HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

January 14, 2008

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Sabina I. Howell
Board Counsel
Pennsylvania State Board of Medicine
Bureau of Professional and Occupational Affairs
P. O. Box 264
Harrisburg, PA 17105-2649

Re: 49 PA Code, Chapters 16 and 18, Nurse Midwife Prescriptive Authority

Dear Ms. Howell,

The Hospital and Healthsystem Association of Pennsylvania (HAP), on behalf of its more than 225 members, 114 of which currently have obstetrical services licensed by the Pennsylvania Department of Health, appreciates the opportunity to provide comments on the State Board of Medicine's proposed regulations addressing Nurse Midwife Prescriptive Authority.

Nurse midwives provide an essential role in providing safe, timely, and effective care to women throughout the Commonwealth. The new law and regulations should promote and enhance the ability of nurse midwives to practice in accordance with their professional education. HAP appreciates the Board of Medicine's commitment to the timely promulgation of regulations implementing Act 50 of 2007 (House Bill 1255), which provide for nurse midwife prescriptive authority. After reviewing the proposed regulations, HAP would like to offer the following comments and/or recommendations to improve or clarify the draft regulations.

§ 18.1. Definitions

Midwife Definition - In the proposed regulations, the Board of Medicine has amended the definition of midwife. The additional language proposed by the Board serves to reinforce that a relationship needs to exist between a midwife and a collaborating physician; however, existing regulations (§ 18.5. (a) - § 18.5. (c) Collaborative agreements) are already explicit in this regard. HAP recommends that the Board of Medicine retain the current definition of midwife as the relationship that needs to exist between the midwife and the collaborating physician is already explicitly outlined in regulations and a midwife is simply an individual licensed by the Board to practice midwifery.

Midwife Colleague - The Board of Medicine has introduced a new term and definition in the proposed regulations. HAP is unclear about the reasons for including this definition, particularly since Act 50 of 2007 does not include this language or any provisions related to midwife colleague. HAP recommends that this definition and any references to midwife colleague be deleted from the regulations as it appears as if the Board is introducing a requirement that a midwife have an established relationship with another midwife for coverage.

§ 18.5. Collaborative agreements

§ 18.5(f) - In proposed § 18.5(f), the Board requires that the collaborative agreement must satisfy the other requirements as set forth in the other provisions (a-e) in this section and requires that the collaborative agreement be submitted to the Board for review. HAP questions what action the Board intends when it uses the term "review" in this section. HAP has serious concerns if the intent is to bring the collaborative agreement before the Board for review and approval in that this will likely cause unnecessary delay in allowing a nurse midwife to practice in the Commonwealth. HAP has sunshined other professional licensure Boards where practice agreements subject to review and approval by certain professional licensure boards has resulted in extraordinary delays in allowing certain professionals the ability to practice in a timely manner.

HAP would support appropriate review for consistency with the provisions set forth in the regulations by Board staff who are knowledgeable and well versed in the practice of midwifery. Such a review should be restricted to ensuring that a collaborative agreement exists; that the collaborative agreement addresses midwife protocols in some manner; any modifications to the midwife protocol are clearly identified; and language exists in the collaborating agreement if the collaborating physician authorizes the midwife to relay order to other health care practitioners. Such a process would allow for timely review; clarification, if warranted with respect to the content of the nurse midwife protocols and collaborative agreement; appropriate referral to legal counsel and/or the Board if issues of concerns are identified; and increased efficiency in permitting nurse midwife professional practice, but does not require that all submitted collaborative agreements come before the full Board for review and approval. HAP is uncertain whether the Board of Medicine employs staff that can adequately perform those reviews, and would suggest that the Board investigate how the Board of Nursing staff conducts reviews of collaborative agreements for prescriptive authority.

§ 18.6. Practice of midwifery

§ 18.6 (6)(i), (ii)
For purposes of clarity, HAP recommends that these provisions related to midwife prescriptive authority be relocated to into subsection § 18.6a. Prescribing, dispensing and administering drugs.

§ 18.6a. Prescribing, dispensing and administering drugs

§ 18.6a.(a)(2)(i) - Consistent with Act 50 of 2007, the Board of Medicine has proposed that a midwife may not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain. Given this restriction in the law and the fact that midwives may care for pregnant women with a history of chronic pain, it may be appropriate to indicate that the collaborative agreement provide how women with chronic pain will be managed between the nurse midwife and collaborating physician.

HAP also recommends that the Board of Medicine include a provision that is currently part of the certified registered nurse practitioner (CRNP) regulations as a fifth provision in this section of the proposed midwife regulations.

(v) A midwife may not delegate prescriptive authority specifically assigned to the midwife by the collaborating physician to another health care provider.

§ 18.6a.(b)(1) – This subsection deals with what information needs to be maintained on a prescription written by a midwife. HAP questions why the name of the collaborating physician does not need to appear on the prescription blank as specified in the current certified registered nurse practitioner (CRNP) regulations. Specifically, in § 21.284 (g), the Board of Nursing regulations related to CRNP practice require, **"A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in §16.91 (relating to identifying information on prescriptions and orders for equipment and service)."** HAP recommends that the Board consider amending this proposed provision to be consistent with what is required for CRNPs and because it would enhance the ability of a pharmacist to contact the collaborating physician if a concern about the prescription was indicated.

(1) Prescription blanks must bear the license number of the midwife and name of the midwife in printed format at the top of the blank. The collaborating physician shall also be identified as required in §16.91 (relating to identifying information on prescriptions and orders for equipment and service).

§ 18.6a.(c) - This subsection deals with inappropriate prescribing. The current language in the CNRP regulations is more straightforward than what is being proposed by the Board of Medicine. Specifically, in § 21.284 (d), the Board of Nursing regulations state, **"If a collaborating physician determines that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. The action shall be noted by the CRNP or collaborating physician, or both, in the patient's medical record as soon as possible."** HAP submits the following for consideration by the Board.

(c) Inappropriate prescribing. If a collaborating physician determines that the midwife is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately take corrective action on behalf of the patient. Such immediate action includes notifying the midwife to discontinue prescribing the drug for the patient; having the physician or midwife notify the patient to discontinue use of the drug; and notifying the pharmacy to discontinue the prescription. The action to discontinue the use of the drug shall be noted by the midwife or collaborating physician in the patient's medical record as soon as possible.

§ 18.6a.(d)(i) – This subsection deals with recordkeeping requirements related to prescriptions. HAP would suggest deletion of (i) and instead recommend that the Board require that a record of the prescription be maintained that includes certain information. HAP submits the following for consideration by the Board.

(d) Recordkeeping requirements. Recordkeeping requirements are as follows:
(1) When prescribing a drug, the midwife shall record the following in a patient's medical record that may be maintained either electronically or in hardcopy:
(i) The midwife's name.
(ii) The date the prescription was issued
(iii) The name of the medication prescribed.
(iv) The dose of the medication prescribed.
(v) The amount of medication prescribed.
(vi) The number of refills prescribed.
(vii) The directions for medication use.

§ 18.9. Notification of changes in collaboration

The Board is proposing an entirely new section that does not currently exist related to notification of changes in collaboration. Act 50 of 2007 does not include any language related to what is required with respect to changes made in a collaborative relationship or a collaborative agreement. Further, HAP is unclear about what the Board currently requires with respect to changes related to collaboration and how this language would alter this process. HAP would also suggest that the Board provide greater clarity in the regulations around what requirements the midwife must satisfy with the Board when collaboration with one physician is terminated and the midwife enters into a new collaborating agreement with another physician.

HAP suggests some revisions to this section in order to provide greater clarification around responsibilities of the midwife and collaborating physician.

(a) A midwife shall notify the Board, in writing, of a change or termination of collaboration with a physician within 30 days.

(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days.
HAP questions whether such a requirement is needed with respect to the collaborating physician.

(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.
HAP questions whether failure of physician to also notify the Board is grounds for disciplinary action against the collaborating physician.

(d) A midwife with prescriptive authority who cannot continue to fulfill the requirements for prescriptive authority shall notify the Board and request that the prescriptive authority be placed on inactive status until such time as requirements for prescriptive authority can be satisfied. The midwife shall make application for a midwife license without prescriptive authority.
HAP's reading of the proposed regulation is that the Board would issue a license with prescriptive authority and another license without prescriptive authority rather than one midwife license and then a separate prescriptive authority certificate. Given this approach in the proposed regulations, HAP believes that the midwife would need to make application for license without prescriptive authority if the midwife requests that his/her prescriptive authority be placed on inactive status rather than just surrendering a prescriptive authority certificate.

(e) A midwife shall notify the Board, in writing, of 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.
HAP requests that the Board clarify what changes in address need to be filed with the Board in writing. It appears in the proposed regulations that the Board is requesting that the midwife file changes in address of residence, address of employment, and address of collaborating physician in the proposed regulations. It is unclear whether the Board is requesting only notification of a change in the mailing address, which may be any of those mentioned above, or whether the Board wants to be notified of all of the above addresses and changes to any of these addresses.

HAP appreciates the opportunity to provide comments on the proposed nurse midwife prescriptive authority regulations, and respectfully requests a copy of the final-form regulations. If you have any questions about HAP's comments, please feel free to contact me at 717-561-5308 or by e-mail at lgleighton@haponline.org.

Sincerely,

Lynn G. Leighton

Lynn G. Leighton
Vice President
Professional & Clinical Services

cc: Ms. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

Ms. Fiona Wilmarth
Director, Regulatory Review
Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

Senator Robert Tomlinson
Chairperson
Senate Consumer Protection and Professional Licensure Committee
Room 362
Main Capital Building
Harrisburg, PA 17120-3006

Representative P. Michael Sturla
Chairperson
House Professional Licensure Committee
Room 333
Main Capital Building
Harrisburg, PA 17120-3006