

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: April 21, 2014
ATTENTION: Board Members
SUBJECT: SB 1441 – Proposed Regulations to Implement the Uniform Standards for Substance-Abusing Licensees
FROM: Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

After review and consideration of the public comments received during the 15-day comment period, make a motion to approve the recommended changes to the attached proposed language to implement the Uniform Standards for Substance-Abusing Licensees (Attachment A). Further direct staff to notice the modified language for a second 15-day comment period. If no negative comments are received during the 15-day comment period, authorize the Executive Director to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopting Title 16 California Code of Regulations (CCR) section 1361, and adding sections 1361.5, 1361.51, 1631.52, 1361.53, 1361.54, and 1361.55 with the modified text.

BACKGROUND:

At the February 2014 meeting of the Medical Board of California (Board), Board Members reviewed and considered public comments directed to the modified language on the proposed regulations to implement the Uniform Standards for Substance-Abusing Licensees. Following the discussion, the Board authorized staff to notice the modified language for a 15-day comment period. This 15-day comment period ended at 5:00 p.m. on Friday, April 18, 2014. Two comments were received during this time, one from Consumers Union, and one from the California Medical Association (CMA) (Attachment B).

Comment by Consumers Union, dated April 10, 2014

Consumers Union has asked that section 1361.5(c)(3) dealing with biological fluid testing be amended to specify that the Board may reestablish a testing cycle or take any other disciplinary action if the Board has suspicion that a licensee has committed a violation of a Board's testing program, pursuant to Uniform Standard No. 4.

The current proposed language states the following under 1361.5(c)(3)(D): Nothing precludes the Board from increasing the number of random tests for any reason, in addition to ordering any other disciplinary action that may be warranted.

Moreover, under 1361.5(c)(3)(C), the proposed language indicates the following, in pertinent part: The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays.

While the previously-noticed language gives the Board broad discretion to order and increase biological fluid testing for any reason, Consumers Union asks the language be modified to include additional language found under Uniform Standard No. 4.

The language under Uniform Standard No. 4 is bulky, would create inconsistencies, and necessitate further definition if the Board were to adopt it as it is written. Nonetheless, the Board may wish to consider the following modification under 1361.5(c)(3)(D), by adding the language in red:

(D) Nothing precludes the Board from increasing the number of random tests, or returning the licensee to the first-year testing frequency requirements, in addition to ordering any other disciplinary action that may be warranted, for any reason, including, but not limited to, any suspicion that a licensee has committed a major violation as defined under 1361.52(a).

Comment by CMA, dated April 16, 2014

In order to harmonize the use of “negative biological fluid tests” and “prohibited substance,” under the proposed regulations, CMA has asked for the following amendment to the proposed language under 1361.5(c)(1)(D):

(D) The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests or biological fluid tests indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in section 1361.51(e).

I recommend that the Board adopt this proposed language, as it accounts for the situation where a licensee has a positive biological fluid test, but has a valid prescription for the substance.

Similarly, CMA asks for the following amendment under section 1361.53(c), addressing a request by a substance-abusing licensee to return to practice:

(c) Negative biological fluid testing reports or negative biological fluid testing reports for a prohibited substance, indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in section 1361.51(e), for at least six (6) months, two (2)

positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.

I recommend that the Board adopt this proposed language in concept, but recommend a slight modification, so that the language is consistent with the proposed change to 1361.5(c)(1)(D), above. Thus, I recommend the following change be made to 1361.53(c):

(c) Negative biological fluid testing reports or biological fluid tests indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in section 1361.51(e), for at least six (6) months, two (2) positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.

If the Board Members vote to support these modifications, the motion identified under Requested Action above should be made.

Sharon Levine, M.D.
President, Medical Board of California
Sacramento, California
April 10, 2014

Regarding: Regulations regarding SB 1441 Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Dear Dr. Levine:

As the manager of Consumers Union's Safe Patient Project (SPP),¹ I wanted to follow up with you regarding an issue that came up during the testimony of Michele Monserratt Ramos at the MBC quarterly board meeting on February 6, 2014 regarding regulations on the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees.

During her testimony, which was given on behalf of the SPP CA Network, Ms. Monserratt Ramos raised that concern that the proposed regulations did not explicitly incorporate Uniform Standard #4, which gives *the Board discretion to reestablish a testing cycle or take any other disciplinary action if the Board has suspicion that a licensee has committed a violation of a Board's testing program.*

Clearly, based on the discussion at the meeting, the MBC staff and members believe the current draft of the regulations gives the Board broad discretion to require testing and impose disciplinary action, for any reason. We support that. However, we are concerned that failing to include this specificity in the regulatory language (as is required in Uniform Standard #4) may cause several problems: (1) future Medical Boards may be unaware of their authority to act based on their "suspicion" and (2) physicians who fall under the Board's scrutiny may legally object to the Board taking action based on its "suspicion" since the regulations are not specific regarding this authority.

These are our concerns and we are sending this letter to confirm with you that the Medical Board intends to interpret this section of the regulations to give the MBC authority to act even when it has suspicion, without proof, that a licensee has committed a violation of the Board's testing program or some other major violation. We urge the Board to make an affirmative statement regarding this, for the record, to prevent resistance to its authority in the future.

We are otherwise pleased that the new regulations mostly incorporate the full Uniform Standards, which we believe are essential tools for the Board and staff to respond to these often difficult and

¹ Consumers Union's Safe Patient Project (SPP) is a nationwide campaign that organizes patient safety advocates from across the state of California on issues relating to hospital safety (hospital-acquired infections and medical errors) and physician safety. Our California Safe Patient Network ("CA Network") is working on issues related to the Medical Board of California (MBC).

contentious cases. We appreciate the attention you and the other members of the Medical Board have given this issue in recent months.

Sincerely,

A handwritten signature in black ink that reads "Lisa McGiffert". The signature is written in a cursive, flowing style.

Lisa McGiffert
Director
Consumers Union Safe Patient Project
www.SafePatientProject.org
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512-477-4431 ext 115

CC:

Members, Medical Board of California
Kimberly Kirchmeyer, MBC Executive Director
Kerrie Webb, MBC Senior Staff Counsel
Betsy Imholz, Director of Special Projects, Consumers Union



April 16, 2014

Christine Valine
Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815

Subject: Implementation of SB 1441 — Notice File No. Z2013–0827–11

Dear Ms. Valine:

The California Medical Association (CMA) respectfully submits the following comments for consideration related to the proposed adoption of regulations on the “Implementation of SB 1441”.

CMA is an advocacy organization that represents more than 39,000 California physicians. Dedicated to the health of Californians, CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.

I. BACKGROUND

SB 1441 (Chapter 548, Statutes of 2008) authored by Senator Ridley-Thomas Chair of the Senate Business, Professions and Economic Development Committee, created the Substance Abuse Coordination Committee (SACC or Committee). The law required the Committee, by January 1, 2010, to formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.¹ The final version of these standards was approved on April 6, 2009.

These standards, while approved by SACC, do not have the force of law of regulations and as such, full implementation requires each licensing board to promulgate regulations to adopt these standards pursuant to any applicable requirements under California’s Administrative Procedure Act (APA), Government Code sections 11500 *et seq.* To date, other licensing boards have implemented the standards to varying degrees. A proposal to implement SB 1441 was heard on July 19, 2013, at the Medical Board of California’s (Board) quarterly meeting held in Sacramento, CA. The Board granted the proposal to amend section 1361 in Article 4, Chapter 2, Division 13 and add section 1361.5 entitled “Uniform Standards for Substance–Abusing Licensees.”

¹ Business & Professions Code §315(c).

II. SUMMARY OF CONCERNS

Our comments pertain primarily to the inconsistent use of the terms “negative biological fluid tests” and “prohibited substances”.

Section 1361.5 (c)(1)(D) of Division 13 of Title 16: Clinical Diagnostic Evaluations and Reports

We recommend the following amendment (proposed amendment is underlined) to Section 1361.5 (c)(1)(D) of Division 13 of Title 16:

“(D) The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests or biological fluid tests indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in Section 1361.51(e).”

The provision as proposed currently does not allow for the scenario in which a licensee has a positive biological fluid test result, but has a valid prescription for that substance. Not only is such a scenario reasonably likely to occur, the Board has expressly recognized and accepted the possibility of a permissible positive biological fluid test result. Section 1361.51 (b) provides that “[a] biological fluid test will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.” The proposed amendment to Section 1361.5(c)(1)(D) harmonizes the section with Section 1361.51(b) and clarifies the intent of the regulations to impose disciplinary action for the use of prohibited substances, not for all positive biological test results.

Section 1361.53 (c) of Division 13 of Title 16: Request by a Substance-Abusing Licensee to Return to Practice.

We recommend the following amendment (proposed amendment is underlined) to Section 1361.53 (c) of Division 13 of Title 16:

Section 1361.53 (c) states that before determining whether to authorize the return to practice after the issuance of a cease-practice order, one of the criteria that a licensee must meet is:

“(c) Negative biological fluid testing reports or negative biological fluid testing reports for a prohibited substance, indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in Section 1361.51(e). for at least six (6) months, two (2) positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.”

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Again, this provision does not allow for the scenario in which a licensee has a positive biological fluid test result, but has a valid prescription for that substance. The proposed amendment to Section 1361.53(c) harmonizes the section with Section 1361.5(b) and clarifies the intent of the regulations to impose disciplinary action for the use of prohibited substances, not for all positive biological test results.

In conclusion, CMA supports and encourages appropriate monitoring and disciplinary measures for physicians. Thank you in advance for your consideration of our comments on the proposed regulations. California's physicians look forward to working with you to develop regulations on disciplining physicians with substance abuse issues, while keeping patient care and safety a top priority.

Sincerely,

Yvonne Choong
Senior Director, Center for Medical and Regulatory Policy
California Medical Association