TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS DEPARTMENT OF CONSUMER AFFAIRS

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

Final Statement of Reasons

Subject Matter of Proposed Regulations: Continuing Medical Education and Audits and Cite and Fines

Section(s) Affected: Title 16 of the California Code of Regulations (CCR) sections 1635, 1636, 1638, 1639, 1640, 1641, 1646, 1659.30, 1659.31, 1659.32, 1659.33, 1659.34, and 1659.35.

Updated Information

The initial statement of reasons is included in the file. The information contained therein is updated as follows.

The 45-day public comment period began on November 21, 2024 and ended on January 6, 2025. The Osteopathic Medical Board of California (Board) received written comments as described below. A hearing was not scheduled as part of the initial notice of this rulemaking, but one commenter requested a hearing, which took place on January 8, 2025. No members of the public appeared and requested to provide testimony or written comments at the hearing. A transcript of the hearing is included in the regulatory file. The written comments received during the public comment period as well as the responses to those comments are summarized in the "Objections or Recommendations/responses" section below. The Board considered the comments at its February 13, 2025 Board meeting and authorized modified text changes and the addition of new documents added to the rulemaking file, as discussed below.

Addendum to the Initial Statement of Reasons and Other Documents Added to the Rulemaking File.

The Board posted and circulated an Addendum to the Initial Statement of Reasons that added the following rationales for changes made to this rulemaking:

In accordance with the Administrative Procedure Act (APA), all documents "Incorporated by reference" in a regulation are considered part of the regulation and any agency adopting or

repealing any document incorporated by reference must comply with the same notice and availability requirements as required for other parts of the regulatory text (Cal. Code Regs., tit. 1, § 20). "Incorporation by reference" occurs when a regulation in the California Code of Regulations incorporates another document by referencing it by title and date of issuance or the date it became effective. Once incorporated material is approved, the documents are legally considered a regulation and subject to the same standards as other regulations.

This proposal proposes to repeal an AOA Guide and an AMA Guide ("Guides") from 1986 and 1992 that is currently incorporated by reference by the Board in CCR section 1635(e). Upon review, it was discovered that the Guides with the "Repealed" watermark were not filed, posted on the Board's website, or circulated for public comment along with the proposed regulatory language. Consequently, to ensure that all proposed regulatory changes are included as part of the rulemaking file, the Board is adding the following Guides to the rulemaking file and providing notice to the public.

Modified Text Changes:

Purpose: The Board proposes to delete the originally proposed exemption from the 12hour pain management and treatment of terminally ill and dying patients CME course for physicians that do not reside in California. This exemption originally proposed at CCR section 1635(f)(4) would be deleted, and the Board would strike references to the associated documentation required in CCR section 1636(b)(4) and (d)(4). Cross-referencing and numbering would be corrected throughout the proposal to accommodate the removal of CCR sections 1635(f)(4) and 1636(b)(4), and (d)(4).

Instead, proposed amendments to subsections (f)(1) and (2) of CCR section 1635 would contain revisions to the definition for "direct patient care" to shorten the currently proposed sentence and add clarifying definitions to increase understanding of the scope of the proposed exemptions. Further, the associated exemptions for physicians who do not provide "direct patient care" or "patient consultations" would be revised to insert references to "California patients" and add a new definition for "personal contact". The substantive changes to subsection (f) of CCR section 1635, in pertinent part, follow highlighted with italics to show emphasis, as follows:

(f) Osteopathic physicians and surgeons ("physicians") meeting any of the following criteria at the time of renewal shall be deemed exempt from the requirements of subsection (e)(1):

(1) Physicians practicing in pathology or radiology specialty areas as required by Section 2190.5 of the Code;

(2) Physicians not engaged in direct patient care, meaning. "Direct patient care" means *no*-personal <u>contact</u> or face-to-face interaction with *the-a patient* <u>located in California ("California patient")</u>, including health assessments, counseling, treatments, patient education, prescribing or administering

medications, or any task authorized by the Act or described in Sections 2051 or 2052 of the Code that involves personal interaction with the <u>California</u> patient. <u>"Personal contact" shall include communication by any method of direct</u> <u>interaction with the patient or via telehealth as provided in Section 2290.5 of the</u> <u>Code</u>;

(3) Physicians that do not provide patient consultations regarding a California patient;

(4) Physicians that do not reside in the State of California;

<u>Rationale</u>: The originally proposed language in CCR 1635(f)(4) contains an unfettered exemption from the 12-hour CME pain management course for physicians that do not reside in California. BPC section 2190.5 states, in pertinent part:

(b) **By regulatory action, the board may exempt physicians** and surgeons by practice status category from the requirement in subdivision (a) **if the physician** and surgeon does not engage in direct patient care, does not provide patient consultations, or **does not reside in the State of California**. (Emphasis added.)

By law, the Board may therefore, exercise its discretion to grant or not grant such an exemption to this CME requirement, including to those who reside outside of California. Currently, the Board's proposal lists exemptions for:

- (1) physicians practicing in pathology or radiology (required to be exempted by law),
- (2) physicians not engaged in direct patient care,
- (3) physicians that do not provide patient consultations,
- (4) physicians that do not reside in the State of California,
- (5) physicians who have completed a one-time continuing education course of 12 Credit hours in the subject of treatment and management of opiate-dependent patients; and,
- (6) physicians who are deemed a "qualifying physician" as specified in BPC section 2190.6.

The law at BPC section 2190.5 and the exemption option upon which this current regulatory proposal at CCR 1635(f) is based was enacted by Assembly Bill 2487 in 2001. That bill was enacted in response to the following policy concerns:

For the past 20 years, medical journals have reported that physicians

consistently fail to manage their patient's pain appropriately. These studies also consistently report that the single most important cause of this problem is lack of physician knowledge and awareness regarding appropriate pain management treatments. It is also the intent of the Legislature that this act serve to broaden and update **all physicians'** knowledge bases regarding appropriate care and treatment of terminally ill and dying patients. The Legislature intends that this act provide for the continuing education of **all physicians** on these two topics of medical care. (AB 2487, Stats. 2001, Ch. 518, § 1.) (Emphasis added.)

The option to allow the Board to exempt physicians residing in another state was apparently included in AB 2487 to address those physicians residing in other states who had no California patients. However, the Legislature may not have considered that physicians residing out of state who hold a license issued by this Board may, nevertheless, provide direct patient care or consultations via telehealth or other means to California patients. This is further evidenced by the fact that: (1) the Legislature did not pass any laws relating to telehealth practice until 2011, when BPC section 2290.5 was enacted per Assembly Bill 415, and (2) since 2001, the delivery of health care service and public health information via telehealth has expanded and appears to be a more constant and significant mode of delivering medical care.

In light of those considerations, allowing an outright exemption to this CME requirement based only on out-of-state residence would possibly frustrate the intent and purpose behind enactment of BPC section 2190.5, which could result in: (1) not all physicians taking the 12-hour pain management CME course when they do in fact provide direct patient care and consultations regarding a California patient; and, (2) disproportionate application of the CME requirements, as only physicians not "residing" in the State would be exempted, while all physicians who reside in this State would be required to take the training unless otherwise exempted.

To address this problem, the Board proposes to amend the language as indicated above to ensure that all physicians, regardless of residence, who provide direct patient care (either face-to-face or through "personal contact", i.e., via telehealth or otherwise) or consultations regarding a California patient, would be required to take the mandatory 12-hour CME course within 4 years of their initial license or by their second renewal as mandated by BPC section 2190.5. Since the above-noted exemption would be deleted in this modified text, the proposed questions to applicants at the time of renewal to determine qualifications and the documentation requirements in CCR section 1636(b)(4)(D) and (d)(4)(b) would likewise be deleted as no longer necessary. Corresponding changes would be made to terminology in CCR 1636(b)(4)(C) to add reference to a patient "located in California" to ensure consistent use of terminology for the proposed exemptions across the proposal.

Board Action Continued

After consideration of the foregoing, the Board approved the modified text and the addition of

new documents to the rulemaking file for an additional 15-day comment period with the scope of comments limited to the modified text and the documents added to the rulemaking file.

Specifically, at the February 13, 2025 Board meeting, the Board voted to approve the documents added to the rulemaking file in Attachment 2 of the meeting materials and the proposed modified text in Attachment 6 of the meeting materials and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text and notice of the addition of documents added to the rulemaking file for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Director to make any non-substantive changes to the proposed regulations and the rulemaking documents, and adopt the proposed regulations as provided in the modified text in Attachment 6 of the meeting materials.

The 15-day public comment period extended from March 4, 2025, to March 19, 2025. The Board received one responsive comment supporting the policy change and proposed language and two non-responsive comments. The Board did not receive any adverse comments directed at the modified text or documents added to the rulemaking file, as discussed more fully below.

1 CCR Section 100 Changes

While this rulemaking was pending, the Board initiated a section 100 filing that made nonsubstantive changes to 16 CCR sections 1635, 1636, 1659.30 and 1659.32. The Section 100 filing was approved by the Office of Administrative Law and the changes became effective on January 15, 2025 (OAL Regulatory Action No. 2024-1224-03N). The Order of Adoption was revised consistent with those technical changes and reflects the most recent version of the CCR for Sections 1635, 1636, 1659.30 and 1659.32.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

The Board has determined that the proposed regulations would have no significant impact on small businesses as it impacts individuals. For those impacted, this regulation modifies an existing disclosure requirement making it less onerous and makes compliance more convenient to licensees. This regulatory change also protects public safety and prevents delays in processing licensing renewals that can result in interruptions in patient care.

This regulation only impacts approximately 13,600 osteopathic physicians and surgeons that represent a small percentage of the California population and businesses. The modified text does not change this estimate.

To the extent that individual licensees own a small business, the impact would be minor as the

Board estimates up to 68 individuals may be issued a citation with an estimated average fine amount of \$1,500 fine per year. The modified text does not change this estimate.

The Board notes, licensees may avoid any fines levied by complying with the Board's CME requirements authorized under current law and regulations.

Anticipated Benefits

CME and Audits Benefits

The renewal process will be streamlined and reduce delays from staff having to review CME course completion documentation at the time of renewal. The time-consuming review of CMEs documentation demonstrating compliance will be completed after renewal in a more reasonable time frame for Board staff without the negative impact on licensees and patient care. Licensees will benefit from the streamlined process that allows them to certify compliance and renew without further delay while providing the Board with the authority to randomly audit to confirm compliance. The elimination of reviewing CMEs completion documentation at renewal time will eliminate processing delays, and practice suspension or interruptions in patient care.

The additional authority to randomly audit licensees, who will be subject to possible citation and fine for violations, helps enhance public protection as anyone who fails the audit will not be eligible for their next renewal until they have completed their missing CME. Completion of required number of CMEs as a condition for renewal remains unchanged.

Cite and Fine Benefits

This proposed rulemaking will further consumer protection by updating the Board's cite and fine regulations to clarify that the Board may issue a citation to a licensee (osteopathic physician or postgraduate training licensee), which may contain a fine and/or order of abatement for a violation of any provision in the Osteopathic Act, Medical Practice Act, any regulation adopted by the Board, and any other statute or regulation upon which the Board may base a disciplinary action, in addition to certain specified statutes and regulations. These amendments will help keep the list of citable offenses current, as statutes and regulations are added, repealed, and modified. In addition, the Board will be updating its unlicensed activity citations to ensure greater compliance with the laws under the Board's jurisdiction and the enforcement of provisions prohibiting the unlicensed practice of medicine.

Updating the cite and fine regulations will enhance public protection by authorizing additional enforcement tools that allow the Board to take action for violations that do not rise to the level of warranting discipline but do raise issues that should be brought to the licensee's attention for correction.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board as part of public comments received or at the Board's meetings would be more effective in carrying out the purpose for which the regulation is proposed, or would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. All recommendations provided during this rulemaking were considered by the Board and rejected or accepted as discussed herein.

<u>45-Day Public Comment Period -Summary of Comments Received and Board</u> <u>Responses</u>

Objections or Recommendations/Responses

Summaries of the comments received, and Board responses are provided below.

Comment in Support of Rulemaking Proposals

Commenter #1. Joseph J. Provenzano, D.O. comment received by email 11/27/2024. **Comment Summary:**

Dr. Provenzano commented that he had served on the OMBC board. He indicates that even then when there were 6,000 licensees it was becoming a problem with manual verification of CME. He supports the regulation change.

Board Response to Comment #1:

The Board has considered this comment and welcomes the support for the proposed rulemaking package and acknowledgement that the update and proposed changes are needed. As a result, no changes are necessary in response to this comment.

Adverse Comments and Comments that Want New Changes to CME Policies

Commenter #2. Dr. Michael Strug,, D.O. comment received by email 11/21/2024. **Comments Summary:**

Dr. Strug requested that he be involved in a town hall meeting or discussion about CME requirements. He states that he is an Osteopathic physician in a subspecialty that does not have associated AOA approved credit (Reproductive Endocrinology and Infertility). He completes CME through the American Board of Obstetrics and Gynecology and attends conferences that grant AMA credit. His concern is that there is no AOA approved credit for the subspecialty Reproductive Endocrinology and Infertility which forces him to take AMA courses that he later

has to pay the AOA to convert AMA credit to AOA category 1B credit. He wonders if there is a way for the Board to accept AMA credit for physicians in similar circumstances.

Board Response to Commenter #2:

The Board has considered this comment and provides the following response. In response to his first request, the Board scheduled a regulatory hearing for January 8, 2025 and Dr. Strug was emailed notice of that hearing. However, no members of the public provided comments at that hearing. Regarding whether there is a way for the Board to accept AMA credit, BPC section 2454.5 mandates, in pertinent part:

The board shall require each licensed osteopathic physician and surgeon to complete a minimum of 50 hours of American Osteopathic Association continuing education hours during each two-year cycle, of which 20 hours shall be completed in American Osteopathic Association Category 1 continuing education hours and the remaining 30 hours shall be either American Osteopathic Association accredited as a condition for renewal of an active license.

For purposes of this section, "American Osteopathic Association Category 1" means continuing education activities and programs **approved for Category 1 credit by the Committee on Continuing Medical Education of the American Osteopathic Association**. (Emphasis added.) As a result, according to statute, the above AOA committee determines whether any AMA CME is accepted as qualifying continuing medical education (CME) with the exception of specified AMA CME that would exempt a "qualifying physician" from taking the one-time pain management course as authorized by BPC section 2190.6 and as proposed in CCR section 1635(f)(6)(D). Any other changes in CME policy such as the categories and types of credit or who determines whether it is approved as Category 1 credit would require a statutory change and cannot be done at this time through this rulemaking proposal. The Board rejects this comment.

Commenter #3. Denis Yoshii, DO, comment received by email 11/22/2024.

Comments Summary:

Dr. Yoshii expressed support for updating CME requirements, but as a solo practitioner specializing in allergy and immunology, he had the following concerns and recommendations (the numbering convention for the paragraphs in the original email has been changed to letters A-C for easier review):

A. Administrative and Financial Impact on Solo Practices:

The proposed changes may disproportionately affect small or solo practices due to increased administrative burdens and potentially higher CME-related costs. Please consider offering flexibility for solo practitioners in course selection and record-keeping to minimize disruption to patient care. In addition, every board certification has requirements for specific numbers of hours to maintain board certification. Pediatrics requires 25 hours, and Allergy requires 25 hours, this is made more difficult with the addition of education requirements outside of board certification. The Hospitals all each require 1 hour of fraud and waste, but each hospital uses a different program. And, of course, as many of practitioners have multiple state licenses, each state has its own requirements of not only hours, but 'physician burnout', cultural sensitivity, opioid, dependency. Often each CME requirement places financial stress on the individual and takes time away from family. I did 132 hours of CME these past two years and was still 9 hours short of OMBC CME requirements.

B. Clarity in Audits and Penalties:

While I support the need for audits and transparency, the criteria for citations and fines must be clearly defined to avoid subjective enforcement. Explicit guidelines, individualized guidance of which CME is required for which year, will help ensure compliance and reduce unintended penalties.

C. Enhancing Accessibility to CME:

Providing affordable or Free CME options, particularly online or specialty-specific courses, would benefit practitioners in underserved or rural areas who might otherwise face logistical challenges. Denis Yoshii, DO

Board Response to Comments in Paragraph A. Provided by Commenter #3:

The Board has considered these comments and makes no changes to the language of the regulation based thereon. The Board reiterates its response to Commenter #2 regarding the legislative mandates in BPC section 2454.5 (including risks of addiction course) as well as the requirements for other dedicated CME in BPC sections 2190.1 (implicit bias), 2190.5 (a one-time pain management course) and 2190.3 (as specified for internists and family physicians with older patients or patients with dementia). The Legislature, not the Board, has created these CME requirements. The Board's role is to implement CME requirements set by the Legislature. The Legislature already created flexibility in the types of CME accepted to include exemptions from the pain management course in BPC sections 2190.5 and 2190.6, and allow credit in non- clinical subjects such as record keeping, practice management, and placed a cap on the non- clinical hours to be no more than 15 hours or up to 15% out of the required 50 hours per renewal period at BPC section 2190.15. The purpose of CME is as a tool for maintaining competency and protecting public safety; the number of required hours is considered a minimum number or hours not a maximum. For the foregoing reasons, the Board rejects these comments.

Board Response to Comments in Paragraph B. Provided by Commenter #3:

The Board has considered these comments and makes no changes to the language of the regulation based thereon. The proposed regulations include specific criteria for the Board to use in each individual case in CCR section 1659.31(b) for cite and fine to prevent any arbitrary and capricious cite and fines and orders of abatement. Additionally, when a cite and fine and order of abatement is issued, it would contain the specific facts, violations of statute with the specific sections and the amounts assessed for each violation alleged in the particular case as

required by existing CCR section 1659.30.

As to the request for the Board to provide individualized guidance for CME due each renewal cycle, once this proposal is approved, the Board will be revising its current CME guidance on the Board's website to reflect the proposed changes in this rulemaking. This is one area the proposed rulemaking amendments addressed by adding specific documentation requirements for each statutorily required CME subject and hours and what specific documentation requirements for each required CME in proposed amendments to CCR section 1636. This information is lacking in the current regulations. So, the Board's current rulemaking proposal already addresses the concerns raised about guidance on CME requirements in that regard.

Board Response to Comments in Paragraph C. Provided by Commenter #3:

The concern and recommendation about making CME more accessible and affordable is not something the Board has authority or control over since it is not a CME provider. The Board's role is enforcing the statutory requirements for renewal and CME. In the Board's experience, however, it appears that there are online CME courses already that have expanded to allow greater options for accessibility and to address logistical challenges since the COVID 19 outbreak in 2020.

For the reasons noted above, the Board rejects this comment and makes no further changes in response to this comment.

Commenter # 4. Comments received by email from Evan Moser, DO 11/21/2024. Comments Summary:

Dr. Moser's comments object to the statutorily mandated pain management requirement stating that he does not "believe this is appropriate for all osteopathic physicians." As a radiologist, he explains that he rarely prescribes medications other than occasional conscious sedation for procedures and emphasizes that "[w]e are already required by other regulatory entities to provide CME relevant to those procedures." He indicates that "the same is true for other fields of medicine such as Pathology." He then proceeds to provide examples and rationales for why the "12 CME hours in pain management is just information that I would never use."

Board Response to Comment #4:

Dr. Moser's comments object to the statutorily mandated pain management requirement being required of a radiologist or a pathologist. BPC section 2190.5(c) already exempts radiologists and pathologists from this mandatory requirement. This proposal and the applicable exemptions already mandated by law are listed in one convenient location in proposed amendments to CCR 1635. In fact, the proposed rulemaking specifies all exemptions in CCR section 1635 and the documentation required to demonstrate eligibility for such an exemption in CCR section 1636 to provide greater notice to the regulated community.

For the foregoing reasons, the Board rejects this comment and makes no changes to the language of the regulations based thereon.

Commenter #5. John R. Hawes, Jr., D.O., comment received by email 11/22/2024. Comments Summary:

Dr. Hawes, Jr.'s comments expressed support for improvements in the CME process. His remaining comments focus on a personal issue unique to him where he attended a large CME conference two months after receiving his current license but two weeks before his birthday. These "18 hrs. of category 1-A credits were not needed, nor used," for his current license but, also, not allowed to be used for his next cycle. He complains that this conference, including the cost of travel and hotel, has resulted in unusable CME credits. He states he has been informed that there is "no answer to my dilemma," and attached a copy of his past CME certificate.

Board Response to #5 Comment:

The Board acknowledges the comment expressing support for making CME improvements. Regarding the other comments, BPC section 2454.5 is specific about requiring 50 CME credits for each renewal cycle. Through the years the renewal and CME cycles changed from birth date renewal to date of issuance renewals (as currently specified in BPC section 2456.1 as of January 1, 2023) and that was in part why the rulemaking was needed to update the changes to the statute over the years and eliminate any conflict between the statutory requirements and the outdated regulatory requirements.

The reason that flexibility cannot be provided to licensees to apply excess CME credits to future or past renewal cycles is because the statute specifies that licensees must complete a minimum of 50 hours during each two-year renewal cycle as provided in BPC section 2454.5. For the foregoing reasons, the Board rejects these comments and makes no changes to the language of the regulations based thereon.

Commenter #6. Darrin Cunningham, D.O. comments received by email 11/28/2024. Comment Summary:

Dr. Cunningham wonders why the CME provisions do not allow their CME requirements to be based on their certifying board and the AOA. He notes that he "may be in compliance with my hours for ACOOG AND THE AOA, by having only 25 hours in one year, but I may have 70 hours the next and and 25 the last." He states that he is in compliance at the national level but not in compliance at the state level. He asserts that many physicians hold licenses in several states, with differing CME rules. He states, "I have always thought if my Cme is good enough for my Board to deem me Board Certified then why does the state not think that's good enough." He recommends that the Board adopt a clause that states: "If the physician is in Cme compliance with their Board Certifying entity, they are in compliance in California."

Board Response to Comments for Commenter #6:

Dr. Cunningham's recommendation would be a change in policy of what is required and acceptable CME according to statutory requirements already discussed in the responses to the comments noted above. Such a policy change would have to be done through legislation, not regulations.

For the foregoing reasons, the Board rejects these comments and makes no changes to the language of the regulations based thereon.

Commenter #7. Letter from Tony Khan, DO, OPSC President on behalf of Osteopathic Physicians and Surgeons of California (OPSC) emailed and dated 12/18/2024.

Comments Summary:

The Commenter expresses OPSC's general support for the proposed regulations and appreciates the hard work that has gone into the current draft but has questions and/or concerns pertaining to the following provisions.

A. §1636 – Continuing Medication Education Document

In 1636 the regulations are appropriately being updated to recognize the change in law to 50 hours of CME every two years. OPSC agrees with this change but seeks clarification. In (b)(2) the language clarifies the number of hours (50) and type of CME (AOA). In the subsequent clauses, the language states that 20 of the 50 hours be AOA Category 1, but in (b)(2)(B) the language states that the remaining 30 CME hours maybe earned..."by either the AOA or the American Medical Association (AMA). OPSC suggests CCR section 1636 (b)(2) be amended to include both AOA or AMA CME options since the subsequent (b)(2)(B) allows for both types of CME.

B. §1659.31. Fine Amounts and Criteria to Be Considered

We are interpreting these changes, especially (BB) to dramatically expand the scope of the Board's authority to issue citations and fines. While we wouldn't expect Board staff to go rogue or abuse their power, these changes appear to significantly broaden the types of citations and fines a physician could be subject to by OMBC staff. While we understand this approach may be appealing to avoid having to further update regulations as statutes change, OPSC recommends this section be amended to specify the specific codes violations it seeks to have the authority to issue citations. Doing so will provide osteopathic physicians clarity and certainty as to what provisions are subject to disciplinary actions.

Additionally, it's unclear to OPSC why **§**1659.31 maintains specific provisions subject to fines via (a)(1)(a-w) while deleting various others and then including clauses that give the Board broad authority. Is there a reason for specifying some finable offenses, but not providing an exhaustive list? Or what purpose does the list serve if the Board aims to have broad authority? We suggest deleting the carte blanche provisions and instead specifying the acts that are subject to board fines.

Board Response to Commenter #7's Comments in Paragraph 7.A.:

CCR Section 1636 provides updated specificity on the documentation requirements for CME audits but does not fundamentally alter the fact that BPC section 2454.5 states, in pertinent part:

The board shall require each licensed osteopathic physician and surgeon to complete a minimum of **50 hours of American Osteopathic Association continuing education hours** during each two-year cycle, of which 20 hours shall be completed in American Osteopathic Association Category 1 continuing education hours and the remaining 30 hours shall be either American Osteopathic Association or American Medical Association accredited as a condition for renewal of an active license. (Emphasis added.)

Title 16, CCR Section 1636 adheres to the wording of the statute at BPC section 2454.5 exactly. In order make the suggested change, therefore, this proposed change would first have to be made to the statute at BPC section 2454.5. The consequence of modifying the text as recommended is that the modified language could be deemed inconsistent with BPC section 2454.5 and unauthorized; and, therefore, potentially causing the rulemaking to be denied. All regulatory language must adhere to the statute which authorizes the subject matter. In this case, the proposed regulatory language does adhere to the statute and is in fact updated to adhere to the statute. For the foregoing reasons, the Board rejects these comments and makes no changes to the language of the regulations based thereon.

Board Response to Commenter #7's Comments in Paragraph 7.B.:

BPC section 125.9(a) specifically authorizes any board, bureau or commission in this Department including this Board, to establish, by regulation, "a system for the issuance to a licensee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the board, bureau, or commission where the licensee is in violation of the applicable licensing act or any regulation adopted pursuant thereto." Subdivision (c)(2) of Section 125.9(c)(2) indicates that the boards "may" limit the assessment of administrative fines to only particular violations of the applicable licensing act, but this section does not require such a limitation.

CCR section 1659.31 updates the cite and fine section to include all statutory violations for which the Board has jurisdiction to enforce and as authorized by BPC section 125.9. This change updates the Board's cite and fine authority to match what is currently allowed by statute. Without this change, the Board's enforcement authority was severely limited due to outdated regulations that listed only specified statutes. Listing each statute and promulgating regulations for each new change in law is also a significant barrier to enforcement, one not envisioned by the Legislature. The Legislature assumes that once a law becomes effective, it is assumed the Board would exercise all of its authority to enforce it. This updated language aligns the Board's regulatory authority with its complete statutory authority in real time. It will vastly improve the Board's enforcement by having current enforcement authority for cite and fines and order of abatement and expand the Board's enforcement remedies to include a broad range of nondisciplinary remedies. These changes have the benefit of helping to keep the list of citable offenses current, as statutes and regulations are added, repealed, and modified, and by definition, these changes add new code and regulatory sections to the pool of violations eligible for a citation.

Further, individuals are expected to follow the law, and if they commit a violation, this proposed rulemaking will give the Board the authority to issue a citation at an early stage, where appropriate. This tool is a form of progressive enforcement that serves to protect the public and rehabilitate the license before the licensee's misconduct reaches a point where disciplinary action is necessary for public protection.

While the Board chose to self-limit its citation authority to only particular violations a long time ago, the Board has now determined, in its experience, that a policy change is necessary to provide other enforcement options short of discipline that would aid in the rehabilitation of licensees consistent with its public protection mission. To implement this policy change, the Board needs to revise the existing regulations to claim its full citation authority permitted under the law. The following healing arts boards in this Department have adopted regulations implementing a similar policy, including the State Board of Chiropractic Examiners under 16 CCR section 390, the California State Board of Pharmacy under 16 CCR section 1775, the Board of Registered Nursing under 16 CCR section 1435, the Board of Behavioral Sciences under 16 CCR section 1886.40, the Dental Board of California under 16 CCR section 1023, and the Medical Board of California under 16 CCR section 1364.11 (effective October 1, 2024).

Further, the Board has no concerns that staff would "go rogue" with this expanded authority, since all citations and fines that are issued would need to comply with the Board's criteria in CCR 1659.30 and 1659.31, are generally capped by this Board at \$2500 per citation (except for some extenuating circumstances as specified in Section 1659.31), and subject to appeal and review by the Board. The Board notes that the burden of proving that a citation is warranted is on the Board, and citations may be contested informally through the Board, as well as formally through the Office of Administrative Hearings as authorized by 16 CCR section 1659.34. The reason that some existing codes sections were left unchanged is because they represent current, specific authority for which the Board may issue a citation and fine outside of the Board's licensing Act. Keeping those statutes in the list provides greater specificity regarding these other grounds for citation under the Board's jurisdiction and highlights perhaps lesser-known statutes for better notice to the regulated community. This approach was recently approved for the Medical Board of California's most recent amendments to similar authority in 16 CCR section 1364.11.

For the foregoing reasons, the Board rejects these comments and makes no changes to the language of the regulations based thereon.

Commenter #8. Lucas Evensen, Associate Director, Strategic Engagement, on behalf of the California Medical Association (CMA) comment letter emailed and dated 1/6/2025.

Comment Summary:

The Board is proposing to amend Section 1659.31 to include any provision of the Medical Practice Act (MPA), any regulation adopted by the Board, and any other statute or regulation upon which the Board may base a disciplinary action instead of listing each citable code section in an effort to update the list of citable offenses to help keep the section current as statutes and regulations are added, repealed, and amended. CMA believes that this application is overly broad and could give rise to misinterpretation by licensees about the way the Board may seek redress for situations that come before it.

CMA asserts that the proposed regulations effectively add numerous new code sections to the pool of violations eligible for citation. The CMA alleges that the scope of this policy decision was never contemplated or discussed by the Board, and it was not addressed in the notice of proposed regulatory action. CMA asserts that the Board only contemplated the effect these changes would have on its ability to keep the list of citable offenses current. However, CMA believes that this proposal would have a more substantive impact. If this is the intent of the Board, then the Board should have this discussion and clearly identify which codes it intends to add to the list of citable offenses and continue to maintain that list in regulation.

For these reasons, CMA requests that the Board to revert to the former approach to drafting regulations and list each code section to clearly identify which sections the Board intends to reserve the right to issue a citation for.

Board Response to Comment #8:

The Board reiterates its response to Commenter #7's comments in paragraph B. noted above. As to prior policy discussions, the Board did discuss in detail at various meetings the policy change allowing the Board to have authority to issue citations and fines and abatement orders for any violation that the Board has statutory authorization and jurisdiction to issue. The reasons for the proposed rulemaking were presented to the Board and discussed at public Board meetings on January 19, 2023, August 17, 2023, and August 15, 2024 (see the list in the "Underlying Data" section in the Initial Statement of Reasons and available upon request from the Contact Persons listed in the Notice). The Board did not have any concerns at those meetings and unanimously approved this proposal. This proposal aligns the statutes with the regulations and authorizes the Board to issue citations and fines and abatement orders for any statute or regulation which they are authorized to enforce. Additionally, this provides the Board more enforcement remedies that are not disciplinary in nature for cases that the Board concludes does warrant enforcement action, but not disciplinary action. Citations, fines, and abatement orders are not considered discipline. ("[T]he greatest sanction that could be imposed in the citation proceeding itself was a fine or penalty, not suspension or revocation of his license." Owen v. Sands (2009) 176 Cal.App.4th 985, 994.)

The allegation that the Notice of Proposed Action (Notice) for this rulemaking did not address the scope of this policy decision lacks merit in light of the fact that the Notice specifically provides the following references related to this proposed policy change: The Board's cite and fine regulatory CCR sections 1659.30,1659.31, 1659.32, 1659.33, 1659.34, and 1659.35 are outdated and need updating. Existing law at BPC section 125.9 authorizes the Board to establish, by regulation, a system for the issuance to a licensee of a citation where the licensee is in violation of the applicable licensing act or any regulation adopted by the Board. Section 125.9(c) also authorizes the Board, in its discretion, to limit citations to only particular violations of the applicable licensing act or regulations. **Existing regulations at CCR section 1659.31 reflect Board policy at the time to issue citations and fines for only particular violations of laws or regulations. This proposal would, instead, allow the Board to cite and fine for violation of any laws or regulations under the Board's jurisdiction, including violations of the Osteopathic Act (as established as an Initiative Measure), the Medical Practice Act, the Confidentiality of Medical Information Act, any Board regulation in Division 16, or any other statute or regulation upon which the Board may base a disciplinary action. (Emphasis added.) (Notice, p. 4.)**

Amend 1659.31. This section revises the title, adds authority for the Executive Director to delegate their authority to a designee, clarifies fine amounts, and repeals and adds factors for determining fine amounts, as specified. Existing text at subsection (a) limits, in accordance with BPC section 125.9(c)(2), the issuance of citations with orders or abatement and the assessment of administrative fines to only particular violations of the Board's applicable licensing laws and regulations. This proposal would revise and add language that consolidates existing licensing act and regulations citation authority into broader categories that cover all provisions under the jurisdiction of the Board including violations of the Osteopathic Act (as established as an Initiative Measure), the Medical Practice Act, the Confidentiality of Medical Information Act, or any other statute or regulation upon which the Board may base a disciplinary action.

Further this Notice was approved by the Office of Administrative Law (OAL) prior to the Board initiating the 45-day comment period. Part of the rulemaking process includes OAL reviewing and approving the notice of rulemaking to determine that it complies with the Administrative Procedure Act (APA).

The Board rejects these comments and makes no changes to the language of the regulations based thereon.

Commenter # 9. Kelly Parker, Sr Director, External Affairs and Government Relations, CE Broker by Propelus comment letter received by email and dated 1/3/2025.

Comments Summary:

A. The Commenter supports the Board's effort to update its regulations but has the following comments. One concern is that reducing the CME reporting period from 3 years to 2 years, along with changes to the CME requirements as proposed in §1635, "will lead to confusion among professionals and increase customer service demands (calls/emails) at the board if the rollout is not managed efficiently and effectively." The Commenter asserts that "professionals

prefer using technology solutions for continuing education compliance" and touts the benefits of digital tools, technology for tracking credits, in digital platforms. He highlights the concept of modernized platforms to integrate directly with licensing boards, "enabling automatic submission of CME credits and updates to licensing status, removing the need for manual uploading of documentation."

The Commenter strongly encourages the Board "to modernize the processes with a digital continuing education management solution" to enhance efficiency, "enabling board staff to fully automate audits and achieve 100% automation when managed through a digital platform."

B. The Commenter notes that the proposed changes in section 1641, as well as the proposed changes in sections 1659.30-1659.35, provide further detail and clarification on the cite and fine provisions, but cautions that "they should be carefully calibrated to ensure they serve as both a deterrent and an opportunity for correction." "With the features listed above regarding automated CME tracking and reporting, a digital platform can also assist board staff in determining exactly where a licensee is deficient in their compliance, and to what extent. This is crucial in calculating the appropriate sanction to remedy that deficiency, further lightening the load on staff and making the disciplinary process more efficient, effective, and fair." In summary, the Commenter encourages the Board to adopt an automated, digital CE management system.

Board Response to Comment #9, paragraph A.:

For the following reasons and the reasons set forth above in responses to Commenter #7, the Board rejects these comments and declines to make any changes to the proposed regulations in response to these comments.

The concern raised about changing the CME cycle from 3 years to 2 years was one of many statutory changes made in 2017 by SB 798, chapter 775, Statutes of 2017 that became effective January 1, 2018. Other changes made in that bill included: eliminating the even and odd year issuance of licenses, aligning the CME and the renewal cycles to be the same date of issuance period rather than different cycles. All of these changes simplified and streamlined the Board's licensure requirements that were a source of confusion prior to enactment of this bill. This rulemaking updates the regulations to remove any conflict between the Board's statutes and current regulations that do not account for these statutory changes and make all regulatory requirements consistent with the various statutes that govern licensees as noted in prior responses to comments.

This proposal is not intended to address or impose technology requirements and does not authorize the Board to purchase technology from a private vendor to automate its processes. That authorization occurs outside of the rulemaking process in compliance with state procurement laws and regulations.

Board Response to Commenter #9, paragraph B.

As noted above, this proposal is not intended to address or impose technology requirements and does not authorize the Board to purchase technology from a private vendor to automate its processes. That authorization occurs outside of the rulemaking process in compliance with state procurement laws and regulations.

The Board rejects these comments and makes no changes to the language of the regulations based thereon.

Summary of Comments and Responses to Comments Received During the 15-Day Modified Text Public Comment Period

The Board received one responsive comment in support of the proposed language and policy change. The Board also received two additional comments that were unrelated to the modified text and documents added to the rulemaking file. Comments OMBC received for the 15-day comment period that began on March 4, 2025 and ended on March 19, 2025, are as follows:

Comment #1

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Hello,

I received the notice about the proposed changes and would like to advocate for physicians who are not in AOA subspecialties. I am a Reproductive Endocrinology and Infertility sub-specialist in private practice in San Francisco. I am a the FIRST Osteopathic physician to graduate from my fellowship training program at Stanford and am currently applying for an adjunct clinical faculty position in their Department of Obstetrics and Gynecology. In that role, I will have Stanford medical students shadowing me and am also teaching the residents/fellows. Additionally, I have remained in close contact with my Osteopathic medical school program and have served as a mentor to DO students for research. Most of my CME is obtained through attending conferences through the American Society for Reproductive Medicine and Pacific Coast Reproductive Society, which set the standards for practice in my field, which provide AMA CME credits. Also, there are no conferences providing

similar content specific to my specialty through the AOA. I implore you to consider allowing AMA credits to be allowed in lieu of AOA Category 1 credit for physicians in my circumstances. The process of submitting AMA for conversion to AOA 1 is expensive and discriminatory, providing undue burden to those of us who sought to practice in specialties outside of those offered by the AOA. Thank for your consideration, and I would be happy to review in further detail if given the opportunity.

Best, Mike

Michael Strug, DO, PhD, FACOG Reproductive Endocrinology and Infertility Pacific Fertility Center

Board Response: The Board rejects this comment as non-responsive to the modified text, and documents added to the rulemaking file and declines to make any changes in response to this comment. The comment is outside the scope of the modified text, documents added to the rulemaking file, or to the processes or procedures used by the Board in noticing the modified text and additional documents. The Board's notice of modified text specifically states, in part: "Please note, comments should be restricted to the most recent modifications made to the proposed regulations and any new documents added to the rulemaking file. The Board is not required to respond to comments on other aspects of the proposed regulations received in response to this notice."

Comment #2

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I would like to see an on-going CME tabulation, accessible on line, which doctors can access. Thus, allowing doctors to add, subtract, amend their CME if corrections are needed. This cycle I acquired most of my CME using short On-Line courses...ranging from 0.5 hr to 1.0 hrs of credit. This resulted in over 50 Certificates being sent to Mr. Moran in 4 separate e-mail files. This obviously is not an efficient system. My only other request would be to reject/notify inaccurate or insufficient CME allowing for corrective action before a fine is applied. Thanks,

Sincerely,

John R. Hawes, Jr., D.O. Lic# 20A4986

Board Response: For the reasons set forth in the previous response, the Board rejects this comment as non-responsive to the modified text and documents added to the rulemaking file and declines to make any further changes in response to this comment.

Comment #3

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I am in agreement for the rule change. There is no way we can process the reweals and even new licenses as more doctors come to the state. The M.D. Board has been doing this for years. I served nine years on the OMBC.

Provenzano, D.O.

Board response: The Board accepts this response as supportive of the proposed change and makes no further changes to the text in response to this comment.