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November 13, 2023

Ms. Alexandria Schembra
Associate Program Analyst
Medical Board of California
2005 Evergreen St., Ste. 1200
Sacramento, CA 95815

Re: Testimony of the Consumer Protection Policy Center – Physician and Surgeon Health and Wellness Program

Dear Ms. Schembra:

On behalf of the Consumer Protection Policy Center (CPPC) at the University of San Diego School of Law, I am pleased to submit the following testimony to the Medical Board of California regarding proposed regulations creating a Physician and Surgeon Health and Wellness Program (PHWP).

CPPC Expertise Regarding the Medical Board of California

CPPC is a nonprofit, nonpartisan academic and advocacy center based at the University of San Diego School of Law. For 43 years, CPPC has examined and critiqued California's regulatory agencies that regulate business, professions, and trades, including the Medical Board of California (MBC) and other Department of Consumer Affairs (DCA) health care boards. CPPC's expertise has long been relied upon by the Legislature, the executive branch, and the courts where the regulation of licensed professions is concerned. For example, after numerous reports of problems at MBC's enforcement program were published in 2002, the DCA Director appointed CPPC's then-Administrative Director, Julianne D'Angelo Fellmeth, to the position of MBC Enforcement Monitor pursuant to Business and Professions Code section 2220.1 (now repealed). Over a two-year period, she directed an in-depth investigation and review of MBC's enforcement program and its so-called "diversion program" which purported to monitor substance-abusing licensees. In two exhaustive reports,[1] CPPC's Administrative Director made 65 concrete recommendations to strengthen the Board's programs.

[1] Julianne D'Angelo Fellmeth and Thomas A. Papageorge, *Initial Report of the Medical Board Enforcement Program Monitor* (Nov. 1, 2004); Fellmeth and Papageorge, *Final Report of the Medical Board Enforcement Program Monitor* (Nov. 1, 2005).

With regard to the diversion program, the Enforcement Monitor found that all of the monitoring mechanisms by which it purported to monitor substance-abusing physicians — including required biological fluid testing, required group therapy meeting attendance, worksite monitor requirements and reporting, and treating psychotherapist reporting — were failing; that the program lacked sufficient internal controls to alert program staff to these failures; and that the program had been so under-resourced and understaffed that staff could not have corrected these failures even if they detected them. Of critical importance, the Monitor also found that the program suffered from an absence of enforceable rules or standards to which participants and personnel were consistently held because MBC itself — contrary to applicable provisions in the Business and Professions Code — had failed to exercise any meaningful oversight over the program. These findings echoed the results of three earlier audits of the program by the Auditor General.[2]

Following the publication of the Enforcement Monitor's reports in 2004 and 2005, the Legislature directed the State Auditor to re-audit MBC's diversion program. In June 2007, the Auditor released Report 2006-116R, which concluded that while the program had improved since the 2005 Enforcement Monitor report, many of the problems identified by the Enforcement Monitor had not been corrected. Specifically, the program failed to ensure that all participants were randomly drug tested; failed to adequately monitor and/or require reporting from its various contractors (including urine specimen collectors, group meeting facilitators, and worksite monitors); did not respond to potential relapses in a timely and adequate manner; and did not always require a physician to immediately stop practicing medicine after testing positive for alcohol or a nonprescribed or prohibited drug. Lastly, the Auditor found that MBC — which was charged with overseeing the diversion program — "has not provided consistently effective oversight."

Following receipt of the Auditor's Report, MBC — at its July 2007 meeting — unanimously voted to abolish the diversion program and to seek a repeal of the statutes creating the program. The program was abolished effective July 1, 2008. Thus, MBC has not had a program to monitor substance-abusing licensees for 15 years.

Should MBC Wish to Create a New Program, It Must Comply "Without Deviation" With the Uniform Standards

Also, in 2008, the Legislature passed SB 1441 (Ridley-Thomas) (Chapter 548, Statutes of 2008), which added section 315 *et seq*. to the Business and Professions Code. Section 1 of SB 1441 succinctly stated the Legislature's unmistakable intent regarding the use of substance abuse monitoring programs by health care licensing boards:

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[2] Auditor General of California, *Review of the Board of Medical Quality Assurance* (No. P-035) (August 1982); Auditor General of California, *The State's Diversion Programs Do Not Adequately Protect the Public from Health Professionals Who Suffer from Alcoholism or Drug Abuse* (No. P-425) (January 1985); Auditor General of California, *The Board of Medical Quality Assurance Has Made Progress in Improving its Diversion Program; Some Problems Remain* (No. P-576) (June 1986).

> (a) Substance abuse is an increasing problem in the health care professions, where the impairment of a health care practitioner for even one moment can mean irreparable harm to a patient. … (c) Substance abuse monitoring programs, particularly for health care professionals, must operate with the highest level of integrity and consistency. Patient protection is paramount. (d) The diversion program of the Medical Board of California, created in 1981, has been subject to five external audits in its 27-year history and has failed all five audits, which uniformly concluded that the program has inadequately monitored substance-abusing physicians and has failed to promptly terminate from the program, and appropriately refer for discipline, physicians who do not comply with the terms and conditions of the program, thus placing patients at risk of harm. (e) The medical board's diversion program has failed to protect patients from substance-abusing physicians, and the medical board has properly decided to cease administering the program effective June 30, 2008. … (g) Various health care licensing boards have inconsistent or nonexistent standards that guide the way they deal with substance-abusing licensees. (h) Patients would be better protected from substance-abusing licensees if their regulatory boards agreed to and enforced consistent and uniform standards and best practices in dealing with substance-abusing licensees.

SB 1441 required DCA to convene a "Substance Abuse Coordination Committee" (SACC) to develop "uniform and consistent standards" in 16 specified areas that "each healing arts board ***shall use*** in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program." Bus. & Profs. Code section 315(c) (emphasis added). DCA convened the SACC in 2010, and — following extensive public hearings — it released the original version of the "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (Uniform Standards) in 2011. The current 2019 version of the Uniform Standards is available on DCA's website.

SB 1177 (Galgiani) (Chapter 591, Statutes of 2016) added new section 2340 *et seq*. to the Business and Professions Code, which authorizes MBC to create a new monitoring program for substance-abusing licensees. SB 1177 echoed SB 1441's mandated use of the Uniform Standards by providing that "if the board establishes a program, the program ***shall*** … ***comply*** with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees as adopted by the Substance Abuse Coordination Committee of the department pursuant to Section 315." Bus. & Profs. Code section 2340.2(e) (emphasis added).

Additionally, the Board's own regulations that it adopted following the development of the Uniform Standards confirm its intention that the Uniform Standards "shall" be used "without deviation, for each individual determined to be a substance-abusing licensee." Section 1361, Title 16 of the California Code of Regulations.

Thus, the mandatory use of the Uniform Standards by any new program created by MBC cannot be questioned. Indeed, it is MBC's burden to ensure that the language of these proposed

regulations (and any subsequent regulations affecting the proposed PHWP) is absolutely consistent with the Uniform Standards. Failure to do so in this rulemaking proceeding being conducted pursuant to the Administrative Procedure Act (APA), Gov't Code section 11340 *et seq*., requires rejection of the proposed regulations under the "consistency" standard set forth in Government Code sections 11349 and 11349.1. Furthermore, failure to ensure that the language of these proposed regulations is clear and unambiguously consistent with the Uniform Standards would require rejection of the proposed regulations under the "clarity" standard set forth in those same provisions of the APA.

CPPC recounts this history and these facts because no current member of the Medical Board (the decisionmakers in this rulemaking proceeding) was on the Board during 2004–05 when the Enforcement Monitor issued her reports, or in 2007 when the State Auditor issued her follow-up report, or in July 2007 when MBC voted unanimously to abolish the program. Only three current MBC members were on the Board when SB 1177 was passed in 2016, and when the Board voted to implement SB 1177 in January 2017. The current Board may wish to revisit that decision. Thus, it is important to educate the relevant decisionmakers about the history of MBC's experience with a program purporting to monitor substance-abusing physicians, and with the law now applicable to the operation of such a program. MBC must learn from its past mistakes in operating such a program; as the saying goes, those who ignore history are doomed to repeat it. Any such repetition would cause irreparable harm to patients.

It bears emphasis that the program proposed by this rulemaking is a program of the Medical Board of California. The highest priority of the Medical Board of California is patient protection; when patient protection is inconsistent with some other interest sought to be promoted, patient protection is paramount.[3] This kind of program has been proven on five separate occasions to pose grave risk to patients instead of protecting them. MBC is prohibited from creating a new program that will violate its highest priority; additionally, it is prohibited from creating a new program that is in any way inconsistent with the Uniform Standards. Any such deviation is barred by the Board's own regulations (section 1361, Title 16 of the California Code of Regulations), and by the explicit language of SB 1441 (Bus. & Profs. Code section 315(c)) and SB 1177 (Bus. & Profs. Code section 2340.2(e)).

Inconsistencies with the Uniform Standards

CPPC's primary argument is that the proposed regulations (like the bill that the regulations purport to implement) appear to carve out a distinction between the way so-called "self-referrals" and "Board-referrals" can or should be treated. Specifically, some of the proposed regulations imply that self-referred participants are not fully subject to the Uniform Standards. As discussed above, nothing in the Uniform Standards makes that distinction. In fact, to our knowledge, the term "self-referrals" is used only once in the 29-page Uniform Standards (Standard #14).

[3] Business and Professions Code sections 2001.1, 2229(a) and (c).

The mandatory use of the Uniform Standards by **all** DCA healing arts boards in dealing with **all** substance-abusing licensees participating in substance-abuse monitoring programs is unambiguously clear in two statutes (Business and Professions Code sections 315 and 2340.2 (e)), and existing Board regulation (section 1361, Title 16 of the CCR), and in the Uniform Standards themselves. None of those provisions draw any distinction between self-referred participants and Board-referred participants, and any attempt to do so in these proposed regulations should be rejected.[4] Alternatively, MBC could cure this problem by modifying these proposed regulations to declare that nothing in them is intended to justify any difference in how self-referred and Board-referred participants are to be treated by the PHWP.

Below, CPPC identifies areas in which the proposed regulations conflict with the Uniform Standards. These inconsistencies violate the "consistency" requirement of Government Code sections 11349 and 11349.1. In addition, the language of some of the proposed regulations is so confusing that it is impossible to tell whether they are consistent with the Uniform Standards. These inconsistencies violate both the "clarity" and "consistency" requirements of Government Code sections 11349 and 11349.1. Additionally, some of the proposed regulations duplicate regulatory provisions that MBC has already adopted in a prior rulemaking proceeding — something that adds to the confusion and is prohibited by the APA's "nonduplication" standard. Finally, the PHWP's enabling statute does not authorize at least one provision.

1. **Clinical Diagnostic Evaluation (CDE)**. Uniform Standard #1 requires all program participants to undergo a CDE. Uniform Standard #2 (1) requires all program participants to cease practicing medicine pending the results of the CDE, (2) requires all program participants to undergo twice-weekly drug testing during the cease practice period, and (3) prohibits any return to practice until the participant has demonstrated 30 days of negative drug tests. Uniform Standards #1 and #2 make no distinction between self-referred participants and Board-referred participants.

An existing Board regulation (section 1361.5(c), Title 16 of the CCR) already specifies the CDE requirements of Uniform Standard #1 applicable to a Board-referred participant (in other words, a participant whose license is on probation, one term of which is required participation in the PHWP). Proposed section 1357.10(c) is arguably duplicative of section 1361.5(c), in violation of Government Code sections 11349(f) and 11349.1(a). More importantly, proposed section 1357.10(c) implies that a CDE is optional for a self-referred participant ("If the vendor … requires a participant to undergo a clinical diagnostic evaluation…") when no such option exists in Uniform Standard #1, raising consistency and clarity issues. See also proposed section 1357.10(h)(1), which also implies that the CDE is optional. Proposed sections 1357.10(c) and 1357.10(h)(1)

[4] Critically, so-called "self-referred" participants are often attempting to enter a monitoring program in order to beat a piece of information that they know is imminently arriving at MBC, *e.g.*, a DUI arrest, a hospital disciplinary action reported to MBC under Business and Professions Code section 805, and/or a complaint. In the past, physicians attempted to "self-refer" because that status conferred benefits under now-repealed provisions of the Business and Professions Code. Under the Uniform Standards, self-referred participants are not entitled to special or different treatment.

must be clarified to require the vendor to comply with Uniform Standards #1 and #2 for all participants.

2. **Communication with Employers of Participants.** Uniform Standard #3 concerns the ability of a DCA healing arts board to communicate with a program participant's employer or supervisor — say, for example, concerning a positive drug test. It requires a licensee who is in a diversion program to provide to the board contact information on all employers and supervisors, and to give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring. Uniform Standard #3 makes no distinction between self-referred participants and Board-referred participants.

Proposed section 1357.10(d) also concerns communication between the PWHP and a participant's employer or supervisor. As to Board-referred participants, proposed section 1357.10(d) is duplicative of existing Board regulation 1361.5(c)(2), Title 16 of the CCR. And nothing in proposed section 1357.10(d) requires a vendor to require a self-referred participant to permit communication between the PWHP and the participant's employer or supervisor. Although proposed section 1357(e) requires PWHP participants to provide "disclosure authorizations," the inconsistency between these two sections illustrates a lack of clarity that may permit a future vendor to treat self-referred participants differently from board-referred participants.

3. **Other Provisions That Appear to Draw an Impermissible Distinction Between Self-Referred and Board-Referred Participants**. Several other regulations proposed in this package suffer from the same issue — a confusing and unclear effort to permit self-referred participants to be treated differently from Board-referred participants, which is not permitted by or contemplated in the Uniform Standards. Staff should re-examine proposed sections 1357.10(e)(2), 1357.10(g), 1357.10 (j), 1357.10(k), and 1357.10(l).

4. **No Statute Authorizes the Vendor to Impose Restrictions on a Participant's Medical Practice**. Proposed section 1357.11 assumes that the PHWP vendor is authorized to impose restrictions on a program participant's medical practice ("if a vendor imposes a practice restriction on a participant…"). It prescribes reporting and disclosure requirements concerning such restrictions. CPPC can find no provision in SB 1177 (Galgiani) that authorizes the program vendor to impose any practice restrictions. Under the statute, the vendor is required to report noncompliance, program withdrawal, and/or program termination to the Board (all subject to strict confidentiality provisions). Still, nothing authorizes the vendor to restrict a physician's medical practice. Only MBC can do that. This regulation must be rejected for lack of authority under Government Code sections 11349 and 11349.1.

5. **These Regulations Should Establish a Standing Board Committee to Oversee the PHWP**. As documented above, five prior audits of MBC's former diversion program uniformly found it failed to protect patients from substance-abusing licensees due in large part to the Board's failure to exercise any meaningful oversight over the program. Should this Board

decide to implement SB 1177 by creating a new PHWP, it must also create a mechanism by which Board members actively supervise the functioning of the program.

CONCLUSION

A proper analysis of these proposed regulations requires a detailed focus on the language and intent behind SB 1441 (Ridley-Thomas), SB 1177 (Galgiani), and the Uniform Standards-related rulemaking already conducted by the Board — a daunting task. It also requires a simpler exercise. MBC's statutory priority is public protection. As noted above, that priority is reflected in three different statutes. Further, "where rehabilitation and protection are inconsistent, protection is paramount." Business and Professions Code section 2229(c). When MBC seeks to create a rehabilitation program, it is the Board's burden to ensure that patients are protected above all else. The Board must reject these proposed regulations as unclear, inconsistent with two statutes and the Uniform Standards, duplicative of other Board regulations, and unauthorized.

Sincerely,

Marcus Friedman
Administrative Director
Consumer Protection Policy Center

Cc: Randy W. Hawkins, M.D., President, Medical Board of California
Reji Varghese, Executive Director, Medical Board of California
Senator Richard Roth, Chair, Senate Business, Professions & Economic Development Committee
Assemblymember Marc Berman, Chair, Assembly Business & Professions Committee
Kimberly Kirchmeyer, Director, California Department of Consumer Affairs