has timely appointments available to meet the patient's needs, (3) is within a reasonable travel time and distance, considering the patient's transportation needs, and (4) meets any other specific needs of the patient, such as cultural humility and language capabilities, the ability to treat pregnant individuals or can provide childcare, and others.

We note that other terms in the regulations are either not defined or may be used incorrectly. For example, the term "medication management" is used in several places in the regulations (*See, e.g.*, §§ 10.63.03.04(B)(2)(a)(ii), (B)(6)(b); 10.63.03.05(A)(3)(c), 10.63.04.04(N)(12)), but it is not defined in § 10.63.01. "Medication monitoring" at § 10.63.01.02(b)(78) also only refers to "psychiatric or somatic medications," and should be expanded to include addiction medications. The term "Integrated Behavioral Health Center" at § 10.63.03.15(A)(5) is not defined in the regulations, and we were unclear if this is a new type of service or setting, and if so, what licensure or service requirements would apply. Additionally, the term "face-to-face" is used in § 10.63.02.03(B)(8), but as this term can describe an audio-visual telehealth or in-person encounter, it should be changed to "in-person," as defined in the previous section. However, we encourage the Department to continue to maximize access to MH and SUD services including through telehealth as much as possible, rather than limiting access to in-person care when it is not necessary to do so.

3. Alignment with The ASAM Criteria

We thank the Department for working on another draft of these regulations to incorporate the 4th Edition of the American Society of Addiction Medicine (ASAM) Criteria into these proposals. We encourage the Department not to finalize any of these proposals until the updated draft is released for public comment, so that we can appropriately respond to those changes holistically.

We encourage the Department to pay particular attention to the program services and staffing requirements in the updated levels of care and ensure that the regulatory requirements are

consistent with and no more restrictive than these nationally recognized standards of care that Maryland has incorporated into state law. In addition to revising the levels of care and the integration of withdrawal management, the 4th Edition of the ASAM Criteria require medications for opioid use disorder and alcohol use disorder to be available in all medically managed ASAM levels of care (Levels 1.7, 2.7, and 3.7),[1] not just take-home doses or as part of an opioid treatment program. *See, e.g.*, § 10.63.04.09(B). Accordingly, the Department should add these medications to the licensing requirements for all medically managed ASAM levels of care in the updated §§ 10.63.03 (ASAM Levels 1.7 and 2.7) and 10.63.04 (ASAM Level 3.7). The Department should further ensure, in the regulations, that the clinically managed levels of care (1) have overdose reversal medications onsite, and (2) ensure access to medications for alcohol use and opioid use disorder, as well as psychiatric medications, either by providing all FDA-approved medications for addiction treatment on site or by facilitating access to them externally.[2]

Additionally, we encourage the Department to require and enable all licensed SUD programs to treat all types of SUDs. Various provisions have a strong (and important) focus on opioid use disorder (OUD) and medications for OUD, such as in the SUD residential crisis services program at § 10.63.04.10(D)(2). However, other conditions, such as alcohol use disorder and stimulant disorders, may not be adequately represented in these regulations despite their ongoing prevalence in the State and in overdose fatalities.[3] Marylanders must have access to effective treatment regardless of their type of SUD in these settings and programs.

4. Alignment with the Mental Health Parity and Addiction Equity Act

The standards and requirements of COMAR § 10.63 apply to Medicaid reimbursed programs, facilities, services, and therefore must comply with the Mental Health Parity and Addiction Equity Act (Parity Act), and the Department must ensure that the MH, SUD, and medical/surgical benefits under both the managed care organizations and fee-for-service coverage are comparable. *See* 42 C.F.R. § 438.920. The Department must conduct a full Parity Act compliance analysis on these proposals, separately assessing MH benefits and SUD benefits compared to medical/surgical benefits. The following provisions present potential Parity Act violations:

- **Standards for Provider Admission to Participate in a Network & Medical Management Standards**: *See* 42 C.F.R. § 438.910(d)(2)(i), (iv).
    - To the extent that any of the service requirements or limitations in the proposed §§ 10.63.03 and 10.63.04 are more restrictive than those in The ASAM Criteria, the Department should demonstrate that the development of these standards for network admission (participation as a "willing provider") and medical management standards are comparable to and no more stringent than those for medical and surgical programs. That is, if the Department does not deviate from nationally recognized standards for reimbursing skilled nursing facilities, for

[1] American Society of Addiction Medicine, "The ASAM Criteria," Chapter 7: Medically Managed Treatment (4th Ed. 2023).
[2] *Id.* at Chapter 4: Continuum of Care: Universal Service Characteristic Standards.
[3] *See* Maryland Department of Health, "Data-Informed Overdose Risk Mitigation: 2022 Annual Report" 21, 64 (Aug. 15, 2023), https://stopoverdose.maryland.gov/wp-content/uploads/sites/34/2023/08/8-15-2023-2022-DORM-Annual-Report-Final.pdf.

example, then it should not do so for residential substance use disorder treatment facilities.[4]
    - We also encourage the department to review the restrictions for licensing, such as those under § 10.63.06.02 (such as § 10.63.06.02(B)(2)(c)), to ensure they are no more restrictive than those for medical facilities, as this would affect a provider's admission to the Maryland Medicaid network.
- **Fail First Policies**: The language in 10.63.03.04(A)(2) limits the availability of assertive community treatment (ACT) to adults and minors "whose mental health treatment needs have not been met through traditional outpatient mental health programs," which suggests that the participant has to "fail first" at another level of care before they are able to receive ACT services. We recommend the Department revise this language to ensure that these services are not limited in this way, as we are not aware of any such comparable limitations for medical or surgical services. *See* 42 C.F.R. § 438.910(d)(2)(vi). Outside of the parity context, we oppose any "fail first" requirements for MH and SUD services, as such requirements delay and deter access to medically necessary care.
- **Restrictions Based on Facility Type, Provider Specialty, and Other Criteria That Limit the Scope or Duration of Benefits**: *See* 42 C.F.R. § 438.910(d)(2)(viii).
    - The ratios of providers to patients throughout COMAR § 10.63.03 are internally inconsistent, and it is unclear how these ratios were developed and whether comparable limitations are imposed on medical/surgical services such that these ratios would comply with the Parity Act.
    - Limitations on telehealth service delivery may affect the scope and duration of MH and SUD care that Maryland Medicaid enrollees receive. We encourage the Department to ensure that these restrictions (such as those at §§ 10.63.03.09 and 10.63.04.10) are consistent with best practices and current service delivery, as well as compliant with the Parity Act. More generally, we oppose these regulatory telehealth limitations, as the decision to use telehealth should be made between the treating provider and patient.

We recommend the Department review the draft proposed regulations for parity compliance, and remedy the disparities between MH, SUD, and medical/surgical services, providers, and facilities.

5. Aligning MH Services and Facilities with SUD Services and Facilities

In addition to comparing MH services and SUD services to medical services, the Department should also assess each of these conditions separately to ensure that, for example, SUD services are not more restrictive than MH services. The following provisions in the draft proposed

[4] For example, the draft proposed regulations for ASAM Level 3.5 settings require a minimum of 36 hours of therapeutic activities per week (§ 10.63.04.08(A)(2), (C)(2)), whereas the ASAM Criteria require a minimum of 20 hours of clinical services per week. The ASAM Criteria also do not specify numbers of hours that physicians or other advance practice providers need to be on site, but rather that they could be available via telemedicine, while the draft proposed regulations have an onsite requirement. *See* §§ 10.63.04.08(C)(6)(c), 10.63.04.09(D)(4)(a). Further, to the extent that facilities programs are required to report vacancies, the requirement and process for doing so should be no more stringent than the requirement on comparable medical facilities and program.

regulations suggest less comprehensive care of SUD than MH, as well as additional burdens to accessing SUD treatment:

- To the extent certain services or programs are only available, in writing or in operation due to their setting, to people with MH (such as respite at COMAR § 10.63.03.11(A)), supported employment at § 10.63.03.12(I), and permanent supportive housing at § 10.63.03.13)), we encourage the Department to ensure that comparable services and programs are developed and made available to people with SUD and provide Medicaid reimbursement for such services.
- Additionally, we note that the draft proposed regulations suggest that trainees/interns can provide services in MH settings such as OMHCs (*See* § 10.63.03.05(B)), but that they may not provide counseling, even under appropriate supervision, in SUD treatment programs. *See, e.g.*, § 10.63.03.06(E). We recommend the Department clarify these regulations to ensure that trainees and interns, under appropriate supervision, can perform all of the tasks within their scope of practice.
- We are also concerned about the Certificate of Need requirement for ASAM Level 3.7 programs at § 10.63.04.09(G) and whether this additional barrier to operating a SUD treatment program is reasonable and necessary.

We encourage the Department to work with community stakeholders to remove any unnecessary barriers to treatment and ensure that all SUD services are meaningfully available for Marylanders, both in these regulations and in Medicaid reimbursement practices.

6. Opioid Treatment Programs (§ 10.63.03.16)

We encourage the Department to ensure that the regulations concerning Opioid Treatment Programs (OTPs) are consistent with the revised 42 C.F.R. Part 8 regulations, and are no more restrictive than the Part 8 standards. Maryland-based programs should not have to comply with stricter standards at the state level than those at the federal level. *See* § 10.63.03.16(A). Removing this change in the draft proposed regulations will ensure consistency with the goal of the new regulations – reducing barriers to care – and access to life-saving medications and care.[5] For example, the final federal regulations continuously stress the importance of shared decision-making and patient-centered care plans (42 C.F.R. § 8.12(f)(1)), which should be incorporated into COMAR § 10.63.03.16. This should include removing any unnecessary limitations on care, such as those for take-home doses at § 10.63.03.16(F)(3), insofar as they are inconsistent with 42 C.F.R. § 8.12(i). Similarly, the drug testing provisions at COMAR § 10.63.03.16(J) should be aligned with 42 C.F.R. § 8.12(f)(6). We are also concerned that the provisions for non-voluntary tapering and transferring of patients (COMAR § 10.63.03.16(I)), and particularly that for patients who miss three consecutive medication days or who continue to use substances (§§ 10.63.03.16(I)(3), (4)), are inconsistent with the goals of the federal regulations to reduce barriers to care, promote shared decision-making, and harm reduction. On this latter point, we also note that a key theme of the updated federal regulations is the incorporation of harm reduction into OTPs, and we urge the Department to incorporate this language in its regulations. *See* 42 C.F.R. §§ 8.2, 8.12(f)(4)(i), 8.12(f)(5)(i), 8.12(f)(6).

[5] SAMHSA, "The 42 CFR Part 8 Final Rule Table of Changes" (Jan. 31, 2024), https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes.

As previously noted in Sections 1 and 4, we also encourage the Department to review its Medicaid reimbursement standards for OTPs (including any counseling requirements, telehealth limitations, and provider-to-patient ratios) to ensure that they align with current service delivery in Maryland, with the federal regulations for OTPs, and with the Parity Act requirements.

7. Recovery Residences (§ 10.63.05)

We appreciate the Department's interest in ensuring recovery residences are safe, inclusive, and able to meet the needs of Marylanders. Nonetheless, as this is the first time that such programs are being regulated, we encourage the Department to do more community engagement and outreach prior to moving forward with these proposals. Importantly, recovery residences are primarily organized for safe and recovery-oriented housing, not for clinical care or treatment, and we want to ensure that they can continue to meet this critical need. We also note that it may not be appropriate or necessary to have NARR Level 4 recovery residences due to the redundancy with Level 3.1 of the ASAM Criteria.

While we appreciate that the proposed regulations have contemplated participant rights, grievance procedures, and nondiscrimination protections, we would like additional time to work with the Department to ensure that the rest of the regulations are consistent with the Fair Housing Act, the Americans with Disabilities Act, and a participant's right to due process. We further want to ensure that the financial security and other necessities of residents are protected so they can still retain any financial or other assistance they may be receiving (such as SNAP benefits) and not be required to submit that assistance to the recovery residence as a condition of residency. *See, e.g.,* § 10.63.05.07(B)(1)(e)(x)(bb).

8. Confidentiality of Substance Use Disorder Patient Records Under 42 CFR Part 2

We encourage the Department to review the proposed regulations and identify the provisions in which SUD programs and facilities must comply with 42 C.F.R. Part 2, not just HIPAA. While we appreciate that Part 2 is mentioned in § 10.63.01 and incorporated into the DUI Education Program at § 10.63.05.05, we encourage the Department to add Part 2 to § 10.63.06.02(B)(10) such that programs are required maintain confidentiality of substance use disorder records when using shared spaces. Additionally, under the new § 10.63.06.11, subsection (C)(7) should require that the plan for storing and protecting all records as part of an unplanned discontinuation of program operations complies with 42 C.F.R. Part 2, as appropriate.

9. Youth & Adolescent Services

In the midst of the ongoing youth and adolescent mental health crisis, we recommend the Department continue to evaluate gaps in the continuum of care, both in these regulations and in available facilities and programs. The full continuum of MH and SUD services must be available to individuals of all ages, but we encourage the Department to pay particular attention to what services may be unavailable for youth and adolescents, including residential MH and SUD treatment.

10. Civil Remedies

We note that there are separate civil monetary penalties in §§ 10.63.06.19 and 10.63.09. We encourage the Department to align and consolidate these penalties.

11. Oversight

We encourage the Department to identify who will do the oversight of these standards. We want to ensure there is sufficient funding for meaningful oversight, and that consumers know where to go when they encounter problems.

Thank you for considering our comments. Please do not hesitate to contact us if you have any questions or would like to discuss further.

Sincerely,

Legal Action Center
AHEC West
James Place, Inc.
Maryland Addiction Directors Council
Maryland Coalition of Families
Maryland Peer Advisory Council, MPAC
Maryland Psychiatric Society, Inc.
Maryland Psychological Association
MD Heroin Awareness Advocates
Montgomery Goes Purple
NAMI-MD
NCADD-MD
Pyramid Healthcare, Inc.
Sandstone Care