

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

(2) I.D. Number (Governor's Office Use)

16A-4916

IRRC Number: 2505

(3) Short Title

Physician Assistants

(4) PA Code Cite

49 Pa. Code, §§ 16.11, 16.13, 18.121, 18.122, 18.131, 18.141-18.145, 18.151 – 18.159, 18.161, 18.162, 18.171, 18.172 and 18.181

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Gerald S. Smith, 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)

Proposed Rulemaking
 Final Order Adopting Regulation
 Policy Statement

(7) Is a 120-Day Emergency Certification Attached?

No
 Yes: By the Attorney General
 Yes: By the Governor

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

The proposed regulatory amendment would clarify and update the criteria to reflect current medical practice in the medical doctor community. The language change. The proposed amendments would reduce or eliminate unnecessary restrictions and provide for a smoother work flow between medical doctors and physician assistants.

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

Section 13 of the Medical Practice Act of 1985, 63 P.S. §422.13 authorizes the Board to promulgate regulations that define the services and circumstances under which a physician assistant may perform a medical service, and which define the supervision and personal direction required by the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.

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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.

No.

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

The proposed amendments will permit the expanded use of physician assistants in a manner comparable to other physician extenders of similar education and training. The proposed amendments will also enhance patient access to care by allowing more flexible use of physician assistants in all practice settings.

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

The current regulations prevent the effective use of physician assistants to the full extent of their training. The inability to be able to use physician assistants fully could compromise the access of Commonwealth residents to health care.

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

This proposed regulatory amendment will increase the accessibility of health care and decrease the cost of health care to patients in the Commonwealth by making more efficient use of physician assistants.

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(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.)

The Board has not identified anyone who would be adversely affected by the regulations.

(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.)

45,000 medical doctors and 3,222 physician assistants licensed in the Commonwealth will be required to comply.

(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.

In compliance with Executive Order 1996-1, in drafting and promulgating this regulations, the Board solicited input and suggestions from the regulated community and other parties who identified themselves as interested in the Board's regulatory agenda. The Board considered comments received in preparing proposed rulemaking.

(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.

The Board does not anticipate that any additional costs will be generated by this regulatory amendment. However, since the proposed regulatory amendment will increase the use of physician assistants and decrease the necessity for patients in the Commonwealth to see physicians, it is anticipated that the end result will be a cost saving to Commonwealth residents.

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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 are anticipated 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.

No costs or savings are anticipated by this rulemaking.

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:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings	N/A	N/A	N/A	N/A	N/A	
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	N/A	N/A	N/A	N/A	N/A	
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	N/A	N/A	N/A	N/A	N/A	

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

N/A

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

Program	FY -3	FY -2	FY -1	Current FY
State Board of Medicine	\$3,241,114.51	\$3,861, 200.20	\$4,208,232.09	\$8,774,000.00

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

N/A

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

The non-regulatory alternative would be to leave the regulatory amendment as they are, which would not reflect the current state of the art of medical doctor practice.

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

Alternative regulatory amendments would mandate procedural and specialty processes which would even further hamper the provision of medical services to Commonwealth residents. Further, such regulations would be overly restrictive. This regulatory scheme is to free up the decision making ability of the supervising physician and physician assistant, in order to provide better medical doctor care to the residents of the Commonwealth.

(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.

No.

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

This regulatory amendment broadens the scope of responsibility given to physician assistants by medical doctors. It increases the flexibility which medical doctors have in being able to delegate to and work with physicians assistants. The regulatory amendment is not restrictive, encourages collaboration, and is endorsed by the regulated community. The regulatory amendment will not put the Commonwealth at a competitive disadvantage.

Our bordering states all regulate physician assistants to a similar degree as Pennsylvania. Due to the extensive nature of the revisions proposed by this regulatory amendment, and the widely divergent manner in which other states structure their laws and regulations in addressing the responsibilities of licensed professionals, a true comparison is not practicable.

New York law and regulations permits the physician assistant to engage in medical services which fall within the scope of practice of the supervising physician. Continuous supervision is required, however the physical presence of the physician is not required. Physician assistants in Delaware have no authority to diagnose, prescribe legend drugs or therapeutics, or pronounce a patient dead. Any prescriptive authority is specifically delegated and practice specific. The supervising physician is to be physically present on the premises and immediately available.

In Maryland the physician assistant is the agent of the physician. The prescriptive authority of physician assistants is more narrowly defined than that of Pennsylvania.

In West Virginia, the supervising physician is to observe, direct and evaluate the work, records and practice of each physician assistant. The physical presence of the physician is not required, so long as the physician assistant is operating under the specified direction of the supervising physician. Physician assistants are permitted to write or sign prescriptions at the direction of the supervising physician. A formulary is provided depending on the drug schedule. Physician assistants also must have 2 years of patient care prior to being permitted to write prescriptions, and further, must take clinical pharmacology coursework.

The Ohio State Board of Medicine requires narrowly drawn utilization plans and supervisory agreements that are approved by the Ohio Board. The physician is required to provide oversight, direction and control of the physician assistant. The physician assistant has no independent prescriptive authority, and is to carry out and relay the supervising physician order for medications. The physician assistant is also not allowed to dispense or order medications independently. The physician assistant is not allowed to diagnose, set up a treatment plan or regimen not previously set forth by the physician.

New Jersey limits physician assistants to functioning as an agent of the supervising physician. Activities may only be performed under the direction, order, or prescription of the supervising physician.

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(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 schedule? Please provide the dates, times, and locations, if available.

No public hearings are scheduled. Notwithstanding the foregoing, the public may provide public input during regularly scheduled meetings.

(28) Will the regulations 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.

The regulation will permit medical doctors and physician assistants to commence their working relationship upon filing of the written agreement with the Board. Previously, the above licensees had to await Board approval before starting to work together.

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

N/A

(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 amendments 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 during the course of their implementation and enforcement.

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INDEPENDENT REGULATORY
REVIEW COMMISSION

2505

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

BY: Amy M. Elliott
(DEPUTY ATTORNEY GENERAL)

OCT 04 2005

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 Medicine

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4916

DATE OF ADOPTION: _____

BY: _____

Charles D. Miller, 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
ANDREW C. CLARK

8.16.05

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.

NOTICE OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
49 PA. CODE, CHAPTER S 16 AND 18
PHYSICIAN ASSISTANTS

The State Board of Medicine (Board) proposes to amend its regulations pertaining to physician assistants and their supervising physicians at 49 Pa. Code, Chapter 16, §§16.11 and 16.13, and at Chapter 18, §§18.121, 18.122, 18.131, 18.141-18.145, 18.151-18.159, 18.161, 18.162, 18.171, 18.172 and 18.181, to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Section 13 of the Medical Practice Act of 1985 (Act) (63 P.S. §422.13) authorizes the Board to promulgate regulations that define the services and circumstances under which a physician assistant may perform a medical service, and which define the supervision and personal direction required by the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth.

C. Background and Purpose

Since the physician assistant regulations were last amended in 1993, experience in the application of the regulations has demonstrated the need for amendments that reflect the current state of the art of medical practice as can also be observed in the American Medical Association (AMA) guidelines for physician assistants. The existing regulations prevent the effective use of physician assistants to the full extent of their training. In accordance with Executive Order 1996-1, the Board notified the regulated community that it intended to propose updating its physician assistant regulations and sought predraft input. Numerous medical doctors and physician organizations wrote to support the proposed amendments, noting that the current regulations are, in many ways, overly and unnecessarily restrictive.

D. Description of Amendments

There are extensive revisions proposed in these regulatory amendments. Some of the amendments are in the nature of editorial changes, mostly to conform the regulatory language to the 2002 amendments to the Medical Practice Act. Other changes are more substantive in nature.

The following is a section-by-section summary of the proposed amendments by category.

<u>Editorial Changes</u>	<u>Substantive Changes</u>
§ 18.121 – Purpose	§ 18.142 – Written Agreements
§ 18.122 – Definitions	§ 18.143 – Criteria for registration as a physician assistant supervisor
§ 18.131 – Approved educational programs	§ 18.144 – Responsibility of a primary physician assistant supervisor
§ 18.162 – Emergency Medical Services	§ 18.151 – Role of physician assistant
§ 18.171 – Physician Assistant identification	§ 18.152 – Prohibitions
	§ 18.153 – Executing and relaying medical regimens
	§ 18.155 – Satellite locations
	§ 18.156 – Monitoring and review of physician assistant utilization
	§ 18.157 – Administration of controlled substances and whole blood and blood components
	§ 18.158 – Prescribing and dispensing drugs
	§ 18.161 – Physician assistant employed by medical care facilities

The proposal changes the term “physician assistant supervisor” to “supervising physician” at §18.121 (relating to purpose) and at all other places that it appears in Chapters 16 and 18. The change emphasizes that the physician assistant’s supervisor must be a physician, and eliminates the confusion that sometimes surrounded the term “physician assistant supervisor.”

Proposed §18.122 (relating to definitions) would delete the definition of “direct supervision.” The term “direct supervision” is found only at §18.162 (relating to emergency medical services), which the Board proposes to amend by deleting the requirement that physician assistants provide emergency services only under the direct supervision of the supervising physician.

The definition of “supervision” would also be amended to more accurately reflect how physician assistants are actually supervised and more clearly reflect the important responsibility that the physician

assistant assumes when serving in this role. The changes primarily ease the need for the physical presence and intervention of the physician in oversight of the physician assistant. The amended definition reiterates that the constant physical presence of the supervising physician is not required so long as the supervising physician and physician assistant are or can easily be in contact with one another by radio, telephone or other telecommunication device.

Under examples of the "appropriate degree of supervision" §18.122(iii) would be amended to eliminate the requirement for weekly review of patient charts. The proposed amendment more closely aligns with the practicality of a physician's practice. Current requirements of chart review and counter-signature of all physician assistant charts are cumbersome and ineffective. A review of selected charts which have specific diagnoses or complex medical management would support a more effective use of physician time, and promote quality assurance.

The definition of "medical regimen" would be changed to "a therapeutic, corrective or diagnostic measure undertaken or ordered by a physician or physician assistant acting within the physician assistant's scope of practice and in accordance with the written practice agreement between the supervising physician and the physician assistant." Currently, the text reads that a medical regimen is ordered only by the supervising physician which is for the management of a specific condition and which is incorporated into the written agreement between the supervising physician and physician assistant.

The proposed amendments would define "order" as "an oral or written directive for a therapeutic, corrective or diagnostic measure, including a drug or device to be dispensed for onsite administration in a hospital, medical care facility or office setting". This new language would provide clarity as to the parameters of an order and provide a comprehensive foundation which lends itself to the expanded definition of a medical regime.

Proposed amendments to §18.131 (relating to recognized educational programs) would change approval of physician assistant training programs to recognition of those programs to more accurately reflect that the Medical Board does not approve programs but rather recognizes those that are accredited, as mandated by Section 36(b) of the Act (§ 422.36(b)).

This proposal updates the reference to the training program approvals for physician assistants by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), Commission for Accreditation of Allied Health Educational Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or any successor organization. In 1994, the American Medical Association (AMA) made its accreditation body (CAHEA) independent and changed its name to the Commission for Accreditation of Allied Health Educational Programs (CAAHEP). In 2000, the Accreditation Review Committee (ARC-PA) was created due to the overwhelming growth of physician assistant programs and the difficulties that developed in trying to evaluate them appropriately. The AMA and other physician groups remain active in the accreditation process and occupy seats on the committee.

Section 18.142(a)(2) (relating to written agreements) would be amended so the written agreement will no longer be specific as to the requirement for describing how the physician assistant will assist each physician. The section would be amended to state that the agreement shall list functions that will be delegated to the physician assistant, deleting the requirements that it also describe how the physician assistant will assist each named physician, and the details of how the supervising physician will be assisted. The changes would also have the agreement signed only by each physician acting as a supervising physician or a substitute supervising physician instead of by each physician and the physician assistant. It would also describe how the physician assistant "works with" instead of "assists" each physician. Currently, the regulations specify that the agreement contain procedures selected from the list in §18.151 (relating to role of physician assistant), all other delegated tasks, instructions for use of the physician assistant in the performance of delegated tasks and medical regimens to be administered or relayed by the physician assistant. This requirement inhibits the effective utilization of physician assistants. In addition, it forces the Board to become more directly involved in the approval of practice guidelines for physicians and physician assistants rather than credentialing health care professionals.

Proposed amendments to §§18.144 and 18.156 (relating to responsibility of primary supervising physician and satellite locations) eliminate the requirement for the supervising physician to see each patient on every third visit or at least once a year. The Board proposes to require at § 18.44(4) that the physician determine the need to see each patient based upon the patient's individual needs or at the patient's request. The change recognizes that the involvement of the supervising physician should be predicated on factors such as the practice type, site and the condition of the patient. This would also apply to satellite facilities. Because the existing requirement applies to all patients who are treated by a physician assistant it includes within its application situations in which it is virtually impossible for a physician to meet. For example, if a patient is seen by a physician assistant for a minor problem and does not return within a year to be seen by the physician, the physician cannot comply with the requirement. Attempts to meet the requirements of the existing regulation result in inefficient use of resources. The physician assistant can easily manage a patient with a well-controlled chronic problem who is checked periodically to see if all is well. However, if the patient is checked only once annually, a physician must be involved due to the requirements of the existing regulation. Experience has demonstrated that the existing regulation is counter-productive. The option remains for the patient to request to be seen by the supervising physician.

The Board also proposes to modify §18.151 (relating to role of the physician assistant). This section currently includes a list of tasks that the physician assistant can perform (subject to the proviso that the list is not all-inclusive). The list of tasks physician assistants can perform in the current regulations is somewhat limiting. Although the regulation states that the list is not intended to be all-inclusive, the Board is prohibited by court rulings from rendering advisory opinions. Therefore, one is left to speculate as to whether or not a given task not on the list, but critical to a particular practice, is permitted. The proposal would replace the list with statements

that the physician assistant may practice medicine with physician supervision and perform duties as delegated by the physician. As revised, this section would establish as a baseline standard that the physician assistant should be authorized to perform any medical service delegated by the physician.

Currently §18.152 prohibits a physician assistant from pronouncing death. The amendments proposed to §§18.151 and 18.152 would allow a physician assistant to pronounce a patient dead and also allow a physician assistant to authenticate with his or her signature any form related to pronouncing death. Physician assistants who practice in long term care facilities, hospital wards, hospice care or in hematology/oncology, among other specialties, encounter circumstances where they may be the only medical care provider available at the time of a patient's death. Allowing delegation of the pronouncement of death simplifies procedures for the patient's family at a difficult time. The amendment allows only pronouncement of death. Certification as to the cause of death continues to be reserved for the supervising physician or a coroner as set forth in 35 P.S. § 450.502.

Revised §18.151 would also allow the physician assistant to sign any form that otherwise requires a physician's signature as permitted by the supervising physician, state or federal law and facility protocol, if applicable. This will relieve the physician of much routine paperwork such as signing forms for school physicals.

Among the list of those things in §18.152 that a physician assistant may not do is the performance of a medical service without physician supervision as set forth in the written agreement.

The proposed amendments to §18.153 (relating to executing and relaying medical regimens) change the 12 hour requirement for the physician assistant to relate all medical regimens executed or relayed while the physician was not present to the supervising physician to 36 hours. This is also reflected in §18.158 (relating to prescribing and dispensing drugs) for all medications prescribed or dispensed and is applicable to prescribing or dispensing "in accordance with the written agreement." The 12-hour timeframe in both aspects of the current regulations proved to be overly restrictive. It is not uncommon that a treatment for a minor illness done late in the day goes unreported until the start of the next business day, more than 12 hours later. For physician assistants taking weekend call, the reporting for minor problems would not occur until the following Monday.

The board proposes to amend §18.153(b) relating to executing and relaying medical regimens by extending the period for reporting to the supervising physician from 12 to 36 hours in §18.155(b)(4) and the outside period for countersignature from three to ten days as in §18.153(c). For satellite facilities, the proposed revisions would also lengthen the time for counter-signature to 10 days. During pre-draft input, the medical doctor community advised the Board that the current 3-day counter-signature requirement is too restrictive and causes compliance problems. The regulation does not take into consideration weekends or a supervising

physician's vacation schedules. This is particularly troublesome for satellite facilities. By expanding to a 10-day signature, compliance becomes more practical. This change is also incorporated into §§18.142 and 18.158 (relating to written agreements and prescribing and dispensing drugs, pharmaceutical aids and devices).

Current §18.157 (relating to administration of controlled substances and whole blood and blood components), provides that a physician assistant may administer controlled substances as well as whole blood and blood components if that authority is addressed in the written agreement and is separately ordered by the supervising physician specifying a named drug for a named patient. The Board proposes to eliminate the requirement for the separate order of the supervising physician specifying the drug and patient and allowing it to be addressed only in the written agreement and be administered by the physician assistant on that authority. The Board believes that the current language creates an unnecessary barrier to utilization of physician assistants in surgical, hematology/oncology, pain management, and hospice care.

Section 18.158 (relating to prescribing and dispensing drugs) currently includes a formulary of categories of drugs that a physician assistant may prescribe if permission is granted in the written agreement. The supervising physician reviews this formulary and chooses those categories of drugs that he or she will allow the physician assistant to prescribe or dispense. The list becomes a part of the written agreement that must be submitted to the Board. The amendment would eliminate the formulary. Instead, new subsections (a) and (b) state that the physician can delegate prescribing, dispensing and administration of drugs and therapeutic devices to the physician assistant if the drug or device is permitted under the written agreement. The physician assistant would be subject to the regulations of the Board and the Department of Health regarding dispensing standards, prescribing and labeling. The proposal would have the written agreement only contain a list of those categories of drugs that the physician assistant may not prescribe. The existing formulary suffers from the same limitations noted with the list of tasks a physician assistant can perform. The current formulary is out of date and places restrictions on common drugs used to treat patient problems routinely managed by physician assistants. For example, the management of warfarin sodium therapy for atrial fibrillation, deep venous thrombosis, and mechanical heart valves has become commonplace in the family practice setting. Physician assistants are routinely called upon to adjust medication levels. The proposal would delete current restrictions on prescribing of blood formation or coagulation drugs.

Currently, §18.158(a)(4) creates a 90-day waiting period after approval by the Federal Food and Drug Administration (FDA) for a new drug or new uses for a drug before a physician assistant can prescribe it. The amendments eliminate that waiting period. The original purpose has been overcome by practice in recent years. Because physicians provide ongoing input and oversight in the treatment of patients by the physician assistants, delaying the prescribing for 90 days is overly restrictive.

The proposal also deletes a statement in §18.158(b)(4) specifying that the supervising physician assumes responsibility for all prescriptions and dispensing of drugs by the physician

assistant. However, §18.144 (relating to responsibility of primary supervising physician) requires the supervising physician to assume responsibility for the performance of the physician assistant, so this change is editorial in that it simply eliminates redundancy.

The proposal further deletes subsection (g), which states that the physician assistant may only prescribe or dispense drugs for a patient under the care of the supervising physician. Physician assistants often provide care to patients in a practice that are new patients or regularly see one of the primary supervisor's partners. This section is also redundant and limiting because the supervising physician assumes ultimate responsibility for every patient seen by the physician assistant as set forth in 18.402(a)(6) and Section 17(c) of the MPA.

The Board proposes to eliminate a prohibition in §18.158(c)(4)(i) preventing a physician assistant from prescribing or dispensing a pure form or combination of drugs. The Board finds the prohibition is vague and unnecessary due to the current state of training received by PAs. Pre-draft input suggested that experience has demonstrated that PAs have the knowledge and skill to properly perform this function.

The amendments in § 18.158(c)(4)(iii) and (iv) eliminate the statement in that a physician assistant may not prescribe or dispense drugs not approved by the FDA. Existing law already prevents anyone, including physicians, from prescribing or dispensing drugs not approved by the FDA.

The proposal removes in 18.158(c)(4)(v) the prohibition on a physician assistant prescribing or dispensing parenteral drugs other than insulin or emergency allergy kits or other approved drugs. Comments provided in pre-draft input advised that this regulation is overly restrictive.

Section 18.158(c)(4)(viii) currently states that a physician assistant may not issue a prescription for more than a 30-day supply of medication except in cases of chronic illness where the physician assistant can write for a 90-day supply. It also states that the physician assistant can authorize refills up to 6 months from the original prescription. This proposal seeks to eliminate these limitations. The existing limitation proved too restrictive. For example, it is not unusual to prescribe contraceptives for a year for healthy individuals or prescribe medications for the management of stable chronic conditions. The existing limitations can cause patients to incur additional costs for unnecessary office visits in order to continue receiving the medication.

The amendments to §18.158, adds in §18.158(a)(5) a provision authorizing the physician assistant to receive, sign for and distribute drug samples. This provision will allow the physician assistant to relieve the supervising physician of this duty and allow the physician assistant to dispense samples of medications he or she is already authorized to dispense.

In addition, this proposal in §18.158(a)(6) specifically mentions that the physician assistant who will prescribe controlled substances must register with the Federal Drug

Enforcement Administration (DEA). The proposal in §18.158(b)(2) also specifies that space on prescription blanks must be provided for the physician assistant to record his or her DEA number. This change reminds the physician assistant of the requirement to register and serves to bring the physician assistant's practice into conformance with federal law.

The current regulations do not allow physician assistants to prescribe or dispense Schedule I or II controlled drugs. This proposal in §18.158(a)(3) calls for allowing them to prescribe or dispense Schedule II controlled drugs for initial therapy up to a 72-hour dose and requires that they notify the supervising physician within 24 hours. It would also allow the physician assistant to write a prescription for a Schedule II controlled drug for up to a 30-day supply if originally ordered and approved for ongoing therapy by the supervising physician. There are many physician and physician assistant specialties that deal with chronic pain management. In specialties such as oncology, surgery, anesthesiology or in the family practice setting, physician assistants are an integral part of patient care. Managing the patients' pain in these 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 therapy or need to renew prescriptions when the physician is not immediately available but his or her 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.

Current § 158(c)(4)(iii) does not allow physician assistants to prescribe medications for uses not approved by the FDA. This proposal would no longer prohibit this "off-label" prescribing, but instead mandates that the physician assistant follow the supervising physician's instructions and the written agreement. The FDA approves uses of medications for the purpose of marketing by the manufacturer, not for use by physicians. Off-label use may represent the best standard of care. The decision to use a medication for such a purpose should be left to the clinician. The best example of an off-label use of a drug is the millions of prescriptions for aspirin after myocardial infarction. Off-label use of drugs is common in areas such as AIDS-related treatment, oncology and pediatrics. In pediatrics, as many as 80% of drugs are administered off-label because manufacturers are understandably reluctant to enroll young children in clinical trials of many drugs.

The amendments to § 158 also would delete the prohibition against a physician assistant compounding ingredients when dispensing drugs except for adding water at subparagraph (4)(vii). There are several medication mixtures that are commonly used in practice. One is the mixture of Benadryl, viscous Lidocaine, and Maalox in the treatment of stomatitis secondary to chemotherapy. Pediatric groups will typically combine decongestants and cough suppressants in other doses than commercially available.

Section 18.161(b) (Physician assistant employed by medical care facilities currently calls for the physician assistant to only be responsible to a maximum of three supervising physicians.

The proposed amendment to §18.161 (relating to physician assistant employed by medical care facilities) calls for allowing supervising physicians to make that determination by deleting this requirement. Health professional regulations should allow for flexible and creative innovation and appropriate use of all members of the health care workforce. Medical facilities should be allowed some flexibility in staffing and team deployment so long as they maintain proper supervisory arrangements. The current regulation restricts the ability of the physician assistant to serve as house staff in a medical care facility for more than three physicians. This is particularly true in the surgical subspecialty setting. Physician assistants may rotate as frequently as every month to different surgical subspecialties and be responsible to multiple surgeons in the process. The current regulations restrict this ability.

These amendments propose a new subsection (b) that addresses the practice of physician assistants in emergency situations in §18.162 (relating to emergency medical services). The emergency situations addressed are those in a disaster situation and not in the normal course of a medical practice. The additions allow for the use of those licensed in other states to function without the usual requirements for themselves and the physicians working with them.

The amendments in §18.171 (relating to physician assistant identification) maintain the requirement that a physician assistant wear an identification tag bearing the term "physician assistant" but would modify the requirement for it to be in 16 point or larger type to being an easily readable type. The typeface for 16 point is excessively large, particularly for individuals with lengthy or hyphenated names. Finally, the amendments render the regulations gender neutral.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation, the Board solicited input and suggestions from the regulated community and other parties who have identified themselves as interested in the Board's regulatory agenda.

F. Fiscal Impact and Paperwork Requirements

There is no adverse fiscal impact or paperwork requirement imposed on the Commonwealth, political subdivision, or the private sector.

G. Sunset Date

The board continuously monitors 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 26, 2005, 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 shall specify the regulatory review criteria which 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.

I. Public Comment

Interested persons are invited to submit written comments, recommendations, or objections regarding the proposed regulation to Gerald S. Smith, 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.
Chairperson

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:

(2) Physician assistant [certificate] license.

(c) The following registrations are issued by the Board:

(1) Registration as a [physician assistant supervisor] supervising physician of a physician assistant.

* * *

§ 16.13 Licensure, certification, examination and registration fees.

* * *

(c) *Physician Assistant* [*Certificate*] License

* * *

Registration, [physician assistant supervisor] supervising physician.....\$35.00
Registration of additional [supervisors] supervising physicians..... \$ 5.00

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

Subchapter D. PHYSICIAN ASSISTANTS

GENERAL PROVISIONS

§ 18.121. Purpose.

This subchapter implements section 13 of the act (63 P.S. § 422.13) pertaining to physician assistants and provides for the delegation of certain medical tasks to qualified physician assistants by [physician assistant supervisors] supervising physicians when the delegation is consistent with the written agreement.

§ 18.122. Definitions.

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

* * *

[*Direct supervision* - The physical presence of the physician assistant supervisor on the premises so that the physician assistant supervisor is immediately available to the physician assistant when needed.]

* * *

Drug - A term used to describe a [drug] medication, device or agent which a physician assistant prescribes or dispenses under §18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices).

* * *

Medical regimen – [A therapeutic, corrective or diagnostic measure ordered by a physician assistant supervisor which is required for the management of a specific condition and which is incorporated into the written agreement] A therapeutic, corrective or diagnostic measure performed or ordered by a physician, or performed or ordered by a physician assistant acting within the physician assistant's scope of practice, and in accordance with the written agreement between the supervising physician and the physician assistant.

* * *

Order – An oral or written directive for a therapeutic, corrective or diagnostic measure, including a drug to be dispensed for onsite administration in a hospital, medical care facility or office setting.

* * *

Physician assistant - An individual who is [certified] licensed as a physician assistant by the Board.

Physician assistant examination – An examination to test whether an individual has accumulated sufficient academic knowledge to qualify for [certification] licensure as a physician assistant. The Board recognizes the certifying examination of the NCCPA.

Physician assistant program -- A program for the training and education of physician assistants which is [approved] recognized by the Board and accredited by the Committee on Allied Health Education and Accreditation (CAHEA), Commission For Accreditation of Allied Health Educational Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or any successor agency.

[Physician assistant supervisor]—A physician who is identified as a supervising physician of a physician assistant in the written agreement and is registered with the Board as such.]

* * *

Primary [physician assistant supervisor] supervising physician - A [physician assistant supervisor] medical doctor who is registered with the Board and designated in the written agreement as having primary responsibility for directing and supervising the physician assistant.

Satellite location - A location, other than the primary place at which the [physician assistant supervisor] supervising physician provides medical services to patients, where a physician assistant provides medical services.

Substitute [physician assistant supervisor] supervising physician - A [physician assistant supervisor] supervising physician who is registered with the Board and designated in the written agreement as assuming primary responsibility for a physician assistant when the primary [physician assistant supervisor] supervising physician is unavailable.

Supervising physician – A physician who is identified in a written agreement as the physician who supervises a physician assistant.

Supervision – [The control and personal direction exercised by the physician assistant supervisor over the medical services provided by a physician assistant. Constant physical presence of the physician assistant supervisor is not required so long as the physician assistant supervisor and the physician assistant are, or can easily be, in contact with each other by radio, telephone or telecommunications. Supervision requires the availability of the physician assistant supervisor to the physician assistant.] Oversight and direction of, and responsibility for, the medical services rendered by a physician assistant. The constant physical presence of the supervising physician is not required so long as the supervising physician and the physician assistant are, or can be, easily in contact with each other by radio, telephone or other telecommunications device.

An appropriate degree of supervision includes:

- (i) Active and continuing overview of the physician assistant's activities to determine that the physician's directions are being implemented.
- (ii) Immediate availability of the [physician assistant supervisor] supervising physician to the physician assistant for necessary consultations.
- (iii) Personal and regular [– at least weekly -] review by the [physician assistant supervisor] supervising physician of the patient records upon which entries are made by the physician assistant.

Written agreement – The agreement between the physician assistant and [physician assistant supervisor] supervising physician, which satisfies the requirements of §18.142 (relating to written agreements).

PHYSICIAN ASSISTANT EDUCATIONAL PROGRAMS

§ 18.131. [Approved] Recognized educational programs/standards.

(a) The Board [approves] recognizes physician assistant educational programs [developed] accredited by the [accreditation review committee for the physician assistant, and accredited by the] American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), Commission for Accreditation of Allied Health Education Programs (CAAHEP), Accreditation Review Commission (ARC-PA) [of the American Medical Association] or any successor organization. Information regarding approved programs may be obtained directly from ARC-PA at its website www.arc-pa.org.

(b) The criteria for [certification] recognition by the Board of physician assistant educational programs will be identical to the essentials developed by the various organizations listed in this section or other accrediting agencies approved by the Board.

**[CERTIFICATION] LICENSURE OF PHYSICIAN ASSISTANTS AND
REGISTRATION OF [PHYSICIAN ASSISTANT SUPERVISORS] SUPERVISING
PHYSICIANS**

§ 18.141. Criteria for [certification] licensure as a physician assistant.

The Board will approve for [certification] licensure as a physician assistant an applicant who:

- (1) Satisfies the [certification] licensure requirements in §16.12 (relating to general qualifications for licenses and certificates).
- (2) Has graduated from a physician assistant program [approved] recognized by the Board.

* * *

§ 18.142. Written agreements.

(a) The written agreement required by section 13(e) of the act (63 P.S. §422.13(e)) shall satisfy the following requirements. The agreement shall:

- (1) Identify and be signed by the physician assistant and [each physician the physician assistant will be assisting] each physician acting as a supervising physician. At least one physician shall be a medical doctor.
- (2) Describe the manner in which the physician assistant [will be assisting each named physician] works with each supervising physician. The description shall list functions to be delegated to the physician assistant[, including:
 - (i) Selected procedures enumerated in §18.151 (relating to the role of the physician assistant) and other delegated tasks.

(ii) Instructions for the use of the physician assistant in performance of delegated tasks.

(iii) Medical regimens to be administered or relayed by the physician assistant].

(3) Describe the time, place and manner of supervision and direction each named physician will provide the physician assistant, including the frequency of personal contact with the physician assistant.

(4) Designate one of the named physicians who shall be a medical doctor as the primary [physician assistant supervisor] supervising physician.

(5) Require that the supervising physician shall countersign the patient record completed by the physician assistant within a reasonable amount of time. This time period shall not exceed 10 days.

[(5)] (6) Identify the locations and practice settings where the physician assistant will serve.

(b) The written agreement shall be approved by the Board [as satisfying the foregoing requirements in subsection (a) and as being consistent with relevant provisions of the act and regulations contained in this subchapter].

(c) A physician assistant or [physician assistant supervisor] supervising physician shall provide immediate access to the written agreement to anyone seeking to confirm the scope of the physician assistant's authority.

§ 18.143. Criteria for registration as [physician assistant supervisor] a supervising physician.

(a) The Board will [approve for registration as] register a [physician assistant supervisor] supervising physician [an] applicant who:

(1) Possesses a current license without restriction to practice medicine and surgery in this Commonwealth.

(2) Has [submitted] filed a completed [application] registration form accompanied by the written agreement (see §18.142 (relating to written agreements)) and the required fee under §16.13 (relating to licensure, certification, examination and registration fees). The [application] registration requires detailed information regarding the physician's professional background and specialties, medical education, internship, residency, continuing education, membership in American Boards of medical specialty, hospital or staff privileges and other information the Board may require.

(3) Includes with the [application] registration, a list, identifying by name and license number, the other physicians who are serving as [physician assistant supervisors] supervising physicians of the designated physician assistant under other written agreements.

(b) If the [applicant] supervising physician plans to utilize physician assistants in satellite locations, the [applicant] supervising physician shall provide the Board with supplemental

information as set forth in §18.155 (relating to satellite locations) and additional information requested by the Board directly relating to the satellite location.

(c) The Board will keep a current [register of approved] list of registered supervising physicians. The [register] list will include the physician's name, the address of residence, current business address, the date of [approval] filing, satellite locations if applicable, the names of current physician assistants under [his] the physician's supervision and the physicians willing to provide substitute supervision.

§ 18.144. Responsibility of primary [physician assistant supervisor] supervising physician.

A primary [physician assistant supervisor] supervising physician shall assume the following responsibilities. The supervisor shall:

* * *

(3) Arrange for a substitute [physician assistant supervisor] supervising physician. (See §18.154

(relating to substitute [physician assistant supervisor] supervising physician.)

(4) [See each patient in his office every third visit, but at least once a year.] Review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.

* * *

(7) Accept full professional and legal responsibility for the performance of the physician assistant and the care and treatment of [his] the patients.

§ 18.145. Biennial registration requirements; renewal of physician assistant [certification] license.

(a) A physician assistant shall register biennially according to the procedure set forth in §16.15 (relating to biennial registration; inactive status and unregistered status).

(b) The fee for the biennial registration of a physician assistant [certificate] license is set forth in §16. 13 (relating to licensure, certification, examination and registration fees).

(c) To be eligible for renewal of a physician assistant [certification] license, the physician assistant shall maintain [his] National certification by completing current recertification mechanisms available to the profession and recognized by the Board.

(d) The Board will keep a current [register] list of persons [certified] licensed as physician assistants. The [register] list will include:

- (1) The name of each physician assistant.
- (2) The place of residence.
- (3) The current business address.
- (4) The date of initial [certification] licensure, biennial renewal record and current [physician assistant supervisor]supervising physician.

PHYSICIAN ASSISTANT UTILIZATION

§ 18.151. Role of physician assistant.

[The physician assistant shall, under appropriate direction and supervision by a physician assistant supervisor, augment the physician's data gathering abilities in order to assist the physician in reaching decisions and instituting care plans for the physician's patients. Physician assistants may be permitted to perform the following functions. This list is not intended to be all-inclusive.

- (1) Screen patients to determine need for medical attention.
- (2) Review patient records to determine health status.
- (3) Take a patient history.
- (4) Perform a physical examination.
- (5) Perform developmental screening examination on children.
- (6) Record pertinent patient data.
- (7) Make decisions regarding data gathering and appropriate management and treatment of patients being seen for the initial evaluation of a problem or the follow-up evaluation of a previously diagnosed and stabilized condition.
- (8) Prepare patient summaries.
- (9) Initiate requests for commonly performed initial laboratory studies.
- (10) Collect specimens for and carry out commonly performed blood, urine and stool analyses and cultures.

(11) Identify normal and abnormal findings on history, physical examination and commonly performed laboratory studies.

(12) Initiate appropriate evaluation and emergency management for emergency situations, for example, cardiac arrest, respiratory distress, injuries, burns and hemorrhage.

(13) Perform clinical procedures such as:

- (i) Venipuncture.
- (ii) Intradermal tests.
- (iii) Electrocardiogram.
- (iv) Care and suturing of minor lacerations.
- (v) Casting and splinting.
- (vi) Control of external hemorrhage.
- (vii) Application of dressings and bandages.
- (viii) Administration of medications, except as specified in §18.158 (relating to prescribing and dispensing drugs), intravenous fluids, whole blood and blood components except as specified in §18.157 (relating to administration of controlled substances and whole blood and blood components).
- (ix) Removal of superficial foreign bodies.
- (x) Cardio-pulmonary resuscitation.
- (xi) Audiometry screening.

(xii) Visual screening.

(xiii) Carrying out aseptic and isolation techniques.

(14) Provide counseling and instruction regarding common patient problems.]

- (1) The physician assistant practices medicine with physician supervision. A physician assistants may perform those duties and responsibilities, including the ordering, prescribing, dispensing, and administration of drugs and medical devices, as well as the ordering, prescribing, and executing of diagnostic and therapeutic medical regimens, as directed by the supervising physician.
- (2) The physician assistant may provide any medical service as directed by the supervising physician when the service is within the physician assistant's skills, forms a component of the physician's scope of practice, is included in the written agreement and is provided with the amount of supervision in keeping with the accepted standards of medical practice.
- (3) The physician assistant may pronounce death, but not the cause of death, and may authenticate with their signature any form related to pronouncing death.
- (4) The physician assistant may authenticate with his or her signature any form that may otherwise be authenticated by a physician's signature as permitted by the supervising physician, state or federal law and facility protocol, if applicable.
- (5) The physician assistant shall be considered the agents of the supervising physician in the performance of all practice-related activities including the ordering of diagnostic, therapeutic, and other medical services.

§ 18.152. Prohibitions.

(a) A physician assistant may not:

* * *

(3) Maintain or manage a satellite location under §18.155 (relating to satellite locations) unless [approved by] such maintenance or management is registered with the Board.

(4) Independently practice or bill patients for services provided.

* * *

(8) [Pronounce a patient dead.

(9)] Perform a medical service without the supervision of a [physician assistant supervisor] supervising physician.

(b) A [physician assistant supervisor] supervising physician may not:

(1) Permit a physician assistant to engage in conduct proscribed in subsection (a).

(2) Have primary responsibility for more than two physician assistants.

§ 18.153 Executing and relaying medical regimens.

(a) A physician assistant may execute a written or oral order for a medical regimen or may relay a written or oral order for a medical regimen to be executed by a health care practitioner subject to the requirements of this section.

(b) As provided for in the written agreement, [The] the physician assistant shall report orally or in writing, to a [physician assistant supervisor] supervising physician, within [12] 36 hours, those medical regimens executed or relayed by [him] the physician assistant while the [physician assistant supervisor] supervising physician was not physically present, and the basis for each decision to execute or relay a medical regimen.

(c) The physician assistant shall record, date and authenticate the medical regimen on the patient's chart at the time it is executed or relayed. The [physician assistant supervisor] supervising physician shall countersign the patient record within a reasonable time not to exceed [3] 10 days, unless countersignature is required sooner by regulation, policy within the medical care facility or the requirements of a third-party payor.

(d) A physician assistant or [physician assistant supervisor] supervising physician shall provide immediate access to the written agreement to anyone seeking to confirm the physician assistant's authority to relay a medical regimen or administer a therapeutic or diagnostic measure.

§ 18.154 Substitute [physician assistant supervisor] supervising physician.

(a) If the primary [physician assistant supervisor] supervising physician is unavailable to supervise the physician assistant, the primary [physician assistant supervisor] supervising physician may not delegate patient care to the physician assistant unless [he has made] appropriate arrangements for substitute supervision are in the written agreement and the

substitute physician is registered as a [physician assistant supervisor] supervising physician with the Board.

(b) It is the responsibility of the substitute [physician assistant supervisor] supervising physician to ensure that supervision is maintained in the absence of the primary [physician assistant supervisor] supervising physician.

(c) During the period of supervision by the substitute [physician assistant supervisor] supervising physician, [he] the substitute supervising physician retains full professional and legal responsibility for the performance of the physician assistant and the care and treatment of the patients treated by the physician assistant.

(d) Failure to properly supervise may provide grounds for disciplinary action against the substitute [physician assistant supervisor] supervising physician.

§ 18.155. Satellite locations.

(a) *[Approval]Registration of satellite location.* A physician assistant may not provide medical services at a satellite location unless the supervising physician has [obtained specific approval from] filed a registration with the Board.

(b) *Contents of Statement.* A separate [application] *Statement* shall be made for each satellite location. [To obtain approval for each satellite location a physician assistant supervisor] *Statement* shall demonstrate that:

(1) The physician assistant will be utilized in an area of medical need.

(2) There is adequate provision for direct communication between the physician assistant and the [physician assistant supervisor] supervising physician and that the distance between

the location where the physician provides services and the satellite location is not so great as to prohibit or impede appropriate support services.

(3) [The supervisor will see each patient every third visit, but at least once a year.] The supervising physician shall review directly with the patient the progress of the patient's care as needed based upon the patient's medical condition and prognosis or as requested by the patient.

(4) The [supervisor] supervising physician will visit the satellite location at least weekly and devote enough time onsite to provide supervision and personally review the records of [each patient] selected patients seen by the physician assistant in this setting. The supervising physician shall notate those patient records as reviewed.

(c) *Failure to comply with this section.* Failure to maintain the standards required for a satellite location may result not only in the loss of the privilege to maintain a satellite location but also may result in disciplinary action against the physician assistant and the [physician assistant supervisor] supervising physician.

§ 18.156. Monitoring and review of physician assistant utilization.

(a) Representatives of the Board will be authorized to conduct scheduled and unscheduled onsite inspections of the locations where the physician assistants are utilized during the [physician assistant supervisors'] supervising physician's office hours to review the following:

(1) Supervision of the physician assistant. See §§18.144 and 18.154 (relating to responsibility of primary [physician assistant supervisor]) supervising physician; and substitute [physician assistant supervisor] supervising physician).

* * *

(5) Compliance with [certification] licensure and registration requirements. See §§18.141 and 18.145 (relating to criteria for [certification] licensure as a physician assistant; and biennial registration requirements; renewal of physician assistant [certification] license).

(6) Maintenance of records evidencing patient and supervisory contact by the [physician assistant supervisor] supervising physician.

(b) Reports shall be submitted to the Board and become a permanent record under the [physician assistant supervisor's] supervising physician's registration. Deficiencies reported shall be reviewed by the Board and may provide a basis for loss of the privilege to maintain a satellite location and disciplinary action against the physician assistant and the [physician assistant supervisor] supervising physician.

(c) The Board reserves the right to review physician assistant utilization without prior notice to either the physician assistant or the [physician assistant supervisor] supervising physician. It is a violation of this subchapter for a [physician assistant supervisor] supervising physician or a physician assistant to refuse to comply with the request by the Board for the information in subsection (a).

* * *

§ 18.157. Administration of controlled substances and whole blood and blood components.

(a) In a hospital, medical care facility or office setting, [The] the physician assistant may order or administer, or both order and administer, controlled substances and whole blood and blood components if the authority to order and administer these medications and fluids is expressly set forth in the written agreement [and the administration of these medications and fluids is separately ordered by the physician assistant supervisor and the physician assistant supervisor specifies a named drug for a named patient].

(b) The physician assistant shall comply with the minimum standards for ordering and administering controlled substances specified in §16.92 (relating to prescribing, administering and dispensing controlled substances).

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

[(a) The Board adopts the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification to identify drugs which a physician assistant may prescribe and dispense subject to the restrictions specified in subsection (c).

(1) Categories from which a physician assistant may prescribe and dispense without limitations are as follows:

- (i) Antihistamines.
- (ii) Anti-infective agents.
- (iii) Cardiovascular drugs.
- (iv) Contraceptives ---for example, foams and devices.
- (v) Diagnostic agents.
- (vi) Disinfectants---for agents used on objects other than skin.
- (vii) Electrolytic, caloric and water balance.
- (viii) Enzymes.
- (ix) Antitussives, expectorants, and nucleolytic agents.
- (x) Gastrointestinal drugs.
- (xi) Local anesthetics.
- (xii) Serums, toxoids and vaccines.
- (xiii) Skin and mucous membrane agents.
- (xiv) Smooth muscle relaxants.

(xv) Vitamins.

(2) Categories from which a physician assistant may prescribe and dispense subject to exclusions and limitations listed:

(i) *Autonomic drugs*. Drugs excluded under this category: Sympathomimetic (adrenergic) agents.

(ii) *Blood formation and coagulation*. Drugs excluded under this category:

(A) Anti-coagulants and coagulants.

(B) Thrombolytic agents.

(iii) *Central nervous system agents*. Drugs excluded under this category:

(A) General anesthetics.

(B) Monoamine oxidase inhibitors.

(iv) *Eye, ear, nose and throat preparations*. Drugs limited under this category: Miotics and mydriatics used as eye preparations require specific approval from the physician assistant supervisor for a named patient.

(v) *Hormones and synthetic substitutes*. Drugs excluded under this category:

(A) Pituitary hormones and synthetics.

(B) Parathyroid hormones and synthetics.

(3) Categories from which a physician assistant may not prescribe or dispense are as follows:

(i) Antineoplastic agents.

(ii) Dental agents.

(iii) Gold compounds.

(iv) Heavy metal antagonists.

(v) Oxytocics.

(vi) Radioactive agents.

(vii) Unclassified therapeutic agents.

(viii) Devices.

(ix) Pharmaceutical aids.

(4) New drugs and new uses for drugs will be considered approved for prescribing and dispensing purposes by physician assistants 90 days after approval by the Federal Drug Administration unless excluded in paragraphs (2) and (3).

(b) If the physician assistant supervisor intends to authorize a physician assistant to prescribe or dispense drugs, the supervisor shall:

(1) Establish a list of drugs, based on the categories listed in subsection (a), which the physician assistant may prescribe or dispense. The physician assistant supervisor shall assure that the physician assistant is able to competently prescribe or dispense those drugs.

(2) Submit the list of drugs to the Board, in duplicate, on a form supplied by the Board, and signed by both physician assistant supervisor and the physician assistant. The list will become part of the physician assistant's written agreement if it is consistent with the approved classification.

- (3) Notify the Board, in duplicate, on a form supplied by the Board, of an addition or deletion to the list of drugs. The amendment will become part of the physician assistant's written agreement if it is consistent with the approved classification.
 - (4) Assume full responsibility for every prescription issued and drug dispensed by a physician assistant under his supervision.
 - (5) Maintain a copy of the list of drugs submitted to the Board in his principal office and at all locations where the physician assistant practices under his supervision for review or inspection without prior notice by patients, the Board or its agents. The physician shall provide a pharmacy with a copy of the drug list upon request by the pharmacist.
 - (6) Immediately advise the patient, notify the physician assistant and, in the case of a written prescription, advise the pharmacy, if the physician assistant is prescribing or dispensing a drug inappropriately. The physician shall advise the patient and notify the physician assistant to discontinue using the drug, and in the case of a written prescription, shall 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 physician.
- (c) Restriction on a physician assistant's prescription and dispensation practices are as follows:
- (1) A physician assistant may only prescribe or dispense a drug approved by the Board from the categories specified in subsection (a).

- (2) 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 physician's instructions and written agreement.
- (3) A physician assistant shall comply with the minimum standards for prescribing and dispensing controlled substances specified in §16.92 (relating to prescribing, administering and dispensing controlled substances) and the regulations of the Department of Health relating to Controlled Substances, Drugs, Devices and Cosmetics, 28 Pa. Code §§25.51-25.58 (relating to prescriptions), and packaging and labeling dispensed drugs. See §§16.93 and 16.94 (relating to packaging; and labeling of dispensed drugs) and 28 Pa. Code §§ 25.91--25.95 (relating to labeling of drugs, devices and cosmetics).
- (4) A physician assistant may not:
- (i) Prescribe or dispense a pure form or combination of drugs listed in subsection (a) unless the drug or class of drug is listed as permissible for prescription or dispensation.
 - (ii) Prescribe or dispense Schedules I or II controlled substances as defined by section 4 of the Controlled Substances, Drug, Device, and Cosmetic Act (35 P.S. §780-104).
 - (iii) Prescribe or dispense a drug for a use not permitted by the Food and Drug Administration.
 - (iv) Prescribe or dispense a generic or branded preparation of a drug that has not been approved by the Food and Drug Administration.
 - (v) Prescribe or dispense parenteral preparations other than insulin, emergency allergy

- kits and other approved drugs listed in subsection (a).
- (vi) Dispense a drug unless it is packaged in accordance with applicable Federal and State law pertaining to packaging by physicians. See §§16.93 and 16.94.
- (vii) Compound ingredients when dispensing a drug, except for adding water.
- (viii) Issue a prescription for more than a 30-day supply, except in cases of chronic illnesses where a 90-day supply may be prescribed. The physician assistant may authorize refills up to 6 months from the date of the original prescription if not otherwise precluded by law.
- (d) The requirements for prescription blanks are as follows.
- (1) Prescription blanks shall bear the certification number of the physician assistant and the name of the physician assistant in printed format at the heading of the blank, and a space for the entry of the Drug Enforcement Administration registration number as appropriate. The physician assistant supervisor shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).
- (2) The physician assistant supervisor is prohibited from presigning prescription blanks or allowing the physician assistant to use a device for affixing a signature copy on the prescription. The signature of a physician assistant shall be followed by the initials "PA-C" or similar designation to identify the signer as a physician assistant.
- (3) The physician assistant may use a prescription blank generated by a hospital if the information in paragraph (1) appears on the blank.]

- (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. A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if it was originally prescribed by the supervising physician and approved by the supervising physician for 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 must register with the Drug Enforcement Administration.

- (b) The requirements for prescription blanks are as follows:
- (1) Prescription blanks shall 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 shall also be identified as required in §16.91 (relating to identifying information on prescriptions and orders for equipment and service).
 - (2) The signature of a physician assistant shall 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) The supervising physician shall immediately advise the patient, notify the physician assistant and, in the case of a written 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 prescription, shall 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 supervising physician.

[(e)](d.) Recordkeeping requirements are as follows:

* * * *

- (2) When dispensing a drug, the physician assistant shall record [his] 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 [physician assistant supervisor] supervising physician within [12] 36 hours, a drug prescribed or medication dispensed by [him] the physician assistant while the [physician assistant supervisor] supervising physician was not physically present, and the basis for each decision to prescribe or dispense in accordance with the written agreement.
- (4) [The physician assistant supervisor shall countersign the prescription copy or medical record entry for each prescription or dispensation within a reasonable time, not to exceed 3 days, unless countersignature is required sooner by regulation, policy within the medical care facility or the requirements of a third-party payor.] The supervising physician shall countersign the patient record within 10 days.
- (5) The physician assistant and the [physician assistant supervisor] 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 shall 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 labelling of drugs.

A physician assistant shall comply §§ 16.92, 16.93 and 16.94 (relating to prescribing, administering and dispensing controlled substances, packaging and labeling of dispensed drugs) and regulations of the Department of Health relating to 28 Pa. Code §§25.51 – 25.58 (relating to prescriptions) and packaging and labeling dispensed drugs. See §16.94 and 28 Pa. Code §§25.91 – 25.95 (relating to labeling of drugs, devices and cosmetics).

§ 18.159. Medical records.

The [physician assistant supervisor] supervising physician shall timely review the medical records prepared by the physician assistant to ensure that the requirements of §16.95 (relating to medical records) have been satisfied.

MEDICAL CARE FACILITIES AND EMERGENCY MEDICAL SERVICES

§18.161. Physician assistant employed by medical care facilities.

- (a) A physician assistant may be employed by a medical care facility, but shall comply with the requirements of the act and this subchapter.
- (b) [The physician assistant may not be responsible to more than three physician assistant supervisors in a medical care facility.
- (c)] This subchapter does not require medical care facilities to employ physician assistants or to permit their utilization on their premises. Physician assistants are permitted to

provide medical services to the hospitalized patients of their [physician assistant supervisor] supervising physician if the medical care facility permits it.

§ 18.162 Emergency medical services.

(a) A physician assistant may only provide medical service in an emergency medical care setting if the physician assistant has training in emergency medicine, functions within the purview of his written agreement and is under the [direct] supervision of the [physician assistant supervisor] supervising physician.

(b) A physician assistant licensed in this state or licensed or authorized to practice in any other state of the United States who is responding to a need for medical care created by a declared state of emergency or a state or local disaster (not to be defined as an emergency situation which occurs in the place of one's employment) may render care consistent with relevant standards of care.

IDENTIFICATION AND NOTICE RESPONSIBILITIES

§18.171. Physician assistant identification.

(a) A physician assistant may not render medical services to a patient until the patient or the patient's legal guardian has been informed that:

- (1) The physician assistant is not a physician.
- (2) The physician assistant may perform the service required as the agent of the physician and

only as directed by the [physician assistant supervisor] supervising physician.

(3) The patient has the right to be treated by the physician if the patient desires.

(b) It is the [physician assistant supervisor's] supervising physician's responsibility to be alert to patient complaints concerning the type or quality of services provided by the physician assistant.

(c) In the [physician assistant supervisor's] supervising physician's office and satellite locations, a notice plainly visible to patients shall be posted in a prominent place explaining that a "physician assistant" is authorized to assist a physician in the provision of medical care and services. The [physician assistant supervisor] supervising physician shall display [his] the registration to supervise in [his] the office. The physician assistant's [certificate] license shall be prominently displayed at any location at which [he] the physician assistant provides services. Duplicate [certificates] licenses may be obtained from the Board if required.

(d) The physician assistant shall wear an identification tag which uses the term "Physician Assistant," in [16 point] easily readable type. The tag shall be conspicuously worn.

§18.172. Notification of changes in employment.

(a) The physician assistant is required to notify the Board, in writing, of a change in or termination of employment or a change in mailing address within 15 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 physician assistant shall provide the Board with [his] the new

address of residence, address of employment and name of registered [physician assistant supervisor] supervising physician.

(b) The [physician assistant supervisor] supervising physician is required to notify the board, in writing, of a change or termination of [his] supervision of a physician assistant within 15 days.

(c) Failure to notify the Board of changes in employment or a termination in the physician/physician assistant relationship is a basis for disciplinary action against the physician's license, [physician assistant supervisor] supervising physician's registration and the physician assistant's [certificate] license.

DISCIPLINE

§18.181. Disciplinary and corrective measures.

(a) A physician assistant who engages in unprofessional conduct is subject to disciplinary action under section 41 of the act (63 P.S. §422.41). Unprofessional conduct includes the following:

(1) Misrepresentation or concealment of a material fact in obtaining a [certificate] license or a reinstatement thereof.

* * * *

(7) Impersonation of a licensed physician or another [certified] licensed physician assistant.

* * * *

(10) Continuation of practice while the physician assistant's [certificate] license has

expired, is not registered or is suspended or revoked.

* * * *

(12) The failure to notify the [physician assistant supervisor] supervising physician that the physician assistant has withdrawn care from a patient.

(b) The Board will order the emergency suspension of the [certificate] license of a physician assistant who presents an immediate and clear danger to the public health and safety, as required by section 40 of the act, (63 P.S. §422.40).

(c) The [certificate] license of a physician assistant shall automatically be suspended, under conditions in section 40 of the act.

(d) The Board may refuse, revoke or suspend a physician's [approval to supervise a physician assistant] registration as a supervising physician for engaging in any of the conduct proscribed of Board-regulated practitioners in section 41 of the act (63 P.S. §422.41).



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
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October 26, 2005

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

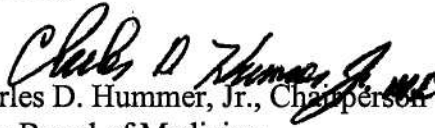
Re: Proposed Regulation
State Board of Medicine
16A-4916: Physician Assistants

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to physician assistants.

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., Chairperson
State Board of Medicine

CDH/SIH:sb

Enclosure

cc: Albert H. Masland, Chief Counsel
Department of State
Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
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-4916
 SUBJECT: BPOA: State Board of Medicine; Physician Assistants
 AGENCY: DEPARTMENT OF STATE #2505

TYPE OF REGULATION

- 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

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 REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
10/26/05	<i>Sandra J. Hager</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
10/26/05	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
10/26/05	<i>Stephen F. Hoffman</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
10/26/05	<i>C. Lee Brun</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)