Title 16. OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing has been scheduled.

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

This proposed regulatory action amends current regulations related to license renewal requirements for the Continuing Medical Education (CME), reporting cycle and reporting requirements and citation, fines and abatement order provisions.

Section(s) Affected: Division 16 of 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, 1659.35.

Background and Statement of the Problem

The Board currently licenses approximately 13,600 osteopathic physicians and surgeons throughout California. The Board's highest priority is to protect consumers through its licensing, regulatory and disciplinary oversight of the osteopathic medical profession. The Board is authorized by the Osteopathic Act (Initiative Measure) and statute to establish necessary rules and regulations for the enforcement of the Osteopathic Act and the Medical Practice Act as it applies to osteopathic physicians ("physicians") and postgraduate training licensees in accordance with Business and Professions Code (BPC) section 2450 for the laws relating to the practice of medicine. (Bus. & Prof. Code (BPC), § 2018).

CME and Audit Issues and Problems Addressed

The Osteopathic Initiative Act provides that "the law governing licentiates of the Osteopathic Medical Board of California is found in the Osteopathic Act and in Chapter 5 of Division 2,1 relating to medicine." (See Business and Professions Code (BPC) section 3600.) BPC section 2452 provides, in part: "This chapter applies to the Osteopathic Medical Board of California so far as consistent with the Osteopathic Act." Provisions relating to CME for all physicians and surgeons are contained in Article 10 (commencing with Section 2190) of the Medical Practice Act (Chapter 5 of Division 2 of the BPC), which contains provisions mandating certain CME standards as well as authorizing the Board to consider other forms of dedicated CME.

Existing law at BPC section 2454.5, which was first enacted in 1989, requires the Board to adopt and administer standards relative to continuing education ("CE" or "CME"). Those mandates include requiring each physician to demonstrate satisfaction of CE at intervals of not less than one year and nor more than two years and require each physician to complete a minimum of 50 hours of American Osteopathic Association (A0A) education during each two-year cycle, of

which 20 hours must be completed in AOA Category 1 and the remaining 30 hours in either AOA or American Medical Association (AMA) accredited CE.

Existing regulations in Article 9 (commencing with CCR section 1635 adopted in 1987) specify that physicians must complete 150 hours within a three-year period to satisfy the CME requirement and further defines the content of the 150-hour requirement as including a minimum of 60 hours of CME in Category 1-A or 1-B defined by the American Osteopathic Association (AOA). Further, regulations at CCR sections 1638, 1639 and 1640 set forth requirements for physicians to provide copies of specified progress reports with their renewal application (a copy of their Individual Activity Report, completion certificates or other reports from any program approved by the Board). Existing regulations do not authorize the Board to issue citations in lieu of disciplinary action for noncompliance with CME requirements.

The primary purpose of these proposed regulations is to change the CME reporting requirements to update current regulations consistent with changes in law, add new program recommended procedures for approving CME, and add new options for enforcement of CME requirements, including: authorizing a certification process of reporting CME compliance as part of renewal in lieu of providing documentary evidence of completion for renewal, repealing CME requirements for receiving education from Board-approved providers as specified that are superseded by BPC section 2454.5 , creating new records documentation and recordkeeping requirements, and new sanctions for noncompliance with CME requirements. The regulatory action also updates the Board's regulations consistent with the provisions of Business and Professions Code section 2454.5 that changed the CME reporting cycle from three (3) years to no more than two (2) years, decreases the number of CMEs from 100 hours to 50 hours, and adds new mandatory CME course work that must be completed for every renewal.

The overarching policy change is to shift from a manual review by staff of every CME prior to each licensee's renewal to an automated process that involves licensees certifying compliance with CME requirements and being able to renew without submitting further documentation; while staff follows up with audits of CMEs after the renewal to determine compliance. If the audit determines that the licensee did not comply with CME requirements, this proposal would authorize the Board to issue a citation, fine and/or abatement order that requires completion of the deficient CMEs as a condition of renewal.

Other CME Issues and Problems Addressed

Currently, Board review of CME hours at the time of each renewal causes delays in renewals, back log in the review process and in some cases suspension of licensee practice, which causes interruptions in patient care. The primary problem being addressed with these proposed changes is to eliminate the Board review of CMEs at the time of renewal and shift the Board's review of CMEs to an audit system. This change will streamline renewal for both the Board and licensees. The change would substitute submission of hard copies proof of completion of CMEs at every renewal with licensee certification of completion of required CMEs as a condition of-renewal by licensees. In order to ensure compliance with CE requirements and protect public safety from incompetence in the profession, the Board is seeking authorization to conduct a

follow-up random audit of every licensee as specified. Licensees must still complete their required CMEs for each renewal cycle and retain their CME documentation for each cycle for six (6) years for audit purposes. Licensees who fail the audit will be fined and will have to make up the CME as a condition of renewal.

Since 2018, there have been several significant statutory changes to CME requirements for renewals. In 2017, BPC 2454.5 was amended to change the CME cycle from a three year cycle to a two year cycle, to eliminate the even and odd year issuance of initial licenses and align the CME cycle with the renewal cycle by SB 798, chap.775, statutes of 2017 effective January 1, 2018. The Board requested in 2021 that that the Legislature change the number of required CMEs from 100 to 50 with 20 CMEs required to be American Osteopathic Association (AOA) and the remaining 30 CMEs can be either AOA or American Medical Association (AMA) approved, which was approved and signed into law effective January 1, 2022 (see Underlying Data, SB 806, Stats. 2021, ch. 649). In response to the opioid crisis, the Legislature added a mandatory CME course requirement on risks of addiction associated with the use of Schedule II drugs to be completed each renewal cycle, effective January 1, 2019 (see Underlying Data, SB 1109, Stats. 2018, ch. 693). All of these changes were enacted at BPC section 2454.5.

In 2022, the Board requested the Legislature eliminate the prorated initial license fee and birth month renewal cycle for initial licenses at BPC section 2456.1, which was approved and signed into law effective January 1, 2023 under SB 1443 (Stats. 2022, ch. 625). In addition, other statutorily mandated provisions have been enacted since the Board first adopted its CME regulations at BPC sections 2190.1, 2190.15, 2190.3, and 2190.6; those statutes require dedicated CME in specified content areas and authorize exemptions, as applicable. As a result of these many statutory changes, additional revisions to the regulatory sections related to CMEs needed to be updated in order to comply with the various statutory changes that occurred since the Board last updated its CME regulations.

As a result of the foregoing, this proposed language contains significant revisions to the initial three regulatory sections 1635, 1636, 1641 of Title 16 of the California Code of Regulations (CCR) and additional proposed amendments and repeal of specific sections. The Board is also proposing clarifying amendments to CCR sections 1638 and repeal of Title 16, CCR sections 1639 and 1640. This proposal is intended to capture, in one convenient location, all CME standards, waivers, exemptions and requirements for CME consistent with current Board practice.

Citation and Fine Issues and Problems Addressed

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.

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. The Board believes that the Board should also have the authority to cite and fine and/or issue an order of abatement for any violation of the laws and regulations under the Board's jurisdiction to allow implementation of additional enforcement tools for the protection of the public.

Historically, the Board has approved several versions of the cite and fine language. Each time the Board approved amendments, it was to add new statutory or regulatory authority to the list of citable offenses. The last Board-approved cite and fine language updated the cite and fine sections to delete repealed statutes and add new statutory violations. Each year, the Legislature passes new laws, and the Board adopts new regulations for which the Board would possibly need to consider adding to its list of citable offenses. This proposal would consolidate applicable violations located in the Medical Practice Act, the Osteopathic Act, the Confidentiality of Medical Information Act, the Board's regulations or other laws or regulations upon which the board may base a disciplinary action. It makes sense that the Board should be able to consider enforcement options short of discipline for enforcing any of the laws and regulations under its jurisdiction so that the Board may consider options for enforcing violations commensurate with the facts and violations applicable to the particular case and in accordance with the criteria set forth in CCR section 1659.31. This would be permitted by taking a new approach for determining whether a violation is a citable offense that would expand current CCR section 1659.31 to include all laws under the Board's jurisdiction including the specified authorities set forth in this proposal.

In addition, this proposal would implement Board recommended process improvements that should be made to increase the effectiveness of the administration of the Board's citation and fine program and make other grammatical, syntax or technical changes at CCR sections 1659.30, 1659.32, 1659.33, 1659.34 and 1659.35.

Anticipated benefits from this regulatory action

CME and Audits Benefits

The renewal process will be streamlined and reduce delays from staff having to review CMEs at the time of renewal. The time-consuming review of CMEs 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 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.

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. In addition, the Board will be updating its unlicensed activity citations processes to ensure greater compliance with the laws under the Board's jurisdiction and the enforcement of provisions prohibiting the unlicensed practice of medicine.

Specific Purpose of, and Rationale for, Each Adoption, Amendment or Repeal:

Continuing Medical Education Amendments

<u>Change to Title to Remove reference to "(CME)"</u>

Purpose and Rationale: Make a non-substantive change to remove "CME" from the title as unnecessary since that acronym appears later in the text in proposed changes to subsection (b) noted below.

Factual Basis for Amendment to subsection (a) of Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: Subsection (a) adds the wording "osteopathic" and surgeon" to "physician." This conforming change would be made throughout this proposal.

Rationale: The purpose of this amendment is to more accurately describe "physicians" as "osteopathic physicians and surgeons" instead of just "physicians "consistent with the type of physicians regulated by this Board in accordance with the Osteopathic Act and consistent with terminology used throughout the Board's regulations in Division 16.

Factual Basis for Amendments to subsection (b) Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: This proposal would make the following conforming changes consistent with revisions to the Board's CE authority contained in BPC section 2545.5, as follows:

(a) Repeal outdated references to implementation of the Board's initial CE regulations with the removal of "Commencing January 1, 1989,"
(b) Repeal outdated and inconsistent CE requirements to complete 150 hour of CE within a three-year period to satisfy the Board's CME requirement. This proposal would make conforming changes to Title 16 California Code of Regulations (CCR) section 1635 pursuant to changes to BPC section 2454.5 that became effective January 1, 2018. The CME requirements were deleted from this section and the statutory section BPC 2454.5 is referenced instead to define the CME requirements and to specify that these requirements are a "condition of renewal".
(c) The proposal would change references to a three-year compliance period to two consistent with statutory changes include changing the CME reporting cycle from three (3) years to two (2) years, unless otherwise specified as exempt in this section or a waiver is obtained as provided in CCR Section 1637.
(d) This subsection is also amended to require licensees to provide satisfactory documentation of their CME completion or exemption to the Board as specified in the documentation requirements of Title 16, CCR section 1636.

Rationale: Existing law at BPC section 2454.5 authorizes this Board to adopt and administer standards for the continuing education of its licensees. This is the section that defines the Board's CME standards. Without adoption of this proposed language, the Boards statutory language would be inconsistent with the Board's regulatory language. The proposed language updates the CME requirements consistent with the statute and other requirements in this proposal.

The purpose of these amendments and proposed repeals are to replace the outdated and inconsistent regulatory provisions defining CME requirements (minimum 150 hours and three-year reporting period and approved course provider and category areas) with reference to the statutory provisions of BPC section 2454.5 that contain the current CME requirements for hours, reporting, providers and approved categories of education as well as to ensure compliance with this section as a condition of renewal. These changes help ensure that all requirements for renewal are met and ensures that adequate notice is provided to licensees of the requirements that need to be met "as a condition of renewal."

In updating this section to require compliance with BPC section 2454.5(which sets forth the minimum hourly requirements (50 hours with emphasis in specified content areas, the maximum reporting period of up to two years, approved providers, and category of education as mandated by law) and the requirements for pain management and risks of addiction specified in this section, the Board ensures greater notice and compliance with all requirements imposed by law and by the Board. The number of required CME hours is already identified in BPC section 2454.5 but adding that reference in statute provides notice of the CME requirements to affected licensees all in one convenient location, which should avoid licensee

confusion and increase licensee compliance. The Board proposes to delete as superseded and obsolete prior specific language defining the required CME in Title 16 CCR section 1635 that conflicts with the statutorily defined CME requirements.

This amendment conforms to the recent update to BPC section 2454.5 that authorizes the Board to set the CME minimum reporting cycle from three (3) to up to two (2) years. This change is also made to update the regulations, so they are compliant with the statutory changes that was effective January 1, 2018 (see Underlying Data SB 798). In the Board's experience, setting two years as the "CME requirement period" instead of an annual compliance period is sufficient to ensure minimum education and continuing competency are maintained for the protection of the public. Such reporting period harmonizes BPC section 2454.5 with the issuance and expiration period set forth in BPC section 2456.1 for an osteopathic physician and surgeon's certificate, which is two years. The Board adds a cross-reference to the Board's regulatory section 1637 to this section; CCR section 1637 provides criteria for the Board granting a waiver from being required to meet the CME requirements. This proposed addition is necessary to provide in one convenient location a comprehensive list of all references to, and provisions for, waivers or exemptions from compliance with section 1635 CME requirements. This helps provide advance notice to licensees of all the ways they may meet the Board's CME requirements.

Additionally, the reason the Board added the reference to documentation requirements set forth in Title 16, CCR section 1636 in this section is to specify that licensees must comply with both CME requirements in CCR section 1635 and disclosure documentation requirements in 1636 to comply with CME requirements. Specifying the information required in the documentation by cross-reference to CCR Section 1636 prevents any vagueness or misunderstanding about compliance and provides advance notice to licensees that omission of required documentation of CME completion or exemption will not be deemed by the Board to satisfy the demonstration of completion of CME requirements.

Factual Basis for Amendments to subsection (c) Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: This proposal would delete existing subsection (c), which refers to the outdated 150-hour CME requirement, specifies the minimum 60-hour CME in Category 1-A or 1-B as defined by the American Osteopathic Association and further specifies the remaining 90-hour CME requirements that have been superseded by BPC section 2454.5. To make these conforming changes, subsection (c) language detailing the required CME hours and the time frame for completion is deleted (as noted above, those requirements are now set forth in statute at BPC section 2454.5) rendering existing subsection (c) unnecessary.

The Board proposes to add new proposed language at subsection (c) to specify the mandated CME course content requirements as specified within BPC sections 2190.1 and 2190.15 including requirements for courses related to cultural and linguistic competency and an understanding of implicit bias, as well as prohibitions on taking more than 30 percent (15 hours) of CME in the topics listed in BPC section 2190.15 (e.g. Practice management content

designed to provide better service to patients).

Rationale
For deletion of existing subsection (c):

Existing regulation at subsection (c) was first adopted in 1987 and became effective in 1988, before the current CME statute at BPC section 2454.5 was enacted in 1989 (Stats. 1989, ch. 1101, §1). Since then, BPC section 2454.5 was enacted and currently requires, in part, the following:

> The board shall require each licensed osteopathic physician and surgeon to demonstrate satisfaction of the continuing education requirements as a condition for the renewal of a license at intervals of not less than one year nor more than two years. 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. Licensed osteopathic physicians and surgeons shall complete a course on the risks of addiction associated with the use of Schedule II drugs.
>
> 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.

As noted above, the CME requirements are detailed in Business and Professions Code section 2454.5 and covered by the proposed amendments to subsection (b). There are several reasons to repeal this subsection and simply cite to the statute and any other ancillary requirements required by this section as proposed in amendments to subsection (b) above. First, the statute and proposed subsection (b) lists all CME categories and requirements rendering this subsection unnecessary. Second, citing the statute allows for future changes without necessitating promulgating a regulatory change each time and provides more enduring guidance than if these requirements are listed in this section. Third, this amendment avoids conflict with the requirements contained in the statute at BPC section 2454.5, which sets the minimum CME requirements at 50 hours every one or two years, and not 150 hours every three years as currently prescribed by this section.

For addition of new CME course criteria to subsection (c):

The first amendment is 1635 (c)(1) "Any CME course that includes a direct patient care component and is offered by CME provider located in this state shall contain curriculum that includes cultural and linguistic competency and an understanding of implicit bias in the practice of medicine as provided in Section 2190.1 of the Code." "Direct patient care" shall have the meaning as set forth in paragraph (2) of subsection (f)," to ensure consistency in interpretation

throughout the Board's regulations (see explanation of that definition below).

Not all of BPC section 2190.1 is mandatory (as indicated by the use of "may" throughout BPC section 2190.1), or applicable (as the Board does not enforce BPC section 2190 but rather BPC section 2454.5) but the requirement that curriculum include "cultural and linguistic competency" at BPC section 2190.1(b)(1) and an understanding of "implicit bias" at BPC section 2190.1(d)(1) are mandatory provisions and should be included in this section defining CME requirements to ensure consistent application of public policy in these areas across the physician and surgeon professions.

The next amendment 1635 (c)(2) "Any CME courses taken that meet the criteria in Section 2190.15 of the Code shall not together comprise more than 15 hours of the total hours of CME completed by an osteopathic physician and surgeon to satisfy the continuing educational requirement established by Section 2454.5 of the Code." BPC Section 2190.15 allows licensees to take other CME not otherwise related to clinical competency but the mandate within this section is that non-clinical competency related topics such as practice management content designed to provide better service to patients or management content designed to support managing a health care facility cannot comprise more than 15 hours total (the statute says "30 percent" but the Board has done the math here to specify "15 hours" to facilitate greater compliance and understanding of this requirement). This helps ensure that the CME focus is on maintaining clinical competency for the protection of the public.

Factual Basis for Amendment to subsection (d) of Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: This proposal amends subsection (d) and makes the following additional conforming changes to update the Board's CME requirements to current process:

(1) Repeals outdated prior implementation language requiring that "effective January 1, 1989, the three-year CME period shall commence for those licensed on or before January 1, 1989",
(2) Adds new "osteopathic physicians and surgeons" reference before the word "licensed" to more specifically identify the licensee category affected by this regulation,
(3) Delete references to implementation after January 1, 1989 and replace them with references to implementation "on or after" January 1, 2023,
(4) Adds the word "initial" before the words "CME requirement period" to more accurately identify and give notice of when initial CME compliance begins for new licensees,
(5) Delete references to the "three-year" CME requirement period and calculating the CME requirement commencement period on a pro rata basis commencing the first full year subsequent to initial licensure and replace that text with new text that defines the initial CME requirement period as "from the date of initial licensure to the first license expiration date", and,
(6) Delete references to the subsequent "three-year" requirement periods and replace them with references to the subsequent "two-year" CME requirement period.

Rationale: This proposal makes additional conforming changes to Title 16 CCR section 1635 pursuant to statutory changes to BPC section 2456.1 that eliminated the prorated initial license cycle based on birth month effective January 1, 2023. Currently, all licenses are issued from the date of issuance for two years before they expire and are subject to renewal per BPC section 2456.1. Consequently, all references to the "three-year" CME requirement period are being repealed and replaced with the new two-year CME requirement period.

References to prior implementation dates in 1989 for the existing regulations is proposed to be repealed and replaced with a January 1, 2023 effective date to coincide with the most recent changes to CME renewal period requirements enacted by Senate Bill 1443 (Stats. 2022, ch. 625) at BPC section 2456.1. Placing the date in the regulations also provides historical reference and notice to the regulated public and staff when the issuance and renewal period requirements changed.

Within the clarifying language about subsequent and preceding CME period is a change from 3 years to 2 years to conform with the current BPC section 2456.1 defining the license cycle and CME cycle as 2 years, not 3 years. This is necessary to avoid confusion regarding what the current CME requirement periods are after initial license renewal in accordance with the renewal cycles for an osteopathic physician and surgeon's certificate.

Factual Basis for Adoption of new subsection (e) in Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: This proposal would adopt a new subsection (e) that would specify all conditions of renewal of an osteopathic physician and surgeon licensee in a narrative format. This proposal would specify that, in addition to meeting the requirements in subsections (b) (for completing and providing satisfactory documentation of their CME completion) and (c) (for CME course criteria), all osteopathic physicians and surgeons shall complete the following as conditions of renewal unless otherwise exempted or a waiver is obtained as specified:

(1) a one-time, 12-hour CME course in pain management and the treatment of terminally ill and dying patients meeting the requirements as specified in this section and BPC section 2190.5 within 4 years of their initial license or by their second renewal date, whichever occurs first; and,

(2) a course on the risks of addiction associated with the use of Schedule II drugs as specified.

(3) if applicable, all general internists and family osteopathic physicians who have a patient population of which over 25 percent are 65 years of age or older shall complete at least 10 hours in a course required by Section 2190.3 of the Code

This proposal would also propose to prescribe the minimum course content for the risks of addiction course outlined in paragraphs (1) (A)-(C) of subsection (e). Specifically, subsection (1) (A) defines a course in pain management and the treatment of terminally ill and dying patients to include the practices for pain management in medicine, palliative and end-of-life care for

terminally ill and dying patients, and the risks of addiction associated with the use of Schedule II drugs.

Subsection (1)(B) further clarifies the meaning of "risk of addiction" in BPC section 2190.5 by including a description of the minimum course content the Board deems acceptable to satisfy this CME requirement that includes: regulatory requirements for prescribers and dispensers, strategies for identifying substance use, and procedures and practices for treating and managing substance use disorder patients.

Subsection (1) (C) clarifies that CME hours earned in fulfillment of the one-time CME required by BPC section 2190.5 completed within any cycle shall be counted by the Board towards the total CME requirements required to be completed during each CME requirement period as set forth in BPC section 2454.5.

Rationale: The purpose of this amendment is to include the total CME requirements required to be completed as a condition of renewal in one location. These requirements provide notice to licensees of the exact requirements; and ensures greater compliance through a complete listing of all requirements for CME renewal in one convenient narrative format.

<u>One-time Course Required by BPC section 2190.5 at new subsection (e)(1)</u>

Existing law at BPC section 2190.5 requires physicians to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. Section 2190.5 further specifies that this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, and that all physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The proposal is therefore necessary to fully implement the requirements to mandate the taking of this one-time course as a condition of renewal for all osteopathic physician licensees by restating these statutory requirements for the convenience of the licensees and by providing advance notice of the minimum expected content for an acceptable CME course to meet this BPC Section 2190.5 statutory mandate.

The Board, in its experience, believes these content areas are necessary as minimum course content requirements for instruction in pain management and the treatment of terminally ill and dying patients. This amendment is necessary to ensure that physicians receive at least the minimum training and specific instruction needed for continuing education and training on practices for pain management and treatment of terminally ill and dying patients in medicine. Patient comfort in the form of pain management before, during, and after treatment or a procedure is an essential component of patient care.

The addition of this course content requirement helps licensees keep current on developments in many areas of patient care and pain management including: the delivery of anesthetic and the management of postprocedural pain, pain diagnosis, management strategies for specific medical conditions that cause pain (including palliative and end-of-life care), and the risks of

addiction associated with the use of Schedule II drugs (as further defined at subsection (e)(1)(B) and discussed below related to subsection (e)(2)).

To avoid licensee confusion regarding whether this CME counts towards the total CME requirements in accordance with BPC section 2454.5, the Board adds specific direction at subsection (e)(1)(C) that it will count these hours towards fulfillment of the total CME required to be completed during each CME requirement period.

The text approved by the Board at its August 15, 2024 meeting for this subsection included incorrect cross-references to subsection (**d**)(1)(A) in subsection (e)(1)(B) when the correct cross-reference to the course on the risks of addiction associated with the use of Schedule II drugs is actually listed in subsection (**e**)(1)(A). This renumbering error occurred when the Board added a new subsection (c) to this proposal. The Executive Director has corrected this typographical error to list the correct cross-reference as subsection (e)(1)(A) within this subsection under the Executive Director's delegation of authority by the Board at its August 2024 meeting to make non-substantive edits to the text. The Board considers this change to be non-substantive in accordance with California Code of Regulations, Title 1, section 100 since it believes correcting the numbering here would not alter the existing regulations' requirements, rights or responsibilities for any person affected by the proposed regulations.

<u>Course in Risks of Addiction Associated with Use of Schedule II Drugs (subsection (e)(2))</u>

Existing law at BPC section 2454.5, also mandates completion of the following CME for osteopathic physicians and surgeons as a condition of renewal:

> "Licensed osteopathic physicians and surgeons shall complete a course on the risks of addiction associated with the use of Schedule II drugs."

However, BPC section 2454.5 does not specify what that course content for that course, at a minimum, must contain. As a result, to fully implement Section 2454.5's directive and specify those course content requirement minimums, the Board proposes to add new subsection (e)(2) with a cross-reference to the definition for minimum course content adopted at proposed new subsection (e)(1)(B), which implements the course content for the other similar Schedule II course requirement at BPC section 2190.5.

In the Board's experience, this proposal contains the following minimum content necessary for continuing education and training in the risks of addiction associated with the use of Schedule II drugs: regulatory requirements for prescribers and dispensers, strategies for identifying substance use, and procedures and practices for treating and managing substance use disorder patients. The Osteopathic Act authorizes the Board to "enforce those portions of the Medical Practice Act identified as Article 12 (commencing with Section 2220), of Chapter 5 of Division 2 of the Business and Professions Code, as now existing or hereafter amended, as to persons who hold certificates subject to the jurisdiction of the Osteopathic Medical Board of California…" (see BPC section 3600-5).

The Medical Practice Act mandates compliance with requirements for provisions of law regulating the prescribing, dispensing, or administration of dangerous drugs, as defined in Chapter 9 (commencing with Section 4000) of the Business and Professions Code, or controlled substances, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or the licensee faces potential discipline for unprofessional conduct per BPC sections 2234(a) (unprofessional conduct includes violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of the Medical Practice Act) and 2238 (violation of any federal statute or federal regulation or any of the statutes or regulations of this state regulating dangerous drugs or controlled substances constitutes unprofessional conduct).

Compliance with regulatory requirements for licensees also includes California's drug prescribing and monitoring program, the Controlled Substance Utilization Review and Evaluation System (CURES per Health and Safety Code Section 11165.1), for which osteopathic physicians and surgeons, as prescribers, must comply, including any requirements by the California Department of Justice's Office of the Attorney General who administers the program (see Cal. Code Regs., tit. 11, § 820). This proposal will help licensees stay current, informed, and more compliant with these and other requirements regulating drug prescribing and administration. These requirements are enacted to monitor controlled substances administration by prescribers and protect patients from risk of harm from inappropriate prescribing including risks of drug overdose and death.

By mandating this minimum course content, the goal is to ensure licensees who prescribe such drugs do so responsibly due to the high risk of misuse and both physical and psychological dependence by the patient. Further, a more informed, better educated licensee results in better patient health outcomes and compliance with the Osteopathic and Medical Practice Acts in the prescribing, dispensing or administration of dangerous drugs or controlled substances.

To avoid licensee confusion regarding whether this CME counts towards the total CME requirements in accordance with BPC section 2454.5, the Board adds specific direction at subsections (e)(2)(A) that it will count these hours towards fulfillment of the total CME required to be completed during each CME requirement period. In addition, to avoid unnecessary and duplicative CME requirements (when both the BPC 2190.5 and BPC 2454.5 4 requirements cover the same subject matter), the Board specifies at subsection (e)(2)(B) that the Board shall deem this course requirement met when the licensee has already completed the 12-hour CME course specified in subsection (e)(1) during the CME requirement period.

<u>Non-substantive Corrections</u>

The text approved by the Board at its August 15, 2024 meeting for this subsection included incorrect cross-references to subsection (**d**)(1)(B) and (d)(1) in subsection (e)(2) when the course and the correct definition for the risks of addiction associated with the use of Schedule II drugs is actually listed in subsections (**e**)(1) and (e)(1)(B). This renumbering error occurred when the Board added a new subsection (c) to this proposal. The Executive Director has corrected this typographical error to list the correct cross-reference as subsection (e)(1)(B) and

(e)(1) within this subsection under the Executive Director's delegation of authority by the Board at its August 2024 meeting to make non-substantive edits to the text. The Board considers this change to be non-substantive in accordance with California Code of Regulations, Title 1, section 100 since it believes correcting the numbering here would not alter the existing regulations' requirements, rights or responsibilities for any person affected by the proposed regulations.

Addition of Patient Population Related CME requirement, paragraph (3)

Existing law at BPC section 2190.3, also mandates completion of the following mandatory CME hours as part of renewal:

> All general internists and family physicians who have a patient population of which over 25 percent are 65 years of age or older shall complete at least 20 percent of all mandatory continuing education hours in a course in the field of geriatric medicine or the care of older patients.

This amendment references the mandated requirement for dedicated CME in this practice area as specified by BPC section 2190.3 and defines the required hours as 10 hours (the statute says "20 percent" of the mandated CME and the math is done here to state "10 hours" to facilitate greater compliance) for ease of use and better guidance to licensees regarding statutory requirements for CME for those licensees in this practice area.

Factual Basis for Repeal of Existing Subsection (e) in Title 16 CCR Section 1635 Required Continuing Medical Education (CME).

Purpose: This proposal repeals Subsection (e) that references obsolete "Category 1-A" requirements including incorporating by reference of the American Osteopathic Association's (AOA) "Continuing Medical Education Guide" with directions on how to maintain a copy by mail and noting the most recent publication date of 1992. It further defines Category 1 CME by the American Medical Association as contained in a "Physicians Recognition Award Information Booklet", which is incorporated by reference with directions on how to obtain the information by mail and noting the most recent publication date as January 1986.

Rationale: This section was used by the Board to define CME requirements for this section prior to 2000. However, since that time, the CME requirements are defined in BPC section 2454.5 and AOA and AMA Category 1 (since BPC section 2454.5 does not limit eligible CME to Category 1-A only) course content listings are available on-line. Licensees are readily familiar with the process of identifying AOA or AMA accredited CME on-line and have not expressed any complaints about finding AOA Category 1 or AMA accredited course work in fulfillment of the CME requirements in BPC section 2454.5 (see: the AOA's 2019-2021 "Continuing Medical Education Guide for Osteopathic Physicians" online at https://osteopathic.org/index.php?aam-media=/wp-content/uploads/CME-guide-2019-2021.pdf, and "The AMA Physician's Recognition Award and credit system" 2017 revision at: https://www.ama-assn.org/system/files/pra-booklet.pdf).

As a result, there is no longer a need to list these outdated references in regulation. Instead, a new subsection (f) is added that lists the exemptions to the CME requirements for the 12-hour course specified in subsection (e)(1) would be adopted to replace this outdated section (as discussed below).

Factual Basis for Adopting New Subsection (f) in Title 16 CCR Section 1635 Required Continuing Medical Education

Purpose: The proposal would specify all the conditions under which osteopathic physicians (with the use of shortform "physicians" for ease of review of this subsection) would be exempt from the requirements to take the 12-hour course as authorized by BPC sections 2190.5 and 2190.6 and specified in subsection (e)(1) of CCR section 1635. This would include:

(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 no personal or face-to-face interaction with the patient, 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 patient,
(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, including eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders; or,
(6) Physicians who are deemed a "qualifying physician" as specified in Section 2190.6 of the Code, which means a physician meets any of the following conditions:

(A) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties,
(B) The physician holds an addiction certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine,
(C) The physician holds a board certification in addiction medicine from the American Osteopathic Association.
(D) The physician has completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, or the American Psychiatric Association. Such training shall include:
(aa) opioid maintenance and detoxification;
(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
(cc) initial and periodic patient assessments (including substance use

monitoring);
(dd) individualized treatment planning, overdose reversal, and relapse prevention;
(ee) counseling and recovery support services;
(ff) staffing roles and considerations;
(gg) diversion control; and,
(hh) other best practices.
(E) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule Ill, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the U.S. Secretary of Health and Human Services by the sponsor of such approved drug.

Rationale:

Introductory paragraph and subparagraphs (1)-(4): Exemptions from the 12-hour course requirement per BPC section 2190.5

Existing law at BPC section 2190.5 requires that each physician complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. However, pursuant to subdivision (b) of Section 2190.5, the Board may, by regulatory action, exempt physicians by practice status category from the course requirement 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. In addition, subdivision (c) of BPC section 2190.5 provides that the mandatory continuing education course requirements does not apply to physicians and surgeons practicing in pathology or radiology specialty areas.

The purpose of this amendment is therefore to set "by regulatory action" those practice status categories that are exempt from the 12-hour course requirement consistent with the authority in BPC sections 2190.5 and 2190.6. It is the Board's understanding that these practice status categories are exempt since the patient care issues would not normally occur in these practice environments or would be addressed by those physicians who would be responsible for direct patient care in California and therefore this CME is not required for these licensees. In addition, this proposal would place all the CME requirements including exemptions derived from BPC section 2190.5 in the same regulatory section 1635 that defines CME requirements. This addition avoids unnecessary confusion for staff and licensees so they can easily locate all the requirements and exemptions in one place.

To avoid confusion over the scope of the "direct patient care" exemption, the Board adds a definition for "direct patient care" as existing law does not define it. Such care would include: no personal or face-to-face interaction with the patient, 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 patient. The Board understands that this definition most

effectively covers what such direct patient care includes from a practice perspective.

Paragraphs (5) and (6): Exemptions from the 12-hour course requirement per BPC section 2190.6

> Business and Professions Code section 2190.6 provides:
>
> (a)**As an alternative to Section 2190.5**, a physician and surgeon may complete a one-time continuing education course of 12 credit hours in the subject of treatment and management of opiate-dependent patients, including eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders.
>
> (b) **A physician and surgeon who meets the requirements, as determined by the board, of a "qualifying physician"** under clause (ii) of subparagraph (G) of paragraph (2) of subsection (g) of Section 823 of Title 21 of the United States Code, the Comprehensive Addiction Recovery Act of 2016 (Public Law 114-198), **as that clause read on January 1, 2018**, **shall be deemed to have met the requirements of subdivision (a).**
>
> (c) A physician and surgeon who chooses to comply with this section as an alternative to Section 2190.5 shall complete the requirements of this section by the physician and surgeon's next license renewal date.
>
> (d) The board **shall determine** whether a physician and surgeon has met the requirements of this section.
> (Emphasis added above.)

The Board interprets the above language to provide licensees with at least two other alternatives to satisfying the 12-hour course requirement of BPC section 2190.5, as follows:

> (A) a one-time continuing education course of 12 credit hours in the subject of treatment and management of opiate-dependent patients, including eight hours of training in buprenorphine treatment; or,
>
> (B) A physician and surgeon who meets the requirements, as determined by the board, of a "qualifying physician" under specified clauses of 21 U.S.C. 823 "as it read on January 1, 2018.

This proposal would demonstrate how the Board would "determine" whether a physician met the criteria for these types of exemptions from the 12-hour course requirement, in particular for what the Board determines is a "qualifying physician" pursuant to BPC section 2190.6. This determination is required to be made by this Board by law and further specificity is necessary for the reasons set forth below.

The language in subsection (b) of BPC section 2190.6 refers to a federal law, originally enacted as the federal Drug Addiction Treatment Act of 2000 (as part of Title XXXV, Section 3502 of the Children's Health Act in 21 U.S.C. § 823), that permits physicians who meet certain qualifications to treat opioid addiction with Schedule III, IV, and V narcotic medications that have been specifically approved by the Food and Drug Administration for that indication. The "qualifying physician" definition for that federal law has been amended numerous times since 2000 and 2018, and the law at 21 U.S.C. section 823 does not currently read the way it did on January 1, 2018 (the words "qualifying physician" have been struck and "qualifying practitioner" replaced with new criteria). All of this makes it unclear what a "qualifying physician" means under the federal law cited in BPC section 2190.6(b) as "it read on January 1, 2018." This makes it difficult for the regulated community and Board staff to implement this alternative, which is essentially an exemption from the BPC section 2190.5 12-hour course requirement.

After extensive research by the Board's Regulations Counsel, it was determined that the law as it read in 2018 was the law enacted in 2016 by Public Law 114-198 and a copy of the law as so enacted and read in 2018 is included as Underlying Data in this rulemaking. The proposed amendments at subsections (f)(5) and (6) would resolve this confusion by listing the requirements to qualify for this "qualifying physician" and equivalent course exemption and meet the mandates specified in either BPC sections 2190.5 or 2190.6. The proposed amendments would read as follows:

> (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, including eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders; or,
> (6) Physicians who are deemed a "qualifying physician" as specified in Section 2190.6 of the Code, which means a physician meets any of the following conditions:
> (A) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties,
> (B) The physician holds an addiction certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine,
> (C) The physician holds a board certification in addiction medicine from the American Osteopathic Association.
> (D) The physician has completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, or the American Psychiatric Association. Such training shall include:
> (aa) opioid maintenance and detoxification;
> (bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
> (cc) initial and periodic patient assessments (including substance use monitoring);
> (dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;
(ff) staffing roles and considerations;
(gg) diversion control; and,
(hh) other best practices.

(E) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule Ill, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the U.S. Secretary of Health and Human Services by the sponsor of such approved drug.

These amendments define the details of the "qualifying physician" exemption that is referenced in BPC Section 2190.6. By adding these amendments to CCR section 1635, all of the existing statutorily required CMEs would be included in this section in one location and help promote greater understanding of and compliance with all of the CME requirements and acceptable alternatives.

Factual Basis for Amendments to the Title of Title 16 CCR Section 1636 Continuing Medical Education Progress Report (proposed to be re-titled as "Documentation").

Purpose: This proposal would revise the title to section 1636 by deleting the words "progress report" and replaces it with "Documentation" to more accurately convey the content of the information proposed to be covered by this section.

Rationale: The purpose of revising the title is to clarify that this section specifies the exact documentation requirements for demonstrating compliance with CME requirements. "Progress Report" was not an accurate description of this section since that documentary requirement is proposed to be repealed by this proposal and replaced with new documentation requirements as more fully detailed below.

Factual Basis for Amendment to Introductory Sentence and Repeal Subsections (a)-(d) of Title 16 CCR Section 1636 Continuing Medical Education Documentation.

Purpose: This proposal revises the wording used to refer to a physician to add the word "osteopathic" to more accurately describe the title of the Board's licensees. For consistency, this reference is revised throughout the proposal to reference licensed physicians as "osteopathic" physicians and surgeons. This subsection is renumbered to "a" to accommodate the deletion of the existing subsections and for better organization of this section.

This proposal also adds a cross-reference to the required report "as provided in subsection (b)" and deletes the words "This may be accomplished by" as necessary to implement the Board's proposed policy shift from submission of actual CME completion documents with the renewal application as part of the renewal CME reporting requirements to a document certifying completion within the applicable CME requirement period.

The Board also proposes to repeal existing subsections (a)-(d) related to the current process of

submitting hard copies of completed CME as part of the required report with the renewal application, that currently includes the following options for reporting completion of required CME:

(a) a copy of their computer printout of CME activity,
(b) copies of any certificates given for the CME credit hours of attendance at any Board-approved program, and,
(c) progress reports from any Board-approved program showing CME credit hours of attendance.

The Board also proposes to repeal subsection (d) which currently specifies that the CME categories are defined by Section 1635(e), a subsection that the Board proposes to repeal in this rulemaking.

Rationale: The primary purpose of this new subsection (a) and its proposed amendments is to set up a new, simpler documentation requirement to demonstrate compliance with CME requirements. Currently, Board review of paper copies submitted with the renewal application in compliance with existing subsections (a)-(c) of this section causes delays in renewals, back log in the review process and in some cases suspension of licensee practice, which causes interruptions in patient care. The primary problem being addressed with these proposed changes is to eliminate the Board review of the paper copies showing proof of completion of CMEs at the time of renewal to licensee certification of completion of required CMEs as a condition of-renewal by licensees (as specified below in the proposed adoption of subsection (b)).

As discussed above, the revision of the wording for osteopathic physician and surgeon is to more accurately describe the type of physician regulated by this Board. In addition, the Board proposes to repeal subsection (d) since the definition for CME categories that must be accepted by the Board is now listed in BPC section 2454.5 and therefore the reference to CCR section 1635(e) is proposed to be repealed as unnecessary (also see rationale for repeal of CCR section 1635(e) more fully explained above).

Factual Basis for Adoption of New Subsection (b) in Title 16 CCR Section 1636 Continuing Medical Education Documentation.

Purpose: This proposal adds a new subsection (b) that lists the specific required "satisfactory documentation" needed to demonstrate compliance with CME reporting requirements as specified in CCR section 1635. Subsection (b) specifically requires a written statement to the Board, signed and dated by the licensee (a shortform for licensed osteopathic physicians and surgeons created for ease of reference) which discloses the information listed in subsections (b)(1)-(6).

Subsection (b) (1) requires the licensee's personally identifying information including full legal name (first, middle, last, suffix (if any)), license number, mailing address, telephone number and email (if any). Subsection (b) (2) requires disclosure of compliance with the CME

requirements of BPC section 2454.5, specifically whether during the two years immediately preceding their license expiration date, the licensee completed a minimum of 50 hours of American Osteopathic Association (AOA) CME, of which at least:

(A) 20 hours were completed in AOA Category 1 CME as defined in Section 2454.5 of the Code, and,
(B) the remaining 30 CME hours were earned for coursework accredited by either the AOA or the American Medical Association (AMA).

Subsection (b) (3) requires a disclosure of compliance with the one-time 12 hour CME course as specified by CCR section 1635, specifically whether within four years of their initial licensure or by their second renewal, the licensee completed a one-time 12-hour CME course in the subjects of pain management and the treatment of terminally ill or dying patients ("pain management course") as specified by Section 1635.

Subsection (b) (4) requires a disclosure if the licensee has not completed the pain management course referenced in subsection (b)(3), whether the licensee meets one of the listed criteria in subparagraphs (A)-(F) that would qualify as an exemption to the otherwise required CME completion of one-time 12-hour CME course in pain management (as defined in this subsection) and further specified in section 1635. The listed exemptions consistent with BPC sections 2190.5 and 2190.6 for this disclosure would include:

(A) The licensee is practicing in pathology or radiology specialty areas,
(B) The licensee is not engaged in direct patient care as defined in Section 1635,
(C) The licensee does not provide patient consultations, or,
(D) The licensee does not reside in the State of California.
(E) The licensee completed a one-time continuing education course of 12 credit hours in the subject of treatment and management of opiate-dependent patients, including eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders; and,
(F) The licensee meets one of the conditions listed in paragraph (6) of subsection (f) of Section 1635 for a "qualifying physician."

Subsection (b) (5) requires a disclosure whether the licensee has completed the risk of addiction associated with the use of Schedule II drugs course as specified in CCR section 1635, including a course in pain management as referenced in subsection (b) (3).

Subsection (b)(6) requires a disclosure regarding whether the licensee obtained a waiver from the Board for all of any portion of the current CME requirements specified in Section 1635 for this CME reporting period in accordance with Section 1637.

Subsection (b) (7) requires the licensee to certify under penalty of perjury under the laws of the State of California that all of the statements made in response to disclosures required by subsections (b) (1) – (6) are true and correct.

Rationale: This proposal is necessary to avoid confusion and specify the required "satisfactory documentation" needed to be provided to the Board as a condition of renewal as proposed in CCR section 1635(b). The new disclosure requirements are a result of the shift in Board policy to allow licensees to self-certify compliance with CME requirements and renew their license more easily. This Board policy change was created to solve the problems caused by delays related to license renewal when documentation reviews could not keep up with current demand or licensees did not timely file their documentation with their renewal applications, resulting in licensees not being eligible for renewal and required to suspend practice. Thus, the Board chose to change the reporting requirements to solve the problem.

The purpose of this new section is to specify the exact information required to be in the written disclosures that certify completion of CME and compliance with subsection 1635. The specific disclosure requirements provide notice to licensees of the written information they need to demonstrate compliance with CMEs in a more simple, straightforward but comprehensive manner by signing a written statement attesting to compliance with the requirements prescribed by law and regulation for CME compliance reporting. This process would help ensure greater CME reporting compliance and fewer licensees adversely impacted by delays in processing renewals.

The information required by subsection (b)(1) (submission of personally identifiable information) is necessary to identify the licensee and properly record receipt of reporting documentation by the Board in the Board's records. The contact information is also necessary to communicate with the licensee quickly and effectively regarding any information reported in compliance with this subsection.

The information required by subsection (b)(2) (disclosure of completion of 50 hours of CME as specified) is necessary to verify compliance with existing CME requirements contained in BPC section 2454.5 in a more simplified, yet comprehensive manner. In addition, it is necessary to comply with the legislative mandate for the Board to "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."

The information required by subsection (b)(3) (completion of a one-time 12-hour CME pain management course) is necessary to verify compliance with BPC section 2190.5 without undue burden to the licensee. As noted above in the rationale for CCR section 1635(d)(1), existing law at BPC section 2190.5 requires physicians to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. Section 2190.5 further specifies that this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, and that all physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. This proposal would be implemented in the form of a simple disclosure requirement regarding

whether this 12-hour pain management course has been completed within the time prescribed by BPC section 2190.5 (within 4 years of their initial licensure or by their second renewal). This proposal is also necessary to ensure consistency in interpretation of the 12-hour pain management course requirements for renewal as cross-referenced here and as specified in newly proposed amendments to CCR section 1635.

Current regulations do not set forth a simple method for identifying those licensees who may be exempt from the 12-hour pain management course referenced in subsection (b)(3) of this section. This proposal at subsection (b)(4) would implement such a process by permitting a licensee to show compliance by demonstrating exemption through disclosure of meeting any of the following criteria that would form the basis for exemption (as noted in the rationale for adoption of new CCR section 1635(f) above):

(1) The licensee is practicing in pathology or radiology specialty areas,
(2) The licensee is not engaged in direct patient care as defined in Section 1635,
(3) The licensee does not provide patient consultations,
(4) The licensee does 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, including eight hours of training in buprenorphine treatment, or other similar medicinal treatment, for opioid use disorders; or,
(6) Physicians who are deemed a "qualifying physician" as specified in Section 2190.6 of the Code, which means a physician meets any of the following conditions:

(A) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties,
(B) The physician holds an addiction certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine,
(C) The physician holds a board certification in addiction medicine from the American Osteopathic Association.
(D) The physician has completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, or the American Psychiatric Association. Such training shall include:
(aa) opioid maintenance and detoxification;
(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
(cc) initial and periodic patient assessments (including substance use monitoring);
(dd) individualized treatment planning, overdose reversal, and relapse prevention;
(ee) counseling and recovery support services;
(ff) staffing roles and considerations;
(gg) diversion control; and,
(hh) other best practices.

(E) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule Ill, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the U.S. Secretary of Health and Human Services by the sponsor of such approved drug.

The information required by subsection (b)(5) (completion of a course on the risks of addiction associated with the use of Schedule II drugs) is necessary to verify compliance with the requirement for completing a course in pain management as required by BPC section 2454.5 and as proposed to be defined and implemented in CCR section 1635. This helps ensure consistency in interpretation of the pain management course requirements for renewal as cross-referenced here and as specified in newly proposed amendments to CCR section 1635.

The disclosure required by subsection (b)(6) (relating to whether the licensee has obtained a CME waiver per CCR 1637) is necessary to enable licensees to report all methods of compliance, including the waiver option in response to inquiry by the Board for the applicable CME reporting period. This enables the Board to fully capture all pathways to CME compliance.

The certification requirement in subsection (b)(7) requires licensees to certify under penalty of perjury that all statements made in response to disclosures required by subsections (b)(1)-(6) (that form the basis for the entire CME reporting requirement) is true and correct. The Board relies upon licensees' self-reported information in evaluating applications or other forms submitted for processing by the Board. This requirement helps ensure that the representations on the written statement are accurate, truthful and made in good faith. In addition, the certification under penalty of perjury helps ensure the reliability of the statements to the Board (since certifying under penalty of perjury can have a deterrent effect on those who may be considering not providing true, accurate or complete information), and provides the Board with the option of seeking sanctions and referring the matter to law enforcement in the event that such information is not true, complete or accurate. ["The oath or declaration must be in such form that criminal sanctions of perjury might apply where material facts so declared to be true, are in fact not true or are not known to be true." *In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 [holding modified *by Laborde v. Aronson* (2001) 92 Cal.App.4th 459.]

Factual Basis for Adoption of New Subsection (c) in Title 16 CCR Section 1636 Continuing Medical Education Documentation.

Purpose: Existing regulations do not authorize the Board to establish a process by which licensees who self-report CME compliance would be subject to random audit of their CME hours. This proposal adds this standard at subsection (c), and establishes the Board's CME audit process that subjects licensees to random audits to demonstrate that they did in fact meet CME requirements for the CME reporting period being audited. The audit process requires licensees to respond to the Board's written audit request within 65 days of the date of the Board's written request and to document their compliance with CME requirements of this article (including, for example, exemptions from a CME requirement claimed by the licensee per subsection (b)(4)) and/or provide (depending on whether the audit relates to a CME completion requirement) the records required to be retained pursuant to subsection (d) (as further

described below).

Rationale: The purpose of this subsection is to establish the Board's authority and process for auditing licensee compliance with CME requirements and the basis of the licensee's declarations and representations to the Board provided in their CME report to the Board per CCR 1636(b). This proposed audit is in response to the Board's approval of the policy shift from having the staff manually review and approve the renewals to allowing the licensees to self-certify CME compliance as a condition of renewing their license. The Board created the audit system to protect public safety by ensuring licensees truly complete their CME requirements to maintain ongoing competency. These changes do not impact public safety because the licensees are audited within the same time frame as currently reviewed. If a licensee fails the audit, they will be fined pursuant to Title 16 CCR sections 1641 and 1659.31 and will be required to complete the missing CME as a condition of their next renewal. Their license will not be renewed until the deficient CMEs are completed. The CME requirements that protect public safety remain the same, just the reporting process changes.

The audit is needed to ensure licensees meet their CME licensure requirements that they certify they have met and thus are eligible for renewal. Currently, staff reviews all CMEs and if complete manually renews each licensee, which prevents licensees being renewed unless they complete the required CMEs. This proposed self-certification and audit process will save time for both staff and licensees and is the reason for making these changes in the CME reporting and renewal process. While completion of CME remains a condition of renewal, the self-certification system is based on trust subject to a future audit to verify compliance.

The random audit will protect public safety by ensuring that licensees complete their CMEs, and the Board will hold them accountable if they fail the audit. Random audits are a process that has been successfully implemented by other Boards in this Department without compromising public protection (see e.g., Cal. Code Regs., tit. 16, § 1399.617). If licensees fail the audit, they will be issued a citation, fine and an abatement order requiring them to complete the deficient CMEs and will not be renewed until they have completed their deficient CMEs as further explained below in the rationale for proposed changes to CCR section 1641.

In addition to the proposed random audit process requirement, the Board is proposing adding a new regulatory requirement for responding and documenting compliance with all CME requirements in this article. Existing regulation does not require a licensee to respond to a Board inquiry within a prescribed timeframe or document compliance with the Board's CME requirements in this article. This proposed requirement is necessary to enable the Board to contact and adequately investigate CME reporting under this new audit process. Generally, in the Board's experience, 65 days is sufficient time for a licensee to locate responsive documents, respond to board inquiries and mail the information to the Board as requested. However, in the Board's experience, some licensees ignore requests to respond to the Board altogether.

This 65-day response and documentation requirement would balance the need for the licensee to have adequate time to respond to audit requests with the Board's need to more effectively investigate compliance with CME requirements. Making it a violation to not respond to a Board

inquiry within a certain time period (as proposed with changes to CCR section 1641 noted below) would also help assist the Board with more effectively enforcing the laws under its jurisdiction, for the protection of the public. The Board adds a cross-reference to (d) of this section when specifying what records might be requested by a CME audit. Subsection (d), as further explained below, would set for the "satisfactory documentation" licensees would be required to retain for each CME requirement period for a minimum of six years from the completion date.

Factual Basis for Adoption of New Subsection (d) Title 16 CCR Section 1636 Continuing Medical Education Documentation.

Purpose: This proposal adds subsection (d), which requires that licensees retain documents demonstrating compliance for each CME required period for six years from the completion date of the courses or condition(s) claimed as credit towards satisfaction of, or exemption from, CME requirements set forth in CCR section 1635. This amends the current requirement of retention of CME documents from four years (currently at CCR section 1641, proposed to be repealed) to six years. This subsection requires licenses selected for audit to submit documentation of their compliance as specified by this article; and requires specific information to be included to be in compliance with subsection (d). The proposal would add a list of what "documents demonstrating compliance" would include in subsections (d) (1) – (d) (4).

Subsection (d) (1) lists what information must be included in the CME Activity Summary report from the AOA to be acceptable documentation of compliance with this section. This would include, at a minimum, all of the following on official AOA letterhead or other document issued by the AOA bearing an AOA insignia:

(d) Licensee's name;

(B) Licensee's license number, and,

(C) All CME course credits reported to the AOA during the relevant CME reporting requirement period, including: (i) CME course or activity name, (ii) CME sponsor/provider name, (iii) CME credit type (e.g., Category type, for example Category 1A or 1B), (iv) CME credit hours earned or each course or activity by the licensee and submitted by the licensee for AOA approval, (v) all credits applied or accepted by the AOA by course or activity, and, (vi) completion dates for each CME course or activity.

Subsection (d) (2) lists what information must be included in any transcripts or certificates of completion from a CME course provided accredited by the AOA or American Medical Association (AMA) to be acceptable documentation of compliance of this section. This would include, at a minimum, all of the following:

A) the name of the licensee,

(B) the title of the course(s)/program(s) attended,

(C) the amount of CME credit hours earned,

(D) the dates of attendance,

(E) the name of the CME provider, and,

(F) For AOA accredited courses, CME credit type (e.g., Category type, for example Category 1A or 1B).

Subsection (d) (3) lists what information is required to be included in CME documentation from CME providers for AMA accredited course hours earned to be acceptable documentation of compliance of this section. This would include reports from any CME course provider accredited by AMA, to be furnished by the licensee, and listing at a minimum:

(A) the name of the licensee,

(B) the title of the course(s)/program(s) attended,

(C) the amount of CME credit hours earned,

(D) the dates of attendance, and,

(E) the name of the CME provider.

Subsection (d)(4) lists what information is required to be included for proof of any exemptions claimed by the licensee from the 12-hour pain management course, which would include, as applicable:

(A) For claims of practice exemption per paragraph (4), subparagraphs (A)-(C) of subsection (b), copies of employment records or letters or other documents from an employer showing the licensee's name, dates of practice, and confirming the type of practice claimed as represented by the licensee on their report;

(B) For claims of out of state residency per paragraph (4), subparagraph (D) of subsection (b), copies of an unexpired drivers' license or other state-issued identification in the name of the licensee, or utility bills, bank or mortgage statements, vehicle registration or insurance documents, or tax documents showing the licensee's name and out of state address and dated within the last 3 months prior to the date of submission to the Board.

(C) For claims of completion of alternative CME coursework as specified in paragraph (4), subparagraphs (E) or (F) of subsection (b), any of the documents specified in paragraphs (1)-(3) of this subsection.

(D) (i) For claims of exemption as a "qualifying physician" based on specialty certification as specified in paragraph (4), subparagraph (F), certification received directly from the applicable certifying body of the licensee's certification in a specialty that includes a document containing, at minimum, the following:

(aa) Licensee's name;

(bb) Licensee's address,

(cc) Name of the specialty board,

(dd) Name of specialty,

(ee) Date certification in the specialty was issued,

(ff) Date certification in the specialty expires, and,

(gg) on official letterhead or other document issued by the specialty organization bearing their insignia.

Submission of a licensee's Official Physician Profile Report from the American Osteopathic Association directly to the Board electronically that lists the specialty certifications claimed by the licensee shall be deemed compliant with the requirements of this paragraph.

(ii) For claims of exemption as a "qualifying physician" due to the licensee being an investigator in one or more clinical trials leading to the approval of a narcotic drug as specified by Section 1635, a copy of a letter or other document, signed and dated by the sponsor showing submission of a statement from the sponsor to the U.S. Secretary of Health and Human Services that includes the licensee's name and that the licensee was an investigator in one or more clinical trials leading to the approval of a specified narcotic drug in schedule Ill, IV, or V for maintenance or detoxification treatment.

Rationale: The purpose of this amendment is to specify what information must be included in any CME documentation of completion or exemption in order to be accepted by the Board as demonstrating compliance with this section and CCR section 1635(b). In the Board's experience, the required information for subsections (d)(1)-(4) represents the minimum required information that must be included in documentation to verify completion or exemption from CME requirements. For completion of CME hours, this information will help identify the licensee, verify the source of training as an accredited sponsor/provider, the hours of training, the CME course subject and category type (for example, pain management course, Category 1A or 1B), and completion of training on specified dates in compliance with the requirements of this article. This information is also the information required to verify information previously provided by the licensee to the Board as part of the Board's audit process requirements (discussed above for CCR 1636 (b)).

The CME categories required to be disclosed on the documentation (Category 1 AOA for 20 of the 50 CME hours and the remaining 30 CME hours AOA or AMA accredited), and the original source documentation that the Board will accept remains essentially unchanged from current processes under this proposal. However, listing the specific information required in regulation provides notice to licensees of what information must be included in the documentation to be deemed acceptable by the Board. In the past, the Board received incomplete documentation that was missing critical information so listing exactly what the required documentation needs to contain helps ensure greater CME compliance and therefore fewer CME violations and more timely renewals.

The requirement that licensees retain their CME completion or exemption documentation longer from four (4) years as currently prescribed by CCR section 1641 to six (6) years is to ensure the Board has access to CME records in the event that the audits take longer or the Board has an enforcement action pending (Accusation or citation) that causes the Board's investigation or prosecution to take longer than the current 4-year time frame. The consequence of not having a record retention policy longer than four (4) years is that if the Board fails to complete timely audits, licensees are not required to produce or retain records for review. This potential consequence could create a loophole in the Board's audit and enforcement authority. As a result, the Board chooses to avoid this potential consequence by lengthening the CME retention time frame to six (6) years to ensure adequate public protection and enforcement of the laws under its jurisdiction.

Documentation of Exemptions from the 12-hour course required by BPC 2190.5

As a result of adding new CME requirements and applicable exemptions to section 1635, the Board is also including corresponding documentation requirements for those added exemptions to help licensees understand what is needed to prove exempt status claimed at the time of renewal. Specific documentation requirements are important to provide notice to applicants what documentation is required and deemed acceptable by the Board. Not meeting either the CME requirements in section 1635 and/or the documents requirement in this section would be a violation of the CME requirements. Subsection (d) adds documentation requirements related to the categories of compliance listed in CCR section 1635 and that are commonly used to substantiate these types of CME education, specialty training or exemptions.

(d)(4)(A) requirements: For claims of waiver based on practice areas (pathology or radiology specialty areas, not engaged in direct patient care or does not provide patient consultations), the information required to be retained is necessary to help verify the licensees' identity and link it to their claimed status of practice exemption from an external source, thereby ensuring proper authentication of the licensee's claimed exemption. This includes letters or other documents showing the licensee's name, dates of practice, and confirming the type of practice claimed as represented by the licensee on their report pursuant to CCR section 1636, subdivision (b).

(d)(4)(B) requirements: For claims of out of state residency, the Board requires retention of

commonly accepted documentation to demonstrate residency (see e.g., Cal. Code Regs., tit. 13, § 15.01 (DMV requirements to establish residency). Such documents would include copies of an unexpired drivers' license or other state-issued identification in the name of the licensee, or utility bills, bank or mortgage statements, vehicle registration or insurance documents, or tax documents showing the licensee's name and out of state address. To ensure the residency claim is currently applicable, the Board requires that the documents be dated within the last 3 months prior to the date of submission to the Board.

(d)(4)(C) requirements: For claims of exemption based upon completion of alternative CME coursework as claimed in subsection (b)(4)(E) (per BPC 2190.6(a) this claimed exemption includes a 12 hour course in the subject of treatment and management of opiate-dependent patients) or as claimed in subsection (b)(4)(F) (per BPC 2190.6(b) -- qualifying physician who took not less than 8 hours of specified training related to opioid maintenance and detoxification, etc.), the Board would require the same types of documentation of completion of CME as it requires for other types of CME as specified above in the rationale for subsections (b)(1)-(3). This requirement is necessary to ensure that licensees are given adequate notice that CME documentation requirements are the same for demonstrating CME completion, regardless of the purpose (i.e., as part of claimed exemption). This also ensures consistency in Board implementation and avoids confusion for the regulated community. In addition, the text approved by the Board at its August 15, 2024 meeting for this subsection included incorrect cross-references to subparagraph(D) in subsection (d)(4)(C) when the correct cross-reference for CME alternative coursework is actually listed in subsection (b)(E) and (F). The Executive Director has corrected this typographical error to list the correct cross-reference as subparagraphs (E) and (F) of subsection (b) within this paragraph under the Executive Director's delegation of authority by the Board at its August 2024 meeting to make non-substantive edits to the text. The Board considers this change to be non-substantive in accordance with California Code of Regulations, Title 1, section 100 since it believes correcting the numbering here would not alter the existing regulations' requirements, rights or responsibilities for any person affected by the proposed regulations.

(d)(4)(D)(i) requirements: For claims of exemption as a "qualifying physician" based on specialty certification, the Board requires specified documentation that, in its experience, most accurately ensures the credential was earned. This includes confirmation from the direct source, including receipt directly from the applicable certifying body of the licensee's certification in a specialty that includes a document containing, at minimum, the following:

(aa) Licensee's name;

(bb) Licensee's address,

(cc) Name of the specialty board,

(dd) Name of specialty,

(ee) Date certification in the specialty was issued,

(ff) Date certification in the specialty expires, and,

(gg) on official letterhead or other document issued by the specialty organization bearing their insignia.

In lieu of the foregoing, the Board would accept as compliant the submission of a licensee's "Official Physician Profile Report" from the American Osteopathic Association sent directly to the Board electronically that lists the specialty certifications claimed by the licensee. In the Board's experience reviewing these reports, the Official Physician Profile contains substantially all of what the Board believes is necessary to verify receipt of mandated training or receipt of specialty certifications and its electronic delivery directly to the Board helps ensure the accuracy and authenticity of the information reported for the licensee.

(d)(4)(D)(ii) requirements: For claims of exemption due to the licensee being an investigator in one or more clinical trials leading to the approval of a narcotic drug as specified in CCR section 1635, the Board would require the following to ensure verification of the credential claimed:

a copy of a letter or other document, signed and dated by the sponsor showing submission of a statement from the sponsor to the U.S. Secretary of Health and Human Services that includes the licensee's name, and that the licensee was an investigator in one or more clinical trials leading to the approval of a specified narcotic drug in schedule Ill, IV, or V for maintenance or detoxification treatment.

This documentation requirement is derived from and consistent with the requirement to qualify as an investigator in the applicable federal law as it read in 2018 (see Underlying Data, where status as an investigator was demonstrated "by a statement submitted to the Secretary by the sponsor of such approved drug"). As a result, the Board believes that a copy of such a statement provided by the sponsor of the approved drug to the federal agency for proof of such investigator status would be sufficient indicia of reliability to be accepted as evidence of the licensee's status as an investigator for the Board's CME exemption.

Factual Basis for Repeal of Subsection (c) in CCR Section 1638 CME Requirement for Inactive Certificate

Purpose: This proposal will repeal the words "have completed a minimum of 20 hours Category 1-A as defined by the American Osteopathic Association (AOA) during the 12-month immediately preceding the licensee's application for restoration" and instead replace it with a new requirement that licensees comply with the requirements for restoring an inactive certificate to an active status in CCR Section 1646.

This proposal also deletes subsection (c) of this section, which refers to "CME categories are defined by section 1635(e)".

Rationale: Title 16, California Code of Regulations (CCR) Section 1638 sets CME standards for

inactive certificate holders, including requirements for restoring an inactive certificate to active status in subsection (b). Upon review, however, it was discovered that existing subdivision (b) is inconsistent with the requirements for restoring an inactive certificate to active status in existing CCR section 1646(b), which requires a fee to also be paid to reinstate to active status. Changes are proposed to address this problem by striking existing subdivision (b) of this section and instead cross-referencing to requirements in CCR section 1646, which contains a more complete list of the requirements for restoration. Additionally, as discussed further below, CCR section 1646 is amended to include the complete application process and added language to define the time frame for acceptable CME submission for restoration to an active status.

The Board also amends Subsection (c) that refers to the CME requirements of 1635 (e), which is proposed to be repealed in this rulemaking (see rationale above for explanation of the repeal at CCR section 1635(e)). As a result, this provision is obsolete and conflicts with BPC section 2454.5 statutory requirements for acceptable CME and therefore should be repealed to avoid inconsistency with BPC section 2454.5 and to avoid licensee confusion over what is acceptable CME.

Factual Basis for Repeal of CCR Section 1639 Approved Continuing Medical Education

Purpose: Existing regulation enacted in 1988 specifies the CME programs approved by the Board, which includes:

(a) Those programs certified by the American Osteopathic Association (AOA) as category I and II credit and those certified by the American Medical Association (AMA) as category I.
(b) Those programs which qualify for prescribed credit from the AOA specialty groups.
(c) Those programs meeting the criteria set forth in Section 1640 and offered by other organizations and institutions.
(d) CME categories are defined by Section 1635 (e).

This proposal deletes (repeals) the entire section with no replacement amendments as superseded by enactment of BPC section 2454.5. The Board retains the title of this section for historical reference.

Rationale: CCR Section 1639 defines CME requirements, which through the years has been revised by statutory amendments rendering this section obsolete and in conflict with the current statutory requirements for CME. The Board is proposing to delete this entire section 1639 “approved continuing medical education” as unnecessary as the law defines what approved continuing education programs that as specified BPC 2454.5 and the law mandates that the Board require licensees to complete specified CME accredited by either the AOA or AMA and only requires certain hours to be completed as Category 1 (which means either Category 1A or 1B would be acceptable by law). BPC section 2454.5 states, in 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. Licensed osteopathic physicians and surgeons shall complete a course on the risks of addiction associated with the use of Schedule II drugs.

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.

Additionally, this section is no longer needed to define approved CME programs since all approved CME defined in BPC 2454.5 are either approved by the American Osteopathic Association (AOA) or the American Medical Association (AMA). The other programs listed in current section 1639 (as set forth in subsections (a) or (b)) would be covered by the BPC 2454.5 definition AOA or AMA approved. There are no CMEs that are accepted by the Board to meet the CME requirement that are not either approved by the AOA or AMA and the Board no longer approves CME programs as set forth in current CCR section 1640. As explained above, subsection (d), referring to an obsolete CME category proposed to be repealed in CCR section 1635(e), would be repealed as no longer necessary and confusing for licensees. For these reasons, the entire section of CCR section 1639 is being proposed to be repealed.

Factual Basis for Repealing CCR Section 1640 Criteria for Approval of CME Programs

Purpose: This proposal deletes (repeals) the entire section 1640 "criteria for approval of CME programs." The title would be retained for historical reference. This section currently contains criteria for Board approval, which includes:

(1) Requirements that each program in which a licensee participates shall be administered in a responsible, professional manner.
(2) Minimum requirements for measuring programs on a clock-hour basis that includes additional standards for faculty, program content, education objectives, minimum methods of instruction, evaluation criteria, and requirements for course organizers to maintain a record of attendance of each participant.
(3) Requirements that the Board will randomly audit courses or programs submitted for credit in addition to any course or program for which a complaint is received.
(4) Minimum standards for course organizers to provide documentation to the Board if an audit is made.
(5) Prohibits credit from being granted for the required CME hours for any course deemed unacceptable by the Board after an audit has been made pursuant to this section.

The repeal of CCR section 1640 would eliminate the Board's authority to approve CME programs, CME providers and specify the criteria for both.

Rationale: This section provides the criteria for approval of CME programs. While there is an argument that the Board still retains authority to set minimum criteria for approved programs

per BPC section 2190, which authorizes the Board to "adopt and administer standards for the continuing education" of its licensees, it has not done so for decades because it relies exclusively on the American Osteopathic Association (AOA) to approve CME and CME providers. As a result, the Board has no need to have this approval authority.

This section was initially utilized to specify a criterion for CME providers to comply with in order to have their CME programs and course work acceptable by the Board. Over the years, the AOA and AMA have become the main approvers of all CME providers and specific CME course content and credits, so the Board no longer approves CME programs or course work. The Board does not anticipate that this will change in the future; the AOA and AMA will always be the approvers of CME providers and CME content. As a result, this section is no longer needed. It is also being eliminated to avoid any confusion that the Board has separate criteria for CME providers, programs, and CME because it effectively does not.

Additionally, the other reason for repealing this section is that it contains obsolete references to regulatory sections such as 1635 (e) that are being repealed under this proposal, and it references section 1639, which would otherwise have to be amended if it were not being repealed. It is cleaner to simply repeal this entire section that the Board does not intend to use in the future.

Factual Basis for Amendment to Subsections (a)-(b) and Repeal of Subsection (c) in Section 1641 Sanctions for Non-Compliance.

Purpose: This proposed amendment to subsection (a) removes the number of required hours currently set at 150 hours (approved or prorated share) pursuant to CCR 1635(d) (which the Board proposes to revise consistent with statutory changes to BPC section2454.5) from this section. The reference to subdivision (d) in CCR section 1635 would also be repealed, and a reference only to a licensee who has "not satisfied the CME requirements" pursuant to section 1635 requirements generally; and the reporting cycle (CME requirement period) is updated from three years to two years consistent with the changes proposed to be made at CCR section 1635. The words "osteopathic" and "and surgeon" would also be added to accurately reflect the Board's licensees and the use of the gendered pronouns "his or her" replaced with "their." Finally, the last sentence would be revised to add the words "or provide satisfactory documentation of CME completion as provided in Section 1636", thus prohibiting renewal if satisfactory documentation is not provided as specified in CCR Section 1636.

Amendments to existing subsection (b) adds the language "a citation and fine", and "or" to the sentence that sets the disciplinary actions that can be taken for non-compliance. The words "osteopathic" and "and surgeon" would also be added to accurately reflect the Board's licensees and the use of the gendered pronouns "his or her" replaced with "their." This proposed revision to subsection (b) also adds "to fail to provide accurate or complete information in response to a Board inquiry," to the existing language that makes it unprofessional conduct for licensees to fail "to comply with the provisions of this article."

This proposal repeals as unnecessary subsection (c), as the current proposal moves the

requirement to retain CME compliance documentation to CCR section 1636 (d) (as noted in the rationale for changes to CCR 1636(d) above). While this amendment deletes (c), it does not eliminate the requirement to retain CME documents. That six-year retention requirement would now be contained in CCR section 1636 (d).

Rationale: CCR Section 1641 both defines non-compliance and contains the consequences of non-compliance. This section does update the reference to CME requirements to be the entire section 1635 not just subsection d because 1635 has been significantly revised to include new statutory requirements and referencing BPC section 2454.5 as the location that defines CME requirements. These changes are therefore necessary to make consistent changes enacted by law and those proposed to be made in this rulemaking.

Subsection (a)

The revisions striking the 150-hour approved CME and prorated share pursuant to CCR section 1635(d) are necessary to ensure consistent interpretation of the Board's currently proposed CME requirements. As noted in the rationale for CCR section 1635(d) revisions, this proposal makes additional conforming changes to CCR section 1635 pursuant to statutory changes to BPC section 2456.1 that eliminated the prorated initial license cycle based on birth month effective January 1, 2023, and these changes in this subsection would make those changes consistent with those proposed at CCR section 1635(d).

Changes made to strike the 150-hour approved CME and three-year CME reporting requirement and replace them with general references to CCR section 1635 and a new two-year CME requirement period are necessary to repeal outdated and superseded portions of the Board's regulations. The purpose of these amendments and proposed repeals are to replace the outdated and inconsistent regulatory provisions defining CME requirements (minimum 150 hours and three-year reporting period) with the proposed changes to CCR section 1635 (which incorporates the requirements for compliance at BPC section 2454.3 and biennial renewal at BPC section 2456.1). As noted in the rationale above for CCR section 1635, the Board is implementing a new biennial renewal process based upon self-certification that replaces outdated and ineffective renewal processes. These changes are necessary to implement those changes consistently throughout this article.

Subsection (b)

Under existing regulation for this section, non-compliance has always been considered unprofessional conduct for misrepresentation or failure to comply with CME requirements, but citation and fine was added to this proposal as a possible consequence for non-compliance for those instances as well as when a licensee fails to provide accurate or complete information in response to a Board inquiry. BPC section 125.9 authorizes the 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…" As proposed for this subsection and in changes proposed to 1659.31 discussed

below, it would be grounds "for a citation and fine" for a licensee to (1) misrepresent compliance with the provisions of this article, (2) to fail to provide accurate or complete information in response to a Board inquiry, or (3) fail to comply with the provisions of this article. This is necessary for the Board to be authorized to enforce the provisions in the most effective way possible for the protection of the public and to help ensure continuing competency in the profession.

BPC section 2234 provides that "The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following…," but does not specify in Section 2234 that failure to provide accurate or complete information in response to a Board inquiry constitutes unprofessional conduct. The courts have recognized that statements that unprofessional conduct "is not limited to" its list of examples means unlisted conduct may be "unprofessional conduct" subject to discipline. (Unprofessional conduct is not limited to list of items in unprofessional conduct statute and "[u]nprofessional conduct is that conduct which breaches the rules or ethical code of a profession or conduct which is unbecoming a member in good standing of a profession." (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, [57]5.) (*People v. Arias* (2008) 45 Cal.4th 169, 182 [it is a "general rule of statutory construction that '[u]se of the language "including, but not limited to" in the statutory definition is a phrase of enlargement rather than limitation' "]; Pe*ople v. Williams* (2010) 184 Cal.App.4th 142, 147, the phrase "strongly indicates that the categories listed in the statute were not intended to be exclusive"]; *Sanchez v. State of California* (2009) 179 Cal.App.4th 467, 484, [the phrase means a list is not exclusive]. This proposed interpretation is also consistent with other boards that regulate the medical profession (see e.g., Cal. Code Regs., tit. 16, § 1399.617).

Currently, subsection (b) makes it unprofessional conduct for a licensee to "misrepresent" his or her compliance with the CME requirements, which usually involves proof of some level of intent, knowledge or deceit to establish a violation. Although, under this proposal, licensees would provide a written statement with their renewal application that they are in compliance with CME requirements, the Board has found that licensees sometimes provide incomplete or inaccurate statements and information to the Board when investigating CME compliance, including providing statements and documentation of CME credit from unapproved CME providers, providing incomplete certificates of completion, or providing certificates of completion that do not apply to the current renewal period. Upon review, licensees often disclaim any knowledge or intent to misrepresent compliance to the Board.

The Board should be authorized to determine whether to impose discipline or issue a citation if the licensee fails to provide accurate or complete information in responding to the regulating authority. Such conduct is evidence of the licensee's inability to meet minimum standards and exercise good judgment in dealing with the Board, and possibly the regulated public. However, current regulations do not address such conduct in a manner that would allow the Board to decide whether issuance of a fine or discipline would be more effective in remediating the conduct. This amendment would make grounds for issuance of a citation (and a citable offense per proposed changes to CCR section 1659.31) and unprofessional conduct to fail to provide accurate or complete information in response to a Board inquiry. This would assist the Board in

more effectively addressing these judgment-related and compliance deficiencies by essentially providing the Board with discretion to either discipline or issue a citation to a licensee for unprofessional conduct if they fail to provide accurate or complete information to the Board.

Subsection (c)

This proposal would repeal existing requirements for physicians to retain records for a minimum of four years of all CME programs attended which indicate the title of the course or program attended, dates of attendance, the length of the course or program, the sponsoring organization and the accrediting organization, if any. The board proposes to repeal this section as unnecessary and in conflict with the proposed changes to CCR section 1636, subsection (d), which would set the retention schedule for CME documentation demonstrating compliance at six years from the completion date of the courses claimed as credit towards satisfaction of the CME requirements in CCR section 1635. Proposed subsection (d) of CCR section 1636 would also specify the type and content of the documents the board would accept as satisfactory documentation in compliance with proposed changes to CCR section 1635(b). As a result, the Board proposes to repeal this section as unnecessary to implementation of the revised CME reporting program.

Factual Basis for Amendment to Subsections (b), (d) and (e) in Section 1646 Procedure for Obtaining an Inactive Certificate or for Restoration to Active Status.

Purpose: In subsection (b), the proposal would delete references to requirements for completing "Category 1-A" as a condition of restoring an inactive certificate to active status by striking the "-A" consistent with current requirements for the Board to accept all Category 1 CME as specified in BPC section 2454.5. The Board would also strike the reference to "preceding" from the requirements for completion and instead add a sentence that would add to the current requirement to complete 20 hours of AOA CME that it be completed during the 12-month period "immediately preceding the licensee's completed application for restoration, submit a completed application for restoration, and pay the fee set forth in Section 1690 of this Division and the Controlled Substance Utilization Review and Evaluation System (CURES) fee currently required by Section 208 of the Code. A new definition would be added for a completed application for restoration, which would include all of the following:

(1) Licensee's Full Name (First), (Middle), (Last), (Suffix, if any),
(2) Licensee's License (Certificate) Number,
(3) Licensee's Address,
(4) Licensee's Email Address,
(5) Licensee's Telephone Number,
(6) An affirmative statement that during the 12-month period immediately preceding the date of the filing of this application, the licensee completed a minimum of 20 hours in AOA Category 1 CME, and,
(7) The following statement, signed and dated by the licensee: "I am requesting that the Osteopathic Medical Board of California activate my license."

The Board also proposes to repeal existing subsection (d), which refers to "CME categories are defined by Section 1635(e)" and renumber subsection (e) to (d) accordingly for better organization and ease of reference.

Rationale: Existing regulations are inconsistent with statutory changes and Board operations and need to be updated to remove outdated references to "Category 1-A", specify that 20 hours of CME shall be completed during the time frame "immediately preceding" the licensee's completed application for restoration, and define what the Board would consider to be a "completed application for restoration". This proposal would add these requirements to ensure currency of knowledge in the profession prior to reactivation of an inactive licensee's certificate. This proposal would further specify that licensees are required to submit a completed application, as specified in this section, the fee specified in CCR section 1690 and the CURES fee as specified in BPC section 208. This helps avoid deficiencies in the application process and ensure applications are processed according to the minimum information and fees needed, in the Board's experience, to restore a license to active status as quickly as possible.

This proposed application would include information to help identify the licensee in the Board's records and make corresponding changes to their license history and facilitate communication in cases where follow-up communication may be necessary, including full name, license (certificate) number, address, email address and telephone number. To confirm completion of the required CME requirements according to this section as a condition precedent to license restoration, the Board requires attestation and provision of an affirmative statement that during the 12-month period immediately preceding the date of the filing of this application for restoration, the licensee completed a minimum of 20 hours in AOA Category 1 CME. To confirm the licensee's affirmative intention to reinstate to active status, the Board requires a declarative statement, signed and dated by the licensee, requesting that the Board activate their license. This simple, streamlined application process helps avoid confusion, eases re-entry into active practice and helps facilitate access to more licensed physicians for the benefit of the public.

Existing regulations also do not specify all the required fees currently required by law to be submitted to restore a certificate to active status. In addition to the renewal fee in CCR section 1690 as mandated for restoration by BPC section 704, licensees are required to pay as part of their renewal the Controlled Substance Utilization Review and Evaluation System (CURES) fee per BPC section 208. The Department of Consumer Affairs has not adopted regulations to reduce the fee prescribed by Section 208; therefore, the fee is currently set at $9 per licensee per Section 208. Although inactive licensees are exempt from paying the CURES fee per BPC section 208(b)(2), once they decide to reactivate their license, this proposal would provide affected licensees with notice regarding the fact that they must comply with all license restoration requirements including payment of the renewal fee and CURES fee.

The Board also amends Subsection (d) that refers to the CME requirements of 1635 (e), which is proposed to be repealed in this rulemaking (see rationale above for explanation of the repeal at CCR section 1635(e)). This provision is obsolete and conflicts with BPC section 2454.5 statutory requirements for acceptable CME and therefore should be repealed to avoid inconsistency with

BPC section 2454.5 and to avoid licensee confusion over what is acceptable CME.

Citation and Fine Amendments (starting on p. 14 of the proposed text)
The following amendments update the cite and fine regulatory sections 1659.30, 1659.31, 1659.32, 1659.33, 1659.34, and 1659.35 to include all applicable past and current statutory changes and regulatory changes that have occurred since 2005. Besides updating these sections, the overarching policy change is to consolidate the applicable violations contained in the Medical Practice Act, the Osteopathic Act and Division 16 in Title 16 of the CCR by replacing the myriad of individual statutory and regulatory sections with more inclusive references to the Medical Practice Act, Osteopathic Act and Division 16, Title 16 the regulatory sections dedicated to the Osteopathic Medical Board of California.

In compliance with Assembly Concurrent Resolution No. 260 of 2018, the Board is also updating its regulatory language throughout the proposal to comply with this resolution that state agencies should use gender neutral pronouns and avoid the use of gendered pronouns throughout this proposal. The Board also proposes to make conforming and non-substantive changes to initial cap the word "Board" throughout the proposal to make it consistent with the shortform reference in CCR section 1602. Specific changes that would be addressed by this proposal include the following.

Factual Basis for Amendments to Subsections (a)-(c) in CCR Section 1659.30 Authority to Issue Citations and Fines

Purpose: Proposed amendments to subsection (a) capitalizes the word "Board."

Existing regulations at subsection (b) provide the Board's Executive Director designee the authority to issue citations, fines, and orders of abatement for violations listed in Section 1659.31 based upon criteria set forth in that section. This amendment to subsection (b) would authorize the Executive Director to further delegate to "their designee" this same authority.

Proposed amendments at subsection (b) also adds new authority for the Executive Director or their designee to issue citations containing "both" "administrative" fines and orders of abatement to allow flexibility in addressing violations and allows for the Board to determine the best approach to ensuring compliance and remediation of the issue.

The postgraduate training licensee is added to the list of those individuals upon whom a citation and fine and/or order of abatement may be issued.

Proposed amendments to subsection (c) add new authority to serve citations on licensees by regular mail at their last known address in accordance with Business and Professions Code section 124, which permits a board in this Department to give written notice to licensees of any order by regular mail addressed to the last known address of the licensee or by personal service, at the option of the board.

Rationale: Making clarifying and other changes to the Board's citation regulations will help

assist staff and the regulated community with notice and consistent enforcement and compliance with the laws under the Board's jurisdiction. Changes to this section are being made to implement the enforcement program's workload more effectively.

In subsection (a), the proposes to make conforming and non-substantive changes to initial cap the word "Board" throughout the proposal to make it consistent with the shortform reference in CCR section 1602.

The purpose of amendments to subsection (b) is to establish who is authorized to issue citations on behalf of the Board. This proposal is necessary for the Board to provide the Executive Director with consistent authority to delegate responsibilities to a designee. Allowing a designee authority facilitates daily operations and timely performance of enforcement duties.

Changes to the wording in subsection (b) related to the addition of the words "administrative" and, "or both" is necessary to clarify and give advance notice to the regulated community regarding the specific types of actions that the Executive Director or their designee will be authorized to determine (citations containing orders or abatement, administrative fines, or both fines and orders of abatement). BPC section 125.9 authorizes the Board to establish such a program, and to issue orders of abatement and fines. The issuance of fines and orders of abatement, or both, is necessary for protection of the public, and deterrence from future violations by licensees. The word "and" is proposed to be deleted and a comma inserted after "or both" for grammatical reasons pursuant to the Executive Director's authority delegated by the Board.

The addition of the "postgraduate training licensee" to the list of citable persons in subsection (b) addresses any ambiguity over whether such actions apply to them, and that the Board has two separate license types: Osteopathic Physician and Surgeon and Postgraduate Training (per BPC section 2064.5). It is necessary to make this amendment to further provide notice that the Executive Director or designee has authority to issues citations, fines, and orders of abatement for both license types under the jurisdiction of this Board.

The proposed amendments to subsection (c) include reference the Board's authority to serve licensees citations by regular mail instead of by certified mail as currently required by this subsection. BPC section 124 provides:

> Notwithstanding subdivision (c) of Section 11505 of the Government Code, whenever written notice, including a notice, order, or document served pursuant to Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), or Chapter 5 (commencing with Section 11500), of Part 1 of Division 3 of Title 2 of the Government Code, is required to be given by any board in the department, the notice may be given **by regular mail** addressed to the last known address of the licensee or by personal service, at the option of the board. (Emphasis added.)

According to BPC section 125.9(b)(4), hearings to appeal a citation must be held in accordance with the applicable provisions of the Administrative Procedure Act (APA) contained in Chapter 5

(commencing with Section 11500). As a result, service of citations containing hearing rights by regular mail would be authorized to be served upon licensees by regular mail in accordance with BPC section 124.

The Board also notes that the California Evidence Code provides support for such a practice. Evidence Code 641 (the "mailbox rule") provides the following legal presumption of receipt: "A letter correctly addressed and properly mailed is presumed to have been received in the ordinary course of mail." The APA also permits service in a variety of ways according to Government Code section 11440.20 including that service or notice by mail may be made by first-class mail, registered mail, or certified mail, by mail delivery service, by facsimile transmission if complete and without error, or by other electronic means as provided by regulation, in the discretion of the sender unless otherwise provided by statute.

Authorizing regular mail service will eliminate the need for the Board to have to serve the citation in person or have proof that the mail was delivered by having to require the signature on the certified mail receipt. This will result in more effective enforcement of the laws and regulations by adopting a simplified process for service of citations on licensees.

Factual Basis for Amendment 3 CCR Section 1659.31 Fine Amounts and Criteria to Be Considered

Revision of Title.
Purpose: This section used to be entitled "Citable Offenses" and is being replaced with the wording "Fine Amounts and Criteria to Be Considered."

Rationale: This title change would more accurately convey the content of this regulatory section consistent with the changes proposed.

Designee Changes.
Purpose: This proposal would add the words "or their designee" to the introductory sentence and subsections (a)(1), (a)(2), (b)(1) and (b)(2) of this section consistent with the proposed change to CCR section 1659.30, which delegates authority to issue citations and fines to "designee" of the Executive Director. Since not all criteria listed in this section are "applicable" to every violation, the word "applicable" is added before the word "factors" in the introductory phrase as well.

Rationale: This section lists the statutes and regulations for which the Board's Executive Director has authority to issue citations, fines, and orders of abatement and to set fine amounts using specified criteria. To implement the enforcement program's workload more effectively and consistently, this proposal would authorize the Executive Director to further delegate to "their designee" this same authority and require them to consider the same factors in setting the amount of the fine as set forth for the Executive Director in this section.

Repeal of phrase referencing BPC section 125.9(b)(3) and mitigation criteria and amendment to add new cross-reference to new criteria at subsection (b)

Purpose: The Board proposes to repeal the following phrase in the introductory sentence requiring the Executive Director to consider factors listed in: "subdivision (b)(3) of Section 125.9 of the code and also the extent to which such person has mitigated or attempted to mitigate any damage or injury caused by the violation." The phrase would be amended to replace "subdivision" with "subsection" for consistency of terminology throughout this section and replace the rest of the phrase with a reference to the "applicable" factors listed in "subsection (b)."

Rationale: This is necessary to mandate that the Executive Director consider the factors listed in (b), which includes new factors required by law to be considered based on the type of citation authority being used. The newly proposed subsection (b) would include the factors required to be considered for violations of the Confidentiality of Medical Information Act (Civ. Code, § 56.10) and the listed criteria for other types of violations consistent with the authority set forth in BPC section 125.9(b)(3) ("as applicable" depending on the type of violation involved in the particular case), which is not referenced in the existing text. This amendment is therefore necessary to implement the Board's policy decision to add other criteria that the Executive Director or their designee must consider for the appropriateness of the amount of the fine consistent with proposed changes to subsection (b) of this section.

<u>Fine Amounts and Ranges amendments to subsection (a)(1) and (a)(2) renumbered to add a new subsection (a)(2), renumber (b) to (c)</u>

Purpose: "Unless otherwise provided in this section" (to make the exceptions the general rule clearer), this proposal would set the floor for most fine amounts at $100 and retain the existing cap of $2500 per citation as well as existing authority to increase the amount above $2500 per citation if certain criteria are met (see existing subsection (b), renumbered to (c) due to amendments to other subsections).

The Board would also specify other caps in this section at newly added subsection (a)(2) that are prescribed by law for issuing fines for violations of BPC sections 2244 (requirements for specimens in locked containers capped by law at $1,000), 2262 (alteration of medical records capped by law at $500), and the caps prescribed by law for violating the Confidentiality of Medical Information Act ("CMIA" -- as set forth in Civil Code section 56.36(c)). As a result, the reference to "except as specified in items 34 and 41 below" would be repealed as unnecessary since those fine cap exceptions would be covered by the proposed addition of subsection (a)(2).

Rationale: Setting the floor at $100 is the minimum necessary, in the Board's experience, to obtain compliance for the citations generally issued by the Board. Regarding subsection (a)(2), this proposed rulemaking is necessary to add language setting forth the range for any fine amount to be levied under applicable code sections and shall consider the factors listed under those code sections when levying a fine. Under this proposal, the Executive Director or designee shall not levy a fine that exceeds $2500 or in other applicable sections of California law. It is necessary to account for limitations set forth in other applicable sections, since they may impose a limit that is different than $2500 and without these amendments, the Board's

regulations would be inconsistent with the applicable fine authorities, causing confusion and inconsistency in the issuance of specified fines. For example, BPC section 2244 indicates that the Board may impose a fine against a licensee not to exceed the sum of $1,000 for a violation of that section, which is less than the limits provided for under this subsection. BPC section 2262 similarly sets the cap for issuing fines to $500. Conversely, the CMIA authorizes, but does not require, higher fine assessments for second and subsequent violations of the law, including up to $250,000 (Civil Code section 56.36(c)(3)(B)). Consequently, the proposed changes to this subsection are necessary to ensure that the Board's Executive Director or their designee official issues citations in compliance with the relevant citation and fine laws.

<u>Further Amendments to Subsection (a)(1): Bases for Issuing a Citation – Consolidation of licensing act and regulatory provisions and addition of new authority to issue citations for violations of any laws under the Board's jurisdiction and any regulations adopted by the Board thereto.</u>

Purpose: 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. As discussed under the "Problems Being Addressed and Benefits of Cite and Fines" sections, above, 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. Updating the cite and fine regulations will enhance public protection by improving this administrative tool allowing 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.

To implement that policy change, this proposed rulemaking will renumber the paragraphs within this subsection (renumbered as (a)(1)) for better organization) and delete existing subsection (a), paragraphs (23) – (51) and (54) – (56), as the citable code sections referenced in those subdivisions are contained in the Medical Practice Act, or the Board's regulations and would therefore be covered by proposed paragraphs (Y), (Z), (AA), and (BB). The Osteopathic Act, the Medical Practice Act (as it relates to persons regulated by this Board), Civil Code section 56.10 (Confidentiality of Medical Information Act), any other statute or regulation upon which the Board may base a disciplinary action, and the Board's regulations are being added to this section in their entirety as separate entries under section 1659.31, subdivision (a)(1), paragraphs (X), (Y), (Z), (AA) and (BB), respectively.

The remaining and new paragraphs under section 1659.31, subdivision (a)(1) will be renumbered accordingly.

Rationale: BPC section 125.9 authorizes the 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 where the licensee is in violation of the applicable

licensing act or any regulation adopted pursuant thereto. Though BPC section 125.9 authorizes the Board to establish a citation program where citations may be issued to any person that is in violation of the Board's applicable licensing acts or any regulation, the Board has not yet done so and currently only authorizes citations and fines to be issued for violations of specified statutes (as set forth in existing subsection (a), paragraphs (1)-(56)).

Currently, when other violations not listed do not rise to a level warranting discipline through an administrative action, the Board addresses these violations with the licensee through education efforts or delays action until further violations warranting discipline occur. The Board needs a tool to address more serious violations of all the laws administered by it that do not rise to the level of an administrative action to enforce the laws under its jurisdiction more effectively, better address remediation efforts with the licensee and to protect the public.

Adding references at proposed paragraphs (Y), (Z), (AA) and (BB) enables the Board to issue citations, fines and orders of abatement for violations of any provision of the Osteopathic Act, Medical Practice Act, the Board's regulations, or any other laws and regulations under the Board's jurisdiction will help keep the list of citable offenses current as statutes and regulations are added, repealed, and modified. To further implement that policy change, the proposal would delete, as duplicative and unnecessary, those statutes and regulations listed in paragraphs (23) – (51) and (54) – (56) as those referenced authorities are contained in the Medical Practice Act or the Board's regulations and would therefore be covered by proposed paragraphs (Y), (Z), and (AA). Further, this proposed rulemaking clarifies the Board's authority to assess fines to the full extent outlined by applicable code sections and in a more logical order than currently exists in subsection (a) by moving specific fine "cap" amounts specified in law and at paragraphs (a)(34) and (a)(41) to a new proposed subsection (a)(2)).

Civil Code section 56.36 of the CMIA authorizes this Board as a licensing agency of a health care provider (Board licensees) to issue citations as specified for violations of the CMIA. For greater notice to licensees and staff and to ensure that fines are assessed in accordance with Civil Code section 56.10 (the relevant fine amount caps in the CMIA) for violations of patient confidentiality as specified in the CMIA, the Board adds a reference to Civil Code section 56.10 to its list of citable offenses in paragraph (X) of subsection (a)(1).

In addition, Subsection (BB) adds a new reference to any other statute or regulation upon which the Board may base a disciplinary action. The purpose of this reference is to provide the Board with authority to enforce statutes and regulations that they can otherwise base enforcement actions on that may not be specifically listed (for example: BPC section 141 (disciplinary action by another state, agency of the federal government or another country for substantially related acts)). This section provides a commonsense consolidation of citation authority that eliminates the cumbersome need to add every new statute or regulation that the Board has authority to enforce through formal discipline but also allows the Board a reasonable alternative of issuing a citation in lieu of disciplinary action for those cases that may not rise to the level of needing restriction on practice.

<u>Other Clarifying Changes to Update Existing Authority in Subsection (a)(1) (paragraph (S)</u>

(existing number (a)(20)) and repeal of existing paragraph (a)(16))

Purpose: At paragraph (S), the Board proposes to repeal a reference to subsection (b) of BPC section 802 as that provision formerly contained a reference to this Board, which has been renumbered to subsection (a) by law. Since subsection (b) of BPC section 802 currently refers to licensed marriage and family therapists and not licensees of this Board, the Board proposes to correct and update the cross-referenced subsection to subsection (a).

A reference to BPC section 655.6 in existing subsection (a), paragraph (16) would be deleted as obsolete, as that statute was repealed in 2008.

Rationale: These changes are necessary to update the Board's existing authority to allow the Board's Executive Director or their designee to issue citations, fines and orders of abatement accurately and consistently in accordance with the Board's most current legal authority and give adequate notice to licensees of this option for taking enforcement action short of discipline.

Adoption of new subsection (b)(1) – new factors to be considered when determining the amount of an administrative fine.

Purpose: This proposal would add a new list of the factors the Executive Director or designee must consider when setting the fine amount for those fines other than those assessed per subsection (b)(2) for violations of the CMIA (discussed below). In amending the factors, reference to BPC section 125.9 was deleted to make room for a more expansive criteria to consider factors that are commonly considered by the Executive Director in increasing or decreasing the amount of the fine assessed based upon the conduct of the cited person in a particular case but not covered by existing regulations. The criteria is listed in this section in subsection (b)(1) and includes existing criteria currently required to be considered by the Board under (b)(3) of BPC section 125.9 as well the following additional criteria: (A)"bad faith" of the cited person, (C) evidence that the violation was willful; and (E) the extent to which the cited person has cooperated with the Board.

Rationale: The amendments to subsection (b)(1) are necessary to require the Board's Executive Director or their designee to consider the factors listed in BPC section 125.9, subdivision (b), paragraph (3) or other factors set by Board policy as provided in this section. BPC section 125.9(b)(3) requires the Board to consider, in assessing a fine the appropriateness of the amount of the fine with respect to factors *such as* the gravity of the violation, the good faith of the licensee, and the history of previous violations (emphasis added). The use of the words "such as" impliedly authorizes the Board to consider those other factors that, in its experience, would allow the Executive Director to consider as aggravating the penalty (increasing the fine amount) or mitigating it (decreasing the fine amount).

The complete list of the factors proposed to be adopted and the reasoning for why each factor is proposed to be included looks like this:

(A) The good or bad faith of the cited person.

[Rationale: "Good faith" is required to be considered by the Board by law per BPC section 125.9. "Bad faith" is usually considered by the Board to be an aggravating factor in fixing the fine amount as it shows a tendency towards dishonesty or deception.]

(B) The gravity of the violation.

[Rationale: This factor is required to be considered by the Board by law per BPC section 125.9.]

(C) Evidence that the violation was willful.

[Rationale: Willful violations are usually considered by the Board to be an aggravating factor in fixing the fine amount as it shows a deliberate disregard for the rules under which the licensee operates.]

(D) History of previous violations.

[Rationale: History of violations required to be considered by the Board by law per BPC section 125.9 and can be aggravating or mitigating depending on the licensee's history.]

(E) The extent to which the cited person has cooperated with the Board.

[Rationale: Consideration of this factor is important in determining the fine amount as the extent to which the cited person has cooperated can be aggravating (if no cooperation) or mitigating (cooperated) depending on the licensee's conduct in this regard. Cooperation shows progress in ensuring that such conduct does not recur.]

(F) The extent to which the cited person has mitigated or attempted to mitigate any danger or injury caused by the violation.

[Rationale: Consideration of this factor is important to consider in lowering the proposed fine amount as it shows the licensee's self-reflection and desire to address the violation, which are primary goals of any enforcement action taken by the Board.]

<u>Adoption of new proposed subsection (b)(2) setting fine amount for assessments of violations of the Confidentiality of Information Act</u>

Purpose: This proposal would specify how the Executive Director, or their designee would assess a fine amount for violation of Civil Code section 56.10 and require them to consider the factors listed in Section 56(d) of the Civil Code.

Rationale: This proposal is necessary to ensure that the Executive Director or their designee assesses a fine for violation of Civil Code section 56.10 in accordance with the CMIA. When determining the fine amount for a violation of Civil Code section 56.10, which is a section under

the Confidentiality of Medical Information Act, the Board's Executive Director or their designee must consider the relevant factors set forth under Civil Code section 56.36, subdivision (d), including but not limited to, the following: (1) Whether the licensee has made a reasonable, good faith attempt to comply with this part; (2) The nature and seriousness of the misconduct; (3) The harm to the patient, enrollee, or subscriber; (4) The number of violations; (5) The persistence of the misconduct; (6) The length of time over which the misconduct occurred; and (7) The licensee's assets, liabilities, and net worth.

This proposal provides a valuable regulatory tool for educating licensees and achieving compliance with patient confidentiality requirements by providing advance notice of this authority and the amount of the fine the Board's Executive Director or their designee may issue and factors to be considered when determining the fine to be imposed under the CMIA. In turn, this proposed rulemaking will further consumer protection by ensuring that the fines assessed comport with the objectives of protecting patient confidentiality in the CMIA.

Amendments to subsection (c)

Purpose: This subsection permits the Executive Director to increase the fine amount above the cap of $2500 currently listed in subsection (a) if one or more of the circumstances listed here applies. The proposed amendments to subsection (c) would include the following:

(1) Corrects a cross-reference to the fine amounts in subsection (a) to subsection (a)(1) to avoid confusion regarding which citations might be increased above the $2500 cap, and for consistency with the renumbering of (a) to (a)(1) in this section.
(2) Adds the words "at least" to this subsection so that it would read: "Notwithstanding the administrative fine amounts specified in subsection (a)(1), a citation may include a fine between $2501 and $5000, if at least one or more of the following circumstances apply:"
(3) Amends subsection (b)(1) (renumbered as (c) here for clarity and better organization of this section) to remove the word "relationship" and replace it with the word "threat."

Rationale: This section retains existing circumstances for increase the fine amount above the cap of $2500 currently listed in subsection (a) with minor changes for greater comprehension of the existing standards and when they would be implemented to increase fines up to $5,000 as authorized by BPC section 125.9(b)(3). Adding the words "at least" is necessary to avoid ambiguity regarding whether all or even one circumstance is needed to trigger consideration of a fine amount between $2501 and $5000. With the addition of "at least", it is readily apparent that only one circumstance could trigger consideration of a fine amount between $2501 and $5000.

Use of the word "relationship" has generated confusion over what precisely is intended to trigger this circumstance as it is unclear to what degree the "relationship" would be deemed serious enough to warrant an increased fine amount. The Board proposes to resolve that ambiguity by replacing it with the word "threat", which more clearly describes, in commonly understood terms, a person likely to cause damage or danger or who has the potential to cause

serious harm (definition provided by Oxford Languages on-line dictionary, March 21, 2024).

Factual Basis for Amendments to Subsection (a) in CCR Section 1659.32 Compliance with Orders of Abatement

Purpose: The proposed amendments to subsection (a) authorizes the Executive Director to further delegate to "their designee" this same authority with respect to enforcing this section by issuance of an orders of abatement to correct a violation. Gendered pronouns "his or her" would be deleted and replaced with "their".

Rationale: To implement the enforcement program's workload more effectively, this proposal would authorize the Executive Director to further delegate to "their designee" this same authority with respect to enforcing this section. In compliance with Assembly Concurrent Resolution No. 260 of 2018, the Board is also updating it regulatory language to comply with this resolution that state agencies should use gender neutral pronouns and avoid the use of gendered pronouns throughout this proposal.

Factual Basis for Amendments to CCR Section 1659.33 Citations for Unlicensed Practice

Purpose: This proposal would add new subsection numbering (a)-(d) for each existing paragraph for better organization of concepts in this section. It would add a new requirement to subsection (a)(as renumbered) to authorize the Executive Director to further delegate to "their designee" this same authority to issue citations, fines and orders of abatement for individuals who are unlicensed and practicing medicine.

This proposal also adds to subsection (a) the term "postgraduate licensee" to the other license classification requiring a license to practice clarifying the other category of unlicensed practice for which the Board may take action. This would clarify that the Board has two separate license types for which citations, fines and orders of abatement could be issued.

This proposal also deletes language in subsection (a) that limits the authority of the Executive Director and the eligible violations for issuing citations, fines, and orders of abatement. The current language being deleted limits issuance of citations for unlicensed practice to an otherwise licensed physician whose license status is delinquent (a) or an applicant that practices prior to the issuance of their license. There are other instances where it may be deemed that someone may be practicing medicine which may be determined by the Executive Director to be eligible to issue a citation, fine and order of abatement. Deleting this language allows other instances of unlicensed practice of medicine to be determined to be a citable offense and for which the Board may take enforcement action and provides the Board with greater options for protecting the public other than referral for criminal prosecution.

This proposal would add a new subsection (b)(1) that would set forth the Notice requirements according to standards set by State Administrative Manual (SAM) section 8293.1 for cited persons who may be subjected to collection of an unpaid fine and the requirements for Notice that the Board must meet before sending any unpaid fine to the Franchise Tax Board in

accordance with the FTB's Interagency Intercept Program, which would state:

> If any fine amount remains unpaid after the effective date of the final citation order, the executive director or their designee shall send a written notice at intervals of 30, 60 and 90 days from the effective date of the final citation order to the cited person containing, at a minimum, the following statements:
>
> "Our records show that you have a $[insert citation amount owed] delinquent debt due to the Osteopathic Medical Board of California. You have 30 days to voluntarily pay this amount before we submit your account to the Franchise Tax Board (FTB) for interagency intercept collection.
>
> FTB operates an intercept program in conjunction with the State Controller's Office, collecting delinquent liabilities individuals owed to state, local agencies, and colleges. FTB intercepts tax refunds, unclaimed property claims, and lottery winnings owed to individuals. FTB redirects these funds to pay the individual's debts to the agencies, including this Board. (Government Code Sections 12419.2 and 12419.5.)
>
> If you have questions or do not believe you owe this debt, contact us within 30 days from the date of this letter. A representative will review your questions/objections. If you do not contact us within that time, or if you do not provide sufficient objections, we will proceed with intercept collections."
>
> After the initial 30-day notice, any subsequent notices shall contain references to any prior notice(s), including the date any prior notice was sent, and what further actions, including collection fees, may be taken in the collection process.

This proposal adds in proposed subsection (b)(2) the remedy for unpaid fines of referral to the Franchise Tax Board's (FTB) tax refund intercept program in accordance with Government Code section 12419.2, and the 6-month timeframe for when referral would occur after the effective date of the final citation order once notice has been given in accordance with paragraph (b)(1). Under current law, the Board may submit a request to the Franchise Tax Board (FTB) to intercept any refund owed to a taxpayer and transfer the funds to the board if the taxpayer owes the Board a debt. This section defines when the remedy of collection can be triggered by the Board to provide sufficient time for notice and other informal collection efforts, which is six months from the due date in the final order of the Board. It also specifies what personal information is required to be transmitted to the FTB to initiate the interception of any tax refund due pursuant to the FTB's program as authorized by Government Code sections 12419.2 and 12419.5, which includes the cited persons' name, social security number and the amount of their unpaid fine.

Additionally, a definition for the word "final" is added, as follows in proposed new subsection (d)-(a) the Board's contested citation decision is effective and the cited person has exhausted all methods for contesting the citation under section 1659.34, or, (b) the cited person did not contest the citation decision and the timeframes for contesting a citation under section 1659.34

have passed.

Rationale: The Board provides the following rationales for each of the above noted changes:

Designee and Addition of Postgraduate Trainee Licensee Category Changes (subsection (a))

The delegation authority to a designee is added to create to implement the enforcement program's workload more effectively. BPC section 148 authorizes this Board to establish, by regulation, a similar system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the jurisdiction of the Board. Consequently, reference to the Postgraduate Training License was added to provide clarity that this section also applies to this license type issued by the Board as well.

Repeal of Text Limiting Issuance of Unlicensed Activity Citations to Applicants and Licensees Who Are Delinquent (subsection (a))

When the existing regulation was first adopted, it was anticipated that cases in which a person who had never previously held a license would be prosecuted criminally for unlicensed activity in accordance with Business and Professions Code section 2052. However, in situations where the Board receives a complaint that a person who had never applied for or been licensed as an osteopathic physician and surgeon had seen patients, performed patient exams and identified themselves as an osteopathic physician, the Board would have no recourse but to refer the matter for criminal prosecution. However, in cases where there is no actual patient harm, such prosecutions can be declined. As a result, the Board would have no legal recourse to prevent further violations of the law and to protect consumers since the Board has no current authority to issue a citation, fine and order of abatement for unlicensed activity to persons who had never been previously licensed by the Board or applied for a license with the Board due to the current limitations in Section 1659.33.

Upon review of Section 1659.33, the Board determined that this section should be amended to authorize the Board's Executive Director or their designee to issue an administrative citation to any unlicensed person who has performed services for which licensure as an osteopathic physician or postgraduate training licensee is required, regardless of whether the individual had ever been previously licensed by the Board or applied for licensure with the Board. As Section 1659.33 is currently written, the Board's Executive Director is only authorized to issue a citation and order of abatement and levy fines in the case of an osteopathic physician and surgeon who had previously held a license and then practiced with a delinquent license or applied for a license with the Board and practiced prior to issuance. However, as discussed further below, there is more than one way for an individual to be considered unlicensed.

However, legally there is no distinction between an individual who has previously held a license and allowed it to expire and an individual who has never had a license; both have the status of being "unlicensed." As the California Court of Appeal has explained it in a case involving a real estate broker's delinquent license:

> There is nothing in the law which compels a licensed real estate broker to continue in business or to renew his license, and if he does not do so he is unlicensed after the expiration date. That is the status which appellant achieved as of midnight, June 30, 1951, and which it has retained ever since. It was, therefore, unlicensed when it contracted to serve defendants as a real estate broker and when, according to its allegations, the cause of action here sued upon arose. (*Mortgage Finance Corp. v. Strizek* (1957) 148 Cal.App.2d 817, 819.)

Some other examples of existing statutory unlicensed practice are practicing during a disciplinary ordered suspension or refusing to cease practice when no longer licensed after revocation. This change clarifies that these and other statutory provisions designating unlicensed practice would be included under this section's authority.

To avoid the occurrence of the type of problems mentioned above, the Board would like to expand the authority of the Executive Director or their designee to issue citations and fines to those who have never been licensed and are holding or have held themselves out as an osteopathic physician and surgeon or postgraduate training licensee. The Board's proposed amendment to Section 1659.33 will allow the Executive Director or their designee to do so consistent with BPC section 148. The issuance of a citation, an order of abatement, and a fine by the Executive Director or their designee would not preclude the Board from also pursuing criminal charges against an individual for performing medical services as an osteopathic physician and surgeon or postgraduate training licensee without a license.

Addition of Notice Requirements and FTB Tax Intercept Referral Process (subsection (b)(1)-(2))

Adding the FTB tax refund intercept remedy for collection of unpaid fines provides clarity and notice to the regulated public of this process authorized by law for the Board to use this specific collection remedy. Government Code section 12419.2 authorizes the State Controller under the authority of Government Code section 12419.5 in conjunction with the FTB, to develop a program to cross-match individuals social security numbers who owe state agencies money and intercept any tax refunds owed to an individual and send them to the agency to whom the outstanding debt is owed (in this case, a fine) (see Underlying Data, Franchise Tax Board Interagency Intercept Collections Program Information, State Administrative Manual (SAM) section 8293.1).

The amendments to subsection (b)(1) include newly added paragraph (1) to ensure adequate notice of, and comply with, administrative requirements for enforcing debt collection by way of the Franchise Tax Board's tax intercept program. The Board also adds citations to the authorizing Government Code sections 12419.2 and 12419.5 to provide greater transparency and explanation regarding the authority for the FTB program's processes and procedures and the types of revenues that may be impacted by this program (tax refunds but not online game prizes of ninety-nine dollars ($99) or lower by California State Lottery Retailers). This addition of the exact wording and the timelines for notice (intervals of 30, 60 and 90 days) are necessary to comply with standards set by the Department of General Services in the State Administrative Manual (SAM) section 8293.1 and Franchise Tax Board's state agency instructions for

authorizing tax refund intercepts by the Board (see Underlying Data). The Board has no discretion to not follow these mandates, including the content and the timing of these notices, and the Board's Pre-Intercept Notice must be "identical or substantially similar" to the one provided by the FTB (as reflected in the text currently being proposed) or the Board risks suspension by the FTB of the Board's ability to use tax intercepts for the FTB program.

In subsection (b)(2), the Board proposes to prescribe the Board's current practice of referral in accordance with current FTB tax intercept program requirements to provide affected individuals with advance notice of the Board's process after notice in compliance with paragraph (1) has been sent to the cited person, which includes:

(A) Referral to FTB if any fine amount remains unpaid six months after the effective date of the final citation order,

(B) Requires the Executive Director to submit the request to the FTB for interagency intercept collection of any tax refund due to the cited person in accordance with the program established by FTB pursuant to Government Code sections 12419.2 and 12419.5 (regarding the State Controller's authority to offset any amount due a state agency from a person or entity, against any amount owing that person or entity by any state agency (including tax refund using the person's social security number as an identifier; and,

(C) The submission of the cited person's name, social security number and the amount of their unpaid fine to the FTB as part of the request to initiate an intercept of any tax refund owed the cited person under the FTB's program. This information is being provided in this proposal to provide notice to affected cited persons and fully disclose the scope of the personal information used to match a cited person in the FTB program.

In the Board's experience, six months is sufficient time for the affected individuals to resolve any issues regarding payment with the Board after their citation. Establishing this process in regulation provides authority and guidance to the Executive Director or their designee regarding Board policy to pursue this option in cases where the individual fails or refuses to comply with a final Board order requiring payment of a fine for unlicensed activity after a reasonable time (six months). This ensures consistency in the Board's enforcement of its unlicensed activity citation program.

<u>Addition of the definition for "final" for "final" citation order (subsection (d))</u>

Defining what constitutes "final" that would trigger the board's authority to use this remedy gives adequate notice of when the Board may use the remedy in accordance with legal standards for when an order or judgment may be considered final. This definition is necessary to give notice of and establish the time for when the decision is considered "final" if it is not contested. This definition is necessary to establish that the appeals process has come to an end (as set forth in CCR section 1659.34), no further challenges to the citation may be made, and the individual shall comply with all orders made in the citation. This establishes an end to the process by which the Board may proceed with required actions to enforce the Board's order.

Factual Basis for Amendment to CCR Section 1659.34 Contest of Citations

Purpose: Except for changes to correct gendered pronouns to "their", this section remains unchanged.

Rationale: In compliance with Assembly Concurrent Resolution No. 260 of 2018, the Board is updating its regulatory language to comply with this resolution that state agencies should use gender neutral pronouns and avoid the use of gendered pronouns throughout this proposal.

Factual Basis for Amendment to CCR Section 1659.35 Public Disclosure: Records Retention

Purpose: The only amendment to this section is to replace the word "resolution" with "issuance."

Rationale: Existing regulation requires the Board to purge citations that have been resolved 10 years from the date of "resolution." The reason for changing the wording to "issuance" is to clarify when the exact purge date is under this section would occur using an unambiguous date. The word "resolution" in this context is vague as to which resolution date the Board is referring. Does resolution mean payment date or the final date when all appeals have been exhausted? This ambiguity can result in inconsistent implementation of the Board's records retention schedule. The new text sets the date of issuance as the firm date the clock begins for the 10-year purging timeframe, making it easier to track and implement for staff and for cited persons to understand.

Underlying Data

1. Agenda January 19, 2023, Board meeting
2. Meeting Materials: Regulatory Memo and Proposed Language (presented at January 19, 2023, Board meeting), also referenced in the August Board meeting packet as Addendum A
3. January 19, 2023, Board Meeting Minutes
4. Agenda August 17, 2023, Board meeting
5. Meeting Materials: Regulatory Memo and Proposed language presented at the August 17, 2023, Board meeting (including Addenda B and C. Addendum A is the regulatory memo and proposed language referenced above).
    a. Addendum A: Originally Proposed Text for Continuing Medical Education Requirements Approved by the Board on January 19, 2023
    b. Addendum B: Proposed Regulatory Language (Combining Amendments to both CME and Citation and Fine Requirements)
    c. Addendum C: Franchise Tax Board Interagency Intercept Collections Program Information
6. August 17, 2023, Board Meeting Minutes
7. Senate Business and Professions and Economic Development Committee Analysis, dated April 24, 2017, SB 798. [Includes description of the change from 3 yrs. to 2yrs, elimination of even/odd months expiration, aligns CME cycle with license expiration cycle.]

8. Assembly Committee on Business and Professions Analysis, dated June 12, 2018, SB 1109. [Includes description of the risk of addiction CME requirement.]
9. Assembly Committee on Business and Professions Analysis, dated July 14, 2021, SB 806. [Includes the description of a change reducing required CME hours from 100 to 50.]
10. Assembly Business and Professions Committee Analysis, dated June 28, 2022, SB1443. [Includes description of the elimination of the prorated license issuance by birthdate and expiration.]
11. Agenda, Relevant Meeting Materials: Regulatory Memo, Attachments and Proposed Language (presented at August 15, 2024, Board meeting) and Draft Excerpt Minutes of the August 15, 2024 Board Meeting

Fiscal Impact

This proposal is intended to streamline the Board's licensing renewal process, while ensuring licensees comply with CME requirements. According to the Board, staff is currently unable to process renewal applications in a timely manner and Board management is required to assist with the CME verification workload.

Current Process: The Board currently processes approximately 6,800 license renewal applications per year and verifies every renewing licensee has fulfilled the CME requirements prior to approval. The CME verification process typically takes 40 minutes per application, which results approximately 4,500 hours (2.6 positions) of annual workload.

However, the Board only has 2.0 staff allocated for this workload. As a result, renewal application approvals may be delayed, and Board management must assist with this workload.

Proposed Process: This proposal will allow the Board to streamline the renewal license approval process, while also ensuring CME compliance by creating a robust CME audit and enforcement process. In the event a licensee fails a CME audit, the Board will be authorized to issue a citation and fine, *with an average estimated fine amount of $1,500 per citation*.

The Board estimates the new CME review and auditing process, including the issuance of a citation and fine will reduce total workload to approximately 3,300 hours (1.9 positions). As a result, the Board will be able to process renewal applications with existing staffing in a timely manner and Board management will be able to focus on other high priority areas.

Under this proposal, Board staff will verify each renewing licensee (6,800) has certified CME compliance prior to license renewal approval. Staff will then audit approximately 10 percent (680) of renewal applications for CME compliance and estimates up to 10 percent (68) of these audits will reveal non-compliance and result in a citation and fine.

The Board projects up to 20 individuals issued a citation and fine will request an informal conference, of which 2 individuals may seek a formal appeal.

The Board estimates total workload and costs ranging from approximately $357,700 to $466,700 per year and up to $4.1 million over a ten-year period as follows:

Osteopathic Medical Board of California
Continuing Medical Education - Fiscal Impact (Workload Costs)*

CME Compliance	Unit Cost	Volume	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Intake & Acknowledgement (10 mins)	$18	6,800	$122,400	$126,072	$129,854	$133,750	$137,762	$141,895	$146,152	$150,537	$155,053	$159,704	$1,403,179
CME Review & Audit (180 mins)	$315	680	$214,200	$220,626	$227,245	$234,062	$241,084	$248,317	$255,766	$263,439	$271,342	$279,482	$2,455,563
Issuance of Citation & Fine (120 mins)	$210	68	$14,280	$14,708	$15,150	$15,604	$16,072	$16,554	$17,051	$17,563	$18,089	$18,632	$163,704
Informal Conference (45 mins)	$79	20	$1,580	$1,627	$1,676	$1,727	$1,778	$1,832	$1,887	$1,943	$2,001	$2,062	$18,113
Appeal Processing (60 mins)	$105	2	$210	$216	$223	$229	$236	$243	$251	$258	$266	$274	$2,407
Attorney General & Office of Admin Hearing	$2,500	2	$5,000	$5,150	$5,305	$5,464	$5,628	$5,796	$5,970	$6,149	$6,334	$6,524	$57,319
Total Costs:	**$3,227**	-	**$357,670**	**$368,400**	**$379,452**	**$390,836**	**$402,561**	**$414,638**	**$427,077**	**$439,889**	**$453,086**	**$466,678**	**$4,100,286**

AGPA: Associate Governmental Program Analyst @ $105/hr (includes DCA Distributed Administration), plus a three percent annual growth factor

The Board projects issuing up to 68 citation per year with an average fine amount of $1,500 per citations, which would result in revenues of approximately $102,000 per year and up to $1.02 million over a ten-year period.

Business Impact

The Board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts:

This regulation only applies to approximately 13,600 osteopathic physicians and surgeons, which is a small number of Californians directly affected. The underlying CME requirement is in place to protect public safety by ensuring continuing medical competency for those licensed to provide patient care.

Economic Impact Assessment

The Board has determined that this regulatory proposal will have the following effects:

This regulatory proposal will not create or eliminate jobs within the State of California because it simply changes existing reporting requirements to be more convenient for osteopathic physicians and surgeons. Additionally, only osteopathic physicians and surgeons are impacted by this change.

This regulatory proposal will not create new business or eliminate existing businesses within the State of California because it is only a change in a professional reporting requirement for one relatively small profession.

This proposal will not affect the expansion of businesses currently doing business within the State of California because the regulations' narrow scope only applies to osteopathic physicians and surgeons.

This regulatory proposal benefits the health and welfare of California residents as follows. The

renewal process will be streamlined and reduce delays from staff having to review CMEs at the time of renewal. The time-consuming review of CMEs 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 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.

For changes proposed in the Board's citation and fine program, 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.

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.

The Board estimates up to 68 individuals may be issued a citation, which with an estimated average fine amount of $1,500 fine per year, would result in annual costs of $102,000 and up to $1.02 million over a ten-year period. The Board notes, licensees may avoid any fines levied by complying with the Board's CME requirements authorized under current law and regulations.

This regulatory proposal does not affect worker safety because the regulations are not related to worker safety.

This regulatory proposal does not affect the state's environment because the regulations are not related to the State's environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

No such alternatives have been proposed, however the Board welcomes comments from the public.

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business:

No such alternatives have been proposed, however the Board welcomes comments from the public.