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Russ Weber Key Point Health Services Jordan Fisher Blotter Director, Office of Regulation and Policy Coordination Maryland Department of Health 201 West Preston Street, Room 534 Baltimore, MD 21201 via email to mdh.regs@maryland.gov

RE: Comments on Notice of Proposed Action 24-190-P

Dear Ms. Fisher Blotter:

Please accept this letter as the comments of the Community Behavioral Health Association of Maryland (CBH) on Notice 24-190-P, proposed regulations to create civil monetary penalty regulations for behavioral health providers in COMAR 10.63.08.

CBH is the leading voice for community-based providers serving the mental health and addiction needs of vulnerable Marylanders. Our 89 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.

CBH supports regulations that clearly define provider expectations and effectively enable government oversight of behavioral health providers. To address substandard care in Maryland's public behavioral health system, CBH is generally supportive of strengthening the existing COMAR 10.63.06.18 regulations governing civil monetary penalties for Maryland's licensed behavioral health programs.

We are concerned, however, that several aspects of the proposed regulations in COMAR 10.63.08 place burdens on Maryland's behavioral health providers are far exceed requirements in other areas of health care. We offer below suggested edits to the proposed regulations that balance a stronger, more effective approach to oversight with a fair approach that does not single out behavioral health care to be held to higher standard than any other health sector in Maryland.

Recommendation: Establish a unitary standard for civil monetary penalties.

There must be a single standard for the imposition of civil monetary penalties for behavioral health licensing violations. The Maryland Department of Health already has authority to levy civil monetary penalties on Medicaid claims that violate the conditions of payment (COMAR 10.66) and for "material and egregious" violations

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of the behavioral health licensing standards (COMAR 10.63.06.18). Our comments below are based on the assumption that the proposed regulations in COMAR 10.63.08 will replace COMAR 10.63.06.18, and that COMAR 10.63.06.18 will be deleted in its entirety before the proposed changes in COMAR 10.63.08 go into effect. If our assumption is incorrect, then we recommend setting an effective date for COMAR 10.63.08 tied to the rescission of COMAR 10.63.06.18.

Recommendation: Establish a level of harm for civil monetary penalties, as in other areas of health care.

The existing regulations in COMAR 10.63.06.18 authorize penalties for "material and egregious" violations of the laws and regulations. The proposed standard in COMAR 10.63.08 imposes a penalty for simply "material" violations. This is a lower standard than other areas of health care. Nursing homes and residential treatment centers are liable for penalties based on the seriousness of harm.¹ We recommend a similar standard for Maryland's behavioral health providers.

It is unfair to single behavioral health providers out for penalties with no demonstration of patient harm, particularly when behavioral health providers already face more administrative requirements than other sectors of health care. As a matter of equity and efficient use of government resources, CBH recommends that COMAR 10.63.08.02B(1) be amended to limit the use of penalties to "more than minimal harm," the same threshold penalty standard used for Maryland nursing homes.²

Proposed Regulation with CBH Edit

.02 Definitions. ...

B. Material Violation

(1) "Material violation" means any course of conduct, including a single incident, that may cause a program, individual, or organization to fail to comply with any statutory, regulatory, or contractual requirement <u>that</u> <u>results in more than minimal harm to patients</u>.

¹ See, e.g., COMAR 10.07.04.19A, COMAR 10.07.02.71A.

² COMAR 10.07.02.71A.



Recommendation: "Material violation" definition should include actual, not alleged, violations and eliminate noncompliance with corrective action plan as duplicative.

CBH recommends two technical corrections to the definition of "material violation" contained in COMAR 10.63.08.02B(2). We recommend deleting the phrase "may violate" in (c) because penalties are only appropriate for actual violations, not alleged violations. We also recommend deleting (d), which allows the levying of penalties for failure to comply with a corrective action plan. This provision is already included as a standalone ground for penalties later in COMAR 10.63.08.03F. Including it in the definition of "material violation" is unnecessary, redundant, and potentially confusing.

Proposed Regulation with CBH Edit

.02 Definitions. ...

B. Material Violation ...

(2) "Material violation" includes but is not limited to:

(a) Fraudulent or other behavior which influences or may influence the payment or receipt of money or other property;

(b) Practices which affect or may affect the health or safety of any individual;

(c) Practices which violate or may violate participant rights; or

(d) Failure to comply with a plan of correction or correct deficiencies after receiving a notice of deficiencies.

Recommendation: Treat behavioral health like other areas of health care and eliminate exponential liability for every service and site.

In COMAR 10.63.08.03D, the Department proposes the authority to levy penalties as a separate violation for each site and each service. The average CBH member delivers five types of licensed services in three Maryland counties, so our average member's potential liability for civil monetary penalties increases by a factor of 15. <u>This is radically higher liability than any other area of health care, and it introduces too much risk into an already challenging business for behavioral health providers</u>. No other area of health care creates separate liability for each service and location.³

The proposed penalties in COMAR 10.63.08 are already higher than other areas of health care and liability begins at a lower threshold with no demonstration of patient harm, unlike other areas of health care. Creating exponential liability by defining every service and site as a separate violation is inequitable and destabilizing. CBH urges the Department to delete this provision in its entirety.

Proposed Regulation with CBH Edit

.03 Civil Money Penalty — Imposition.

D. If a violation occurs at multiple site locations of an organization, each location will constitute a separate violation. If there are multiple services at a location and the violation occurs with multiple services, each service will constitute a separate violation.

³ See, e.g., COMAR 10.07.04.19A, COMAR 10.07.02.71A.



Recommendation: Modify factors to set penalty level to include mitigating factors and level of patient harm as in other areas of health care.

We recommend modifying the factors used to determine the amount of a civil monetary penalty in COMAR 10.63.08.03G to better reflect the standards imposed in other areas of health care. While G(3) specifies that an organization's negative compliance history may be a factor in setting the penalty, we recommend adding language citing an organization's positive history of compliance, similar to the standard for Maryland nursing homes.⁴

We also recommend deleting the phrase "possibly inhibiting an individual's ability to receive quality services" from G(6) as one of the factors in setting the level of penalty. For starters, providers should not be liable for "possible" harms, only actual ones. In addition, conflating substandard care with health or safety risks is not appropriate grounds for setting a penalty.

Proposed Regulation with CBH Edit

.03 Civil Money Penalty — Imposition.

G. In determining whether a civil money penalty is to be imposed and in setting the amount of the civil money penalty, the Department shall consider each of the following:

(1) The number, nature, and seriousness of the violation or violations;

(2) The extent to which the deficiency or deficiencies are part of an ongoing pattern;

(3) The organization's history with the Department, including **prior history of compliance or** any prior actions that would indicate whether the violation is an isolated occurrence or represents a pattern of behavior;

(4) The efforts made by the organization to correct the violations and any continuation of conduct after notification of possible violations;

(5) The organization's level of cooperation with the Department or its agents as it relates to the review of the program;

(6) The degree of risk to the health, life, or safety of individuals as a result of the violations, *including possibly inhibiting an individual's ability to receive quality services, and appropriate care and treatment*; and

(7) Any other reasonable mitigating factors.

Thank you for your consideration of these comments. We welcome any questions or further discussion about the recommendations described here. Please contact me at shannon@mdcbh.org.

Sincerely,

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Shannon Hall Executive Director

⁴ COMAR 10.07.02.71D(6).