MEDICAL BOARD OF BOARD

INITIAL STATEMENT OF REASONS

Hearing Date:  July 29, 2016

Subject Matter of Proposed Regulations:  Midwife Assistants

Section(s) Affected:  Division 13, Title 16, Chapter 3, Article 6, California Code of Regulations (CCR) add sections: 1379.01, 1379.02, 1379.03, 1379.04, 1379.05, 1379.06, 1379.07, 1379.08, and 1379.09.

Specific Purpose of each adoption, amendment, or repeal:

1. Problem Being Addressed:

The Legislature adopted Business and Professions Code (BPC) section 2516.5 to permit licensed midwives and certified nurse-midwives to use midwife assistants in their practices.  BPC section 2516.5 sets forth some minimum requirements for midwife assistants, references standards for medical assistants established by the Board pursuant to BPC section 2069, and indicates under subsection (a)(1) that the “midwife assistant shall be issued a certificate by the training institution or instructor indicating satisfactory completion of the required training.”  The section, however, does not specify such details as what the training entails, who can conduct the training, and who can certify that a midwife assistant meets the minimum requirements.  These details have been left to the Medical Board of California (Board) to establish via regulations.  Additionally, subsection (b)(4) authorizes midwife assistants to “[p]erform additional midwife technical support services under regulations and standards established by the board.”

Accordingly, the purpose of this proposed rulemaking is to further define BPC section 2516.5 to make specific the requirements for midwife assistants, the administration of training of midwife assistants, and the requirements for certifying organizations.  These regulations are necessary for consumer protection to ensure that midwife assistants have the proper training and supervision.

2. Anticipated Benefits from this Regulatory Action:

This proposed rulemaking will further define BPC section 2516.5 to make specific the requirements for midwife assistants, the administration of training of midwife assistants, and the requirements for certifying organizations.  The minimum requirements set forth in the proposed regulations are necessary to further the Board’s mission of consumer protection by ensuring that midwife assistants have the proper training and supervision.
3. **Specific Purpose of Each Proposed New Section:**

Section 1379.01 specifies that licensed midwives and certified nurse midwives may supervise midwife assistants and authorize midwife assistants to perform the services referenced in BPC section 2516.5(b)(1). This section further indicates that the supervising licensed midwife or certified nurse midwife is responsible for the patient’s treatment and care. This section is necessary for consumer protection to ensure proper supervision of midwife assistants, to provide a limit on the types of services midwife assistants may be authorized to perform, and to clearly state that the supervising licensed midwife or certified nurse midwife is responsible for the care and treatment of his or her patient.

Section 1379.02 specifies each midwife assistant shall have a Neonatal Resuscitation Certification from the American Academy of Pediatrics. This section is necessary for consumer protection to ensure that midwife assistants are properly trained in neonatal resuscitation by a reputable agency.

Section 1379.03 specifies each midwife assistant shall maintain certification in basic life support from the American Heart Association or the American Safety and Health Institute. This section is necessary for consumer protection to ensure that midwife assistants are properly trained in basic life support by a reputable agency.

Section 1379.04 specifies each midwife assistant shall have received training in Center for Disease Control “Guidelines for Infection Control in Health Care Personnel” and must demonstrate to the supervisor that he or she understands infection control. This section is necessary for consumer protection to ensure that midwife assistants are properly trained in infection control using guidelines from a reputable agency. This section is modelled after the Board’s regulations for medical assistants pursuant to 16 CCR section 1366.4.

Section 1379.05 specifies the minimum training a midwife assistant shall complete. This section is necessary for consumer protection to ensure that midwife assistants have met a minimum level of didactic and hands-on training, and demonstrate satisfactory performance of tasks they will be authorized to do, before they begin performing the services with patients. This section is modelled after the Board’s statutes and regulations for medical assistants pursuant to BPC sections 2069 and 2070, and 16 CCR section 1366.1, as directed by BPC section 2516.5(a)(1) and (b)(2).

Section 1379.06 specifies how midwife assistant training shall be administered and certified. This section is necessary for consumer protection to ensure that training of midwife assistants is administered and certified by a licensed midwife or certified nurse midwife, or by an appropriate secondary, postsecondary, or adult education program. This section is modelled after the Board’s regulations for medical assistants relating to the administration of training pursuant to 16 CCR section 1366.3, as generally directed by BPC section 2516.5(a)(1) (stating, the midwife assistant is a person who “has had at least the minimum amount of
hours of appropriate training pursuant to standards established by the board for a medical assistant pursuant to Section 2069.

Section 1379.07 specifies the minimum requirements certifying organizations for midwife assistant training must meet to receive Board approval. This section is necessary for consumer protection to ensure that certifying organizations meet minimum standards in requirements for training and competence of midwife assistants before they will grant them certification or recertification. This section is modelled after the Board’s regulations for approved certifying organizations for medical assistants pursuant to 16 CCR section 1366.31, as generally directed by BPC section 2516.5(a)(1) (stating, the midwife assistant is a person who “has had at least the minimum amount of hours of appropriate training pursuant to standards established by the board for a medical assistant pursuant to Section 2069.” Further, section 2516.5(a)(1) references “certificates,” so the Board is defining minimum requirements for certifying organizations based on requirements for medical assistants consistent with the statute.

Section 1379.08 specifies changes Board approved certification agencies must report to the Board and timeframes for reporting the changes to the Board. This section is necessary for consumer protection to ensure that certifying organizations keep the Board informed of changes to their standards, so that the Board may ensure the organizations continue to meet the minimum requirements set forth in proposed section 1379.07. This section also indicates that the certifying organizations are subject to review every five years by the Board to ensure compliance with the standards. This section is modelled after the Board’s regulations regarding certifying organizations for medical assistants pursuant to 16 CCR section 1366.32, as generally directed by BPC section 2516.5(a)(1) (stating, the midwife assistant is a person who “has had at least the minimum amount of hours of appropriate training pursuant to standards established by the board for a medical assistant pursuant to Section 2069.” Further, section 2516.5(a)(1) references “certificates,” so the Board is defining minimum requirements for certifying organizations based on requirements for medical assistants consistent with the statute.

Section 1379.09 – specifies process times for the Board to review an application from a certifying organization. This section is necessary to ensure that applications from certifying organizations are processed in a timely fashion by the Board. This will help to foster access to certified midwife assistants in an efficient manner. This section is modelled after the Board’s regulations for approved certifying organizations for medical assistants pursuant to 16 CCR section 1366.33.

**Factual Basis/Rationale**

BPC section 2516.5 became effective on January 1, 2016, permitting licensed midwives and certified nurse-midwives to use midwife assistants in their practices. BPC section 2516.5 sets forth some minimum requirements for midwife assistants, references standards for medical assistants established by the Board pursuant to BPC section
The responsibility for making BPC section 2516.5 more specific lies with the Board through this rulemaking process.

**Underlying Data**

The Board held an interested parties meeting on February 3, 2016, to get input on drafting the proposed regulations for midwife assistants. On March 10, 2016, the proposed draft midwife assistants regulations were presented to the Midwifery Advisory Council (MAC) for discussion, and were approved with amendments for presentation to the Board.

Staff prepared a report for the May 6, 2016 Medical Board of California meeting (agenda item 18) regarding the need to add CCR sections 1379.01, 1379.02, 1379.03, 1379.04, 1379.05, 1379.06, 1379.07, 1379.08, and 1379.09.

At the May 6, 2016 Board meeting, the Board adopted a motion directing staff to begin the regulatory process to add CCR sections 1379.01, 1379.02, 1379.03, 1379.04, 1379.05, 1379.06, 1379.07, 1379.08, and 1379.09 to further define BPC section 2516.5 to provide clarification regarding the training requirements and scope of practice for midwife assistants.

**Business Impact**

The addition of CCR sections 1379.01, 1379.02, 1379.03, 1379.04, 1379.05, 1379.06, 1379.07, 1379.08, and 1379.09 will not have a significant adverse economic impact on businesses. This initial determination is based on the fact that these regulations will likely have a positive economic impact for the state, since licensed midwives and certified nurse midwives will now be permitted to hire midwife assistants meeting the qualifications as set forth in these proposed regulations and pursuant to BPC section 2516.5.

**Economic Impact Assessment**

The Board has made the initial determination that this regulatory proposal will have the following impact:

- It is likely to create jobs for midwife assistants, instructors, and employees of certifying organizations. It is not likely to eliminate jobs within the State of California. This initial determination is based on the fact that prior to January 2016, midwife assistants were not permitted by statute or regulation. Under BPC
section 2516.5, midwife assistants are now permitted under the law, and the regulations will set forth minimum requirements for midwife assistants, instructors, educational programs, and certifying organizations, and create new job opportunities in the state.

- It is not likely to create or eliminate existing businesses within the State of California, however, existing businesses may expand to meet demand for this new position. This initial determination is based on the fact that prior to January 2016, midwife assistants were not authorized by statute or regulation. Under BPC section 2516.5, midwife assistants are now allowed under the law, and the regulations will set forth minimum requirements for midwife assistants, instructors, educational programs, and certifying organizations. It is likely that educational programs and certifying organizations will expand to fill the need to train and certify midwife assistants, but the number of individuals interested in becoming midwife assistants is not expected to be great enough to anticipate the creation of new businesses.

- It will likely result in the expansion of businesses currently doing business within the State of California. This initial determination is based on the fact that prior to January 2016, midwife assistants were not authorized by statute or regulation. Under BPC section 2516.5, midwife assistants are now allowed under the law, and the regulations will set forth minimum requirements for midwife assistants, instructors, educational programs, and certifying organizations. It is likely that educational programs and certifying organizations already familiar with medical assistant requirements will expand to fill the need to train and certify midwife assistants.

- It will benefit the health and welfare of California residents, because the regulations will set forth minimum requirements for midwife assistants, instructors, educational programs, and certifying organizations to further consumer protection.

- It will have a positive impact on worker safety, because the proposed regulations will set forth minimum requirements for midwife assistants, which include infection control.

- It will not have an impact on the state’s environment, because the regulations will simply set forth minimum requirements for midwife assistants, instructors, educational programs, and certifying organizations.

**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 which were considered and the reasons each alternative was accepted or rejected:

1. Do not proceed with the rulemaking to add the sections identified. This alternative was rejected because BPC section 2516.5 needs to be made more specific to support the Board’s mission of consumer protection by identifying the minimum requirements for midwife assistant training, the minimum requirements for instructors and training programs, and the minimum requirements for certifying organizations.

2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate, because it supports the Board’s mission of consumer protection by identifying the minimum requirements for midwife assistant training, the minimum requirements for instructors and training programs, and the minimum requirements for certifying organizations.