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IRRC
Independent Regulatory Review Commission

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SECTION I: PROFILE

(1) Agency:
Department of State, Bureau of Professional and Occupational Affairs, State Board of Osteopathic Medicine

(2) Agency Number:

Identification Number:
16A-5318

IRRC Number: 2644.

(3) Short Title:
Physician assistant prescriptive authority

(4) PA Code Cite:
49 Pa. Code §§ 25.142, 25.162 and 25.177-25.178

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: **Thomas A. Blackburn, Regulatory unit counsel, Department of State; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; tblackburn@state.pa.us**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; jmckeever@state.pa.us**

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5: **State Board of Osteopathic Medicine (717)783-4858; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-osteopathic@state.pa.us**

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- X Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

Regulatory Analysis Form

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

This rulemaking implements prescriptive authority for physician assistants practicing under the supervision of osteopathic physicians, as authorized by section 10(p) of the Osteopathic Medical Practice Act (act) (63 P.S. § 271.10(p)).

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments:	11/19/2007
B. The date or dates on which public meetings or hearings will be held:	N/A
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	Publication
D. The expected effective date of the final-form regulation:	Publication
E. The date by which compliance with the final-form regulation will be required:	Effective date
F. The date by which required permits, licenses or other approvals must be obtained:	N/A

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

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the second Wednesday of each month. More information can be found on the Board's website (www.dos.state.pa.us/ost).

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by sections 10(h) and 10(p) of the act (63 P.S. §§ 271.10(h) and 271.10(p)).

Regulatory Analysis Form

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Yes. Section 10(p) of the act requires the State Board of Osteopathic Medicine (Board) and the State Board of Pharmacy "to jointly develop regulations to permit a physician assistant to prescribe and dispense drugs at the direction of a licensed physician."

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

In enacting section 10(p) of the act, the General Assembly recognized the need to provide prescriptive authority to physician assistants licensed by the Board. Patients, physician assistants, physicians, pharmacists and other health care workers will benefit from the rulemaking by establishing prescriptive privileges for physician assistants practicing under the supervision of osteopathic physicians that are consistent with those currently in effect for physician assistants practicing under the supervision of physicians licensed by the State Board of Medicine.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

This rulemaking is not based upon any scientific data, studies, or references.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

The Board does not foresee any groups being adversely affected by the rulemaking.

(16) 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.

All physician assistants and osteopathic physicians licensed by the Board will be required to comply with the rulemaking. The Board currently licenses approximately 6,000 osteopathic physicians and certifies approximately 3,200 physician assistants who may practice under the supervision of a physician.

SECTION III: COST AND IMPACT ANALYSIS

(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. Explain how the dollar estimates were derived.

Because the rulemaking permits physician assistants to prescribe under the supervision of a physician, rather than the physician personally prescribing, the Board estimates that there will be an unquantifiable savings to patients as a whole. There are no other costs or savings to the regulated community associated with compliance with the proposed rulemaking.

(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. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with compliance with the proposed 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. Explain how the dollar estimates were derived.

There are no costs or savings to state government associated with compliance with the proposed rulemaking.

(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:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	NA	NA	NA	NA	NA	NA
COSTS:						
Regulated Community						
Local Government						

State Government						
Total Costs	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**

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

Program	FY –3 (FY 05-06)	FY –2 (FY 06-07)	FY –1 (FY 07-08) projected	Current FY (FY 08-09) budgeted
Pa. State Board of Osteopathic Medicine	$818,896	$822,869	$761,791	$1,349,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

No adverse effects or costs have been associated with compliance with the proposed rulemaking. Therefore, the anticipated savings to patients from better utilization of the education, training and skill of physician assistants in prescribing outweighs any anticipated costs of compliance.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

In drafting the proposed rulemaking, the Board received input from the Pennsylvania Society of Physician Assistants and the Pennsylvania Osteopathic Medical Association. Both the Board and the State Board of Pharmacy discussed the proposed and final rulemakings at regular public board meetings, which are routinely attended by members of the regulated communities, their professional associations and other stakeholders.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered.

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 regulations.

The rulemaking is not more stringent and does not overlap or conflict with any federal requirements.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

Physician assistants in Delaware, Maryland, New Jersey and New York, Ohio and West Virginia may have prescriptive authority and may prescribe within certain limitations.

The rulemaking is consistent with regulations of the State Board of Medicine and will not put Pennsylvania at a competitive disadvantage with other states.

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

This proposed regulation would not affect other regulations of the Board or other state agencies.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This proposed rulemaking would not require any additional recordkeeping or other paperwork.

(28) 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 determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

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

State Board of Osteopathic Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5318

_____
DATE OF ADOPTION:

BY: _____
Joseph C. Gallagher, Jr., DO

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: _____
Andrew C. Clark

MAY 21 2009
DATE OF APPROVAL

(Deputy General Counsel
(~~Chief Counsel~~,
~~Independent Agency~~
(Strike inapplicable title)

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

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

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE

49 Pa. Code, Chapter 25, Subchapter C
§§ 25.142, 25.162, 25.177-25.178
PHYSICIAN ASSISTANT PRESCRIPTIVE AUTHORITY

The State Board of Osteopathic Medicine (Board) amends its regulations by amending §§ 25.142 and 25.162 (relating to definitions; criteria for registration as supervising physician) and adding §§ 25.177-25.178 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices; medical records), to read as set forth in Annex A.

Description and Need for the Rulemaking

Section 10(p) of the Osteopathic Medical Practice Act (act) (63 P.S. § 271.10(p)) authorizes the Board to promulgate jointly with the State Board of Pharmacy regulations "to permit a physician assistant to prescribe and dispense drugs at the direction of a licensed physician." Because the Board has not yet promulgated regulations to implement this statutory provision, physician assistants practicing under the direction of a physician licensed by the Board do not yet have prescriptive privileges. This situation has caused a great deal of confusion in health care settings, because a physician assistant licensed by the State Board of Medicine (medical board) is permitted to prescribe and dispense drugs under the direction of a physician licensed by the medical board in accordance with the medical board's regulation at 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices). This rulemaking is intended to resolve this confusion by permitting physician assistants who are practicing under the direction of an osteopathic physician to prescribe drugs in a manner similar to the practice of physician assistants under the direction of physicians licensed by the medical board.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 37 Pa.B. 5598 (October 20, 2007) with a 30-day public comment period. The Board received written comments from the following members of the public: the Pennsylvania Rural Health Association, the Pennsylvania Society of Physician Assistants, the Pennsylvania Osteopathic Medical Association (POMA), and the Pennsylvania Medical Society. The Board also received written public comments from a large number of physician assistant students, certified physician assistants (practicing under the supervision of both medical doctors and osteopathic physicians), medical doctors and osteopathic physicians, instructors in physician assistant education programs, osteopathic medical students, and pharmacists, all of whom generally urged the Board to finally promulgate regulations authorizing a physician assistant practicing under the supervision of an osteopathic physician to prescribe drugs. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1-745.12). The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

Many commenters strongly encouraged the Board to align its physician assistant prescription authority regulations with those of the medical board. Because ensuring the provisions mandate the same requirements for both areas of medical practice would alleviate any confusion and provide consistency in the various practice settings, the HPLC also commented that the Board's regulations should be consistent with those of the medical board. IRRC agreed and urged the Board to amend proposed §§ 25.177(a)(3), 25.177(c), 25.177(d)(1), 25.177(d)(4) and 25.178 to match corresponding

provisions of the medical board's physician assistant prescriptive authority regulations. The Board has attempted to be as consistent as possible with the medical board's requirements for physician assistant prescribing and dispensing of drugs.

The HPLC noted that proposed § 25.177(a)(3) requires a physician assistant to notify the supervising physician "as soon as possible, but in no event longer than 24 hours from the issuance of" a prescription for a Schedule II controlled substance. The HPLC questioned whether the means of notifying the supervising physician is left to the discretion of the physician or physician assistant. The Board has not set forth in its regulation the means of notification, but will leave that to the physician and the supervising physician to determine as part of their practice, whether or not included in the written agreement. The medical board also does not specify the means of notification in its requirement at § 18.158(a)(3).

The HPLC also noted that proposed § 25.177(a)(3) would permit a physician assistant to write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal of a prior prescription and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to writing the renewal. The HPLC contrasted this provision with the medical board regulation at § 18.158(a)(3) (physician assistant may write prescription for Schedule II controlled substance for up to a 30-day supply if approved by supervising physician for ongoing therapy). POMA opposed permitting a physician assistant to prescribe Schedule II narcotics without the involvement of the supervising physician. In response to these comments, the Board initially revised the rulemaking to permit a physician assistant to write a prescription for a Schedule II controlled substance for up to a 30-day supply of ongoing therapy if the patient was examined within the first 30 days by the supervising physician. However, upon disapproval by IRRC as discussed below, the Board again revised this provision to read as follows (with emphasis to identify the revised provisions):

> (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. <u>The physician assistant shall have no authority to prescribe a Schedule II controlled substance after the initial therapy of up to a 72-hour dose, until the patient has been examined by the supervising physician and the supervising physician has reviewed and approved the prescription of a Schedule II controlled substance by the physician assistant for up to a 30-day supply. Thereafter, (i) if the supervising physician determines and documents that the patient is chronically ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply of the Schedule II controlled substance, only if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 30 days; and (ii) if the supervising physician determines and documents that the patient is terminally ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the prescription of a Schedule II controlled substance by the physician assistant is</u>

reviewed and approved by the supervising physician at least every 120 days. The prescription must clearly state on its face that it is for initial or ongoing therapy.

As stated in the Board's report pursuant to section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)):

> The Board adopted this revision of § 25.177(a)(3) in order to clarify the words of the regulation and implement the intent of a majority of the Board members when it took formal action to approve the rulemaking.
>
> The Board focused on the clarity and scope of the words "ongoing therapy" in the sentence: "A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30 day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician." Board members were concerned that this language is unduly vague, could be subject to multiple interpretations and did not adequately express the intent of the Board that there be ongoing physician involvement in the prescription of Schedule II controlled substances by physician assistants with respect to chronic conditions. The added language was adopted to make crystal clear the intent and requirements of the rulemaking.
>
> It is important to note that this subsection deals with **only** the prescription of Schedule II controlled substances. These are defined in Pennsylvania law as substances with "a high potential for abuse, currently accepted medical use in the United States, or currently accepted medical use with severe restrictions, and abuse may lead to severe psychic or physical dependence." 35 P.S. § 780-104(2) (emphasis added). The Board strongly believes that, for the protection of the public, ongoing physician supervision and involvement with patient care is essential for the long-term prescription of Schedule II controlled substances. The Board believes that this revision clarifies the wording of the rulemaking. The requirement for ongoing involvement of physicians is particularly important with respect to the prescription of substances where, in the words of the statute, "abuse may lead to severe psychic or physical dependence." The language adopted by the Board will help to make certain that the public is protected when physician assistants prescribe Schedule II controlled substances.

The HPLC questioned whether the term "professional samples" as used in proposed § 25.277(a)(5) (physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients) would include scheduled drugs and, if so, whether there would be appropriate oversight. These professional samples do not include scheduled drugs. Believing that doing so should be the responsibility of the physician, POMA also opposed permitting a physician assistant to request, receive, sign for or distribute professional samples. The supervising physician, who is responsible to supervise the physician assistant, through their written agreement may set the parameters of the physician assistant's prescribing and dispensing of drugs, including

involvement with professional samples. The Board has not revised the rulemaking in response to this comment. The medical board's requirement at § 18.158(a)(5) is identical.

The HPLC questioned when it would be appropriate for the physician assistant's DEA registration number to appear on the prescription as required by proposed § 25.177(b)(2) (signature of physician assistant must be followed by initials "PA-C" or similar designation to identify signer as physician assistant; when appropriate, physician assistant's DEA registration number must appear on prescription). It is appropriate to include the DEA registration number of a prescriber who prescribes a Schedule II drug. The medical board's requirement at § 18.158(b)(2) is identical.

The HPLC asked for clarification as to whether a pharmacy would be responsible for filling a prescription outside the physician assistant's authority and therefore an inappropriate prescription for which proposed § 25.177(c) would require the physician assistant or supervising physician to notify the pharmacy to discontinue. A pharmacist is always free to question a prescription, including contacting the physician assistant or supervising physician for additional information. Upon receipt of information that the physician assistant is not permitted to prescribe the specified drug or is otherwise prescribing outside the scope of the written agreement or Board requirements, the pharmacist may refuse to fill the prescription. The Board has also corrected the typographical error of the term "supervision physician" in § 25.177(c) to "supervising physician" as noted by the HPLC.

Finally, the HPLC questioned why proposed § 25.177(d)(4) requires the supervising physician to countersign the patient record at least weekly and proposed § 25.178 requires the supervising physician to review the medical records at least weekly, although the medical board only requires it to be done within 10 days. The Board believes that this shorter period of time of a round single week is easier to remember and simpler to apply. Additionally, within the definition of "supervision" at § 25.142, the Board previously set forth an appropriate degree of supervision to include "periodic and regular – at least weekly – review by the supervising physician of the patient records upon which entries are made by the physician assistant." And as discussed below, new § 25.162(a)(4)(vi) also requires the supervising physician to countersign the patient record within 10 days.

IRRC also noted that the Board had not defined the term "written agreement," though the medical board has defined it in § 18.122 (written agreement is defined as the agreement between the physician assistant and supervising physician, which satisfies the requirements of § 18.142 (relating to written agreements)). In § 25.142 (relating to definitions), the Board has now defined "written agreement" as "the agreement between the physician assistant and supervising physician, which satisfies the requirements of § 25.162(a)(4)." Because the proposed regulations did not include any provision equivalent to § 18.142, the Board has also revised § 25.162(a)(4) revised to include requirements substantially equivalent to those of § 18.142, substituting of course the term "osteopathic physician" for "medical doctor." In addition, § 25.162(a)(4)(ii) requires that the description of the manner in which the physician assistant will assist each named physician be in detail and that the functions to be delegated to the physician assistant include the procedures enumerated in § 25.171(a) (relating generally to physician assistant utilization). Section 25.162(a)(4)(iii) requires that the written agreement must describe detailed instructions for the use of

the physician assistant in the performance of delegated tasks. Section 25.162(a)(4)(iv) requires that the method and frequency, in addition to the time, place and manner, of supervision and direction each named physician will provide must be described in the written agreement. And, § 25.162(a)(4)(viii) requires that the written agreement provide the name, address and telephone number of at least two physicians who can substitute for the supervising physician whenever unavailable.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions and will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Effective date

The final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin.*

Statutory Authority

The final rulemaking is authorized under sections 10(h) and 10(p) of the act (63 P.S. §§ 271.10(h) and 271.10(p)).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 10, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 5598, to IRRC and the chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments received from IRRC, the HPLC, the SCP/PLC and the public.

The Board delivered the final rulemaking to IRRC and the chairpersons of the HPLC and the SCP/PLC on February 26, 2009. Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on March 10, 2009, the HPLC approved the final-form rulemaking. On April 1, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on April 2, 2009, and disapproved the final-form rulemaking. As stated in IRRC's order of disapproval received by the Board on April 13, 2009, IRRC disapproved the final-form regulation at the request of the Board, acting through its chair, in order to permit the Board to revise § 25.177(a)(3).

Under section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)), on May 11, 2009, the

Board delivered a revised final rulemaking to IRRC and the chairpersons of the HPLC and the SCP/PLC, including the report required by that section. Under section 7(c.1) of the Regulatory Review Act (71 P.S. § 745.7(c.1)), IRRC met on _____ ___, 2009, and approved the final-form rulemaking. Under section 7(d) of the Regulatory Review Act (71 P.S. § 745.7(d)), on _____ ___, 2009, the final-form rulemaking was approved by the HPLC. On _____ ___, 2009, the final-form rulemaking was deemed approved by the SCP/PLC.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Regulatory Unit Counsel, Department of State, by mail to P.O. Box 2649, Harrisburg, PA 17105-2649, by telephone at (717) 783-4858, or by e-mail at st-osteo@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 37 Pa.B. 5598.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Osteopathic Medical Practice Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 25 are amended, by amending §§ 25.142 and 25.162 and by adding §§ 25.177-25.178, to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin.*

Joseph C. Gallagher, Jr., DO, Chairman
State Board of Osteopathic Medicine

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

SUBCHAPTER C. PHYSICIAN ASSISTANT PROVISIONS

GENERAL PROVISIONS

* * * * *

§ 25.142. Definitions.

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

* * * * *

WRITTEN AGREEMENT – THE AGREEMENT BETWEEN THE PHYSICIAN ASSISTANT AND SUPERVISING PHYSICIAN, WHICH SATISFIES THE REQUIREMENTS OF § 25.162(a)(4).

* * * * *

§ 25.162. Criteria for registration as supervising physician.

(a) The Board will approve for registration as a supervising physician, an applicant who:

* * * * *

(4) Has submitted ~~an application, approved by the Board, containing a detailed description of the manner in which the physician assistant will assist the physician in his practice, a list of functions to be delegated to the physician assistant including the procedures enumerated in § 25.171(a) (relating to generally) and other specified delegated tasks, detailed~~

~~instructions for the use of the physician assistant in the performance of delegated tasks, the method and frequency of supervision, the geographical location where the physician assistant will serve, and the name, address and telephone number of at least two physicians who can substitute for the applicant when he is either absent or otherwise unavailable.~~ A WRITTEN AGREEMENT THAT SATISFIES THE FOLLOWING REQUIREMENTS. THE AGREEMENT MUST:

(I) IDENTIFY AND BE SIGNED BY THE PHYSICIAN ASSISTANT AND EACH PHYSICIAN THE PHYSICIAN ASSISTANT WILL BE ASSISTING WHO WILL BE ACTING AS A SUPERVISING PHYSICIAN. AT LEAST ONE PHYSICIAN SHALL BE AN OSTEOPATHIC PHYSICIAN.

(II) DESCRIBE IN DETAIL THE MANNER IN WHICH THE PHYSICIAN ASSISTANT WILL BE ASSISTING EACH NAMED PHYSICIAN. THE DESCRIPTION MUST LIST FUNCTIONS TO BE DELEGATED TO THE PHYSICIAN ASSISTANT INCLUDING THE PROCEDURES ENUMERATED IN § 25.171(A) (RELATING TO PHYSICIAN ASSISTANT UTILIZATION GENERALLY) AND OTHER DELEGATED TASKS.

(III) DESCRIBE DETAILED INSTRUCTIONS FOR THE USE OF THE PHYSICIAN ASSISTANT IN THE PERFORMANCE OF DELEGATED TASKS.

(IV) DESCRIBE THE TIME, PLACE AND MANNER, METHOD AND FREQUENCY OF SUPERVISION AND DIRECTION EACH NAMED PHYSICIAN WILL PROVIDE THE PHYSICIAN ASSISTANT, INCLUDING THE FREQUENCY OF PERSONAL CONTACT WITH THE PHYSICIAN

ASSISTANT.

(V) DESIGNATE ONE OF THE NAMED PHYSICIANS WHO SHALL BE AN OSTEOPATHIC PHYSICIAN AS THE PRIMARY SUPERVISING PHYSICIAN.

(VI) REQUIRE THAT THE SUPERVISING PHYSICIAN SHALL COUNTERSIGN THE PATIENT RECORD COMPLETED BY THE PHYSICIAN ASSISTANT WITHIN A REASONABLE AMOUNT OF TIME. THIS TIME PERIOD MAY NOT EXCEED 10 DAYS.

(VII) IDENTIFY THE LOCATIONS AND PRACTICE SETTINGS WHERE THE PHYSICIAN ASSISTANT WILL SERVE.

(VIII) PROVIDE THE NAME, ADDRESS AND TELEPHONE NUMBER OF AT LEAST TWO PHYSICIANS WHO CAN SUBSTITUTE FOR THE APPLICANT WHEN HE IS EITHER ABSENT OR OTHERWISE UNAVAILABLE.

* * * * *

PHYSICIAN ASSISTANT UTILIZATION

* * * * *

§ 25.177. Prescribing and dispensing drugs, pharmaceutical aids and devices.

(a) *Prescribing, dispensing and administration of drugs.*

(1) The supervising physician may delegate to the physician assistant the prescribing, dispensing and administering of drugs and therapeutic devices.

(2) A physician assistant may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substances, Drug, Device, and

Cosmetic Act (35 P.S. §780-104).

(3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. ~~A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to the writing of the renewal.~~ THE PHYSICIAN ASSISTANT SHALL HAVE NO AUTHORITY TO PRESCRIBE A SCHEDULE II CONTROLLED SUBSTANCE AFTER THE INITIAL THERAPY OF UP TO A 72-HOUR DOSE, UNTIL THE PATIENT HAS BEEN EXAMINED BY THE SUPERVISING PHYSICIAN AND THE SUPERVISING PHYSICIAN HAS REVIEWED AND APPROVED THE PRESCRIPTION OF A SCHEDULE II CONTROLLED SUBSTANCE BY THE PHYSICIAN ASSISTANT FOR UP TO A 30-DAY SUPPLY. THEREAFTER, (I) IF THE SUPERVISING PHYSICIAN DETERMINES AND DOCUMENTS THAT THE PATIENT IS CHRONICALLY ILL, THE PHYSICIAN ASSISTANT MAY WRITE A PRESCRIPTION FOR A SCHEDULE II CONTROLLED SUBSTANCE FOR UP TO A 30-DAY SUPPLY OF THE SCHEDULE II CONTROLLED SUBSTANCE, ONLY IF THE PRESCRIPTION OF A SCHEDULE II CONTROLLED SUBSTANCE BY THE PHYSICIAN ASSISTANT IS REVIEWED AND APPROVED BY THE SUPERVISING PHYSICIAN AT LEAST EVERY 30 DAYS; AND (II) IF THE SUPERVISING PHYSICIAN DETERMINES AND DOCUMENTS THAT THE PATIENT IS

TERMINALLY ILL, THE PHYSICIAN ASSISTANT MAY WRITE A PRESCRIPTION FOR A SCHEDULE II CONTROLLED SUBSTANCE FOR UP TO A 30-DAY SUPPLY IF THE PRESCRIPTION OF A SCHEDULE II CONTROLLED SUBSTANCE BY THE PHYSICIAN ASSISTANT IS REVIEWED AND APPROVED BY THE SUPERVISING PHYSICIAN AT LEAST EVERY 120 DAYS. The prescription must clearly state on its face that it is for initial or ongoing therapy.

(4) A physician assistant may only prescribe or dispense a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant and only in accordance with the supervising physician's instructions and written agreement.

(5) A physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients.

(6) A physician assistant authorized to prescribe or dispense, or both, controlled substances shall register with the 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 physician assistant and the name of the physician assistant in printed format at the heading of the blank. The supervising physician's name and license number must also be printed or preprinted on the prescription.

(2) The signature of a physician assistant must be followed by the initials "PA-C" or similar designation to identify the signer as a physician assistant. When appropriate, the physician assistant's DEA registration number must appear on the prescription.

(3) The supervising physician is prohibited from presigning prescription blanks.

(4) The physician assistant may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.

(c) *Inappropriate prescription.* The supervising physician shall immediately advise the patient, notify the physician assistant and, in the case of a written or oral prescription, advise the pharmacy if the physician assistant is prescribing or dispensing a drug inappropriately. The supervising physician shall advise the patient and notify the physician assistant to discontinue using the drug and, in the case of a written or oral prescription, notify the pharmacy to discontinue the prescription. The order to discontinue use of the drug or prescription shall be noted in the patient's medical record by the ~~supervision~~ SUPERVISING physician.

(d) *Recordkeeping requirements.* Recordkeeping requirements are as follows:

(1) When prescribing a drug, the physician assistant 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 physician assistant's name in the patient's medical records.

(2) When dispensing a drug, the physician assistant shall record the physician assistant'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.

(3) The physician assistant shall report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to prescribe or dispense in accordance with the written agreement.

(4) The supervising physician shall countersign the patient record at least weekly

in accordance with § 25.178 (relating to medical records).

(5) The physician assistant and the supervising physician shall provide immediate access to the written agreement to anyone seeking to confirm the physician assistant's authority to prescribe or dispense a drug. The written agreement must list the categories of drugs which the physician assistant is not permitted to prescribe.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A physician assistant shall comply with this section and with the regulations of the Department of Health at 28 Pa. Code §§ 25.51 – 25.58 and 25.91 – 25.95 (relating to prescriptions; and labeling of drugs, devices and cosmetics).

§ 25.178. Medical records.

The supervising physician shall timely review, at least weekly, the medical records prepared by the physician assistant to ensure that the requirements of § 25.213 (relating to medical records) have been satisfied.

REPORT OF THE STATE BOARD OF OSTEOPATHIC MEDICINE:

RESPONSE TO IRRC'S ORDER DISAPPROVING FINAL RULEMAKING 16A-5318 (PHYSICIAN ASSISTANT PRESCRIPTIVE AUTHORITY)

On February 26, 2009, the State Board of Osteopathic Medicine delivered final rulemaking 16A-5318 (physician assistant prescriptive authority) to the Independent Regulatory Review Commission (IRRC), the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC). On March 11, 2009, the HPLC approved this final rulemaking, and on April 1, 2009, the SCP/PLC was deemed to have approved the final rulemaking. At its meeting on April 2, 2009, IRRC disapproved the final rulemaking. As stated in its disapproval order of April 13, 2009, IRRC disapproved the final rulemaking at the request of the Board, acting through its chair, in order to permit the Board to revise § 25.177(a)(3) (relating to physician assistant prescribing Schedule II controlled substance). IRRC found that without support from the promulgating agency, this regulation does not meet the reasonableness criterion set forth in the Regulatory Review Act and is not in the public interest under section 5.2(b)(3) of the Regulatory Review Act (71 P.S. § 745.5b(b)(3)). The Board has revised the final rulemaking under section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)) and now submits this report responding to IRRC's disapproval order, as required by section 7(c) and 1 Pa. Code § 311.3(3).

As initially proposed, § 25.177(a)(3) would have provided:

> (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to the writing of the renewal. The prescription must clearly state on its face that it is for initial or ongoing therapy.

In response to comments from the public and IRRC, the Board initially revised this section to read as follows (with emphasis supplied to show the changes):

> (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician. The prescription must clearly state on its face that it is for initial or ongoing therapy.

At its meeting April, 8, 2009, the Board approved this section to read as follows (with emphasis supplied to show the changes):

> (3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. The physician assistant shall have no authority to prescribe a Schedule II controlled substance after the initial therapy of up to a 72-hour dose, until the patient has been examined by the supervising physician and the supervising physician has reviewed and approved the prescription of a Schedule II controlled substance by the physician assistant for up to a 30-day supply. Thereafter, (i) if the supervising physician determines and documents that the patient is chronically ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply of the Schedule II controlled substance, only if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 30 days; and (ii) if the supervising physician determines and documents that the patient is terminally ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 120 days. The prescription must clearly state on its face that it is for initial or ongoing therapy.

The Board adopted this revision of § 25.177(a)(3) in order to clarify the words of the regulation and implement the intent of a majority of the Board members when it took formal action to approve the rulemaking.

The Board focused on the clarity and scope of the words "ongoing therapy" in the sentence: "A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30 day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician." Board members were concerned that this language is unduly vague, could be subject to multiple interpretations and did not adequately express the intent of the Board that there be ongoing physician involvement in the prescription of Schedule II controlled substances by physician assistants with respect to chronic conditions. The added language was adopted to make crystal clear the intent and requirements of the rulemaking.

It is important to note that this subsection deals with **only** the prescription of Schedule II controlled substances. These are defined in Pennsylvania law as substances with "a high potential for abuse, currently accepted medical use in the United States, or currently accepted medical use with severe restrictions, and abuse may lead to severe psychic or physical dependence." 35 P.S. § 780-104(2) (emphasis added). The Board strongly believes that, for the protection of the public, ongoing physician supervision and involvement with patient care is essential for the long-term prescription of Schedule II controlled substances. The Board believes that this revision clarifies the wording of the rulemaking. The requirement for ongoing involvement of physicians is particularly important with respect to the prescription of substances where, in the words of the statute, "abuse may lead to severe psychic or physical dependence." The language adopted by the Board will help to make certain that the public is protected when physician assistants prescribe Schedule II controlled substances.

Joseph C. Gallagher, Jr., DO, Chairman
State Board of Osteopathic Medicine

Comments shall be submitted within 30 days of the publication of this Secretarial Letter in the *Pennsylvania Bulletin*. Reply comments may be filed 20 days thereafter.

JAMES J. MCNULTY,
Secretary

[Pa.B. Doc. No. 07-1898. Filed for public inspection October 19, 2007, 9:00 a.m.]

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Prescriptive Privileges for Physician Assistants

The State Board of Osteopathic Medicine (Board) proposes to adopt §§ 25.177 and 25.178 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices; and medical records), to read as set forth in Annex A.

A. *Effective Date*

The proposed rulemaking will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

Section 10(h) and (p) of the Osteopathic Medical Practice Act (act) (63 P. S. § 271.10(h) and (p)) authorizes the Board to promulgate this rulemaking. Section 10(h) of the act provides the Board the general authority to "establish such rules and regulations, relating to physician assistants, as it deems necessary to protect the public and to implement the provisions of [the] act." Section 10(p) of the act requires the Board to work with the State Board of Pharmacy to "jointly develop regulations to permit a physician assistant to prescribe and dispense drugs at the direction of a licensed physician." This proposed rulemaking was jointly developed and approved by the Board and the State Board of Pharmacy at regularly scheduled public meetings.

C. *Background and Purpose*

Currently, physician assistants are permitted to prescribe and dispense drugs under the direction of a physician licensed by the Board in accordance with 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices). At this time, however, physician assistants practicing under the direction of a physician licensed by the Board do not have prescriptive privileges. This situation has caused a great deal of confusion in health care settings. This proposed rulemaking is intended to resolve this confusion by permitting physician assistants who are practicing under the direction of an osteopathic physician to prescribe drugs in a manner similar to the practice of physician assistants under the direction of allopathic physicians.

D. *Description of Proposed Regulations*

Proposed § 25.177(a) would permit a supervising physician to delegate to the physician assistant the prescribing, dispensing and administering of drugs and therapeutic devices. Paragraph (2) would prohibit physician assistants from prescribing or dispensing Schedule I controlled substances. Paragraph (3) would allow them to prescribe or dispense Schedule II controlled drugs for initial therapy up to a 72-hour dose and requires that the physician assistant notify the supervising physician within 24 hours from the issuance of the prescription. It would also allow a physician assistant to write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to the writing of the renewal. The prescription would have to clearly state on its face that it is for initial or ongoing therapy.

There are many physician and physician assistant specialties that deal with chronic pain management. In specialties such as oncology, surgery or anesthesiology, and in the family practice setting, physician assistants are an integral part of patient care. Managing the patients' pain in those settings often requires the ability to write prescriptions for Schedule II narcotics on both a short- and long-term basis. At times, patients may require ongoing therapy or need to renew prescriptions when the physician is not immediately available but the physician assistant is available. Also, there are many physician assistants that work in settings such as emergency rooms, walk-in clinics and industrial clinics. The inability to write a prescription for a Schedule II narcotic impedes the care of the patient in these settings. Allowing for a 72-hour supply of medicine until a physician sees that patient enhances the care rendered by the physician assistant.

Section 25.177(a)(4) would permit a physician assistant to prescribe or dispense only if the patient is under the care of the supervising physician and only in accordance with the supervising physician's instructions and written agreement. Section 25.177(a)(5) would permit a physician assistant to request, receive and sign for professional samples and distribute professional samples to patients. Section 25.177(a)(6) would require a physician assistant authorized to prescribe or dispense controlled substances to register with the Drug Enforcement Administration.

Section 25.177(b) would set forth provisions pertaining to prescription blanks and would prohibit a supervising physician from presigning prescription blanks. Section 25.177(c) would require the supervising physician to immediately advise the patient, notify the physician assistant and, in the case of a written or oral prescription, advise the pharmacy, if the physician assistant is prescribing or dispensing a drug inappropriately. In addition, the order to discontinue use of the drug or prescription would be required to be noted in the patient's medical record by the supervising physician.

Section 25.177(d) would set forth the requirements for recordkeeping relating to prescriptions written by physician assistants. In particular, a physician assistant would be required to keep a copy of the prescription and number of refills in a file; and the physician assistant would be required to record the physician assistant's name, name of the medication, amount and dose of medication dispensed and date of medication dispensed in the patient's medical records. The physician assistant would be required to report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to prescribe or dispense in accordance with the written agreement. Paragraph (4) would require that the supervising physician countersign the

patient record at least weekly. Paragraph (5) would require that a physician assistant comply with these regulations and Department of Health regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.

Section 25.178 would require that the supervising physician timely review, at least weekly, the medical records prepared by the physician assistant to ensure that the existing requirements pertaining to medical records have been satisfied.

E. *Input form the Regulated Community*

The Board solicited input from the Pennsylvania Society of Physician Assistants and the Pennsylvania Osteopathic Medical Association. In addition, as required by section 10(p) of the Osteopathic Medical Practice Act, the proposed rulemaking was reviewed and approved by the State Board of Pharmacy.

F. *Fiscal Impact and Paperwork Requirements*

The proposed rulemaking would have no adverse fiscal impact on the Commonwealth or its political subdivisions and would impose no additional paperwork requirements on the Commonwealth or the public sector.

G. *Sunset Date*

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

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 10, 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 Boards, the General Assembly and the Governor of comments, recommendations or objections raised.

I. *Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Beth Michlovitz, Board Counsel, State Board of Osteopathic Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of the proposed rulemaking in the *Pennsylvania Bulletin*.

CHARLES P. FASANO, D. O.,
Chairperson

Fiscal Note: 16A-5318. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter C. PHYSICIAN ASSISTANT PROVISIONS

PHYSICIAN ASSISTANT UTILIZATION

§ 25.177. Prescribing and dispensing drugs, pharmaceutical aids and devices.

(a) *Prescribing, dispensing and administration of drugs.*

(1) The supervising physician may delegate to the physician assistant the prescribing, dispensing and administering of drugs and therapeutic devices.

(2) A physician assistant may not prescribe or dispense Schedule I controlled substances as defined by section 4 of The Controlled Substances, Drug, Device and Cosmetic Act (35 P. S. § 780-104).

(3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the patient was examined at the time of renewal and the patient's ongoing therapy was reviewed and approved by the supervising physician prior to the writing of the renewal. The prescription must clearly state on its face that it is for initial or ongoing therapy.

(4) A physician assistant may only prescribe or dispense a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant and only in accordance with the supervising physician's instructions and written agreement.

(5) A physician assistant may request, receive and sign for professional samples and may distribute professional samples to patients.

(6) A physician assistant authorized to prescribe or dispense, or both, controlled substances shall register with the 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 physician assistant and the name of the physician assistant in printed format at the heading of the blank. The supervising physician's name and license number must also be printed or preprinted on the prescription.

(2) The signature of a physician assistant must be followed by the initials "PA-C" or similar designation to identify the signer as a physician assistant. When appropriate, the physician assistant's DEA registration number must appear on the prescription.

(3) The supervising physician is prohibited from presigning prescription blanks.

(4) The physician assistant may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.

(c) *Inappropriate prescription.* The supervising physician shall immediately advise the patient, notify the physician assistant and, in the case of a written or oral prescription, advise the pharmacy if the physician assistant is prescribing or dispensing a drug inappropriately. The supervising physician shall advise the patient and notify the physician assistant to discontinue using the drug and, in the case of a written or oral prescription, notify the pharmacy to discontinue the prescription. The order to discontinue use of the drug or prescription shall be noted in the patient's medical record by the supervision physician.

(d) *Recordkeeping requirements.* Recordkeeping requirements are as follows:

(1) When prescribing a drug, the physician assistant 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 physician assistant's name in the patient's medical records.

(2) When dispensing a drug, the physician assistant shall record the physician assistant'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.

(3) The physician assistant shall report, orally or in writing, to the supervising physician within 36 hours, a drug prescribed or medication dispensed by the physician assistant while the supervising physician was not physically present, and the basis for each decision to prescribe or dispense in accordance with the written agreement.

(4) The supervising physician shall countersign the patient record at least weekly in accordance with § 25.178 (relating to medical records).

(5) The physician assistant and the supervising physician shall provide immediate access to the written agreement to anyone seeking to confirm the physician assistant's authority to prescribe or dispense a drug. The written agreement must list the categories of drugs which the physician assistant is not permitted to prescribe.

(e) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A physician assistant shall comply with this section and with the regulations of the Department of Health in 28 Pa. Code §§ 25.51—25.58 and 25.91—25.95 (relating to prescriptions; and labeling of drugs, devices and cosmetics).

§ 25.178. Medical records.

The supervising physician shall timely review, at least weekly, the medical records prepared by the physician assistant to ensure that the requirements of § 25.213 (relating to medical records) have been satisfied.

[Pa.B. Doc. No. 07-1899. Filed for public inspection October 19, 2007, 9:00 a.m.]

State Board of Osteopathic Medicine
Regulation 16A-5318: Prescriptive Privileges for Physician Assistants
Proposed Regulation

PROPOSAL: Regulation 16A-5318 is Proposed Regulation which was delivered to the House Professional Licensure Committee on October 10, 2007. The House Professional Licensure Committee has until December 10, 2007 to submit comments on the Proposed Regulation.

PROPOSED REGULATION ANALYSIS: Regulation 16A-5318 would add §§25.177 and 25.178 of the State Board of Osteopathic Medicine regulations. The additions are as follows:

Section 25.177(a), "Prescribing, dispensing, and administration of drugs," permits a physician assistant to prescribe, dispense, and administer drugs and therapeutic devices in accordance with the following guidelines:

- Schedule I drugs:
  - Physician assistants are not permitted to dispense or prescribe any drugs in this class
- Schedule II drugs:
  - Physician assistants are authorized to prescribe initial therapy for a dose lasting no longer than 72 hours.
  - After a physician reviews and approves a patient's therapy, the physician assistant may write a prescription for a 30 day supply.
  - The prescription must clearly state that it is prescribed for initial or ongoing therapy.
- Miscellaneous requirements:
  - A physician assistant may only prescribe a drug for a patient if that patient is under the care of the physician supervising the physician assistant.
  - A physician assistant may dispense professional samples to patients.
  - In order to prescribe or dispense any scheduled substances, they must register with the Drug Enforcement Administration.

Section 25.177(b), "Prescription blanks," requires a prescription blank to include the name and license number of the physician assistant, if prescribing scheduled drugs the DEA registration number, the name and license number of the supervising physician, and the signature of the physician assistant followed by the initials PA-C or similar designation. The physician is prohibited from presigning prescription blanks. A prescription blank may be generated by a hospital as long as the required information is printed on them.

Section 25.177(c), "Inappropriate prescription," requires that the physician immediately:

- notify the patient and advise them to discontinue use;
- notify the pharmacy if the physician assistant is prescribing a drug inappropriately and if the prescription to a certain patient must be discontinued;
- and notify the physician assistant
- note in the patient's record that the physician ordered the patient to discontinue use of the drug.

Section 25.177(d), "Recordkeeping requirements." A physician assistant shall keep a copy of the prescription and number of refills in the physician assistant's ready reference file, or record the name, dose, number of refills, date of prescription, and the physician assistant name in the patient's records. Within 36 hours, the physician assistant must report to the supervising physician any drug prescribed or dispensed and the reasoning for prescribing the drug. The supervising physician must countersign the patient record weekly. The written agreement between the physician and the physician assistant must be made available to anyone seeking to confirm the physician assistant's ability to prescribe or dispense a drug. A written agreement must list the categories of drugs that a physician may not prescribe.

Section 25.177(e), "Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs." This provision requires a physician assistant to comply with this section and the Department of Health regulations.

Section 25.278, "Medical Records," requires the supervising physician to weekly review the medical records that the physician assistant prepared.

RECOMMENDATION: It is recommended the House Professional Licensure Committee take no formal action until final regulations are promulgated and submit the following comments:

1. The Committee suggests that the regulations under the Medical Board be consistent with those under the Osteopathic Medicine Board. Ensuring the provisions mandate the same requirements for both areas of medical practice would alleviate any confusion and provide consistency in the various practice settings.

2. In §25.177(a)(3), a physician assistant is required to notify the supervising physician of the prescription as soon as possible, but does not state how the physician is to be notified. The Committee would like to know if this is left up to the discretion of the physician or physician assistant.

3. In §25.177(a)(3), the proposed regulation adds language requiring the physician to examine the patient for a renewal of a prescription for a Schedule II drug. The Committee notes that the regulations for the allopathic physician assistants do not contain this requirement; and only requires a physician's approval.

4. The Committee would like clarification on the following points regarding §25.177(a)(3):
   A. Please clarify whether the patient must be examined by the physician or the physician assistant prior to the renewal of the prescription for the Schedule II drugs.
   B. Currently, is a patient examined prior to renewing a prescription for a Schedule II drug in allopathic practice? If not, how does the Board explain the difference between the requirements for the osteopathic physician assistant and the allopathic physician assistant?
   C. This provision requires a physician's approval and exam prior renewal for the Schedule II drug. However, in the allopathic bill, it merely states that the renewal of the prescription be for "ongoing therapy" with no requirement for physician's prior approval. The committee requests an explanation regarding the difference.

5. Section 25.177(d)(4) states that a physician shall countersign the patient record at least weekly, however, the allopathic requirement is within ten days. The Committee requests the reasoning for the shorter period of time.

6. In §25.277(a)(5), the Committee notes that a physician assistant may request, receive, and sign for professional samples and may distribute these to patients. Do professional samples include any scheduled drugs? If so, the Committee questions the lack of oversight for this in the regulation.

7. The Committee would like to know when it is appropriate for the physician assistant's DEA registration number to appear on the prescription, as stated in §25.277(b)(2).

8. With regard to §25.277(c), the Committee would like clarification as to whether pharmacies will need to know that a certain physician assistant is authorized to prescribe certain medications. If so, will the pharmacist be responsible for filling a prescription that a physician assistant writes inappropriately? Otherwise, will the responsibility for any inappropriate prescriptions fall on the supervising physician?

9. The Committee would like to point out a typographical error in §25.277(c). The last two words of the last sentence read "supervision physician" instead of "supervising physician."

House of Representatives
Professional Licensure Committee
December 4, 2007

PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

December 19, 2007

Charles P. Fasano, D.O., Chairperson
State Board of Osteopathic Medicine
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5318 (IRRC #2644)
State Board of Osteopathic Medicine
Prescriptive Privileges for Physician Assistants

Dear Chairperson Fasano:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable P. Michael Sturla, Majority Chairman, House Professional Licensure Committee
Honorable William F. Adolph, Jr., Minority Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Osteopathic Medicine Regulation #16A-5318 (IRRC #2644)

Prescriptive Privileges for Physician Assistants

December 19, 2007

We submit for your consideration the following comments on the proposed rulemaking published in the October 20, 2007 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Osteopathic Medicine (Board) to respond to all comments received from us or any other source.

1. Possible conflict with existing regulations.

This regulation will allow osteopathic physicians to delegate the prescribing, dispensing and administering of drugs and therapeutic devices to physician assistants. Under current regulations of the State Board of Medicine found at 49 Pa. Code §§ 18.158 and 18.159, medical doctors can delegate this authority to physician assistants. As noted by the Board, this situation has caused confusion in health care settings.

Commentators have stressed the importance of aligning this proposed rulemaking exactly with the existing regulations of the State Board of Medicine. This would eliminate any confusion that two different sets of regulations would create amongst the regulated community. We agree and urge the Board to amend the following sections of the proposed rulemaking to be consistent with the State Board of Medicine's regulations: § 25.177(a)(3); § 25.177(c); § 25.177(d)(1); § 25.177(d)(4); and § 25.178.

2. Written agreement. – Clarity.

The phrase "written agreement" is used in §§ 25.177(a)(4) and 25.177(d)(5). This phrase is not defined in 49 Pa. Code Chapter 25. We note that the phrase is defined in § 18.122 of the State Board of Medicine's regulations on physician assistants. We suggest that a definition of "written agreement" be added to this rulemaking.

HOUSE PROFESSIONAL LICENSURE COMMITTEE
2009-2010 LEGISLATIVE SESSION

Rep. Michael P. McGeehan, Chairman

Marlene Tremmel, Esq.,
Executive Director

Dianne I. Nichols, Esq.
Legal Counsel

March 11, 2009

Joseph C. Gallagher, Jr., D.O.
State Board of Osteopathic Medicine
P.O. Box 2649, Harrisburg, PA 17105-2649

RE: Final Omitted Regulation 16A-5318
State Board of Osteopathic Medicine
Prescriptive Privileges for Physician Assistants

Dear Dr. Gallagher

The House Professional Licensure Committee on this date approved Regulation 16A-5318

Sincerely,

Michael P. McGeehan
Chairman, House Professional Licensure Committee

PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

April 13, 2009

Joseph C. Gallagher, Jr., D.O., Chair
State Board of Osteopathic Medicine
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5318 (IRRC #2644)
State Board of Osteopathic Medicine
Prescriptive Privileges for Physician Assistants

Dear Mr. Gallagher:

The Independent Regulatory Review Commission disapproved your regulation on April 2, 2009. Our order is enclosed and will be available on our website at www.irrc.state.pa.us.

Within 40 days of receipt of our order, Section 7(a) of the Regulatory Review Act requires you to select one of the following options: (1) proceed with promulgation under Section 7(b); (2) proceed with promulgation under Section 7(c); or (3) withdraw the regulation. If you do not take any action within this period, the regulation is deemed withdrawn.

If you or your staff have any questions, please contact me at 783-5506.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Robert M. Tomlinson, Chair, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Chair, Senate Consumer Protection and Professional Licensure Committee
Honorable Michael P. McGeehan, Chair, House Professional Licensure Committee
Honorable William F. Adolph, Jr., Chair, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER

Commissioners Voting:

Arthur Coccodrilli, Chairman
George D. Bedwick
Nancy Sabol Frantz, Esq.
Karen A. Miller
John F. Mizner, Esq.

Public Meeting Held April 2, 2009

Regulation No. 16A-53118 (#2644)
State Board of Osteopathic Medicine
Prescriptive Privileges for Physician Assistants

On October 10, 2007, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the State Board of Osteopathic Medicine (Board). This rulemaking amends 49 Pa. Code Chapter 25. The proposed regulation was published in the October 20, 2007 *Pennsylvania Bulletin* with a 30-day public comment period. The final-form regulation was submitted to the Commission on February 26, 2009.

This final-form regulation would permit physician assistants practicing under the supervision of osteopathic physicians to prescribe, dispense and administer drugs and therapeutic devices.

Dr. Joseph C. Gallagher, Jr., Chair of the Board, appeared at the public meeting on April 2, 2009, and represented that he was fully authorized to request, on behalf of the Board, that we disapprove this final-form regulation to allow the Board the opportunity to revise § 25.177(a)(3) pertaining to prescriptions for Schedule II controlled substances. Without support from the promulgating Board, this regulation does not meet the reasonableness criterion set forth in the Regulatory Review Act and is not in the public interest. 71 P.S. § 745.5b(b)(3). Therefore, in response to the Board's request, we disapprove this regulation.

BY ORDER OF THE COMMISSION:

Regulation #16A-5318 (IRRC #2644) is disapproved.

Arthur Coccodrilli, Chair

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE

DATE: **May 13, 2009**

SUBJECT: **Revised Final Rulemaking for Redelivery:**
State Board of Osteopathic Medicine
Physician Assistant Prescriptive Authority (16A-5318)

TO: **Andrew C. Clark, Deputy General Counsel**
Office of General Counsel

FROM: **Thomas A. Blackburn, Regulatory Unit Counsel**
Department of State

Other than as discussed in the preamble, there are no significant legal and policy issues presented by this amendment to the regulations of the State Board of Osteopathic Medicine concerning physician assistant prescriptive authority.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

TAB

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF OSTEOPATHIC MEDICINE
P.O. Box 2649
Harrisburg, PA 17105-2649
(717) 783-4858

May 22, 2009

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

Re: Final Regulation
State Board of Osteopathic Medicine
16A-5318: Physician Assistant Prescriptive Authority

Dear Chairman Coccodrilli:

Enclosed is the report of the State Board of Osteopathic Medicine prepared in accordance with section 7(c) of the Regulatory Review Act, 71 P.S. § 745.7(c), following disapproval of the final form regulation by the Independent Regulatory Review Commission. The Board has amended the final form regulation and resubmits the regulation for approval in accordance with the Regulatory Review Act.

Sincerely,

Joseph C. Gallagher, Jr., D.O., Chairperson
State Board of Osteopathic Medicine

JCG/TAB:rs
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Peter V. Marks, Sr., Executive Deputy Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Thomas A. Blackburn, Regulatory Counsel
Department of State
Sabina I. Howell, Board Counsel
State Board of Osteopathic Medicine
State Board of Osteopathic Medicine

IRRC

Independent Regulatory Review Commission

TRANSMITTAL SHEET FOR REPORT PURSUANT TO SECTION 7(b) and 7(c) OF THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5318
SUBJECT:	PHYSICIAN ASSISTANT PRESCRIPTIVE AUTHORITY
PA CODE:	49 Pa. Code §§ 25.142, 25.162, 25.177-25.178
AGENCY:	DEPARTMENT OF STATE, BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS, STATE BOARD OF OSTEOPATHIC MEDICINE

TYPE OF REPORT

☐ Agency Report contains final-form regulation **without revision,** the findings of the Commission and agency response and recommendation pursuant to Section 7(b) of the Regulatory Review Act.

X Agency Report contains revised final-form regulation, the findings of the Commission and agency response and recommendation pursuant to Section 7(c) of the Regulatory Review Act.

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/22/09	Kristin Zaller	HOUSE COMMITTEE: PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN **Michael McGeehan**
5/22/09	Mary Walmer	SENATE COMMITTEE: CONSUMER PROTECTION AND PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN **Robert Tomlinson**
5/22/09	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5318
SUBJECT:	PHYSICIAN ASSISTANT PRESCRIPTIVE AUTHORITY
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF OSTEOPATHIC MEDICINE

TYPE OF REGULATION

Proposed Regulation

X 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

RECEIVED
2009 MAY 22 AM 9:40
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
5/22/09	Kristin Mullen	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Michael O'Brien
5/22/09	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Robert Tomlinson
5/22/09	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

May 21, 2009