BOARD OF REGISTERED NURSING
FINAL STATEMENT OF REASONS

Hearing Dates: September 21, 2015 & December 11, 2015

Subject Matter of Proposed Regulations: Abortion by Aspiration Techniques

Adopt Section 1463.5 and 1485.5

Updated Information

The Initial Statement of Reasons is included in the file. As a result of modifications to the regulatory proposal, the information contained therein is updated as follows:

- Due to a technical error, the original Notice was not mailed out to interested parties and the Board is re-noticing this proposed regulation in order to comply with Government Code Section 11346.5.
- The original language was incompletely noticed on or about August 7, 2015.
- The public hearing was held on September 21, 2015.
- Minor changes were made to the language based on public comments received between August 7, and September 21, 2015 and the Board conducted a 15 day comment period for the new language beginning October 8 and ending October 23, 2015.
- No additional public comments were received during the 15 day comment period.
- The hearing on December 11, 2015 was for the amended language approved by the Board and considered during the 15 day comment period. During this comment period a letter was received, but it was withdrawn from the record.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

This action will not have a significant adverse economic impact on small businesses; the regulatory proposal affects nurse practitioners or certified nurse midwives seeking to perform abortion by aspiration techniques.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or 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.

Objections or Recommendations/Responses – September 21, 2015
The Board received comments during the 45-day comment period. There were some changes were made as a result of these comments.

1. To support the Board’s adoption of the Board-approved proposed regulatory language, which will provide California nurse practitioners and certified nurse-midwives a method by which to become competent in performing abortion by aspiration techniques, as authorized by statute.

Accept Proposed Response: At the April 2015 Board meeting, the Board approved proposed language that was erroneously not submitted to the Office of Administrative Law. Therefore, we accept the comments to change the language to the Board approved language from the April 2015 Board meeting.

Comments and Responses:

2. Concern that the placement and titles of proposed section 1463.5 and 1485.5 are somewhat unclear and misleading. Proposed modification to the section titles and placement are as follows:

   Proposed Modification: Renumber and rename section 1463.5 to 1462.5 – Approved Training Standards for Abortion by Aspiration Techniques.
   Renumber and rename section 1485.5 to 1484.5 – Approved Training Standards for Abortion by Aspiration Techniques. **Reject.**

   Response: The numbering system of the Board approved language do not affect the education standards of the regulations in the Nursing Practice Act, it only deals with abortion by aspiration techniques. Therefore, the proposed modification is rejected.

3. Concerned that the proposed regulations, as drafted, might incorrectly imply that standardized procedures are no longer required for NPs and CNMs to perform abortion by aspiration, so long as one of the three educational/training requirements are met. Section 2725.4 of the Business and Professions Code (AB 154) states that in order to perform an abortion by aspiration techniques, an NP or CNM must "adhere to standardized procedures." **Reject.**

   Response: The proposed regulations do not affect the standardized procedures that are currently set in existing law. The NPs and CNMs would still have to abide by the standardized procedures because they are already in law. The proposed modification to the text is rejected.

4. Concerned that the language in the proposed regulations is far too generalized, and thus will not provide adequate guidelines for educational entities, including continuing education (CE) providers. It is crucially important that the educational standards effectively provide for patient safety. As such, we suggest adding more specificity with regard to the didactical and clinical requirements for adequate training. It may be wise to make specific reference to the competency based curriculum and training protocols established by the Health Workforce Pilot Project (HWPP) No. 171. **Accept.**

   Response: The language set forth in the comments is accepted. BCP 2725.4 sets forth the requirement to perform abortion by aspiration techniques. In this section it states that the competency-based training protocol established by Health Work-force Pilot Project (HWPP) No. 171 shall be used. The HWPP 171 is the most current research in regards to competency-based curriculum and training plan for education for primary care clinicians in early abortion care. Therefore, the language is accepted as it is shown to be effective and it stands to be a good source of guidance in establishing adequate standards for training recognized by the Board.

5. For regulations implementing the law that which occurred as a result of the study, we ask that in order for results to continue to be as positive as they have been, that the regulations mirror the training as determined through the process of the study for patient safety and optimal results. The training as specified in the study was:
To be trained for competence in the provision of aspiration abortion an NP or CNM would need a minimum of 40 supervised procedures over at least 6 clinical days, with competence assessed by an authorized physician trainer. To be qualified for training, NPs or CNMs must have a California professional license, basic life support certification, and 12 months or more of clinical experience, including 3 months or more experience in medication abortion provision.

Accept in part.

Response: The training as specified in the comments reflects the HWPP No. 171 competency-based training protocol. The Board does believe that the language does need to set forth guidelines for educational entities. The comment is accepted in part as the Board will add the language that will incorporate the HWPP No. 171 by reference to make the requirements clearer and not generalized.

6. Disagree with the recommendation to add an additional reference to standardized procedures. Accept.
Response: Accept the comments as the reference to standardized procedures are redundant since the proposed regulations are not affecting existing law.

7. Disagree with the recommendation to add greater specificity to curriculum and training guidelines within the proposed regulations. Disagree with including the reference to procedural numbers or specific curriculum requirements within these regulations. Reject.
Response: The training guidelines that the HWPP No. 171 set forth are the most current research in regards to competency-based curriculum and training plan for education for primary care clinicians in early abortion care that are currently being used right now. Training guidelines that are equivalent to this training protocol should be accepted. The Board feels that the addition of incorporating the HWPP No. 171 by reference does not make the regulations too specific. Therefore, this comment is rejected.

8. That educational providers may need guidance in the provision of abortion training program specifics. Any clinical education curriculum starts with the standard of care and evidence-based clinical guidelines followed by competencies which meet those guidelines. For example, the BRN could post FAQs that reference Abortion Clinical and Training Guidelines on the national guideline clearinghouse website and is updated annually (will send website) or core competencies for first trimester abortion care (will send website). There are also a number of professional organizations which use these clinical guidelines to offer early abortion training programs.
Response: This statement does not speak to the text of the proposed regulations. Therefore, it is an irrelevant comment.

Objections or Recommendations/Responses – December 11, 2015

One letter was received, but they withdrew it from the record.