Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) I.D. Number (Governor's Office Use)
16A-4926

IRRC Number: 2656

(3) Short Title
Nurse Midwife Prescriptive Authority

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
49 Pa. Code§§ 16.11, 16.13, 18.1, 18.2, 18.3, 18.5, 18.6, 18.6a, and 18.9	Primary Contact: Sabina I. Howell, Counsel State Board of Medicine (717) 783-7200 Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200

(6) Type of Rulemaking (check one)	(7) Is a 120-Day Emergency Certification Attached?
_X_ Proposed Rulemaking **___ Final Order Adopting Regulation** **___Policy Statement**	**No X** **Yes: By the Attorney General** **Yes: By the Governor**

(8) Briefly explain the regulation in clear and nontechnical language.

The rulemaking details the requirements for nurse midwives to have prescriptive authority.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The rulemaking implements Act 50 of 2007, amended the Medical Practice Act, (63 P.S. §§422.1 – 422.51.1) (act), which directs the State Board of Medicine to establish requirements for authorization of nurse midwives to obtain prescriptive authority in collaboration with medical doctors. Section 21 of the Medical Practice Act of 1985 (63 P.S. §422.21), provides for the various levels of required medical doctor involvement with the care of patients who are being treated by non-physicians.

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Act 50 of 2007 mandates that the Board promulgate this rulemaking.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The rulemaking is put forth in support of the Legislative mandate of Act 50 of 2007 to expand the authorization of nurse midwives to treat a patient's condition by granting prescriptive authority for the treatment of female citizens of the Commonwealth in the treatment of a woman's acute pain during pregnancy.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

The rulemaking has been mandated by legislative initiative.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The rulemaking will enhance the provision of quality care to the female residents and their newborn infants of the Commonwealth. By setting forth guidelines for obtaining prescriptive authority by this class of licensees, the rulemaking reinforces the need for practitioners who are providing midwifery services to residents of the Commonwealth to be knowledgeable in and able to provide for pain management of pregnant women.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are no perceived people or groups of people who would be adversely affected by this rulemaking.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

The only members of the regulated community who will be required to comply with the rulemaking, are those that desire prescriptive authority in the practice of midwifery. Currently there are approximately 334 nurse midwives licensed by the State Board of Medicine in the Commonwealth.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The rulemaking is put forth in support of the Legislative mandate providing for nurse midwives to have prescriptive authority in the Commonwealth. The public, the regulated community and professionals who work with the regulated community all had input into the Legislative mandate. The Legislative mandate was precisely defined. This regulation is a part of the Governor's Prescription for PA.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

It is difficult to estimate the cost to the regulated community. Much will depend upon whether or not nurse midwives choose to obtain the needed education to have prescriptive authority. Many already have the necessary educational requirements met. The regulated community will be required to maintain records of compliance.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

No costs or savings to local governments are generated by this rulemaking.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

The costs associated with implementing this rulemaking are hard to quantify. There will be some costs incurred for auditing, verifying and prosecuting cases relating to completion of education qualifying the nurse midwives for prescriptive authority. There will also be costs for additional licensure verification and processing for this sub-group of nurse midwives. However, the overhead cost involved in these activities will not be overly burdensome, as audit and verification for licensure requirements already takes place. In addition, cost associated with review of applications for midwife license, collaborative agreements and prescriptive authority will be borne by the applicants through fees set forth in § 16.13.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**	**$ N/A**
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	**Unable to**	**quantify**				
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Costs associated with the regulated community's compliance will vary based upon the necessity to acquire the formal education needed to qualify for being granted prescriptive authority. Many in the regulated community will see little, if any, costs. In addition, slight increases in the application fees and biennial renewal fees will be incurred by midwives applying for prescriptive authority. It is impossible to determine how many of the 334 midwives will qualify for and apply for prescriptive authority.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY –3 2004-2005	FY –2 2005-2006	FY –1 2006-2007	Current FY 2007-2008
State Board of Medicine	**$4,426,129.18**	**$5,621,389.18**	**$8,794,000.00**	**$9,348,000.00**

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There should be minimal adverse effects and costs associated with compliance with the rulemaking. The benefits of the regulation are described in sections 11 & 13, above. Further, this rulemaking has been legislatively mandated.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

The implementation of regulations has been legislatively mandated to reflect the on-going need for Pennsylvanians to have easier and more affordable access to health care, especially in underserved areas and pregnant women and their newborns.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The rulemaking reflects the mandate of the legislature, and as such no other regulatory schemes were found to be viable.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

There are no federal standards in this area.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation is particular to licensees of the Board. This regulation promulgates the specific direction of the Legislature. Other states' regulation and utilization of nurse midwives as physician extenders have no relevance to this rulemaking. The rulemaking will not put Pennsylvania at a competitive disadvantage.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings are scheduled. The Board reviews regulatory proposals at regularly scheduled monthly public meetings. A schedule of board meetings can be found on the Department of State's website at www.dos.state.pa.us/bpoa. The Board provided a draft of the proposed regulations to those persons and organizations who have identified themselves as interested in the regulatory proposals of the Board. All public comments will be considered in drafting the final rulemaking.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Yes. Practitioners of nurse midwifery who choose to obtain prescriptive authority will be required to maintain evidence of compliance with the regulations.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has not identified any affected groups or persons that need to be accommodated in any way.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The rulemaking will become effective upon final-form publication.

(31) Provide the schedule for continual review of the regulation.

The Board continuously monitors the effectiveness of its regulations.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

NOV 02 2007
DATE OF APPROVAL

Counsel

Agency
inapplicable

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4926

DATE OF ADOPTION: _____

BY: _____
Charles D. Hummer, Jr., M.D.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: _____
Andrew C. Clark

OCT 12 2007
DATE OF APPROVAL

(~~Executive~~ Deputy General (Counsel)
~~(Chief Counsel,~~
~~Independent~~
~~Strike~~
~~title~~)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTERS 16 and 18
NURSE MIDWIFE PRESCRIPTIVE AUTHORITY

The State Board of Medicine (Board) proposes to amend §§ 16.11, 16.13, 18.1, 18.2, 18.3, 18.5 and 18.6, and to add §§18.6a and 18.9 (relating to prescribing and dispensing drugs; and notification of changes in collaboration), to read as set forth in Annex A.

A. Effective Date

The amendments will be effective upon publication as final-form rulemaking in the Pennsylvania Bulletin.

B. Statutory Authority

The amendments implement the act of July 20, 2007, (P.L. ____, No. 50) (Act 50 of 2007) 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.

C. Background and Purpose

Act 50 of 2007, which became effective September 18, 2007, amended the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.1- 422.51.1) by amending section 2 to define "legend drug"; by adding section 35(c) authorizing prescriptive authority, and by adding section 35(d) providing for collaborative agreements with physicians. Sections 8 and 35(a) of the act (63 P.S. §§ 422.8, 422.35(a)) authorize the Board to promulgate regulations as necessary to carry out the purposes of the act. In addition, section 3 of Act 50 of 2007 requires the Board to promulgate regulations within 12 months of its effective date.

D. Description of Proposed Regulations

Section 16.11 (relating to licenses, certificates and registrations) would be amended to add the issuance of a certificate of prescriptive authority for nurse midwives.

Section 16.13 (relating to licensure, certification, examination and registration fees) would be amended to add fees relating to licensure and prescriptive authority for nurse midwives.

Section 18.1 (relating to definitions) would be amended to revise the name of the national certifying organization recognized by the Board. The definition of "midwife" is amended to reflect that the midwife would practice in collaboration with a board-licensed physician. The definitions of "midwife examination" and "midwife program" would be amended to reflect the name change of the national certifying organization. A definition of "midwife colleague" would be added to refer to another midwife who is available to

substitute for the midwife who has primary responsibility for a pregnant woman under that midwife's care. The definition of "legend drug" would be added as delineated by statute. Section 18.2 (relating to licensure requirements) would also be amended to reflect the recent name change of the national certifying organization.

Subsection 18.3(b) (relating to biennial registration requirements) would be amended to reflect that a midwife must complete the continuing education requirements required under section 12.1 of the Professional Nursing Law, 63 P.S. § 222. This section also requires that in the case of a midwife who has prescriptive authority, 16 of those continuing education hours must include at least 16 hours in pharmacology.

Subsection 18.5 (relating to collaborative agreements) would be amended by adding subsection (f) to require that a physician with whom a midwife has a collaborative agreement must have hospital clinical privileges in the same specialty area of care. The Board also proposes to add subsection (g) to require review of the collaborative agreement by the Board, and subsection (h) to require that the midwife or collaborating physician provide immediate access to the collaborative agreement to anyone seeking to confirm the scope of the midwife's authority.

Section 18.6 (relating to practice of midwifery) would be amended by adding in subsection (5) the authority to prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures, so long as those activities are in accordance with the midwife's collaborative agreement and consistent with the midwife's education and national certification. Subsection (6) would be amended to set forth the criteria for qualifications of the midwife to obtain prescriptive authority from the Board. This section would permit the prescribing, dispensing, ordering, and administration of legend drugs, and Schedule II through Schedule V controlled substances by a midwife who possesses a master's degree or its substantial equivalent, and national certification. Subsection (6)(i) would require that the midwife demonstrate to the Board that the midwife has successfully completed at least 45 hours of course-work specific to advanced pharmacology at a level above that required by as professional nursing education program. In subsection (6)(ii), the proposed requirement is that the midwife act in accordance with a collaborative agreement with a physician that at a minimum identifies the categories of drugs the midwife may prescribe or dispense, as well as the drugs that require referral, consultation or co-management. Subsection (7) would be amended to delete the prohibition against prescribing or dispensing of drugs.

Section 18.6a (relating to prescribing and dispensing drugs) sets forth the parameters of the prescriptive authority of the midwife. Subsection (a) prohibits the prescribing or dispensing of Schedule I controlled substances and restricts the prescribing, dispensing, ordering or administration of a controlled substance except for a woman's acute pain. The proposal also includes a provision in subsection (a)(2)(ii) which would limit the prescribing, dispensing, ordering or administration of a Schedule II drug to 72 hours, and would prohibit the extension of that time limit except with the approval of the collaborating physician.

Subsection (iii) also sets forth the requirement that prescribing, dispensing, ordering or administration of psychotropic drugs only be undertaken after consulting with the collaborating physician. The proposal also includes a provision in subsection (iv) to prohibit the prescribing or dispensing of a drug unless it is in accordance with the collaborative agreement. Subsection 18.6a(a)(3) specifically requires that a midwife who is authorized to prescribe and/or dispense controlled substances be registered with the U.S. Drug Enforcement Administration (DEA).

Section18.6a(b) would set forth the requirements for prescription blanks. It would require that the name and license number of the midwife in addition to a designation that the signer is a midwife be included on the prescription blank. As appropriate, space on prescription blanks must be provided for the midwife to record the midwife's DEA number, when appropriate. This reminds the midwife of the requirement to register with the DEA and serves to bring the midwife's practice into conformance with federal law. Subsection (b)(3) would permit a midwife to use a prescription blank generated by a hospital provided that the name and license number of the midwife is on the blank.

Subsection 18.6a(c) would set forth the process that a collaborating physician must follow in the event the midwife prescribes or dispenses a drug inappropriately. The collaborating physician is required to advise the patient, notify the midwife or midwife colleague, if any, and in the case of a written prescription, advise the pharmacy of the inappropriate prescribing. The midwife, midwife colleague or collaborating physician would also be required by this proposed rulemaking to advise both the patient and the midwife to discontinue the drug use, and advise the pharmacy if there was a written prescription. The order discontinuing use of the drug would be required to be noted in the patient's medical record.

In subsection 18.6a(d), the Board proposes to establish recordkeeping requirements which detail the maintenance of information on any drug prescribed by the midwife and number of refills, if any. If a midwife dispenses a drug, the midwife's name and the name, amount, dose and date dispensed of the medication are to be a part of the patient's medical record.

Subsection 18.6a(e) mandates compliance by the midwife with other sections of Chapter 16, as well as with Pennsylvania Department of Health regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.

Section 18.9 (relating to notification of changes in collaboration) proposes a requirement that the midwife notify the Board in writing of any change regarding the midwife's collaborative agreement, as well as notifying the Board of a change in address. A change in collaboration requires inclusion of the name of the new registered collaborating physician. Subsection (b) requires the collaborating physician to notify the Board in writing within 30 days of a change or termination of collaboration with a midwife. The midwife's failure to notify the Board of changes in employment would

subject the midwife's license to discipline. Finally, subsection (d) would require that a midwife with prescriptive authority must notify the Board within 30 days if the midwife cannot continue to fulfill the requirements for prescriptive authority.

E. Fiscal Impact and Paperwork Requirements

The amendments will have no quantifiable adverse fiscal impact on the Commonwealth or its political subdivisions.

F. Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act, (71 P.S. §745.5(a)), on December 5, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly, and the Governor of comments, recommendations or objections raised.

H. Public Comment

Interested persons are invited to submit written comments, recommendations, or objections regarding the proposed regulation to Sabina I. Howell, Board Counsel, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649 within thirty (30) days following publication for the proposed rulemaking in the Pennsylvania Bulletin.

Charles D. Hummer, Jr., M.D.

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

* * * * *

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

* * * * *

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses and certificates are issued by the Board:

(1) Midwife license.

(2) Midwife certificate of prescriptive authority.

(3) Physician assistant license.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(b) *Midwife License*

[Application.....$ 30

Biennial renewal.....$ 40]

Application for midwife license without prescriptive authority.....$ 50

Application for additional collaborative agreement without prescriptive authority....$ 30

Application for midwife license with prescriptive authority.....$ 70

Application for additional collaborative agreement with prescriptive authority.....$ 50

Biennial renewal of midwife license .....$ 40

Biennial renewal of each prescriptive authority.....$ 25

Verification of licensure .....$ 15

* * * * *

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter A. LICENSURE AND REGULATION OF MIDWIFE ACTIVITIES

§ 18.1. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

[*ACNM* – The American College of Nurse-Midwives] *AMCB* – The American Midwifery Certification Board.

* * * * *

Legend Drug – A drug:

(1) Limited by the Federal Food, Drug and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 *et. seq.*) to being dispensed by prescription.

(2) The product label of which is required to contain the following statement: "Caution: federal law prohibits dispensing without a prescription."

Midwife – A person licensed by the Board to practice midwifery in collaboration with a physician licensed by the Board to practice medicine.

Midwife colleague – 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.

Midwife examination – An examination offered or recognized by the Board to test whether an individual has accumulated sufficient academic knowledge with respect to the practice of midwifery to qualify for a midwife license. The Board recognizes the certifying examination of the [ACNM] AMCB as a midwife examination.

Midwifery practice –[anagement] Management of the care of essentially normal women and their normal neonates – initial 28-day period. This includes antepartum, intrapartum, postpartum and nonsurgically related gynecological care.

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] AMCB as an accrediting body of programs of study in midwifery.

* * * * *

§ 18.2 Licensure requirements.

The Board will grant a midwife license to an applicant who meets the following requirements. The applicant shall:

* * * * *

(4) Have obtained one of the following:

(i) A passing grade on a midwife examination. The Board accepts the passing grade on the certifying examination of the [ACNM] AMCB as determined by the [ACNM] AMCB.

(ii) [ANCM certification] Certification as a midwife by the American College of Nurse-Midwives (ACNM) before the [ACNM] certification examination was first administered in 1971.

* * * * *

§ 18.3 Biennial registration requirements.

* * * * *

(b) As a condition of biennial license renewal, a midwife shall complete the continuing education requirement set forth at section 12.1 of the Professional Nursing Law, 63 P.S. § 222. In the case of a midwife who has prescriptive authority under the act, the continuing education required by the Professional Nursing Law must include at least 16 hours in pharmacology completed each biennium.

(c) The [fee] fees for the biennial [registration] renewal of a midwife license and prescriptive authority [is] are set forth in § 16.13 (relating to licensure, certification, examination and registration fees).

* * * * *

§ 18.5 Collaborative agreements.

* * * * *

(f) The physician with whom a midwife has a collaborative agreement shall have hospital clinical privileges in the specialty area of the care for which the physician is providing collaborative services.

(g) The collaborative agreement must satisfy the substantive requirements as set forth in subsections (a) through (e) and as being consistent with relevant provisions of the act and this subchapter, and must be submitted to the Board for review.

(h) A midwife or 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.

§ 18.6 Practice of midwifery.

The midwife is authorized and required to do the following:

* * * * *

(5) A midwife may, in accordance with a collaborative agreement with a physician, and consistent with the midwife's academic educational preparation and national certification by the AMCB or its successor organizations, prescribe, dispense, order and administer medical devices, immunizing agents, laboratory tests and therapeutic, diagnostic and preventative measures.

(6) A midwife who possesses a master's degree or its substantial equivalent, and national certification, may be eligible to receive a certificate from the Board which shall 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 act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act, in accordance with § 18.6a (relating to prescribing and dispensing 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.

(B) The drugs which require referral, consultation or co-management.

(7) Perform medical services in the care of women and newborns that may go beyond the scope of midwifery, if the authority to perform those services is delegated by the collaborating physician in the collaborative agreement, and the delegation is consistent with standards of practice embraced by the midwife and the relevant physician communities in this Commonwealth[, and the delegated medical services do not involve the prescribing or dispensing of drugs].

[(6)] (8) Refer and transfer to the care of a physician, as provided for in the midwife protocol or a collaborative agreement, or both, those women and newborns whose medical problems are outside the scope of midwifery practice and who require medical services which have not been delegated to the midwife in a collaborative agreement.

[(7)] (9) Review and revise the midwife protocol and collaborative agreements as needed.

[(8)] (10) Carry out responsibilities placed by law or regulation upon a person performing the functions that are performed by the midwife.

§ 18.6a Prescribing, dispensing and administering drugs.

(a) *Prescribing, dispensing and administering drugs.* A midwife who has prescriptive authority may prescribe, administer and dispense drugs as follows:

(1) A midwife may not prescribe or dispense Schedule I controlled substances as defined by section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

(2) A midwife may prescribe, dispense or administer Schedule II through V controlled substances and legend drugs in accordance with the following restrictions:

(i) A midwife may not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain.

(ii) In the case of a Schedule II controlled substance, the dose must be limited to 72 hours and may not be extended except with the approval of the collaborating physician.

(iii) A midwife shall prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

(iv) A midwife shall only prescribe or dispense a drug for a patient in accordance with the collaborative agreement.

(3) A midwife authorized to prescribe or dispense, or both, controlled substances, shall register with the U.S. Drug Enforcement Administration (DEA).

(b) *Prescription blanks.* The requirements for prescription blanks are as follows:

(1) Prescription blanks must bear the license number of the midwife and the name of the midwife in a printed format at the heading of the blank.

(2) The signature of the midwife must be followed by the initials "C.N.M." or similar designation to identify the signer as a midwife. When prescribing controlled substances, the midwife's DEA registration number must appear on the prescription.

(3) A midwife may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.

(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 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.

(d) *Record-keeping requirements.* Record-keeping requirements are as follows:

(1) When prescribing a drug, the midwife shall keep a copy of the prescription, including the number of refills, in a ready reference file; or record the name, amount, directions for use and doses of the drug prescribed, the number of refills, the date of the prescription and the midwife's name in the patient's medical records.

(2) When dispensing a drug, the midwife shall record the midwife's name, the name of the medication dispensed, the amount of medication dispensed, the dose of the medication dispensed and the date dispensed in the patient's medical records.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A midwife shall comply with §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51—25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91—25.95 (relating to labeling of drugs, devices and cosmetics).

* * * * *

§ 18.9 Notification of changes in collaboration.

(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 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 a termination in the collaborating physician/midwife relationship is a 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.

* * * * *

FEE REPORT FORM

Agency: State - BPOA **Date:** September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupation Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Certified Nurse Midwife Application and Collaborative Agreement: $50.00

Estimated Biennial Revenue: $2,000.00 (40 applications x $50.00)

Fee Description:

The fee will be charged to every applicant for certification as a Certified Nurse Midwife

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application as a Certified Nurse Midwife and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time- evaluate initial application	(.50 hr)	13.19
Administrative Overhead:		28.28
	Total Estimated Cost:	41.47
	Proposed Fee:	$50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of $50.00 be established to process an application for certification as a Certified Nurse Midwife.

Certified Nurse Midwife Application And Collaborative Agreement:

Staff receives application, date stamps and forwards to the appropriate staff member(s) responsible for reviewing, evaluating and approving certified nurse midwife applications and collaborative agreements.

Staff assigned to an application review the application, collaborative agreement and supporting documents for completeness; process the application fee; verify that supporting documents are provided; ensure that applicants hold an active Pennsylvania Registered Nurse license and evaluates to ascertain compliance with the Medical Act, regulations and Board policies.

If there are missing documents or incomplete information, the staff may prepare a discrepancy notification(s) or letter of approval and update records in the agency computer system.

FEE REPORT FORM

Agency: State - BPOA **Date**: September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Each Additional Certified Nurse Midwife Collaborative Agreement: **$30.00**

Estimated Biennial Revenue: $1,500.00 (50 applications x $30.00)

Fee Description:

The fee will be charged to evaluate **each** additional Collaborative Agreement for Certified Nurse Midwife approval.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and evaluate each Collaborative Agreement for Certified Nurse Midwife and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-review and prepare app	(.17 hr)	4.40
Administrative Overhead:		28.28
	Total Estimated Cost	32.68
	Proposed Fee:	$30.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of $30.00 be established to process each Collaborative Agreement for Certified Nurse Midwife.

Each Additional Certified Nurse Midwife Collaborative Agreement:

Staff receives application, date stamps and forwards to the appropriate staff member(s) responsible for reviewing, evaluating and approving certified nurse additional collaborative agreement applications.

Staff assigned to an application review the application, collaborative agreement and supporting documents for completeness; process the application fee; verify that supporting documents are provided; ensure that applicants hold an active Pennsylvania Registered Nurse license and evaluates to ascertain compliance with the Medical Act, regulations and Board policies.

If there are missing documents or incomplete information, the staff may prepare a discrepancy notification(s) or letter of approval and update records in the agency computer system.

FEE REPORT FORM

Agency: State - BPOA **Date**: September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupation Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Certified Nurse Midwife and Collaborative Agreement with Prescriptive Authority
Fee: $70.00

Estimated Biennial Revenue: $10,500.00 (150 applications x $70.00)

Fee Description:

The fee will be charged to every applicant for certification as a Certified Nurse Midwife with Prescriptive Authority.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and process an application for certification of a Certified Nurse Midwife with Prescriptive Authority and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time- evaluate initial application	(.50 hr)	13.19
NPA- review and evaluate pharmacology/CE	(.50 hr)	21.50
Attorney-avg. time to review legal issues	(.08 hr)	4.00
Administrative Overhead:		28.28
	Total Estimated Cost:	66.97
	Proposed Fee:	$70.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of $70.00 be established to process an application for certification as a Certified Nurse Midwife with Prescriptive Authority.

Certified Nurse Midwife Application And Collaborative Agreement With Prescriptive Authority:

Staff receives application, date stamps and forwards to the appropriate staff member(s) responsible for reviewing, evaluating and approving certified nurse additional collaborative agreement applications.

Staff assigned to an application review the application, collaborative agreement and supporting documents for completeness; process the application fee; verify that supporting documents are provided; ensure that applicants hold an active Pennsylvania Registered Nurse license and evaluates to ascertain compliance with the Medical Act, regulations and Board policies.

Collaborative agreements with prescriptive authority are reviewed to ensure that applicants hold an active Pennsylvania Registered Nurse license and have successfully completed not less than 45 hours of course work in advanced pharmacology at a level beyond the basic professional nursing education pharmacology. If an evaluation of the advanced pharmacology course work needs to be undertaken, the application documents will be referred to the Nurse Board Nurse Practice Advisor (NPA) for analysis.

If there are missing documents or incomplete information, staff may prepare a discrepancy notification(s) or letter of approval and update records in the agency computer system.

The application, collaborative agreement or supporting documents may require additional review and processing by the Legal Office. Costs of additional review(s) have been averaged over the total number of applications anticipated in a biennial cycle

FEE REPORT FORM

Agency: State - BPOA **Date**: September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Each Additional Certified Nurse Midwife Collaborative Agreement with Prescriptive Authority:
Fee: **$50.00**

Estimated Biennial Revenue: $20,000.00 (400 applications x $50.00)

Fee Description:

The fee will be charged to evaluate **each** additional Collaborative Agreement for Certified Nurse Midwife with Prescriptive Authority approval.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to review and evaluate each Collaborative Agreement for Certified Nurse Midwife with Prescriptive Authority and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-review and prepare app	(.50 hr)	13.19
Attorney-avg. time to review legal issues	(.08 hr)	4.00
Administrative Overhead:		28.28
	Total Estimated Cost	45.47
	Proposed Fee:	$50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of $50.00 be established to process each Collaborative Agreement for Certified Nurse Midwife with Prescriptive Authority.

Each Additional Certified Nurse Midwife Collaborative Agreement With Prescriptive Authority

Staff receives application, date stamps and forwards to the appropriate staff member(s) responsible for reviewing, evaluating and approving certified nurse additional collaborative agreement applications.

Staff assigned to an application review the application, collaborative agreement and supporting documents for completeness; process the application fee; verify that supporting documents are provided; ensure that applicants hold an active Pennsylvania Registered Nurse license and evaluates to ascertain compliance with the Medical Act, regulations and Board policies.

If there are missing documents or incomplete information, staff may prepare a discrepancy notification(s) or letter of approval and update records in the agency computer system.

In situations where the application, collaborative agreement or supporting documents require additional review or if a determination regarding compliance cannot be made, the application may require review and processing by the Legal Office. Costs of additional review(s) have been averaged over the total number of applications anticipated in a biennial cycle.

FEE REPORT FORM

Agency: State - BPOA **Date**: September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Biennial Renewal Fee: Certified Nurse Midwife: $40.00
Estimated Biennial Revenue: $6,000.00 (150 applications x $40.00)

Fee Description:

The fee will be biennially to every applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine administrative overhead, specifically helping to defray the difference between the Board's total biennial expenditures and its total biennial revenues from non-renewal sources.

Analysis, Comment, and Recommendation:

It is recommended that a fee of $40.00 be established for renewal of each Certified Nurse Midwife.

FEE REPORT FORM

Agency: State - BPOA **Date**: September 14, 2007

Contact: Basil Merenda
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Biennial Renewal Fee: Each Prescriptive Authority Certified Nurse Midwife: $25.00
Estimated Biennial Revenue: $10,000.00 (400 applications x $25.00)

Fee Description:

The fee will be biennially to every applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine administrative overhead, specifically helping to defray the difference between the Board's total biennial expenditures and its total biennial revenues from non-renewal sources.

Analysis, Comment, and Recommendation:

It is recommended that a fee of $25.00 be established for renewal of each Prescriptive Authority approval for Certified Nurse Midwife.

SENATE AMENDED
PRIOR PRINTER'S NOS. 1550, 1987, 2177 PRINTER'S NO. 2290

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1255 Session of 2007

INTRODUCED BY WATERS, MYERS, JOSEPHS, BLACKWELL, EACHUS, MANDERINO, PASHINSKI, SOLOBAY, FREEMAN, KULA, LEACH, MURT, EVERETT, CONKLIN, GIBBONS, KORTZ, PICKETT, STABACK, JAMES, SHAPIRO, CALTAGIRONE, CURRY AND SIPTROTH, MAY 10, 2007

SENATOR ARMSTRONG, APPROPRIATIONS, IN SENATE, RE-REPORTED AS AMENDED, JULY 10, 2007

AN ACT

Amending the act of December 20, 1985 (P.L.457, No.112), entitled "An act relating to the right to practice medicine and surgery and the right to practice medically related acts; reestablishing the State Board of Medical Education and Licensure as the State Board of Medicine and providing for its composition, powers and duties; providing for the issuance of licenses and certificates and the suspension and revocation of licenses and certificates; providing penalties; and making repeals," PROVIDING FOR THE DEFINITION OF "LEGEND DRUG"; AND further providing for nurse-midwife license. <--

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

~~Section 1. Section 35 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, is amended by adding a subsection to read:~~ <--

SECTION 1. SECTION 2 OF THE ACT OF DECEMBER 20, 1985 (P.L.457, NO.112), KNOWN AS THE MEDICAL PRACTICE ACT OF 1985, IS AMENDED BY ADDING A DEFINITION TO READ: <--

SECTION 2. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS ACT SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

* * *

"LEGEND DRUG." A DRUG:

(1) LIMITED BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT (52 STAT. 1040, 21 U.S.C. § 301 ET SEQ.) TO BEING DISPENSED BY PRESCRIPTION; AND

(2) THE PRODUCT LABEL OF WHICH IS REQUIRED TO CONTAIN THE FOLLOWING STATEMENT: "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

* * *

SECTION 2. SECTION 35 OF THE ACT IS AMENDED BY ADDING A SUBSECTION TO READ:

Section 35. Nurse-midwife license.

* * *

(c) Authorization.--

(1) A ~~nurse-midwife~~ NURSE-MIDWIFE is authorized to practice midwifery pursuant to a collaborative agreement with a physician and regulations promulgated by the board. <--

(2) A ~~nurse-midwife~~ NURSE-MIDWIFE ~~may, consistent with the midwife's academic educational preparation~~ WHO POSSESSES A MASTER'S DEGREE OR ITS SUBSTANTIAL EQUIVALENT and national certification MAY prescribe, dispense, order and administer drugs, including legend drugs and Schedule II through Schedule V controlled substances, AS DEFINED IN THE ACT OF APRIL 14, 1972 (P.L.233, NO.64), KNOWN AS THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT, provided that the ~~midwife~~ NURSE-MIDWIFE demonstrates to the board that: <--

(i) The ~~nurse-midwife~~ NURSE-MIDWIFE has successfully completed at least 45 hours of coursework specific to

advanced pharmacology at a level above that required by a professional nursing education program.

(ii) As a condition of biennial license renewal by the board, a ~~nurse-midwife~~ NURSE-MIDWIFE shall complete the continuing education requirement as required by the act of May 22, 1951 (P.L.317, No.69), known as The Professional Nursing Law. In case of a ~~nurse-midwife~~ NURSE-MIDWIFE who has prescriptive authority under this act, the continuing education required by The Professional Nursing Law, shall include at least 16 hours in pharmacology in that two-year period.

(iii) The ~~nurse-midwife~~ NURSE-MIDWIFE acts in accordance with a collaborative agreement with a physician which shall at a minimum identify the categories of drugs from which the ~~nurse-midwife~~ NURSE-MIDWIFE may prescribe or dispense and.the drugs which require referral, consultation or comanagement.

(iv) The ~~nurse-midwife~~ NURSE-MIDWIFE acts in accordance with the following restrictions:

(A) A ~~nurse-midwife~~ NURSE-MIDWIFE shall not prescribe, dispense, order or administer a controlled substance except for a woman's acute pain. In the case of a Schedule II controlled substance, the dose shall be limited to 72 hours and shall not be extended except with the approval of the collaborating physician. In the case of a Schedule III or IV controlled substance, the prescription shall be limited to 30 days and shall only be refilled with the approval of the collaborating physician.

(B) A ~~nurse-midwife~~ NURSE-MIDWIFE shall prescribe, dispense, order or administer psychotropic drugs only after consulting with the collaborating physician.

(3) A ~~nurse-midwife~~ NURSE-MIDWIFE may, in accordance with a collaborative agreement with a physician and consistent with the ~~midwife's~~ NURSE-MIDWIFE'S academic educational preparation and national certification, prescribe, dispense, order and administer:

(i) Medical devices.

(ii) Immunizing agents.

(iii) Laboratory tests.

(iv) Therapeutic, diagnostic and preventative measures.

(d) Collaborative agreements.--The physician with whom a ~~nurse-midwife~~ NURSE-MIDWIFE has a collaborative agreement shall have hospital clinical privileges in the specialty area of the care for which the physician is providing collaborative services.

Section ~~2~~ 3. The State Board of Medicine shall promulgate regulations to implement the amendment of section 35 of the act within 12 months of the effective date of this act. The board shall report every three months on the status of the regulations to the Consumer Protection and Professional Licensure Committee of the Senate and the Professional Licensure Committee of the House of Representatives. <--

Section ~~3~~ 4. This act shall take effect in 60 days. <--

HB 1255 By Representatives WATERS, MYERS, JOSEPHS, BLACKWELL, EACHUS, MANDERINO, PASHINSKI, SOLOBAY, FREEMAN, KULA, LEACH, MURT, EVERETT, CONKLIN, GIBBONS, KORTZ, PICKETT, STABACK, JAMES, SHAPIRO, CALTAGIRONE, CURRY and SIPTROTH.

Prior Printer's Nos. 1550, 1987, 2177. Printer's No. 2290.

An Act amending the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, providing for the definition of "legend drug"; and further providing for nurse-midwife license.

Referred to PROFESSIONAL LICENSURE, May 10, 2007
Reported as amended, June 19, 2007
First consideration, June 19, 2007
Re-committed to RULES, June 19, 2007
Re-reported as committed, June 20, 2007
Second consideration, June 21, 2007
Re-committed to APPROPRIATIONS, June 21, 2007
Re-reported as committed, June 25, 2007
Third consideration and final passage, June 26, 2007 (201-0)
In the Senate
Referred to CONSUMER PROTECTION AND PROFESSIONAL LICENSURE, June 30, 2007
Reported as amended, June 30, 2007
First consideration, June 30, 2007
Re-referred to APPROPRIATIONS, July 5, 2007
Re-reported as amended, July 10, 2007
Second consideration, July 11, 2007
Third consideration and final passage, July 12, 2007 (48-0)
(Remarks see Senate Journal Page), July 12, 2007
In the House
Referred to RULES, July 13, 2007
Reported as committed, July 13, 2007
House concurred in Senate amendments, July 13, 2007 (200-0)
Signed in House, July 13, 2007
Signed in Senate, July 14, 2007
Presented to the Governor, July 15, 2007
Approved by the Governor, July 20, 2007
Act No. 50

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

December 5, 2007

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Medicine
16A-4926: Nurse Midwife Prescriptive Authority

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to nurse midwife prescriptive authority.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Charles D. Hummer, Jr., M.D., Chairperson
State Board of Medicine

CDH/SIH:klh
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert H. Masland, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Gerald S. Smith, Senior Counsel in Charge
Department of State
Sabina I. Howell, Counsel
State Board of Medicine
State Board of Medicine

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-4926
SUBJECT:	NURSE MIDWIFE PRESCRIPTIVE AUTHORITY
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF MEDICINE

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
12/5/07		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Sturla
12/5/07		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Tomlinson
12/5/07		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
12/5/07		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

November 5, 2007