

DEPARTMENT OF CONSUMER AFFAIRS

**TITLE 16. MEDICAL BOARD OF CALIFORNIA**

**APPROVED CERTIFYING ORGANIZATIONS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** No hearing has been scheduled for the proposed action.

**Subject Matter of Proposed Regulations:** Medical and Midwife Assistant Certifying Organizations and Administration of Training for Medical Assistants

**Section(s) Affected:** Amend Sections 13666.3, 1366.31, and 1379.07 of Article 6, Chapter 2, Division 13, Title 16 of the California Code of Regulations (CCR).

**BACKGROUND AND STATEMENT OF THE PROBLEM**

Medical and midwife assistants are unlicensed individuals who perform non-invasive, routine, technical support services under the supervision of a licensed physician or licensed midwife, respectively, or other authorized licensed medical professional. California law does not require medical or midwife assistants to be certified by an organization approved by the Medical Board of California (Board), unless the assistant will be providing training to other medical or midwife assistants. For those providing training to other medical or midwife assistants, they must be certified.

On November 9, 2018, the Board received a petition for rulemaking pursuant to Government Code section 11340.6 from Ellison Wilson Advocacy, LLC, (Petitioner) on behalf of National Healthcareer Association (NHA), to remove the requirement that medical assistant certifying organizations approved by the Board be non-profit and tax-exempt organizations. The Petitioner stated that “[a]n entity’s status as a nonprofit and/or tax-exempt organization bears no relationship to the quality of a certifying organization or the programs and services it provides,” and further indicated that, “[t]here are better criteria to effectuate the Board’s interest in ensuring that medical assistants are properly certified by legitimate organizations.” (NHA Petition for Rulemaking, p. 4). It further pointed out that under the current regulatory structure, a for-profit certifying organization can simply create a non-profit arm to seek Board approval. (*Id.* at p. 6). The Petitioner suggested that instead of relying on an organization’s non-profit status to be reflective of ethical business practices and good quality, the Board could institute other, more reliable measures, such as requiring accreditation from the National Commission for Certifying Agencies (NCCA), which is the accrediting body of the Institute for Credentialing Excellence. (*Id.* at p. 5).

The Board first considered this petition for rulemaking at its February 1, 2019 quarterly meeting and requested additional information regarding the proposal. At its August 9, 2019 quarterly meeting, the Board reviewed and approved proposed language for this rulemaking, and authorized staff to proceed with the rulemaking process. In addition to addressing the matters raised in the petition for rulemaking, the Board also authorized staff to make changes to the regulations addressing training and certification of medical assistants to make them consistent with current law and improve their readability.

Based on the above information, the Board is proposing to amend 16 CCR sections 1366.3, 1366.31, and 1379.07 as indicated below.

## **SPECIFIC PURPOSE, ANTICIPATED BENEFIT, AND RATIONALE**

### **Amend 16 CCR section 1366.3**

Existing law under 16 CCR section 1366.3 defines a “qualified medical assistant,” clarifies the proper administration of training medical assistants, and identifies the appropriate oversight agencies.

Purpose: The purpose of amending section 1366.3, subdivision (a)(2) is to make it consistent with the Education Code and current law, and to specify that medical assistant education programs must comply with the applicable statutes as well as all regulations adopted pursuant to those sections. The reference to “postsecondary,” and Education Code sections “94310” and “94311” are outdated and no longer correct. Further, this rulemaking also proposes to update the name of the Bureau for Private Postsecondary Education (BPPE) by striking “and Vocational” from the name where it is referenced in subdivision (a)(2) and in subdivision (c)(3). Additionally, this rulemaking strikes the reference to “division” and replaces it with “Board” under subdivision (c)(1) and makes other conforming, non-substantive changes.

Anticipated Benefit: The anticipated benefit to amending section 1366.3, is that this regulation will be made consistent with current law under the Education Code, will update the name of the BPPE, and will clarify that compliance with all regulations adopted pursuant to the referenced statutory sections is required. This rulemaking will also update the language to refer to the “Board” instead of the “division,” which is no longer an applicable reference. Clarity and consistency in this regulation supports the Board’s mission of consumer protection so that the Board may uphold and enforce required standards based on current law.

Rationale: This rulemaking would strike “postsecondary” from the first line of section 1366.3 subdivision (a)(2), because postsecondary programs are overseen by the BPPE, which is referenced further down in this subdivision. This change is necessary to avoid confusion about which oversight agencies oversee which educational programs.

This rulemaking would also correctly refer to the BPPE’s current name by striking “and Vocational” from its name where it is referenced under section 1366.3 subdivision (a)(2)

and (c)(3). This change is necessary to update these subdivisions to reference the BPPE's name correctly to avoid confusing stakeholders.

Further, this rulemaking will strike Education Code sections 94130 and 94311, as they no longer exist, and will add reference to Education Code sections 94885, 94887, and 94885(a)(5), which reflect current requirements for postsecondary institutions and for instructors in private postsecondary institutions. These changes are necessary to update this subdivision to make it consistent with current law and to avoid creating confusion by reference to outdated code sections.

Additionally, this rulemaking will amend this subdivision to add the phrase "and all regulations adopted pursuant to those sections" in reference to Education Code sections 94885 and 94887. This change is necessary to make this subdivision consistent with the Board's more recent language approved to regulate midwife assistants under 16 CCR section 1379.06, subdivision (a)(2). This change also encourages stakeholders to review the regulations required for a postsecondary program to be in compliance with the law.

This rulemaking also changes the word "any" to "all" in reference to meeting the regulatory requirements adopted under Education Code section 94885(a)(5) relating to instructors in private postsecondary institutions. This change is necessary to make this subdivision consistent with the Board's more recent language approved to regulate midwife assistants under 16 CCR section 1379.06, subdivision (a)(2), and this change more accurately reflects the requirement that the instructor shall be in compliance with all required regulations. Moreover, this rulemaking strikes the words "those sections" and replaces it with "that section" for grammatical consistency.

Moreover, reference to "the division" is struck under section 1366.3, subdivision (c)(1), because this is an old term. The Board no longer has "divisions," and each use of this term means "the Board." (BPC, section 2002.)

### **Amend 16 CCR section 1366.31**

Existing law under 16 CCR section 1366.31 provides the requirements for entities seeking approval by the Board to be a medical assistant certifying organization.

Purpose: The purpose of amending section 1366.31 is to replace "division" with "Board" to update the reference to the Board with current language and to strike the requirement for an applicant to provide a social security number. Further, this rulemaking will strike the existing language under subdivision (a)(4) regarding information required on the accrediting organization, and will replace it with more specific language requiring the certifying organization to provide documentation establishing that they are accredited by the NCCA.

This proposal also eliminates the requirement for the applicant to be a non-profit, tax exempt organization.

Additionally, this proposal also clarifies the requirements for certifying a medical assistant by providing reference to the training requirements under 16 CCR section 1366.3(a)(2) and deleting extraneous language in subdivisions (b)(2)(A) and (B).

This rulemaking further amends this section to require a medical assistant certifying organization approved by the Board prior to the requirement for NCCA accreditation to reapply for and demonstrate compliance with all of the requirements of this section by January 1, 2027, or its approval will be terminated.

This proposal also deletes old language under subdivision (c) that is no longer applicable, and makes other clarifying, non-substantive changes to improve readability and to update the subdivision lettering and numbering.

Anticipated Benefit: The anticipated benefit to amending section 1366.31, is that it will eliminate a barrier for medical assistant certifying organizations seeking Board approval by removing the requirement for such organizations to hold a non-profit, tax exempt status. Instead of relying on an organization's non-profit tax exempt status to demonstrate trustworthiness, this proposal will require certifying organizations to be accredited by a well-respected accreditation agency. Certifying organizations that are currently approved by the Board will be given until 2027 to demonstrate accreditation by the NCCA to maintain Board approval. Additionally, this rulemaking will also update the language in this section to refer to the "Board" instead of the "division," which is no longer an applicable reference. Moreover, the proposed amendments will streamline the regulation by cross referencing requirements set forth in other sections and deleting duplicative language. These proposed changes will provide clarity around the requirements for approved medical assistant certifying organizations.

Rationale: The proposed change under section 1366.31, subdivision (a), strikes "division" and replaces it with "Board," which is necessary to remove old language and update it with the correct reference to the Board. (BPC, section 2002.)

The proposed change under section 1366.31, subdivision (a)(2), strikes the language regarding providing a social security number. This amendment is necessary because medical assistant certifying organizations are businesses, not individuals, and social security numbers should not be asked for, nor provided, on applications for Board approval for such organizations.

The proposed change under section 1366.31, subdivision (a)(4), strikes the language asking for the name, address and telephone number of the accrediting organization that accredited the applicant, and adds the requirement for documentation that the certifying organization is accredited by the NCCA. This amendment is necessary to specify which accreditation agency is accepted by the Board. The Board already specifies that the NCCA is the approved accreditation agency for midwife assistant certifying organizations under 16 CCR section 1379.07, so this change is necessary for internal consistency within the Board's regulations. Moreover, the NCCA is a nationally-recognized and respected accrediting body and is the accrediting body required in several provisions of California statutes. (See, e.g., BPC section 2837.103(a)(1)(B);

BPC section 4202 (a)(4); BPC section 4651.1(b); Ins. Code section 10144.51(c)(3)(A); Corp. Code section 25243.5(c.)

The proposed change under section 1366.31, subdivision (b)(1) would strike the existing language requiring the certifying organization to be a non-profit, tax exempt organization. This deletion is necessary to remove an unnecessary barrier for certifying organizations seeking Board approval. According to the rulemaking file for this section from 1999, the requirement for certifying organizations to be non-profit and tax exempt was intended to guard against approving certifying organizations in the business just to make a profit without the intent of establishing a formal training program. Rather than relying on an organization's non-profit tax exempt status, however, this rulemaking will amend this section to specify that the organization will have to demonstrate that they are accredited by the NCCA, which is a better measurement of the organization having legitimate standards for medical assistants seeking certification. Further, considering that the Board approves for-profit medical schools, it no longer makes sense to require medical assistant certifying organizations to be non-profit.

The proposed change under section 1366.31, subdivision (b)(3)(A), would refer to the requirements for a medical assistant training program set forth under 1366.3, subdivision (a)(2), and strike the duplicative language that follows in that subdivision as well as under subdivision (b)(3)(B). This change is necessary for clarity, accuracy, and completeness, and to avoid the need to have to amend multiple regulatory sections if there is a modification to the regulation impacting medical assistant training programs.

The proposed change under section 1366.31, subdivision (b)(3)(E), would clarify that a person meets this requirement by being employed as an instructor in an accredited medical assistant program or institution that meets the requirements under section 1366.3, subdivision (a)(2). While this requirement is currently implied by the existing language, the addition of the cross-reference to section 1366.3, subdivision (a)(2), is necessary to make this regulation more clear.

The proposed change under section 1366.31, subdivision (c) allows any medical assistant certifying organization approved by the Board before this regulatory change becomes effective until January 1, 2027, to be accredited by the NCCA to remain approved by the Board. This date was selected to permit sufficient time for certifying organizations to complete the NCCA accreditation process without being prejudiced by an imminent deadline. This provision is necessary, because one of the Board's approved certifying organizations is not currently accredited by the NCCA, but has initiated the accreditation process through the NCCA.

Finally, this proposed rulemaking would make conforming changes to the lettering and numbering of the subdivisions, and would make additional non-substantive changes to improve readability and internal consistency.

## **Amend 16 CCR section 1379.07 – Approved Certifying Organizations**

Existing law under 16 CCR section 1379.07 provides the requirements for entities seeking approval by the Board to be a certifying midwife assistant organization.

**Purpose:** The purpose of amending section 1379.07, subdivision (a)(4), is to strike the phrase “or an accrediting organization that is equivalent thereto.” This change will make it clear that the Board accepts accreditation from the NCCA. This proposal also eliminates the requirement for the applicant to be a non-profit, tax exempt organization under section 1379.07, subdivision (b)(1) and updates the numbering within the section.

**Anticipated Benefit:** The anticipated benefit to amending section 1379.07 is that it will clarify that the NCCA is the accrediting agency approved by the Board by eliminating the phrase “or an accrediting organization that is equivalent thereto.” This change will prevent the Board from being put in the position of having to compare accreditation agencies for equivalency to the NCCA, and will improve the clarity of this section. Additionally, the anticipated benefit to amending this section is that it will eliminate a barrier for midwife assistant certifying organizations seeking Board approval by removing the requirement for such organizations to hold a non-profit status. Instead of relying on an organization’s non-profit status to demonstrate trustworthiness, this proposal will rely on the existing requirement for midwife assistant certifying organizations to be accredited by the NCCA.

**Rationale:** The proposed change under section 1379.07, subdivision (a)(4), will clarify that the NCCA is the accrediting agency approved by the Board by striking the phrase “or an accrediting organization that is equivalent thereto.” This change is necessary to clarify requirements for applicants and to prevent the Board from having to undertake a comparison of accreditation agencies to determine if they are equivalent to the NCCA. The Board does not have expertise in this area and is concerned about the ambiguity of this requirement. Consequently, the Board determined that this proposed change is necessary to provide clarity to applicants.

The proposed change under section 1379.07, subdivision (b)(1), would strike the requirement that midwife assistant certifying organizations applying for Board approval be non-profit/tax exempt. This deletion is necessary to remove an unnecessary barrier for certifying organizations seeking Board approval. This requirement was based on the regulation for approving medical assistant certifying organizations (section 1366.31), which was enacted in 1999 under the belief that requiring applicants to hold a non-profit tax exempt status would guard against approving certifying organizations in the business just to make a profit without the intent to establish a formal training program. After reviewing this language following receipt of the petition for rulemaking discussed above, the Board decided that this requirement was no longer appropriate as an indicator for quality, especially since the Board approves for-profit medical schools. Instead, the Board determined that the existing requirement for certifying organizations to be accredited by the NCCA was a sufficient measurement of an organization having legitimate standards for midwife assistants seeking certification.

Finally, this rulemaking would make non-substantive, conforming changes to update the numbering of the subdivisions for clarity.

### **Underlying Data**

1. January 31-February 1, 2019 Board Meeting Agenda, Relevant Meeting Materials (includes November 9, 2018 Petition for Rulemaking), and Meeting Minutes
2. August 8-9, 2019 Board Meeting Agenda and Meeting Minutes
3. 2020 NCCA Accreditation Fee Schedule

### **Business Impact:**

The Board has made an initial determination that the proposed regulatory action will have no 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 fact that in addition to other non-substantive changes, the proposed amendments will eliminate the requirement for medical and midwife certifying organization to be non-profit and tax exempt to be approved by the Board, and will instead rely on accreditation by the NCCA to ensure basic standards are met.

While this proposal does require certifying organizations to be accredited by the NCCA, accreditation is already required, and this is an accepted national standard that certifying organizations already seek. Consequently, the Board determined that this will not negatively impact businesses.

### **Economic Impact Assessment:**

This regulatory proposal will have the following effects:

- It is not likely to create or eliminate jobs within the State of California nor create or eliminate existing businesses within California, because it has limited application. Medical and midwife assistants are not required by the Board to be certified to practice, and if they are certified, they are not required to be certified by an organization approved by the Board, with the exception of those individuals who are training other medical and midwife assistants. In addition to clarifying changes to update the language and statutory references, the main purpose for this proposal is to remove a barrier to allow for-profit organizations to seek approval as medical or midwife assistant certifying organizations, which may increase certification options for interested parties. While this proposal does require certifying organizations to be accredited by the NCCA, accreditation is already required, and this is an accepted national standard that certifying organizations already seek.

- It is not likely to eliminate existing businesses nor affect the expansion of businesses currently doing business within the State of California, because it has limited application. Medical and midwife assistants are not required by the Board to be certified to practice, and if they are certified, they are not required to be certified by an organization approved by the Board, with the exception of those individuals who are training other medical and midwife assistants. In addition to clarifying changes to update the language and statutory references, the main purpose for this proposal is to remove a barrier to allow for-profit organizations to seek approval as medical or midwife assistant certifying organizations, which may increase certification options for interested parties. While this proposal does require certifying organizations to be accredited by the NCCA, accreditation is already required, and this is an accepted national standard that certifying organizations already seek.
- It may benefit health and welfare of California residents, because this proposal clarifies and updates the language and statutory references in the regulations, clarifies accreditation requirements, and removes a barrier to allow for-profit organizations to seek approval as medical or midwife assistant certifying organizations, which may increase certification options. Ensuring that regulations are current and clear to stakeholders can further approval and enforcement processes and consequently improve consumer protection.
- It will not have a significant impact on worker safety because this regulatory proposal does not address issues relevant to worker safety.
- It will not have an impact on the state's environment because this regulatory proposal does not address issues relevant 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.

Set forth below are the alternatives that were considered and the reasons each alternative was rejected or accepted:

1. Do not seek a change. This alternative was rejected because the amendments are necessary to update statutory references in the regulations, remove an unnecessary barrier for Board approval, and clarify accreditation requirements for medical and midwife assistant certifying organizations.

2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate because the amendments are necessary to update statutory references in the regulations, remove an unnecessary barrier for Board approval, and clarify accreditation requirements for medical and midwife assistant certifying organizations.