

PHYSICIAN ASSISTANT BOARD

INITIAL STATEMENT OF REASONS

Hearing Date: January 28, 2019

Subject Matter of Proposed Regulations: Audit and Sanctions for Noncompliance

Section Affected: Section 1399.617 of Title 16 of the California Code of Regulations

Specific Purpose of each adoption, amendment, or repeal:

1. Problem being addressed:

Business and Professions Code section 3524.5 permits the Physician Assistant Board (Board) to require a licensee to complete continuing education as a condition of license renewal. In 2010, the Board adopted Article 8 in Division 13.8 and Sections 1399.615 through 1399.619 in Title 16 of the California Code of Regulations, which sets forth requirements for physician assistant licensees' continuing medical education. Under current Section 1399.615, physician assistant continuing medical education (CME) requirements may be met by completing 50 hours of continuing medical education every two years or demonstrating certification by the National Council on Certification of Physician Assistants (NCCPA), which also requires CME to maintain the licensee's certification.

The Board is authorized by Title 16, California Code of Regulations section 1399.617 to audit a random sample of physician assistants who have reported compliance with CME. In the Board's 2012 Sunset Review response to issues raised by legislative staff in the Board's background paper, it was reported that the Board planned to conduct CME audits on a scheduled basis to ensure compliance.

The Board has since randomly selected licensees who self-certify CME compliance on their renewal applications. The Board has sent out contact letters asking the licensees to either send in their CME documentation or ask the NCCPA to send a verification that they have maintained their certification. However, in the most recent audits conducted, licensees have failed to respond to the audit inquiry or to provide complete or accurate information when requested, which is not expressly prohibited conduct under the current regulations. Proposed amendments to subsection (a) of Section 1399.617 would expressly require a licensee to respond to any inquiry by the Board regarding compliance with the CME requirements contained in Article 8 or to provide copies of NCCPA certification records when the records cannot be obtained by the Board. Section 1399.617 also does not currently require licensees to respond to a board inquiry or provide NCCPA certification records within a certain time frame (65 days is proposed) or make it unprofessional to fail to provide accurate or complete information in response to a board inquiry. Proposed amendments to subsections (a) and (b) would implement those requirements.

In addition, the Board's staff reported that there appears to be licensee confusion over how to count hours earned to make up any deficiency uncovered by an audit when hours are earned in the next renewal cycle. Section 1399.617(c) specifies only what the licensee must do if they have not completed the required amount of CMEs during their previous renewal cycle and directs them to "make up any deficiency during the next renewal period." It does not clarify that hours required to be earned to make up any deficiency in CME cannot be counted towards compliance with the next biennial renewal period. Proposed amendments to subsection (c) would expressly provide that hours earned to make up the CME deficiency shall not be counted towards compliance with the next renewal period.

Finally, Section 3527 states, in part, that the "board may order the denial of an application for, or the issuance subject to terms and conditions of, or the suspension or revocation of, or the imposition of probationary conditions upon a physician assistant license ... for unprofessional conduct that includes, but is not limited to ... a violation of the regulations adopted by the board..." Since a violation of Section 1399.617 would be grounds for discipline under Section 3527, the Board proposes to add Section 3527 to the "notes" section of this regulation as a reference statute.

2. Anticipated benefits from this regulatory action:

CME requirements help the Board in its mission of consumer protection by ensuring licensees maintain their professional competency. This regulatory proposal will help to strengthen CME compliance by requiring licensees to respond within specified time frames, provide accurate and complete information in response to CME audits conducted by the Board, and provide the Board with additional enforcement mechanisms for CME audits. Since Section 1399.571 of Title 16 of the California Code of Regulations already authorizes the Board's Executive Officer to issue citations for a violation of any of the Board's regulations, this proposal would allow the Executive Officer to issue a citation for those licensees who fail to respond to the audit inquiry or provide incomplete or inaccurate information when requested, thus ensuring that the Board is better able to obtain CME compliance for the protection of the public. This regulatory proposal will also clear up any confusion for licensees over how to count hours earned to make up any deficiency uncovered by an audit and how those hours are accounted for in the next renewal cycle.

Factual Basis/Rationale

Amend Section 1399.617

Factual basis for the determination that each proposed amendment to Section 1399.617 is reasonably necessary to address the problem for which it is proposed:

Business and Professions Code section 3510 (Section 3510) authorizes the Board to adopt, amend, and repeal regulations that may be necessary to enable it to carry out the provisions of its practice act. Business and Professions Code section 3527 authorizes the Board to discipline a license for unprofessional conduct. Section

1399.571 of Title 16 of the California Code of Regulations (Section 1399.571) indicates that failure to follow a regulation adopted by the board is a citable offense.

At the Board's January 23, 2017 meeting, Board members discussed possible enforcement issues related to noncompliance with CME audits, and the limited ability to address CME audit deficiencies and unresponsive licensees under current regulations. Additional discussion included the process for notifying the unresponsive licensees who were selected for the audit a second time via email and/or certified mail, how much of a fine should be assessed and the inability to renew if the licensee was not in compliance with the audit. At the Board's April 24, 2017 and August 11, 2017 meetings, the Board further discussed possible regulatory proposals and how to address CME compliance issues.

At the Board's October 30, 2017 meeting, the Board discussed and approved proposed changes to Section 1399.617 to further strengthen the Board's authority to require accurate, complete and timely responses to CME audits. In addition, it was noted that current regulations at Title 16, California Code of Regulations Section 1399.571 which authorize the Board's Executive Officer to issue a citation, fine and order of abatement for violation of any board regulation, could be used to help enforce compliance with the new proposed changes to 1399.617. Under Section 1399.571, the fines may range from \$100 to \$5,000. Historically, the Board has issued citations with an average fine in the amount of \$250 to \$500 for these types of violations.

In summary, this proposal would make it a violation of the Physician Assistant Practice Act to fail to respond to the CME audit inquiry or provide complete or accurate information when requested, as well as set parameters for the licensee as to how much time they have to respond to the audit. This regulatory proposal will also clear up any confusion over how to count hours earned to make up any deficiency uncovered by an audit and how those hours are accounted for in the next renewal cycle.

Specifically, the Board proposes the adoption of the following amendments to Section 1399.617 for the following reasons:

- (1) Amend subsection (a) to add requirement that physician assistants "respond to any inquiry by the board regarding compliance with this article".

Article 8 contains requirements for CME compliance at Sections 1399.615 through 1399.619 of Title 16 of the California Code of Regulations. Those requirements include requirements to:

- (a) complete 50 hours of continuing medical education from approved CME providers every two years or demonstrate certification by the National Council on Certification of Physician Assistants (NCCPA) (1399.615 and 1399.616);
- (b) obtain a waiver for CME or request inactive status to be exempt from the CME requirements (1399.618 and 1399.619);
- (c) report compliance with the CME requirements (1399.615);
- (d) document compliance with CME (1399.617); and,
- (e) to provide to the board records of compliance with this article in response to an

audit conducted by the board (1399.617).

All of the foregoing requirements are subject to audit under current Section 1399.617. In the Board's 2012 response to issues raised by state legislative staff in the Board's Sunset Review background paper, it was reported that the Board planned to conduct CME audits on a scheduled basis to ensure compliance.

The Board has since randomly selected licensees who self-certify CME compliance on their renewal applications. The Board has sent out contact letters asking the licensees to either send in their CME documentation or ask the NCCPA to send a verification that they have maintained their certification. However, in the most recent audits conducted, licensees have failed to respond to the audit inquiry and the current regulations do not require that the licensees respond to Board inquiries regarding compliance with the CME requirements contained in Article 8. Existing regulation only requires that the licensee provide the Board records documenting compliance, not respond to inquiries regarding their compliance. To facilitate a thorough and complete investigation of the unresponsive licensee who has been selected for audit, the Board proposes to add authority to require a licensee to respond to a CME compliance audit inquiry.

- (2) Amend subsection (a) to add requirement that physician assistants respond "within 65 days of the board's request."

Existing regulation does not require a licensee to respond to a Board inquiry within a prescribed timeframe. Currently, when the Board selects a licensee for audit, staff send out an initial contact letter regarding compliance with Article 8's CME requirement and request a response within sixty-five (65) days. 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, some licensees ignore the request to respond within this timeframe altogether.

This 65-day response requirement would balance the need for the licensee to have adequate time to respond to audit requests with the Board's need to more efficiently and effectively investigate compliance with CME requirements. Making it a violation to not respond to a Board inquiry within a certain time period would also help assist the Board with more effectively enforcing the laws under its jurisdiction, for the protection of the public.

- (3) Amend subsection (a) to add requirement that if the Board is unable to obtain NCCPA certification records, "the physician assistant shall provide the board with the certification records within 65 days of the board's request."

Existing regulation exempts the licensee from the requirement to provide the Board with their NCCPA certification records if the "board may obtain the records directly from the Commission." The regulation, however, does not authorize the Board to require a licensee to provide the records within 65 days of the Board's request if the Board is unable to obtain the NCCPA's certification records.

Currently, the Board will attempt to obtain records from the NCCPA by entering the

name and address of the licensee into the NCCPA's database (the certification number issued by the NCCPA is not collected from the licensee by the Board and is not a condition of licensure in California). However, if the licensee has changed his or her name since becoming certified or licensed with the Board, or the address used to certify with NCCPA is different from the address provided to the Board, the NCCPA will report "not found" to the Board when certification records actually do exist for the individual. Adding a requirement that the licensee provide the certification records to the Board when records are not found within 65 days of request from the Board will assist the Board to more efficiently and effectively investigate compliance with CME requirements. In addition, it will help encourage licensees to more promptly comply with their documentation and reporting requirements.

- (4) Amend subsection (b) to make it unprofessional conduct to "fail to provide accurate or complete information in response to board inquiry."

Section 3527 of the Business and Professions Code states, in part, that the "board may order the denial of an application for, or the issuance subject to terms and conditions of, or the suspension or revocation of, or the imposition of probationary conditions upon a physician assistant license ... for unprofessional conduct that includes, but is not limited to ... a violation of the regulations adopted by the board..." Title 16, California Code of Regulations section 1399.571 indicates that failure to follow a regulation adopted by the Board is a citable offense. Currently, subsection (b) only 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 licensees certify on renewal that they are in compliance with CME requirements, the Board has found that audited licensees sometimes provide incomplete or inaccurate statements and information to the Board, 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. This amendment would make it unprofessional conduct, and therefore, a violation of the Physician Assistant Practice Act's regulations, to fail to provide accurate or complete information in response to a Board inquiry. This would assist the Board in addressing these judgment-related and compliance deficiencies by essentially providing the Board with discretion to discipline or issue a citation to a licensee for unprofessional conduct if they fail to provide accurate or complete information to the Board.

- (5) Amend subsection (c) to expressly prohibit counting hours used to make up a deficiency towards compliance with the next renewal period.

Existing regulation provides that any licensee who is found not in compliance with the CME requirements “will be required to make up any deficiency during the next biennial renewal period.” Although Section 1399.615(a) makes it clear that physician assistants are required to complete fifty (50) hours of CME for each renewal period, the Board has found that licensees still attempt to claim hours they “owe” (deficiency) for past renewal periods towards their next renewal period. This regulatory proposal would clear up any confusion for licensees over how to count hours earned to make up any deficiency uncovered by an audit and how those hours are accounted for in the next renewal cycle. This proposal would expressly prohibit licensees from counting deficiency hours towards their next biennial renewal period.

Amendment to Section 1399.617 Note:

Business and Professions Code section 3527 states, in part, that the “board may order the denial of an application for, or the issuance subject to terms and conditions of, or the suspension or revocation of, or the imposition of probationary conditions upon a physician assistant license ... for unprofessional conduct that includes, but is not limited to ... a violation of the regulations adopted by the board...” Since a violation of Section 1399.617 would be a basis for imposing discipline pursuant to Section 3527, the Board proposes to add Section 3527 to the “notes” section of this regulation to comply with the “Reference” standard in the Administrative Procedure Act.

Underlying Data

Technical, theoretical or empirical studies, reports, or documents relied upon (if any):

1. Minutes of the Physician Assistant Board’s January 23, 2017 meeting.
2. Minutes of the Physician Assistant Board’s April 24, 2017 meeting.
3. Minutes of the Physician Assistant Board’s August 11, 2017 meeting.
4. Minutes of the Physician Assistant Board’s October 30, 2017 meeting.
5. Response from Physician Assistant Committee to Issues Raised By Committee Staff in The Background Paper For Sunset Review 2012.

Business Impact

This regulation will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts:

The Board has approximately 12,280 licensees for the current fiscal year. The Board only has authority to take administrative actions against a licensee and not a business. Accordingly, the initial or ongoing impact to a business at which a licensee works who is the subject of disciplinary or citation action for violating this regulation cannot be

projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

A licensee who is found to be non-compliant with CME regulations enforced by the Board may also be impacted through the assessment of a citation with an administrative fine pursuant to Section 1399.571, and which may not exceed \$5,000 for each inspection or each investigation made with respect to the violation in accordance with Section 125.9(b)(3) of the Business and Professions Code. Only individual licensees who fail to provide accurate, complete and timely information to the Board in response to an audit would be impacted by this regulation. CME audits began in May 2016. For the fiscal year 2016/2017, the Board issued approximately 540 audits. Of those audits, there were twelve (12) licensees who did not respond to the audit. If this regulation were implemented, the Board would typically issue a citation and fine for any potential violation in the amount of \$250 and an order of abatement to comply with the audit. Also, these audits have indicated that five (5) licensees failed the audit (did not complete CME or provide NCCPA certification proof), and failed to provide accurate information to the CME response on their renewal application. If this regulation were implemented, it is anticipated that the Board would issue a citation and fine of \$500 (\$250 for failing to complete the CME requirement during the renewal cycle and \$250 for failing to provide accurate information on their renewal application) for these violations. Based upon past noncompliance statistics, it is estimated that this would generate \$5,500 annually in revenue for the Board if this regulation were implemented.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the state of California because the proposal imposes specific requirements only on a specific set of licensees who are subject to audit and who fail to comply with audit requirements. A business owned by a licensee who faces disciplinary action due to a violation may incur a significant fiscal impact depending on the nature and severity of the violation. The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore, the number or percentage of businesses that may be impacted cannot be predicted. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business owned by a licensee who is the subject of disciplinary action cannot be projected.

A licensee who is found to be non-compliant with CME regulations enforced by the Board may also be impacted through the assessment of a citation with an administrative fine pursuant to Section 1399.571, and which may not exceed \$5,000 for each inspection or each investigation made with respect to the violation in accordance with Section 125.9(b)(3) of the Business and Professions Code. Only individual licensees who fail to provide accurate, complete and timely information to the Board in response to an audit would be impacted by this regulation. CME audits began in May 2016. For the fiscal year 2016/2017, the Board issued approximately 540 audits. Of those audits, there were twelve (12) licensees who did not respond to the audit. If this regulation were implemented, the Board would typically issue a citation and fine for any potential

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It will not create new business or eliminate existing businesses within the state of California because the proposal imposes specific requirements only on a specific set of licensees who are subject to audit and who fail to comply with audit requirements. A business owned by a licensee who faces disciplinary action due to a violation may incur a significant fiscal impact depending on the nature and severity of the violation. The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore, the number or percentage of businesses that may be impacted cannot be predicted. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business owned by a licensee who is the subject of disciplinary action cannot be projected.

It will not affect the expansion of businesses currently doing business within the state of California because the proposal imposes specific requirements only on a specific set of licensees who are subject to audit and who fail to comply with audit requirements. A business owned by a licensee who faces disciplinary action due to a violation may incur a significant fiscal impact depending on the nature and severity of the violation. The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore, the number or percentage of businesses that may be impacted cannot be predicted. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business owned by a licensee who is the subject of disciplinary action cannot be projected.

This regulatory proposal will benefit the health and welfare of California residents because verification that physician assistants have met the mandatory CME requirement ensures that the physician assistant has maintained, developed, or increased their knowledge, skills, and professional performance to provide services for the public, and the profession. This allows for the physician assistant to serve the public to the best of their abilities and live up to professional standards. CME requirements, and related enforcement mechanisms help the Board in its mission of consumer protection by ensuring licensees maintain their professional competency.

This regulatory proposal will not affect worker safety because the proposal does not involve worker safety. The proposal only identifies the consequence for noncompliance to the CME audit and how the licensees would also have a clearer understanding of how to count hours earned to make up any deficiency uncovered by an audit and how those hours are accounted for in the next renewal cycle.

This regulatory proposal will not affect the state's environment because it does not involve environmental issues.

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 more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Set forth below are the reasons for rejecting any proposed alternatives that would lessen the adverse economic impact on small business:

1. Not amend the regulation: This alternative was rejected because it would not address current compliance deficiencies. Section 1399.617 does not require licensees to respond to a board inquiry within a certain time frame nor does it characterize as unprofessional conduct the failure to provide accurate or complete information in response to a board inquiry. It also does not clarify that hours required to be earned to make up any deficiency in CME cannot be counted towards compliance with the current or next biennial renewal period.
2. Amend the regulation: The Board determined that amending Section 1399.617 would allow the Executive Officer to discipline, or issue a citation, fine and order of abatement for those licensees who fail to respond to the CME audit inquiry or provide complete or accurate information when requested, as well as set parameters for the licensee as to how much time they have to respond to the audit. This regulatory proposal will also clear up any confusion over how to count hours earned to make up any deficiency uncovered by an audit and how those hours are accounted for in the next renewal cycle.