MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: April 29, 2015
ATTENTION: Medical Board of California, Members
SUBJECT: Continuing Medical Education
Proposed Amendments to Sections 1337 and 1338 of
Title 16 of the California Code of Regulations
FROM: Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

Review the comments to the proposed amendments to Sections 1337 and 1338 of Title 16 of the California Code of Regulations (CCR), and staff's responses to those comments to determine whether the proposed rulemaking file 1) should proceed as is; 2) should be withdrawn indefinitely; or 3) should be re-noticed with amendments and/or additional information.

BACKGROUND:

On July 24, 2014, Carol Clothier, Vice President, American Board of Medical Specialties (ABMS), State Health and Public Affairs, made a presentation to the Licensing Committee of the Medical Board of California (Board) regarding maintenance of certification (MOC) requirements. Ms. Clothier asked the Board to consider accepting continuing medical education (CME) credits performed during the MOC process to satisfy the CME requirements for renewal of a physician's and surgeon's license with the Board.

On October 24, 2014, the Board voted to instruct staff to notice the proposed language to amend CCR sections 1337 and 1338 to allow CME that is approved for specialty board MOC as meeting the Board's CME requirements for renewal of a physician's and surgeon's license.

The proposed language was noticed for a 45-day public comment period, which ended on April 20, 2015. The Board received two comments in response to the notice. The comments are attached to this report.

Below, please find a summary of each comment, and staff's recommendations in response.

SUMMARY OF PUBLIC COMMENTS:

Written Public Comment from Stephen H. Miller, M.D., M.P.H.

On March 27, 2015, the Board received public comment from Stephen H. Miller, M.D., M.P.H., by email. (Attachment A)

Dr. Miller expressed his strong support for the proposed amendments to CCR section 1337. Dr. Miller stated the proposed amendments would reduce the regulatory burden on physicians by allowing physicians to participate in MOC to meet or substantially meet the CME requirements. In addition, Dr. Miller stated patients benefit from the proposed rule because it recognizes the importance of a physician's commitment to developing his/her knowledge and skills as part of a rigorous continuous professional development program.

Response:

Staff recommends accepting this comment.

Written Public Comment from the California Medical Association

On April 20, 2015, the Board received public comment from Yvonne Choong, Senior Director, Center for Medical and Regulatory Policy, on behalf of the California Medical Association (CMA). (Attachment B)

Comments addressing similar concerns are grouped for response:

1) **CMA expressed concern that the amendment could be interpreted to include activities that are not developed in compliance with criteria that helps to ensure that the activities are practice-based, created without commercial influence, incorporate valid content, and are designed to improve physician competence and practice. CMA is concerned that the proposed amendment would allow physicians to complete MOC activities that have not been certified for credit and not developed with the same focus and rigor as certified CME.**

2) **CMA stated that while most ABMS member boards currently require certified CME for compliance with MOC Part II activities, the ABMS has no authority mandate that their member boards require certified CME for learning or self-assessment activities. CMA also expressed concern that the ABMS standards allow for alternatives to certified CME, and leaves this up to each specialty board's internal process for quality control.**

Response:

Staff recommends rejecting these comments. As presented by Carol Clothier at the July 2014 Board Meeting, MOC is based on the six ABMS /Accreditation Council for Graduate Medical Education (ACGME) competencies, which are: 1) professionalism; 2) patient care and procedural skills; 3) medical knowledge; 4) practice-based learning and improvement; 5) interpersonal and communication skills; and 6) systems-based practice. Physicians participating in MOC are expected to engage in continuous learning and

assessment of their medical and surgical knowledge and judgment, their skills, and their professionalism.

3) **CMA pointed out that the proposed amendment would recognize MOC related activities from Board-approved specialty boards that are not ABMS members, and expressed concern that there may be little information regarding the quality standards applicable to their MOC activities.**

Response:

Staff recommends rejecting this comment. Specialty boards seeking Board approval are scrutinized to ensure they meet the statutory and regulatory mandates. These Boards have a vested interest in their members engaging in appropriate MOC CME activities.

4) **CMA stated the Board is at risk of accepting non-certified CME if the MOC CME does not meet the quality standards as certified CME. In addition, CMA is concerned that MOC may not comply with Section 2190.1 of the Business and Professions Code (BPC).**

Response:

Staff recommends rejecting this comment. Some of the MOC CME will not be certified, which is the basis for these proposed amendments. The Board grants CME credit for some activities other than certified CME, such as granting 100 hours of CME credit for passing a board-certifying or recertifying exam. The proposed regulations are creating another pathway for obtaining CME credit beyond taking certified CME. The Board is permitted to create alternative methods for obtaining CME credit, and the Board can give CME credit for some activities outside of BPC section 2190.1.

5) **CMA recommends that the proposed addition to CCR section 1337 be amended to read:**

(g) ***Continuing education that is required for maintenance of certification by American Board of Medical Specialties affiliate boards or other specialty boards approved by the Medical Board of California must be accredited by those organizations listed in Section 1337 subsection (a)(1) and (a)(2) or certified for credit by the American Medical Association Physician's Recognition Award [PRA] Category1^tm (AMA), American Congress of Obstetricians and Gynecologists [ACOG] Cognates, or American Osteopathic Association (AOA) Category 1A.***

Response:

Staff recommends rejecting this comment. Requiring the CME to be certified by the American Medical Association Physician's Recognition Award [PRA] Category1^tm

(AMA), American Congress of Obstetricians and Gynecologists [ACOG] Cognates, or American Osteopathic Association (AOA) Category 1A, will make the proposed amendments meaningless.

6) **CMA expressed concern with regard to the following information in the Notice and Initial Statement of Reasons:**

> **Most [CME providers] are universities and professional associations that are involved in a number of different activities…The proposed amendments are unlikely to create or eliminate jobs…are unlikely to eliminate existing business.**

CMA indicated that IMQ/CMA accredits approximately 240 CME providers, and most are mid-sized or small organizations, including hospitals, medical groups and local or state medical specialty societies. CMA stated that many of the small providers offer certified CME activities that focus on local practice gaps, and apply to local practice settings. CMA expressed concern that even small changes in costs can cause CME providers to withdraw from accreditation programs, reducing the availability of CME programs at the local level.

7) **CMA stated that offering certified CME activities is likely to be more expensive than offering non-certified education activities. Therefore, CME activities that are not specifically related to MOC may be at a competitive disadvantage if physicians elect to focus only on activities that meet MOC requirements, as opposed to certified CME activities that address local practice needs and benefit California patients.**

Response:

The Notice and Initial Statement of Reasons contained information and estimates available to staff through a reasonable search of who provides CME. CMA's statement supports staff's conclusion that most CME providers are involved in a number of different activities, and thus the proposed amendments are unlikely to create or eliminate jobs.

Many MOC CME activities appear to be certified, so it is difficult to quantify the extent of the "competitive disadvantage" to local certified CME providers if this rulemaking goes into effect. Additionally, physicians are not prohibited from taking more CME than required, and CME that is particularly relevant to a physician's practice may still draw attendance, even if not required for licensure.

8) **CMA expressed concern with the following statement from the Initial Statement of Reasons:**

> **Under current regulations, licensed physicians who are participating in MOC to maintain specialty board certification could be required to complete an estimated 12.5 additional hours of CME per year than other physicians not participating in MOC to renew their license.**

CMA indicated that while this statement may be technically accurate for some physicians, the regulatory package does not indicate the percentage of physicians participating in MOC that are required to take additional hours of CME. The fiscal impact analysis potentially overestimates the benefit of the proposed regulations.

Response:

The estimate of 12.5 additional hours of CME per year is based upon the types of activities that make up MOC CME. Physicians have different options for complying with MOC CME. Therefore, it is true that the analysis may be overestimating the benefit of the proposed amendments to the regulations, but it may also be underestimating it, because the Board cannot obtain an exact figure.

9) **CMA stated that the regulatory package assumes that a physician participating in MOC saves $2,500 per year by not having to earn an additional 12.5 credits in order to meet the 50 hours of CME required for licensure. The Board's conclusion was reached based on an estimate of $200 per CME credit. CMA stated that there was no calculation to determine how an estimate of $200 per credit was derived, and no source for the average of between $0 and $1,500 per course. CMA further stated that there is no definitive source to determine an average cost for CME activities, and pointed out that many accredited CME providers in California offer CME at no cost to physicians or at a fee that is much less than the $200 per CME hour. CMA stated that the cost assumptions may have overestimated the savings per physician.**

Response:

Staff agrees with CMA that there is not a definitive source for determining an average cost for CME. When researching the matter, staff discovered there was a wide range of costs, depending on the type of CME provided. The bulk of the courses seemed to fall within the range of $200 per unit. It is an estimate, and will vary from physician to physician. If, however, the estimated cost of CME units is overstated, then the corresponding estimated loss to CME providers is overstated, too, and their loss would be less than the estimate of $26,000 per year.

10) CMA recommended that the Board consider reissuing the Notice and the Initial Statement of Reasons with more complete and correct information for the public to consider and comment upon.

Response:

The Board may instruct staff to proceed with the proposed rulemaking file as is, withdraw the proposed rulemaking file indefinitely, or obtain further information and re-notice the rulemaking file for additional comments. Even if the Board wishes staff to re-notice the proposed rulemaking file with additional information, however, the figures provided will continue to be based on estimates.

Webb, Kerrie@MBC

From: Stephen Miller <shmillermd@yahoo.com>
Sent: Friday, March 27, 2015 9:16 AM
To: Regulations, MBC@MBC
Subject: MOC

Dear Mr. Worden,

I am a retired practicing physician in California, A21651, who is Board Certified in Plastic Surgery and Surgery by the American Boards of Plastic Surgery and Surgery. Although I am retired from active practice, I am an active faculty member of the UCSD PACE program. In order for me to remain current in my specialty and to maintain credibility as a PACE participant, I am actively involved in the Maintenance of Certification (MOC) program of the American Board of Plastic Surgery.
I'm contacting you to express my strong support for the proposed Amendments to Section 1337 of Article 11, Chapter 1, Division 13, of Title 16 of the California Code of Regulations; Continuing Medical Education. The proposed changes would reduce the regulatory burden on practicing physicians like me by allowing participation in the American Board of Medical Specialties' Programs for Maintenance of Certification (MOC) to meet or substantially meet continuing education requirements for licensure.

Patients benefits from this proposed rule because it recognizes the importance of a physician's commitment to developing his/her knowledge and skills as part of a rigorous continuous professional development program. I applaud this effort by the Medical Board of California.

Stephen H. Miller MD, MPH
Voluntary Clinical Professor of Family Medicine and Surgery
University of California, San Diego

California Medical Association
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April 20, 2015

Curtis Worden
Medical Board of California
2005 Evergreen St, Suite 1200
Sacramento, CA 95815

Subject: Medical Board of California - Approved Programs for Continuing Medical Education

Dear Mr. Worden:

The California Medical Association (CMA) respectfully submits for consideration the following comments related to the proposed amendments to the existing requirements for continuing medical education (CME). The comments are in response to the solicitation for comments in a notice of proposed rulemaking posted on March 6, 2015 for California Code of Regulations (CCR), Title 16, Division 13, Chapter 1, Sections 1337 and 1338.The proposed regulatory amendments address two issues: 1) expanding the definition of what constitutes approved continuing medical education, and 2) clarification of the MBC's ability to verify physician information from a primary source. Our comments pertain to the definition of approved CME programs and corrections to the Notice and Initial Statement of Reasons.

The California Medical Association is an advocacy organization that represents more than 40,000 California physicians, residents, fellows and medical students. Dedicated to the health of Californians, CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.

I. Background

The requirement for physicians to participate in CME was established in order to create the most competent licensing population possible, thereby enhancing consumer protection. Under California law, physicians and surgeons must complete at least 50 hours of approved CME during each biennial renewal cycle.

In addition, California has specific regulations that define what qualifies as CME. Organizations in California that are accredited to provide CME by entities such as the Institute of Medical Quality/California Medical Association (IMQ/CMA) or the Accreditation Council for Continuing Medical Education (ACCME), and physicians who claim CME credit for their license renewal, must comply with the state CME laws.

II. Recognition of Maintenance of Certification (MOC) Activities

The proposed change to CCR Section 1337 would expand the definition of CME activities recognized by the MBC to add a new category to the programs currently listed in CCR Section 1337 that qualify to meet the state licensing requirement for the completion of 50 hours of approved CME credits:

> *(g) Continuing education that is required for maintenance of certification by American Board of Medical Specialties affiliate boards or other specialty boards approved by the Medical Board of California.*

The proposed amendment would allow the MBC to recognize non-CME activities that physicians must complete to meet their specialty board's requirements to maintain their board certification.

While the proposed amendment is generally consistent with the CMA's position that continuing medical education contributes to quality of care, we have concerns that the amendment could be interpreted to include activities that are not developed in compliance with criteria that helps to ensure that the activities are practice-based, created independent of commercial influence, incorporate valid content, and are designed to improve physician competence and practice. By meeting these criteria, CME activities that are certified by an accredited CME provider adhere to a standard level of quality. Under the proposed regulations, it is possible that licensees could complete MOC activities that meet their specialty board's requirements but have not been certified for credit, not been developed with the same focus and rigor as certified continuing education activities or reviewed in accordance with a process that assesses program quality.

The Notice and Initial Statement of Reasons included in the regulatory package references a July 2014 MBC meeting in which a presentation was made by staff from the American Board of Medical Specialties (ABMS). The ABMS has adopted standards for its 24 member specialty boards to use in implementing MOC requirements including this guidance on developing CME activities for MOC Part II: Lifelong Learning and Self Assessment (LLS):

> *These requirements should incorporate but not be limited to engagement in CME activities that are accredited (ACCME, AAFP, or AOA) or certified for credit (e.g., AMA Physician's Recognition Award [PRA] Category 1, American Academy of Family Physicians [AAFP], American Congress of Obstetricians and Gynecologists [ACOG] Cognates, or AOA Category 1A.*
>
> *If a learning or self-assessment activity is not accredited by ACCME, the AAFP, or the AOA, the ABMS Member Board must establish an internal process for quality evaluation of materials. ABMS Member Boards will publish and be transparent about their criteria for granting MOC credit for learning and self-assessment materials developed by other organizations.*

The extent to which ABMS specialty boards adhere to the standards is left to the discretion of each specialty board. Although most ABMS member boards currently require certified CME for

compliance with MOC Part II activities, the ABMS has no authority mandate that their member boards require certified CME for their learning or self-assessment activities. The ABMS standards also allow for an alternative to certified CME, but again it is left to each member specialty board to establish its internal process for quality evaluation of non certified CME activities for their MOC Part II requirements. In addition, the MBC's proposed amendment would recognize MOC related activities from specialty boards that are not ABMS members. In such cases, there may be little information regarding the quality standards that would be applied to their MOC activities.

CMA supports the concept that continuing education for physicians is an essential element to sustain current competence in medical practice. However, if eligible MOC activities are not required to be certified for continuing medical education credits by a recognized accreditor, the MBC is at risk of accepting CME hours for activities that do not meet the same quality standards as certified CMA activities. Furthermore, it is also possible that the courses, self assessments and other activities which a specialty board decides to recognize for MOC, may not comply with Section 2190.1 of the Business and Professions Code

RECOMMENDATION #1

CMA recommends that the proposed addition to CCR Section 1337 be amended to read:

> *(g) Continuing education that is required for maintenance of certification by American Board of Medical Specialties affiliate boards or other specialty boards approved by the Medical Board of California* *must be accredited by those organizations listed in Section 1337 subsection (a)(1) and (a)(2) or certified for credit by the American Medical Association Physician's Recognition Award [PRA] Category1^tm^ (AMA), American Congress of Obstetricians and Gynecologists [ACOG] Cognates, or American Osteopathic Association (AOA) Category 1A.*

III. Corrections to the Initial Statement of Reasons

The Notice and Initial Statement of Reasons included in the regulatory package state the rationale and justification for the proposed regulations. Our review of these documents identified inaccurate and incomplete statements that should be addressed in order to provide the public with complete information regarding whether the proposed regulatory change is necessary. The source of these statements is unclear and the only reference is to the July 2014 ABMS staff presentation.

In particular, CMA has concerns with the following statements from the Notice and Initial Statement of Reasons:

1) "Most [CME providers] are universities and professional associations that are involved in a number of different activities….The proposed amendments are unlikely to create or eliminate jobs…are unlikely to eliminate existing business."

In California, IMQ/CMA accredits approximately 240 CME providers, and most are mid size or small organizations including hospitals, medical groups, and local or state medical specialty societies. Many of the smaller providers offer certified CME activities that address local practice gaps and apply to local practice settings. These types of CME programs serve as a mechanism for spreading best practices within departments or across organizations. While the annual revenue of these programs may be small, past experience has shown that even small changes in costs can cause CME providers to withdraw from accreditation programs, reducing the availability of CME programs at the local level.

Offering certified CME activities is likely to be more expensive to the CME accredited provider than offering non certified education activities, since certified activities are required to demonstrate compliance with an array of quality standards. In addition, CME activities that are not specifically related to MOC may be at a competitive disadvantage if physicians elect to focus only on activities that meet MOC requirements, as opposed to certified CME activities that address local practice needs and benefit California patients.

2) "Under current regulations, licensed physicians who are participating in MOC to maintain specialty board certification could be required to complete an estimated 12.5 additional hours of CME per year than other physicians not participating in MOC to renew their license."

While this statement may be technically accurate for some physicians, the regulatory package does not distinguish what percentage of physicians participating in MOC are required to take additional hours. The fiscal impact analysis assumes that <u>all</u> physicians participating in MOC are required to take an additional 12.5 hours annually. This potentially overestimates the benefit of the proposed regulations.

3) Adoption of the proposed regulations will result in "…a savings of $2,500 a year for impacted physicians, and a corresponding loss of potential revenue to CME providers of approximately $26,000 per year."

The regulatory package assumes that a physician participating in MOC saves $2,500 per year by not having to earn an additional 12.5 credits in order to meet the 50 hours of CME required for licensure. The conclusion was reached using an estimate of $200 per CME credit. However, there is no calculation to determine how an estimate of $200 per credit was derived and there is no source for the average of between $0 and $1,500 per course that was cited. In addition, discussions with accreditors indicate that there is no definitive source to determine an average cost for CME activities. In fact, many accredited CME providers in California offer CME at no cost to physicians or at a fee that is much less than $200 per CME hour. As such, the cost assumptions may have overestimated the savings per physician and the scope of the benefits to be gained.

RECOMMENDATION #2

Due to the lack of clarity and incorrect assumptions in the regulatory package, we recommend that the MBC consider reissuing these documents so the public has the opportunity to consider the proposed regulations in the context of more complete and correct information.

Thank you for the opportunity to review these proposed regulations. If you need additional information, please contact Yvonne Choong at (916) 551-2884 or at ychoong@cmanet.org. We look forward to continuing to work with the MBC to develop regulations that promote quality CME programs.

Sincerely,

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