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INDEPENDENT REGULATORY  
REVIEW COMMISSION

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January 10, 2008

Dear Ms. Howell,

We appreciate the opportunity to respond to the Board of Medicine's proposed regulations, which were published in the Pennsylvania Bulletin December 14, 2007 and will now be reviewed by the Independent Regulatory Review Commission. These new regulations are necessary to implement the legislation, HB1255 which was passed in July 2007 for nurse-midwives' prescriptive authority.

Overall the proposed regulations appear to follow the legislative language. We have concerns about some of the new language that has been inserted including changes to the definitions and to the practice of midwifery not related to prescriptive authority. Many changes concerning collaborative agreements are restrictive. Some of the legislative language has been inserted in sections which are confusing and not appropriate, for example, the deletion of the first four sections in the "Practice of Midwifery" and requirements for prescriptive authority put under that same section.

Prescriptive authority is independent of a midwives ability to practice; there are nurse-midwives that do not have a master's degree and will not have prescriptive authority. HB 1255 does not change midwifery practice that is common to all midwives. It only gives midwives with a master's degree the authority to prescribe.

Our recommendations and rationales for the areas of the proposed regulations which we believe must be changed are attached in table form for ease of understanding.

We ask that the Independent Regulatory Review Commission, the Board of Medicine, the Governor and the General Assembly review and make changes to the proposed regulations so that they are written with:

- 1) the intent of the prescriptive authority legislation of HB 1255
- 2) no additional restrictive language that will affect midwifery practice or access and continuity of care for midwifery clients
- 3) clarity, so that anyone reading the regulations for prescriptive authority are certain of what is required of nurse-midwives choosing to prescribe.

Midwives in the Commonwealth of Pennsylvania are committed to provide safe care, to promote access to care and to work with other health care providers so that women and their babies have quality health care.

Sincerely,

Vivian Lowenstein, CNM, MSN  
President, Pennsylvania Association of Licensed Midwives (PALM)

cc: Ms. Kim Kaufman, Executive Director  
and Ms. Fiona Wilmarth, Director of Regulatory Review  
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**MIDWIVES RESPONSE TO PROPOSED BOARD OF MEDICINE REGULATIONS JANUARY 10, 2008**

Proposed BOM Regulations	HB 1255	Recommendations and Rationale
<p><b>18.1 Midwifery definition has been changed in the proposed regulations with the addition of the following</b>  <b>“in collaboration with a physician licensed by the board to practice medicine.”</b></p>	<p>No change in definition of midwife</p>	<ol style="list-style-type: none"> <li>1) The current Regulations contain an accurate and clear definition of a midwife</li> <li>2) Additional clause does not define midwifery and should not be added to the present midwifery definition. The additional clause defines a practice relationship.</li> <li>3) HB 1255 does not call for a change in the midwifery definition</li> <li>4) The collaborative relationship with a physician is already identified in current and proposed regulations in 18.5.</li> </ol>
<p><b>18.1 The following definition of midwifery colleague has been added to the proposed regulations because of the section 18.6a (c) on Inappropriate Prescribing:</b>  <b>“A midwife who is available to substitute for the midwife who has primary responsibility in the management of a pregnant woman under the midwife’s care.”</b></p>	<p>Not in HB 1255</p>	<ol style="list-style-type: none"> <li>1) This definition is unnecessary because there is not always an additional midwife colleague in any given practice.</li> <li>2) The section 18.6a (c) on Inappropriate Prescribing should be re-written to acknowledge that the first health provider that identifies an error should notify the patient.</li> </ol>
<p><b>18.5 (g) The collaborative agreement must satisfy the substantive requirement as set forth in subsections (a) through (e) and as being consistent with relevant provisions of the act and this subchapter, and <u>must be submitted to the Board for review.</u></b></p>	<p>Not a requirement in HB 1255</p>	<ol style="list-style-type: none"> <li>1) It is restrictive to require CNM’s to submit collaborative agreements to the Board of Medicine.</li> <li>2) Collaborative agreements for nurse-midwives have been required since 1989, 18.5 and required to be available in current regulations 18.6 (2) and proposed regulations 18.5 (h).</li> </ol>

Proposed BOM Regulations (cont.)Recommendations and Rationale (cont.)

- 3) Collaborative agreements define a relationship and communication between a midwife and a physician. The Board should not have the jurisdiction of evaluating or judging individual collaborative agreements.
- 4) What does "review" mean? The language is unclear.
- 5) The amount of time that it will take to "review" a midwives collaborative agreement will delay a midwife's ability to begin practice and affect access to care for women. It is not necessary for the board staff to validate that collaborative agreements have been developed, updated, or changed between a midwife and the collaborating physician.
- 6) Currently, midwives with the collaborating physician are responsible to update information on the collaborative agreement. Midwives who have prescriptive authority will be responsible with the collaborating physician to make the necessary changes with categories of drugs.
- 7) There is no evidenced based research showing that submitting collaborative agreements enhances the safety of prescribing practices for physicians, physician's assistants or nurse practitioners.

<u>Proposed BOM Regulations (cont.)</u>	<u>HB 1255 (cont.)</u>	<u>Recommendations and Rationale (cont.)</u>
<b>18.6 (6) Master's degree</b>	A new requirement for prescriptive authority in HB1255	Needs to be moved to 18.6A under the section on Prescriptive Authority. This is confusing under the practice of midwifery because midwives without a Master's degree can still practice but can not prescribe.
<b>18.6: Practice of Midwifery Section #'s 1,2, 3, 4 in the current regulations are missing from the proposed regulations</b>	HB 1255 did not call for a change in #1: definition of midwifery practice or #2: maintaining a midwife protocol and collaborative agreement.	<ol style="list-style-type: none"> <li>1) There is no need to change the current regulations under 18.6 Practice of Midwifery. These current regulations should continue for all midwives because midwives without a master's degree will not have prescriptive authority. #'s 1 and 2 are essential for the practice of midwifery.</li> <li>2) #'s 3 and 4 need to remain in the regulations for midwives who do not have a master's degree and are not prescribing.</li> <li>3) Maintain the original regulatory language under 18.6 Practice of Midwifery to include #'s 1, 2, 3, and 4 in the proposed regulations.</li> </ol>
<b>18.6 (i) The midwife has successfully completed 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program.</b>	Only for prescriptive authority in HB1255	<ol style="list-style-type: none"> <li>1) This is new language and is a requirement for midwives with a master's degree to apply for a certificate for prescriptive authority.</li> <li>2) 18.6 (i) should be moved to a section under 18.2 or 18.3 to include "Certificate for Prescriptive Authority requirements"</li> <li>3) Midwives that do not have a master's degree will not be required to complete 45 hours of advanced pharmacology.</li> </ol>

<u>Proposed BOM Regulations (cont.)</u>	<u>HB 1255 (cont.)</u>	<u>Recommendations and Rationale (cont.)</u>
<p><b>18.6 (ii) the midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify:</b></p> <p><b>A) The categories of drugs from which the midwife may prescribe or dispense.</b></p> <p><b>B) The drugs which require referral, consultation or co-management.</b></p>	<p>Only for prescriptive authority in HB1255</p>	<p>1) This is new language for the collaborative agreement and relates to midwives who have a master's degree and have prescriptive authority.</p> <p>2) 18.6 (ii) and A &amp; B should be moved to 18.5: Collaborative agreements, to identify the requirements for collaborative agreements which include prescriptive authority.</p>
<p><b>18.6 c Inappropriate Prescribing</b></p>	<p>Not in HB 1255</p>	<p>1) This section should be changed to acknowledge that the health care provider who identifies the prescription error should immediately advise the patient.</p> <p>2) A physician should not be responsible to contact a midwifery client. Physicians work collaboratively with midwives, and are not in a supervisory role. They may never have met the midwifery client because there are different models of midwifery care, for example; the physician may be an employee of the midwife or birth center, or have a contractual agreement with a midwife, birth center or clinic.</p> <p>3) This language of the proposed regulations for inappropriate prescribing increases the risk of vicarious liability for physicians.</p>

<u>Proposed BOM Regulations (cont.)</u>	<u>HB 1255 (cont.)</u>	<u>Recommendations and Rationale (cont.)</u>
<p><b>18.9 Notification of changes in collaboration.</b></p> <p>(a) A midwife shall notify the Board, in writing, of a change in or termination of a collaborative agreement or a change in mailing address within 30 days. Failure to notify the Board, in writing, of a change in mailing address may result in failure to receive pertinent material distributed by the Board. The midwife shall provide the Board with the new address of residence, address of employment and <u>name of registered collaborating physician</u>.</p> <p>(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days.</p> <p>(c) Failure to notify the Board of changes in, or a termination in the collaborating physician/midwife relationship is a basis for disciplinary action against the midwife's license.</p> <p>(d) A midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall notify the Board within 30 days of the midwife's request to place the midwife's prescriptive authority on inactive status.</p>	<p>Not in HB1255</p>	<p>1) Change (d) to "A midwife with prescriptive authority who cannot fulfill the requirements for prescriptive authority shall cease to prescribe." Remove a, b and c.</p> <p>2) This proposed language is taken almost word for word from physician assistant's regulations 18.172 "Notification of changes in employment".</p> <p>3) The relationship between a physician assistant and a physician is supervisory. It is different from a midwives collaborative relationship with a physician. The regulatory language from physician assistants should not be applied to midwifery practice. Supervision is different from collaboration. See 18.144 Responsibilities of Primary Physician Assistant Supervisor.</p> <p>4) The language "registered collaborating physician" does not exist in HB 1255 or in current midwifery regulations. There is no requirement for physicians signing a collaborative agreement with a midwife to register anywhere. This would be a deterrent for physicians to work with midwives and affect access to care for women seeking midwifery care.</p>

Recommendations and Rationale (cont.)

- 5) (a) This language of notifying the board of a change of a collaborative physician is restrictive. Changes can occur within a short period of time and having to notify the Board will affect the midwife's ability to continue to practice. The Board has no jurisdiction over contractual business agreements between a midwife and a physician. Notifying the Board every time there is a change in a collaborative agreement or a midwives employment will affect practice continuity.
- 6) (b) Physician's should not have to "notify the board, in writing of a change or termination with a midwife within 30 days". Midwives and physicians together are accountable to develop and update a collaborative agreement as necessary. There are different models of midwifery care, for example midwifery owned businesses, birth centers, or hospital based practices. Physicians may be employees or have contractual agreement with midwives, birth centers and clinics.
- 7) Prescriptive authority is independent of a midwives ability to practice. There is no need to change how collaborative agreements are changed or a change of employment status because of this new legislation.