



Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

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**Re: COMAR 10.63.08 Civil Money Penalty - Response to January 27, 2025 Proposed Regulation Comments**

Dear Community Behavioral Health Association of Maryland:

Thank you for your comments regarding the proposed COMAR 10.63.08 Civil Money Penalty regulations printed in the December 27, 2024 issue of the Maryland Register. The Behavioral Health Administration (BHA) reviewed Community Behavioral Health Association of Maryland (CBH) comments that support CBH's concerns that the proposed regulations place burdens on Maryland's behavioral health providers that far exceed requirements in other areas of health care. The following are BHA's responses to CBH's comments:

**(1) 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 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.

**BHA RESPONSE**

Thank you for your comment. This will be clarified in policy and regulatory guidance.

**(2) 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. 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.

### **BHA RESPONSE**

The regulations do not require harm to patients to levy civil money penalties. The intention of the regulations is both to improve the quality of care for patients, but also to stop the massive amount of fraud, waste, and abuse that has come through the Behavioral Health licensing process in recent years.

BHA has received, on multiple occasions, falsified documents from applicants in which applicants forge the signatures of officials at local health departments, BHA, or produce fraudulent documents such as background checks. These violations may not cause direct harm to patients, but they cost the administration a lot of time and money in the verification of applications and BHA believes that civil money penalties are appropriate to deter this kind of behavior.

BHA also believes that things like consistent failures to report critical incidents may result in providers facing a civil money penalty because, in these situations, it is difficult for a plan of correction to appropriately address the failure to report, but a civil money penalty for each failure to report a critical incident will make it clear to the program the seriousness of the violation. However, it would be inappropriate to require that another patient experience a critical incident in order to demonstrate that the failure to report is causing harm to patients.

In addition, failures to follow common safety protocols do not always cause harm, but the potential danger or harm that could be caused is so significant that it necessitates a civil money penalty. For example, if a program doesn’t replace smoke detector batteries timely, allows an electrical hazard to persist, or encourages the use of space heaters in a dangerous manner, the Department does not believe a residential fire should be necessary in order to levy a civil money penalty. If a provider is not performing regular

maintenance to protect the health and safety of their residents, harm is not required for this to be a material violation of the regulations that might result in a civil money penalty. If a provider is avoiding routine maintenance due to cost, it must be clear that avoidance is also costly.

We appreciate that you believe that the providers that you serve would never engage in such actions, but MDH will not be adding a harm requirement to the Civil Money Penalty regulations.

**(3) 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.

**BHA RESPONSE**

See response to the second comment which also addresses this concern.

**(4) 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. 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. No other area of health care creates separate liability for each service and location. 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.

**BHA RESPONSE**

Thank you for your comment. The Department issues licenses under COMAR 10.63 at the site and service level and believes that issuing civil monetary penalties at the site and

service level is appropriate and consistent with other State regulations for civil monetary penalties.

**(5) 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. 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.

**BHA RESPONSE**

Md. Code Ann., Health-Gen. § 7.5-402 (West) requires the Department to promulgate regulations which include "(6) Provisions for denials, sanctions, suspensions, and revocations of licenses, including imposition of civil monetary penalties, and notice and an opportunity to be heard." There is nothing in the Maryland Code that states that civil monetary penalties are only permitted in cases in which the provider causes "actual" harm.

Maryland law already provides a system to hold a provider liable for the harm they have caused to patients. The patient who has been harmed is free to file a civil action against the provider to recover damages for the actual harm they have suffered. Civil monetary penalties are not intended to replicate the civil litigation process by making a determination regarding whether a provider is or may be liable for the harm caused to a patient.

The role of civil monetary penalties is both as a punitive measure and as a deterrent to discourage providers from engaging in egregious behaviors that have the potential to harm patients. CBH believes the Maryland Department of Health (Department) is "conflating" substandard care with health and safety risks, but the Department has seen many very real situations in which substandard care has put patient health and safety at risk.

BHA appreciates your interest and engagement in our efforts to implement these important civil money penalty regulations. BHA will be issuing additional compliance guidance regarding civil money penalties to assist providers in understanding what actions may result in the receipt of

penalties. We encourage your organization to continue to provide valuable feedback as we work to improve Maryland's licensed behavioral health programs.

Respectfully,

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