AMERICAN COLLEGE OF NURSE-MIDWIVES

January 8, 2008

In our position as co-chairs of the American College of Nurse-Midwives, Region II, Chapter 4 we are offering our comments on proposed regulations. This letter is in response to the proposed rule making by the State Board of Medicine regarding implementing the act of July 20, 2007, (P.L. 324, No. 50) (Act 50) which directs the Board to "adopt, promulgate and enforce regulations that establish requirements for prescriptive authority for midwives to be met by individuals so licensed who elect to obtain prescriptive authority in this Commonwealth." We appreciate the speed and diligence the Board has shown in promulgating regulations to establish requirements for prescriptive authority in a timely manner since the passage of Act 50 in July, 2007. Overall, we are pleased with the regulations, but a few concerns remain.

Region 2 Chapter 4

We are concerned that the Board by its proposed language has introduced, perhaps inadvertently, wording that exceeds the directive of the legislature, and runs counter to the goal of decreasing costs and increasing access to qualified health care providers practicing to the full scope of their education and licensure in this Commonwealth. Some of the Board's proposed language establishes requirements for prescriptive authority for Nurse-Midwives as mandated. However, other proposed language adds additional conditions for practice and creates ambiguous new requirements by:

1) redefining a midwife in the Commonwealth,
2) writing new regulations regarding ambiguous review of collaborative agreements with significant associated costs that could potentially decrease access to midwifery care, particularly large hospital midwifery services, in the Commonwealth,
3) misconstruing the intent of the Act by inserting the word "may" instead of "will" grant a certificate for prescriptive authority if a midwife meets the eligibility requirements of the Act and regulations,
4) misconstruing the master's degree requirement for prescriptive authority by placing it in the section pertaining to the practice of all midwives thus creating ambiguity and potentially affecting access to qualified midwives in the Commonwealth in a time of obstetric provider crisis,
5) restricting the scope of practice to pregnancy only, inadvertently overlooking the important current scope of practice of midwives as providers of non-surgical gynecologic, postpartum, and neonatal health care.

ACNM

We are particularly concerned about the ambiguous collaborative agreement review, new licensure requirements, fee schedule for additional collaborative agreements and interpretation of the "pursuant to" language of Act 50 in the Proposed Regulations. There is no evidence to suggest that the new requirement of submission of collaborative agreements for review is indicated. Midwives have been practicing in Pennsylvania pursuant to collaborative agreements since 1987 (see §18.5 of current regulations), without disciplinary action regarding collaborative agreements and without Board review of those agreements. Additionally, the collaborative agreement must be immediately available (§18.6 (2) of current regulations and §18.5 (h) of proposed regulations) for inspection.

Collaborative agreements are negotiated between midwife(s) and physician(s) practice(s) with various ownership models. Midwives and OB/Gyn physicians work together, as described in a collaborative agreement, to meet patients' health care needs. Because of the nature of providing care in midwifery and obstetrics, a group of midwives may collaborate with a group of physicians who cover call responsibilities on a rotating basis and may hire or lose partners. The potential cost for collaborative agreement review in this setting can run into the thousands of dollars for larger practices without ANY evidence that review is necessary. In several counties in Pennsylvania, large midwifery practices deliver ≥30% of the babies in their county or hospital. In the setting of a group of 10 midwives with prescriptive authority collaborating with 5 physicians in a group practice with a rotating call schedule, the cost to the practice is $700 for initial licensure with prescriptive authority and $2000 for collaborative agreements. The biennial renewal will be $650 for licensure and prescriptive authority and another $2000 for collaborative agreements, assuming there are no staffing changes. This runs counter to common sense, counter to safe precedent since 1987, and counter to the goal of cost effective access to qualified practitioners practicing to the full extent of their training. The prohibitive cost of this collaborative agreement review remains for those midwives who elect not to pursue prescriptive authority. In other words, midwives practicing as they have been since 1987 will also face these new collaborative agreement review fees. These fees have the potential to be unaffordable for practices where midwives earn, on average $60,000 – 75,000/year, paying $25,000 in liability insurance per midwife, plus MCARE if the abatement ends, and DEA fees as applicable. These fees may make it impossible for midwives to work part-time.

The process of collaborative agreement review is not specified. There is potential to disrupt access to care, to delay workforce entry into practice, and increase costs of licensure without evidence of need or efficacy of review by the Board to protect the public. The new requirement seems strange in the setting of a precedent working well since 1987 and in a time of cost containment and access to care issues. Since there is no midwifery board, no midwife on the medical board and no midwifery committee to the medical board, it is unclear where the expertise to review collaborative agreements lies. Collaborative agreements will vary based on practice patterns and clinical skills within the scope of practice of each party to the agreement. There is disincentive for the collaborative agreement to be continuously evaluated and improved if there is a requirement for board review. This is particularly important as the evidence base for practice is fluid and the collaborative agreement includes a description of practice patterns. There will be midwives who prescribe and midwives who don't (by choice or due to lack of a master's degree or

its substantial equivalent). These midwives should be able to continue to practice as they have since 1987 without financial burden of the review of their collaborative agreements.

Again, overall we are pleased with the regulations proposed. We believe that with a few changes building on the work of the Board, the proposed regulations can be made unambiguous, cost effective, remain in line with the directive outlined above and protect the public health of citizens. It is imperative to write regulations that consider the opinions and real world practice experience of the professionals being regulated. The chart below shows language from Act 50, current and proposed regulatory language and suggests alternatives with rationale based on that experience. We ask that the Board implement these changes to correct any inadvertent practice restriction and ambiguity. We remain available to discuss these as necessary and look forward to a resolution that will benefit the citizens of the Commonwealth.

Sincerely,

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Act 50 July 20, 2007	Current Regulations	Proposed Regulations	Suggested Language	Rationale
Definition of ACNM (American College of Nurse-Midwives) is not changed.	§18.1 Definition of ACNM – The American College of Nurse-Midwives	§18.1 Removes the definition of ACNM	§18.1: MAINTAIN: **ACNM – American College of Nurse-Midwives** ADD: **AMCB – American Midwifery Certification Board or its successor** ADD: **ACME – American Commission on Midwifery Education or its successor agency** AMEND: **Midwife Program—An academic and clinical program of study in midwifery which has been approved by the Board or by an accrediting body recognized by the Board. The Board recognizes the [ACNM] ACME as an accrediting body of programs of study in midwifery.**	Nurse-Midwives certified prior to 1991 are certified by The American College of Nurse-Midwives. Nurse-Midwives certified between 1991 and the present are certified by the ACC (ACNM Certification Council), since 2005 known as the AMCB (American Midwifery Certification Board). Therefore, the definitions of ACNM, ACC and AMCB or its successor must be maintained to ensure that licensed midwives in PA are able to continue to practice and ensure access to care. ACME, not AMCB, is the educational program accrediting agency recognized by the ACNM, but is a separate corporate entity. AMCB, and it's predecessors as outlined above, is the only organization conferring certification and administering the certification exam for CM/CNMs.

ACT 50	Current Regulations	Proposed Regulations	Suggested Language	Rationale
Definition of a midwife is not changed by the statute. Authorization is given to practice midwifery pursuant to a collaborative agreement and regulations.	§18.1 midwife: a person licensed by the board to practice midwifery	§18.1 midwife: a person licensed by the board to practice midwifery **in collaboration with a physician to practice medicine**	§18.1 MAINTAIN: **Midwife: a person licensed by the board to practice midwifery**	Prescriptive authority granted under Act 50 does not change the definition of a midwife, therefore the proposed regulations inappropriately redefine midwife. Act 50 language is related to the practice of, not the definition of, midwifery and thus language regarding collaboration properly belongs in the §18.6 Practice of Midwifery. The definition of a midwife is not related to collaboration; collaboration is clearly addressed as a condition of practice elsewhere in the regulations. The World Health Organization definition of a midwife is below: **DEFINITION OF THE MIDWIFE** A midwife is a person who, having been regularly admitted to a midwifery educational programme, duly recognised in the country in which it is located, has successfully completed the prescribed course of studies in midwifery and has acquired the requisite qualifications to be registered and/or legally licensed to practise midwifery… Jointly developed by the International Confederation of Midwives and the International Federation of Gynaecology and Obstetrics.

ACT 50	Current Regulations	Proposed Regulations	Suggested Language	Rationale
Definition of midwifery colleague is not addressed in the statute.	Not addressed in current regulations.	**Midwifery colleague: a midwife who is available to substitute for a midwife who has primary responsibility in the management of a pregnant woman under the midwife's care**	AMEND: **Midwifery colleague: a midwife duly licensed to practice midwifery in the Commonwealth who is in practice with or is available to substitute for another licensed midwife who has primary responsibility in the management of a patient under the midwife's care**	Midwives' scope of practice extends beyond pregnancy care. A colleague may be, but is not limited to, a substitute; many midwives work in group practices and share responsibility for a caseload of patients, share chart review duties and other practice responsibilities. Our revised wording reflects these practice realities. Additionally, midwife colleague seems self-explanatory. Is a definition required?
Inappropriate prescribing is not addressed in the statute.	Not addressed in current regulations.	**§18.6a (c) *Inappropriate prescribing.* The collaborating physician shall immediately advise the patient, notify the midwife or midwife colleague and, in the case of a written prescription, advise the pharmacy if the midwife is prescribing or dispensing a drug inappropriately. The midwife, midwife**	AMEND: **§18.6a (c) *Inappropriate prescribing.* The midwife, midwife colleague or collaborating physician shall immediately advise the patient, notify the midwife (if applicable) and in the case of a written prescription, advise the pharmacy if the midwife is prescribing or dispensing a drug inappropriately. The**	Practice patterns make it most likely that the midwife, midwife colleague, or pharmacist will be the first to identify any inappropriate prescription. The Board's proposed wording seems to indicate that only a collaborating physician can rectify an inappropriate prescription. Midwives themselves must be able to act quickly to rectify any inappropriate prescriptions. Limiting responsibility to collaborating physicians alone is counter to protection of the public's health and transparency of

		colleague or collaborating physician shall advise the patient to discontinue use of the drug and the midwife shall cease prescribing that drug for the patient. In the case of a written prescription, the midwife, midwife colleague, or collaborating physician shall notify the pharmacy to discontinue the prescription. The order to discontinue the use of the drug or prescription must be noted in the patient's medical record.	**midwife, midwife colleague or collaborating physician shall advise the patient to discontinue use of the drug. In the case of a written prescription, the midwife, midwife colleague, or collaborating physician shall notify the pharmacy to discontinue the prescription. The order to discontinue the use of the drug or prescription must be noted in the patient's medical record.**	midwives' professional responsibility and places undue vicarious liability on collaborating physicians.
ACT 50	**Current Regulations**	**Proposed Regulations**	**Suggested Language**	**Rationale**
The physician with whom the nurse-midwife has a collaborative agreement shall have hospital clinical privileges in the specialty area of the care for which the physician	§18.1 Definitions. *Collaborating Physician*—A medical or osteopathic doctor who has hospital privileges in obstetrics, gynecology or pediatrics and who has entered into a	**§18.5(g) the collaborative agreement must satisfy the substantive requirements set forth in subsections (a)—(e) and as being consistent with relevant**	AMEND: **§18.1 *Collaborating Physician*—A medical or osteopathic doctor of obstetrics, gynecology or pediatrics who has entered into a**	Regarding AMEND §18.1: This wording brings the current definition in line with Act 50. Regarding MAINTAIN (a) – (f): We concur that these support protection of public health. Regarding DELETE §18.5 (g): Proposed language for

is providing collaborative services. A nurse-midwife may practice midwifery pursuant to a collaborative agreement;	collaborative agreement with a midwife. §18.6(2) Maintain a midwife protocol and collaborative agreements, and make them available for inspection by clients and the Board upon request. Additionally, in §18.5. Collaborative agreements. (a) A midwife may not engage in midwifery practice without having entered into a collaborative agreement. (b) A midwife shall only engage in midwifery practice in accordance with a midwife protocol and collaborative agreements. (c) A collaborative agreement shall contain either an acknowledgment that the midwife shall practice under the midwife protocol, or that the	**provisions of the act and this subchapter, and shall be submitted to the board for review. (h) the midwife or the collaborating physician shall provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority, and the midwife's ability to prescribe or dispense a drug.** **§18.3 (c) and §18.6 Practice of Midwifery (6) A midwife may be eligible to receive a certificate from the Board which will authorize the midwife to prescribe, dispense, order and administer drugs, including legend drugs and Schedule II through Schedule V controlled substances, as defined in the Controlled Substance,**	**collaborative agreement with a midwife and has hospital privileges in the specialty area of the care for which the physician is providing collaborative services.** **§18.5 Collaborative Agreements.** MAINTAIN **(a) – (f).** DELETE **§18.5 (g) [this section should be amended and moved to §18.6a, see below].** REPLACE §18.5 (g) with AMENDED §18.5 (h): **the midwife or the collaborating physician shall provide immediate access to the collaborative agreement <u>to any client, pharmacist or the Board</u> seeking to confirm the scope of the midwife's authority, and the midwife's ability to prescribe or dispense a**	collaborative agreement review is unclear and ambiguous: a) How long will this review take? b) What is the substance of the review? c) What is the mechanism for updating agreements based on new evidence for practice? d) Will midwives who have been practicing without prescriptive authority, who choose not to pursue prescriptive authority have to meet these new requirements? e) The fee for licensure now appears to include a collaborative requirement plus fees for additional collaborative agreements. These fees may run into the thousands of dollars for group practices. f) Why change the original 1987 requirements that have been working well (no review required)? Regarding AMEND §18.5 (h): The collaborative agreement should be as transparent as possible without exposing the collaborative physician or the midwife to frivolous liability by

	midwife shall practice under the midwife protocol as expanded or modified in the collaborative agreement. (d) Expansions and modifications of the midwife protocol agreed to by the midwife and the collaborating physician shall be set forth, in detail, in the collaborative agreement. (e) If the collaborating physician intends to authorize the midwife to relay to other health care providers medical regimens prescribed by that physician, including drug regimens, that authority, as well as the prescribed regimens, shall be set forth in the collaborative agreement. **Authority** The provisions of this § 18.5 amended under section 2 of the act of April 4, 1929 (P. L. 160, No. 155) (63 P. S.	**Drug , Device and Cosmetic Act (35 P.S. SS 780-101—780-144), in accordance with §18.6a (relating to prescribing, dispensing and administering drugs) provided that the midwife demonstrates to the Board that: (i)The midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by a professional nursing education program. (ii.) The midwife acts in accordance with a collaborative agreement with a physician which must at a minimum identify (A.) The categories of drugs from which the midwife may prescribe or dispense.**	**drug.** INSERT **to §18.6a: <u>the collaborative agreement shall at a minimum identify the categories of drugs from which the nurse-midwife may prescribe or dispense and the drugs which require referral, consultation or comanagment;</u>** AMEND **§18.6 (6) <u>will</u> [may]** <u>be eligible to receive a certificate from the Board which will authorize the midwife to prescribe, dispense, order and administer drugs, including legend drugs and Schedule II – V controlled substances,</u> . . .	making the agreement immediately available to "anyone". Regarding INSERT to §18.6a: regulations pertaining specifically to prescribing, dispensing and administering drugs properly belong in the section thus titled. Regarding AMEND §18.6 (6): ACT 50 grants this authority to midwives meeting stipulated criteria.

	§ 172); and sections 8 and 35(a) of the Medical Practice Act of 1985 (63 P. S. § § 422.8 and 422.35(a)). **Source** The provisions of this § 18.5 adopted January 2, 1987, effective immediately and applies retroactively to December 31, 1986, 17 Pa.B. 24; amended May 19, 1989, effective May 20, 1989, 19 Pa.B. 2161. Immediately preceding text appears at serial page (114029).	**(B.) The drugs which require referral, consultation or co-management.** **Anything pertaining to prescribing should be moved to §18.6a Prescribing, dispensing and administering drugs.**		
ACT 50	**Current Regulations**	**Proposed Regulations**	**Suggested Language**	**Rationale**
A nurse-midwife who possesses a master's degree or its substantial equivalent may prescribe medication.	national certification required to practice; no prescriptive authority	**§18.6 (6) A midwife who possesses a master's degree or its substantial equivalent and National certification, ...**	AMEND: §18.1 definitions **substantial equivalent to a master's degree -- The board recognizes a minimum of 5 years of practice and national certification as a substantial equivalent to a master's degree for the purpose of prescriptive authority.**	Post-baccalaureate Certification programs and master's programs prepare nurse-midwives to sit for the same certifying examination and both graduates hold the same credential upon successful completion of the certifying exam. The advanced pharmacology courses that prepare nurse-midwives for prescriptive practice are the same in certificate and master's programs. For those

				midwives currently licensed in Pennsylvania, a minimum of five years of clinical practice experience, academic preparation and national certification should be recognized as constituting "a substantial equivalent" as related to ability to prescribe.
ACT 50	**Current Regulations**	**Proposed Regulations**	**Suggested Language**	**Rationale**
Notification of Changes in collaboration is not addressed in Act 50.	§18.9 does not exist in current regulations.	**§18.9 Notification of change in collaboration.** **(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**	AMEND §18.9: **(a) If the midwife is unable to maintain a current a collaborative agreement the midwife shall request to place the midwife's license on inactive status and shall cease practicing immediately until a collaborative agreement is in place. (b) If the midwife holds a certificate for prescriptive authority, and cannot maintain the requirements for prescriptive authority, the midwife shall cease prescribing immediately and request to place the**	As discussed above, there should not be Board review of collaborative agreements. Notification of all collaborative changes would be cumbersome and costly (thousands of dollars in many cases) for hospital systems, practices, clients and the Board and has the potential to block timely access to care without any evidence to support necessity of this cumbersome and costly new reporting. Regarding subsection (c): Midwives cannot be held responsible for collaborative physicians' failure to notify the Board of changes in collaboration; they can only be held responsible for their own failure to follow the regulations. Doesn't failure to follow regulations raise the potential for disciplinary action?

		and name of registered collaborating physician. **(b) A collaborating physician shall notify the Board, in writing, of a change or termination of collaboration with a midwife within 30 days** **(c) Failure to notify the Board of changes in or termination of the collaborating physician/midwife relationship is basis for disciplinary action against the midwife's license.** **(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.**	**prescriptive authority certificate on inactive status.** **(c) Any midwife intending to place a license and/or prescriptive certificate on inactive status will notify the board, in writing, of their intent to place their license and/or prescribing certificate on inactive status within 30 days of cessation of practice and/or cessation of prescribing.** **(d) The midwife is responsible for notifying the Board, in writing, within 30 days, of any change in employment mailing address and/or residential mailing address. Failure to notify the board may result in failure to receive pertinent material distributed by the Board.**	In other words, is this subsection necessary? If it is, change the word "is" to "may" regarding "basis for disciplinary action". Notification of a need to place a license and/or prescriptive certificate on inactive status and maintenance of current mailing addresses, however, is appropriate to the protection of public health.