Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency

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

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

16A-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: **Sabina I. Howell , Counsel**
State Board of Medicine (717) 783-7200
Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200**

(6) Type of Rulemaking (check one)

__**Proposed Rulemaking**
_X_**Final Order Adopting Regulation**
___**Policy Statement**

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

_X_ **No**
___ **Yes: By the Attorney General**
___ **Yes: By the Governor**

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

The rulemaking clarifies and updates the criteria to reflect current medical practice in the medical doctor community. The rulemaking reduces or eliminates 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.

Regulatory Analysis Form

(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 rulemaking permits the expanded use of physician assistants in a manner comparable to other physician extenders of similar education and training. The rulemaking also enhances 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 existing regulations prevent the effective use of physician assistants to the full extent of their training. The inability 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 rulemaking increases the accessibility of health care and decreases the cost of health care to patients in the Commonwealth by making more efficient use of physician assistants.

Regulatory Analysis Form

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

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

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

45,000 licensed medical doctors and 3,222 physician assistants certified to practice 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 revised its proposed rulemaking as a result of comments received.

(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, because the rulemaking 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.

Regulatory Analysis Form

(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

Regulatory Analysis Form

(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 existing regulations as they are, which would not reflect the current state of the art of medical doctor and physician assistant 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 healthcare 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. There are no federal standards relating to physician assistants,

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

This rulemaking 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 rulemaking is not restrictive, encourages collaboration, and is endorsed by the regulated community. The rulemaking 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.

Regulatory Analysis Form

(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.

The Board has perceived no group that would need a special accommodation.

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

The rulemaking will become effective upon final-form publication.

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

The Board continuously monitors the effectiveness of its regulations during the course of their implementation and enforcement.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2505

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INDEPENDENT REGULATORY
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 Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4916

DATE OF ADOPTION: _____

BY: _____

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: Andrew C. Clark

DATE OF APPROVAL
JUL 27 2006

(~~Executive~~ Deputy General Counsel)

[ ] 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 MEDICINE
49 PA. CODE, CHAPTER 18 and 16
PHYSICIAN ASSISTANTS

The State Board of Medicine (Board) amends its regulations §§ 16.11 and 16.13 (relating to licenses, certificates, and registrations; and licensure, certification, examination and registration fees) and §§ 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 pertaining to physician assistants and their supervising physicians, to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8) authorizes the Board to promulgate standards for licensing of physician assistants consistent with the requirements of sections 13 and 36 of the act (63 P.S. §§ 422.13 and 422.36). Section 13 of the act authorizes the Board to promulgate regulations which define the services and circumstances under which a physician assistant may perform a medical service.

C. Background and Purpose

The Board has determined that its regulations pertaining to the services and circumstances under which a physician assistant may perform a medical service, which define the supervision and personal direction required by the standards of acceptable medical practice embraced by the medical doctor community in this Commonwealth, are unduly restrictive. 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. Over 1,000 medical doctors, physician assistants and physician organizations wrote to support the proposed amendments, noting that the current regulations are in many ways overly and unnecessarily restrictive.

D. Summary of Comments and Responses to Proposed Rulemaking

Proposed rulemaking was published at 35 Pa. B. 6127 on November 5, 2005. The Board entertained public comment for a period of 30 days during which time the Board received comments from well over 1,000 medical doctors, physician assistants, health care facilities, medical practices, the Philadelphia College of Osteopathic Medicine, professional societies and physician assistant training programs. All of these individuals and entities were overwhelmingly supportive of the amendments. The Pennsylvania Medical Society and the Pennsylvania Society of Physician Assistants were not only

involved in the proposed rulemaking, they were positively disposed to the revisions and urged the rulemaking's expeditious completion.

Specific comments were made by the following: Pennsylvania Rural Health Association; Pennsylvania Association of Nurse Anesthetists, Pennsylvania Association for the Treatment of Opioid Dependence, Pennsylvania State Coroner's Association, The Hospital and Health Association of Pennsylvania (HAP) and Highmark.

Following the close of the public comment period, the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. The following is a summary of the comments and the Board's response:

The Pennsylvania Association of Nurse Anesthetists expressed concern that § 18.145 (relating to biennial registration requirements; renewal of physician assistant certification) could be interpreted to allow delegation of authority to physician assistants to administer general anesthetic agents. The Board believes that the Pennsylvania Association of Nurse Anesthetists is actually concerned about the amendment in § 18.151(a) (relating to role of physician assistant) which includes language that permits physician assistants to administer drugs. The physician assistant training program and re-certification each 6 years by the National Commission on the Certification of Physician Assistant (NCCPA) ensures that physician assistants are constantly kept up to date with the state of technology on general anesthesia and conscious sedation. In addition, oversight by the supervising physician acts as a control on, and verifies the ability of the physician assistant to competently perform appropriately delegated anesthesia services. Further, administration of general anesthetic agents is generally performed in hospital settings and is subject to additional oversight in that setting.

The Pennsylvania Coroner's Association recommended that language in the amendment of § 18.151(c) be clarified to ensure that the supervising physician or the county coroner, in the event the supervising physician is not available, certify the cause and manner of death. The Board agrees with the Pennsylvania Coroner's Association's recommendation, and has included clarifying language.

The Pennsylvania Rural Health Association (PHRA) and HAP both commented on § 18.153(b) (relating to executing and relaying medical regimens) in diametrically opposed directions. The PHRA suggested that the amendment which increased the time for reporting of changes to medical regimens from 12 hours to 36 hours was insufficient and too restrictive. It was suggested that 72 hours was a more reasonable time frame. HAP suggested that 24 hours was more than sufficient to communicate the execution or relaying of a medical regimen. In light of numerous favorable comments, the Board has decided not to alter the amendment.

In § 18.155(b)(4) (relating to satellite locations), the PHRA commented that the time frame requirement for physicians to visit satellite facilities ought to be increased

from "at least weekly" to every 2 weeks or 10 working days. The PHRA advised that the reason for establishment of satellite facilities would be compromised if weekly visits are required. The Board agrees with the PHRA's recommendation and has reduced the requirement for physician visits to 10 days.

The PHRA requested the deletion of the phrase "originally prescribed by the supervising physician" from § 18.158(a)(3) (related to prescribing and dispensing drugs, pharmaceutical aids and devices), as this requirement would be overly restrictive in rural clinics. The Independent Regulatory Review Commission also requested clarification from the Board on the necessity for this language. The Board agrees with the PHRA and has deleted this wording in the amendment.

The Pennsylvania Association for the Treatment of Opioid Dependence expressed concern that § 18.158 would give too much latitude to physician assistants in prescribing methadone, and that the "typical PA" would not be in a position to properly prescribe using their own judgment. The Board acknowledges that although methadone is a Schedule II drug with special societal concerns as relates to addicts, physician assistants who may prescribe this drug are not only specially trained to recognize the signs of addiction, they also work with supervising physicians who are also specially trained in addictions and choose those categories of drugs that the physician assistant is permitted to prescribe or dispense.

The Hospital Association of Pennsylvania (HAP) was generally supportive of the proposed revisions. The primary areas of concern for HAP were §§ 18.142 and § 18.153 (relating to written agreements; and executing and relaying medical regimens). Regarding § 18.142, HAP indicated that the written agreement would have limited applicability in the hospital setting, and that it would not be the authoritative document that would dictate physician assistant practice in a licensed acute or specialty hospital. HAP commented that a hospital could decide to limit the practice of a physician assistant in that setting to be more restrictive than in the written agreement. The Board is fully cognizant of how physician assistants operate within health care facilities, and notes that their functioning in such environments will not change under the amendments. However, in order to clarify to its licensees that health care facilities may restrict the practice of physician assistants, the Board has added language to that effect in § 18.161 (relating to physician assistants employed by medical care facilities).

The concerns of HAP regarding § 18.153 centered on the issuing of written and oral orders given by physician assistants in the setting of health care facilities. HAP recommended that specific language be drafted to address the issuing of orders by physician assistants within health care facilities. The Board agrees with HAP's recommendation, and has included language in § 18.153(c) which addresses HAP's concerns. The remainder of comments by HAP generally address credentialing and licensure matters, and not how physician assistants practice in health care facilities or any change in that practice. The Board has decided that further revision to the amendment is not warranted at this time. The Board will continue to monitor the role and utilization of

physician assistants as is already established in § 18.156 (relating to monitoring and review of physician assistant utilization).

Highmark was generally supportive of the amendments, and noted that they reflect the current standards for medical practice, and allow for the effective use of physician assistants to the full extent of their training. Highmark specifically commented on § 18.158, requesting that the Board retain language on prohibiting prescribing of Schedule II drugs, prohibiting off-label prescribing, and preventing the prescribing and dispensing of drugs until 90 days have elapsed after FDA approval. Highmark also suggested that the Board specify which medications could be ordered by a physician assistant to be refilled annually. As more fully described below, these amendments bring into line how the medical doctor community utilizes physician assistants. The physician assistant is still subject to the regulations of the Board and the Department of Health regarding dispensing standards, prescribing and labeling. In specialties that deal with chronic pain management and 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-term and long-term basis. 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.

Highmark commented that a requirement be added to § 18.142 requiring specific protocols be laid out for communication between physicians and physician assistants when a patient's condition changes suddenly. The Board sees this as contrary to the purpose of this amendment, which provides for the supervising physician to develop protocols based upon the specific nature and setting of the physician's practice. Highmark recommended that language be added to § 18.144 (relating to responsibility of primary supervising physician) that the supervising physician assess the physician assistant's knowledge, abilities and skills on an on-going basis. Highmark acknowledged that supervising physicians have the ultimate responsibility for the physician assistant's work. Experience has shown that when physicians work with physician assistants or other practitioners on an on-going basis, there is naturally an ongoing assessment of that individual's skill, abilities and knowledge. The Board notes that physician assistants must maintain national certification which requires, among other things, periodic re-examination.

The House Professional Licensure Committee (HPLC) directed that the Board consider the comments made by other commentators. The Board has done so. The HPLC requested that Board obtain comments and recommendations from the State Board of Pharmacy (Pharmacy Board) on physician assistants prescribing or dispensing pharmaceuticals. The Board requested comments from the Pharmacy Board. The Pharmacy Board was generally supportive of the amendments. The Pharmacy Board's main concerns were that using a negative formulary would place a delay on dispensing of medications to a patient while waiting for receipt of a copy of the written agreement from the physician assistant in confirming the physician assistant's prescriptive authority. The

Pharmacy Board also commented that some pharmacists report resistance from physician assistants in providing a copy of the written agreement. The Board takes note of this concern, however is cognizant of the fact that a positive formulary would also have required the pharmacist to obtain a copy of the written agreement. Therefore, delay in dispensing of prescribed medications to patients would not change with this amendment. The Pharmacy Board encouraged the Board to remind physician assistants of the requirement to provide a copy of the written agreement when requested, as well as reminding physician assistants to ensure that the supervising physician's name and license number appear on the prescription blank. The Pharmacy Board expressed concern that prescriptions for Schedule II controlled substances might not conform to time limitations of the regulations. The Federal Drug Enforcement Administration (DEA) makes it incumbent upon the pharmacist who fills the prescription to ensure that the physician assistant is prescribing within the parameters established by the state in which that individual practices. The Board has clarified the language in § 18.158(a)(3) and requires physician assistants to state on the prescription blank when the prescription is for initial therapy (for up to 72 hours), and for on-going therapy (up to a 30-day supply) if it was approved by the supervising physician for ongoing therapy. The Board places the onus of complying with these regulations on the physician assistant and the supervising physician, as the physician assistant must notify the supervising physician within 24 hours of the initial therapy prescription. The Board intends to place an article in its next newsletter reminding physician assistants and supervising physicians of their obligation to comply with requests for production of their written agreement upon implementation of this rulemaking.

The HPLC requested that the Board define "supervising physician" in § 18.122 (relating to definitions). That term was already defined in the proposed regulations and continues to be so defined. The HPLC requested clarification that all physicians assisted by physician assistants be called supervising physicians. The Board has modified the definition of supervising physician in § 18.122 to reflect the HPLC's concern.

The HPLC recommended that, to be consistent with the statute, § 18.142 should contain language requiring each physician who supervises a physician assistant to sign the written agreement. The Board notes that requirement is already in the regulations as they were originally promulgated. The HPLC further recommended that language which the Board deleted in proposed rulemaking concerning the approval of written agreements be restored. The Board has complied with this recommendation. The HPLC recommended that the term "works with" in § 18.142 be deleted and the term "assists" be restored for consistency with the statute. The Board has complied with that recommendation.

In § 18.151(b) the HPLC recommended that the phrase "training and experience" be added. The Board has no objection to including this language since it does not alter the intent of the provision and the regulated community believes the language will be understood by practitioners.

The HPLC believes there is a drafting error in § 18.158(a)(3) and recommends that the second sentence be listed as its own paragraph. The Board believes that it is critical that the sentence stay where it is, as it reinforces the mandate for the physician assistant to notify the supervising physician immediately, and no longer than within 24 hours, that a Schedule II drug has been prescribed.

The HPLC requested clarification regarding the duty of confidentiality between a physician assistant and a patient, and how the amendments would impact upon this duty. The Board is not cognizant of any changes in the amendment which would alter the current requirements of patient confidentiality, and how physician assistants interact with patients. There is no change in access to medical records or other patient information from the regulations as they currently exist. The HPLC also requested assurance that the medical regimen changes and counter-signature requirement changes, as well as notification and countersignature changes of prescribing of drugs by a physician assistant in § 18.158 are consistent with medical standards of the medical doctor community. The Board notified the regulated community that it intended to propose updating its physician assistant regulations and sought pre-draft 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. It was due to the ground swell of demand for increasing the flexibility of physician assistant regulations, and the recognition that physician assistants are a valuable and indispensable asset to physicians, that the changes have been made.

In § 18.161(b) the HPLC recommended that the language that addresses the number of physician assistant supervisors a physician assistant may have which was deleted in proposed rulemaking, be restored to be consistent with the statute. The Board has complied with that recommendation.

The HPLC recommended that the language in § 18.171 (relating to physician assistant identification) which is amended to state that the typeface be easily readable, be modified to state that it be at least a specified font size. The Board believes this recommendation for additional language is unnecessary. The regulations prohibit a physician assistant from providing medical service to a patient until that individual or their guardian has been notified that the physician assistant is not a physician, and that the patient has the right to be treated by the physician if the patient desires. Therefore, the Board believes the requirement that the identification tag be easily readable is sufficient.

The HPLC further requested detailed information on the following: a list of states which permit physician assistants to prescribe Schedule II drugs and their limitations; the scope of practice of physician assistants in other states; the supervision requirements of physicians in other states; in-depth information on the training, certification, clinical study, and continuing education of physician assistants; and a list of the types of documents which may be authenticated by a physician assistant. The Board is providing this information to the HPLC as a supplement to the amendment, because it is too voluminous to be incorporated into this preamble.

The Independent Regulatory Review Commission (IRRC) concurred with and incorporated the HPLC's comments as part of its comments. The IRRC recommended that in § 18.122 the phrase "personal direction" be restored in the definition of "supervision". The Board is agreeable to inserting the word "personal" in the revised definition of "supervision". The IRRC requested clarification that the definition of "supervising physician" includes all physicians who are assisted by physician assistants, and that there may be more than one supervising physician. The Board has no objection and has clarified the definition.

The IRRC requested clarification on how the Board would interpret personal contact in § 18.142(a)(3) as the definition of "direct supervision" is being deleted in the amendment. The Board believes that the definition of "supervision", which includes personal direction, in conjunction with the language in § 18.142(a)(3), which states that the written agreement must specify the frequency of personal contact, addresses this concern. Further, the Board is of the opinion that the degree and nature of personal contact is best determined between the supervising physician and the physician assistant. Ultimately, it is the belief of the Board that a form of communication which allows for interactive discussion in some form, be it in person, by telephone, radio, video-conferencing or other means, would accomplish personal contact.

In § 18.158(a)(3) the IRRC requested clarification from the Board on the necessity for the phrase "originally prescribed by the supervising physician." The PHRA, as noted above, requested that this wording be removed. The Board agrees with the IRRC and PHRA, and has deleted this wording in the amendment. Clarification is therefore no longer needed.

The IRRC commented that "at least weekly" or other specific time period be added to the record review requirement in § 18.159 (medical records). The Board has no objection, and has added language that record review be done within 10 days to the amendment.

E. Description of Amendments

The term "physician assistant supervisor" is replaced by "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."

The amendments to § 18.122 (relating to definitions), in addition to being primarily editorial in nature, clarify and emphasize that all supervising physicians still maintain personal direction over physician assistants. The definition of "supervising physician" reflects that any physician who is so designated in a written agreement is a supervising physician over that particular physician assistant. This is also compatible with the deletion of the definition of "direct supervision", a term which was found only at § 18.162 (relating to emergency medical services). The Board amended that section by

deleting the requirement that physician assistants provide emergency services only under the "direct" supervision of a supervising physician.

The definition of "supervision" is also 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, although maintaining the requirement for personal direction. 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) is amended to eliminate the requirement for weekly review of patient charts. The 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" is 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."

The amendments 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 regimen. This is further delineated as it pertains to medical facilities, by language in § 18.161(d) (relating to physician assistant employed by medical care facilities). The new language in this section is responsive to the concerns of medical facilities in their utilization of physician assistants and the integration of those individuals in the fabric of facility operations.

Section § 18.131 (relating to recognized educational programs) amends "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 (§ 63 P.S. 422.36(b)).

The amendment 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 CAHEA its accreditation body, independent and changed its name to CAAHEP. In 2000, 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) is 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 is amended to state that the agreement must 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. Prior to this amendment, the regulations specified 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. The amendment also requires the agreement to be signed only by each physician acting as a supervising physician or a substitute supervising physician instead of by each physician in the practice group, as well as the physician assistant.

Sections 18.144 and 18.155 (relating to responsibility of primary supervising physician; and satellite locations) are amended to eliminate the requirement for the supervising physician to see each patient on every third visit or at least once a year. The Board now requires at § 18.144(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 also applies to satellite facilities. Because the previous requirement applied to all patients who are treated by a physician assistant, it included 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 could not comply with the requirement. Attempts to meet the requirements of the prior regulation resulted 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 had to be involved due to the requirements of the prior regulation. Experience has demonstrated that the prior regulation was counter-productive. The option remains, as always, for the patient to request to be seen by the supervising physician.

Section 18.151 includes a list of tasks that the physician assistant could perform (subject to the proviso that the list is not all-inclusive). The Board determined that the

list of tasks physician assistants could perform was somewhat limiting. Although the regulation stated that the list was 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, would be permitted. The amendment replaces 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 establishes as a baseline standard that the physician assistant should be authorized to perform any medical service delegated by the physician, and which comports with the skills, training and experience of the physician assistant.

Section 18.152 (relating to prohibitions) currently prohibits a physician assistant from pronouncing death. The amendments to §§ 18.151 and 18.152 will 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 Section 502 of the Vital Statistics Law (35 P.S. § 450.502). Further, the amendment provides clarity that in situations where the attending physician is not available the county coroner be advised.

Section 18.151 as amended allows 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 <u>not</u> do is the performance of a medical service without physician supervision as set forth in the written agreement.

The 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, pharmaceutical aids and devices) for all medications prescribed or dispensed and is applicable to prescribing or dispensing "in accordance with the written agreement." The 12-hour time frame in both aspects of the regulations had proven 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 is amending § 18.153(b) by extending the period for reporting to the supervising physician from 12 to 36 hours in §18.155(b)(4) as in §18.153(c). For satellite facilities, the revisions would also lengthen the time for counter-signature to 10 days. During predraft input and during proposed rulemaking, 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. In §§ 18.153(c) and 18.161(d) the Board clarifies further that relaying, execution and recordation requirements or medical regimens and orders comply with written policies of medical facilities. The Board clarifies by these amendments that the written policies of medical care facilities may be more restrictive than the regulations of the Board.

Section 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 is eliminating 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 prior language created an unnecessary barrier to utilization of physician assistants in surgical, hematology/oncology, pain management and hospice care.

Section 18.158 includes a formulary of categories of drugs that a physician assistant may prescribe if permission is granted in the written agreement. The supervising physician would review this formulary and choose those categories of drugs that would allow the physician assistant to prescribe or dispense. The list would become a part of the written agreement that must be submitted to the Board. The amendment eliminates 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 amendment has the written agreement only contain a list of those categories of drugs that the physician assistant may <u>not</u> prescribe. The formulary suffers from the same limitations noted with the list of tasks a physician assistant can perform. The 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 amendment deletes current restrictions on prescribing of blood formation or coagulation drugs.

Section 18.158(a)(4) creates a 90-day waiting period after approval by the 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 amendments also delete 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 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 amendments further delete 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) (relating to delegation) and section 17(c) of the act (63 P.S. § 422.17(a)).

The Board is eliminating a prohibition in §18.158(c)(4)(i), which prevents 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 physician assistants. Pre-draft input suggested that experience has demonstrated that physician assistants have the knowledge and skill to properly perform this function.

Section 18.158(c)(4)(iii) does not allow physician assistants to prescribe medications for uses not approved by the FDA. The amendment 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. Physicians often prescribe drugs for uses other than approved by the FDA. This allows physician assistants to use the same drugs that the supervising physician uses for the same purposes. The decision to use a medication for such a purpose should be left to the physician. 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 Board amends § 18.158(c)(4)(iii) and (iv) to eliminate the statement 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 amendment removes from § 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 predraft input advised that this regulation is overly restrictive.

Section 18.158(c)(4)(viii) 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 when the physician assistant could 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 amendment eliminates these limitations. These limitations 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. These limitations could cause patients to incur additional costs for unnecessary office visits in order to continue receiving the medication.

Section 18.158(a)(5) is amended to add 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 the physician assistant is already authorized to dispense.

In addition, the amendment to § 18.158(a)(6) specifically requires that the physician assistant who will prescribe controlled substances must register with the DEA. The amendment to § 18.158(b)(2) also specifies that space on prescription blanks must be provided for the physician assistant to record the DEA number. This change underscores the requirement to register and serves to bring the physician assistant's practice into conformance with Federal law.

Existing regulations do not allow physician assistants to prescribe or dispense Schedule I or II controlled drugs. The amendment to § 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 also allows the physician assistant to write a prescription for a Schedule II controlled drug for up to a 30-day supply if 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 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.

The Board is amending § 18.158 to delete the prohibition against a physician assistant compounding ingredients when dispensing drugs except for adding water. 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 18.159 (relating to medical records) calls for timely review of medical records. The board clarifies this to state that such review shall not exceed 10 days.

Section 18.161(b) is amended to clarify that health care facilities may have more restrictive requirements for the utilization of physician assistants.

The Board is amending § 18.162 (relating to emergency medical services) by adding a new subsection (b) to address the practice of physician assistants in emergency situations. 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 to § 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 in an easily readable type. The typeface for 16 point can be excessively large, particularly for individuals with lengthy or hyphenated names. Further, physician assistants are already currently prohibited from rendering medical service to a patient until the patient or legal guardian has been informed that they are not a physician, that they are performing the medical service as an agent of the physician and as directed by the supervising physician, and that the patient has a right to be treated by the physician. Finally, the amendments render the regulations gender neutral.

F. Fiscal Impact and Paperwork Requirements

The amendments would have no adverse fiscal impact or additional paperwork requirements imposed on the Commonwealth, its political subdivisions 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 the notice of proposed rulemaking, published on November 5, 2005, at 35 Pa.B. 6127, to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (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 from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on _____ this final-form rulemaking was approved by the HPLC. On _____, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and approved the final-form rulemaking.

I. Contact Person

Further information may be obtained by contacting Sabina I. Howell, Counsel, State Board of Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649 or by e-mail at showell@state.pa.us.

J. Findings

The State Board of Medicine 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) (45 P.S. §§ 1201 and 1202) and the 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) This final-form rulemaking does not enlarge the purpose of proposed rulemaking published at 35 Pa.B. 6127.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing acts identified in Part B of this Preamble.

K. Order

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

(a) The regulations of the Board, 49 Pa. Code Chapters 16 and 18, are amended to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General 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) This order shall take effect on publication in the *Pennsylvania Bulletin.*

_____
Charles D. Hummer, Jr., M.D.
Chairperson

ANNEX A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE -- GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

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

* * * * *

(2) Physician assistant [certificate] <u>license</u>.

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

(1) Registration as a [physician assistant supervisor] <u>supervising physician</u> of a physician assistant.

* * * * *

§ 16.13 Licensure, certification, examination and registration fees.

* * * **

(c) *Physician Assistant* [*Certificate*] <u>*License*</u>

* * *

Registration, [physician assistant supervisor] supervising physician.....$35.

Registration of additional [supervisors] supervising physicians..... $ 5.

* * * * *

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 PERSONALLY 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~~ EACH physician who is identified in a written agreement as ~~the~~ A 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.]

(i) Oversight and PERSONAL 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.

(ii) An appropriate degree of supervision includes:

[(i)](A) * * *

[(ii)](B) Immediate availability of the [physician assistant supervisor] supervising physician to the physician assistant for necessary consultations.

[(iii)](C) Personal and regular [– at least weekly -] review WITHIN 10 DAYS 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) [of the American Medical Association], Commission for Accreditation of Allied Health Education Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or any successor organization. Information regarding ~~approved~~ ACCREDITED programs may be obtained directly from [CAHEA, 515 North State Street, Chicogo, IL, 60610] 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] satisfies the following requirements. The agreement [shall] must :

(1) Identify and be signed by the physician assistant and [each physician and physician assistant who will be assisting] each physician THE PHYSICIAN ASSISTANT WILL BE ASSISTING WHO WILL BE 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] must 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].

* * * * *

(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 may not exceed 10 days.

(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 an] supervising physician applicant who:

* * * * *

(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.

* * * * *

(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:

* * * * *

(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.]

(a) The physician assistant practices medicine with physician supervision. A physician assistant 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.

(b) The physician assistant may provide any medical service as directed by the supervising physician when the service is within the physician assistant's skills, TRAINING AND EXPERIENCE, 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.

(c) The physician assistant may pronounce death, but not the cause of death, and may authenticate with THE PHYSICIAN ASSISTANT'S signature any form related to pronouncing death. IF THE ATTENDING PHYSICIAN IS NOT AVAILABLE, THE PHYSICIAN ASSISTANT SHALL NOTIFY THE COUNTY CORONER. THE AUTHORITY TO RELEASE THE BODY OF THE DECEASED TO THE FUNERAL DIRECTOR SHALL BE THAT OF THE CORONER.

(d) The physician assistant may authenticate with THE PHYSICIAN ASSISTANT'S 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.

(e) The physician assistant shall be considered the agent 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] the 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:

* * * * *

§ 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) [The] As provided for in the written agreement, 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. WHEN WORKING IN A MEDICAL CARE FACILITY, A PHYSICIAN ASSISTANT MAY COMPLY WITH THE RECORDATION REQUIREMENT BY DIRECTING THE RECIPIENT OF THE ORDER TO RECORD, DATE AND AUTHENTICATE THEY RECEIVED THE ORDER, IF SUCH PRACTICE IS CONSISTENT WITH THE MEDICAL CARE FACILITY'S WRITTEN POLICIES. 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 supvisor] 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 shall] The statement must demonstrate that:

* * * * *

(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~~ ONCE EVERY 10 DAYS 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) [The] In a hospital, medical care facility or office setting, 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 nucolytic agents.

(x) Gastrointestianal 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 mydriatrics 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) Restrictions on a physician assistant's prescription and dispension 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 dispension.

(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 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 it was ~~originally prescribed by the supervising physician and~~ approved by the supervising physician for ongoing therapy. 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 must register with the Drug Enforcement Administration.

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

§ 18.159. Medical records.

The [physician assistant supervisor] supervising physician shall timely review, NOT TO EXCEED 10 DAYS, 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.

* * * * *

(b) [The physician assistant may not be responsible to more than three SUPERVISING PHYSICIANS 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.

(c) PHYSICIAN ASSISTANTS GRANTED PRIVILEGES BY OR PRACTICING IN A MEDICAL CARE FACILITY SHALL CONFORM TO POLICIES AND REQUIREMENTS DELINEATED BY THE FACILITY.

§ 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:

* * * * *

(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.

* * * * *

(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 type or larger] 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)].

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18]

Physician Assistants

The State Board of Medicine (Board) proposes to amend §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification examination and registration fees) and §§ 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 pertaining to physician assistants (PA) and their supervising physicians to read as set forth in Annex A.

A. *Effective Date*

The proposed rulemaking will be effective upon final-form publication 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 PA 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 PA 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 PAs. The existing regulations prevent the effective use of PAs to the full extent of their training. The Board notified the regulated community that it intended to propose updating its PA 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 the Proposed Rulemaking*

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

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

The proposed rulemaking amends the term "physician assistant supervisor" to "supervising physician" in § 18.121 (relating to purpose) and at all other places it appears in Chapters 16 and 18. The amendment emphasizes that the PA'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 in § 18.162 (relating to emergency medical services), which the Board proposes to amend by deleting the requirement that PAs 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 PAs are actually supervised and more clearly reflect the important responsibility that the PA assumes when serving in this role. The amendments primarily ease the need for the physical presence and intervention of the physician in oversight of the PA. The amended definition reiterates that the constant physical presence of the supervising physician is not required so long as the supervising physician and PA 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 PA 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 PA acting within the PA's scope of practice and in accordance with the written practice agreement between the supervising physician and the PA. 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 PA.

The proposed amendments would define "order" as "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." 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 PA training programs to recognition of those programs to more accurately reflect that the 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 proposed rulemaking updates the reference to the training program approvals for PAs by the AMA'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 AMA made CAHEA, its accreditation body, independent and changed its name to CAAHEP. In 2000, ARC-PA was created due to the overwhelming growth of PA 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 PA will assist each physician. The section would be amended to state that the agreement list functions that will be delegated to the PA, deleting the requirements that it also describe how the PA will assist each named physician and the details of how the supervising physician will be assisted. The amendments 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 PA. It would also describe how the PA "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 PA in the performance of delegated tasks and medical regimens to be administered or relayed by the PA. This requirement inhibits the effective utilization of PAs. In addition, it forces the Board to become more directly involved in the approval of practice guidelines for physicians and PAs rather than credentialing health care professionals.

Proposed amendments to §§ 18.144 and 18.155 (relating to responsibility of primary physician assistant supervisor; 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 in § 18.44(4) to require that the physician determine the need to see each patient based upon the patient's individual needs or at the patient's request. The amendment 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 PA 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 PA 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 PA 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 amend § 18.151. This section currently includes a list of tasks that the PA can perform (subject to the proviso that the list is not all-inclusive). The list of tasks PAs 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 proposed rulemaking would replace the list with statements that the PA may practice medicine with physician supervision and perform duties as delegated by the physician. As amended, this section would establish as a baseline standard that the PA should be authorized to perform any medical service delegated by the physician.

Currently, § 18.152 (relating to prohibitions) prohibits a PA from pronouncing death. The amendments proposed to §§ 18.151 and 18.152 would allow a PA to pronounce a patient dead and also allow a PA to authenticate with his signature any form related to pronouncing death. PAs who practice in long term care facilities, hospital wards, hospice care or in hematology/oncology, among other specialties, encounter circumstances when 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 section 502 of the Vital Statistics Law of 1953 (35 P. S. § 450.502).

Amended § 18.151 would also allow the PA 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 PA 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 PA 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 time frame 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 PAs taking weekend call, the reporting for minor problems would not occur until the following Monday.

The Board proposes to amend § 18.153(b) 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 3 to 10 days as in § 18.153(c). For satellite facilities, the proposed amendments would also lengthen the time for counter-signature to 10 days. During predraft input, the medical doctor community advised the Board that the current 3-day countersignature 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 amendment is also incorporated into §§ 18.142 and 18.158.

Current § 18.157 (relating to administration of controlled substances and whole blood and blood components) provides that a PA 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 PA on that authority. The Board believes that the current language creates an unnecessary barrier to utilization of PAs in surgical, hematology/oncology, pain management and hospice care.

Section 18.158 currently includes a formulary of categories of drugs that a PA may prescribe if permission is granted in the written agreement. The supervising physician reviews this formulary and chooses those categories of drugs that he will allow the PA 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 subsec-

tions (a) and (b) state that the physician can delegate prescribing, dispensing and administration of drugs and therapeutic devices to the PA if the drug or device is permitted under the written agreement. The PA would be subject to the regulations of the Board and the Department of Health regarding dispensing standards, prescribing and labeling. The proposed rulemaking would have the written agreement only contain a list of categories of drugs that the PA may not prescribe. The existing formulary suffers from the same limitations noted with the list of tasks a PA can perform. The current formulary is out-of-date and places restrictions on common drugs used to treat patient problems routinely managed by PAs. 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. PAs are routinely called upon to adjust medication levels. The proposed rulemaking 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 Food and Drug Administration (FDA) for a new drug or new uses for a drug before a PA can prescribe it. The proposed rulemaking eliminates 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 PAs, delaying the prescribing for 90 days is overly restrictive.

The proposed rulemaking 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 PA. However, § 18.144 requires the supervising physician to assume responsibility for the performance of the PA, so this amendment is editorial in that it simply eliminates redundancy.

The proposed rulemaking deletes subsection (g), which states that the PA may only prescribe or dispense drugs for a patient under the care of the supervising physician. PAs 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 PA as set forth in § 18.402(a)(6) (relating to delegation) and section 17(c) of the act (63 P. S. § 422.17(a)).

The Board proposes to delete a prohibition in § 18.158(c)(4)(i) preventing a PA 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. Predraft 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 PA 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 proposed rulemaking removes from § 18.158 (c)(4)(v) the prohibition on a PA 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 PA may not issue a prescription for more than a 30-day supply of medication except in cases of chronic illness where the PA can write for a 90-day supply. It also states that the PA can authorize refills up to 6 months from the original prescription. This proposed rulemaking 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.

Section 18.158(a)(5) is amended to add a provision authorizing the PA to receive, sign for and distribute drug samples. This provision will allow the PA to relieve the supervising physician of this duty and allow the PA to dispense samples of medications he is already authorized to dispense.

In addition, proposed § 18.158(a)(6) specifically mentions that the PA who will prescribe controlled substances must register with the Federal Drug Enforcement Administration (DEA). Proposed § 18.158(b)(2) also specifies that space on prescription blanks must be provided for the PA to record his DEA number. This amendment reminds the PA of the requirement to register and serves to bring the PA's practice into conformance with Federal law.

The current regulations do not allow PAs to prescribe or dispense Schedule I or II controlled drugs. Proposed § 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 PA 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 PA specialties that deal with chronic pain management. In specialties such as oncology, surgery, anesthesiology or in the family practice setting, PAs 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 PA is available. Also, there are many PAs 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 PA.

Current § 18.158(c)(4)(iii) does not allow PAs to prescribe medications for uses not approved by the FDA. This proposed rulemaking would no longer prohibit this "off-label" prescribing, but instead mandates that the PA 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 this 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 § 18.158 also would delete the prohibition against a PA compounding ingredients when dispensing drugs except for adding water in paragraph (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) (relating to physician assistant employed by medical care facilities) currently calls for the PA to only be responsible to a maximum of three supervising physicians. The proposed amendment to § 18.161 allows 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 PA to serve as house staff in a medical care facility for more than three physicians. This is particularly true in the surgical subspecialty setting. PAs 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.

This proposed rulemaking adds § 18.162(b) to address the practice of PAs in emergency situations. 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 to § 18.171 (relating to physician assistant identification) maintain the requirement that a PA 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. *Fiscal Impact and Paperwork Requirements*

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

F. *Sunset Date*

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

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on 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 must 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.

H. *Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding the proposed rulemaking to Gerald S. Smith, Board Counsel, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication for the proposed rulemaking in the *Pennsylvania Bulletin*.

CHARLES D. HUMMER, Jr., M. D.,
Chairperson

Fiscal Note: 16A-4916. 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 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

Registration of additional **[supervisors] supervising physicians** $5

* * * * *

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.]** 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.]**

(i) 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.

(ii) An appropriate degree of supervision includes:

[(i)] (A) * * *

[(ii)] (B) Immediate availability of the **[physician assistant supervisor] supervising physician** to the physician assistant for necessary consultations.

[(iii)](C) 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) **[of the American Medical Association], Commission for Accreditation of Allied Health Education Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or any successor organization.** Information

regarding approved programs may be obtained directly from CAHEA, 515 North State Street, Chicago, IL 60610. **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] satifies** the following requirements. The agreement **[shall] must:**

(1) Identify and be signed by the physician assistant and **[each physician the physician assistant who 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] must** 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].

* * * * *

(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 may not exceed 10 days.**

(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 an] supervising physician** applicant who:

* * * * *

(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**.

* * * * *

(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:

* * * * *

(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.]

(a) The physician assistant practices medicine with physician supervision. A physician assistant 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.

(b) 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.

(c) The physician assistant may pronounce death, but not the cause of death, and may authenticate with his signature any form related to pronouncing death.

(d) The physician assistant may authenticate with his 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.

(e) The physician assistant shall be considered the agent 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] the 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:

* * * * *

§ 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) **[The] As provided for in the written agreement, 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's 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) **[** ***Separate application requirement*** **]** ***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 shall] The statement must** demonstrate that:

* * * * *

(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] will** 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) **[The] In a hospital, medical care facility or office setting, 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 nucolytic agents.

(x) Gastrointestianal 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 mydriatrics 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) Restrictions on a physician assistant's prescription and dispension 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 dispension.

(ii) Prescribe or dispense Schedule 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.]

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 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 shall register with the Drug Enforcement Administration.

(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 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) *Inappropriate prescription.* 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.* 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 dispension 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 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 labelling of drugs.*** **A physician assistant shall comply with §§ 16.92, 16.93 and 16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51- 25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91- 25.95 (relating to labeling of drugs, devices and cosmetics).**

§ 18.159. 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.

* * * * *

(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:

* * * * *

(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.**

* * * * *

(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)].**

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

September 15, 2006

The Honorable Alvin C. Bush, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

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

Dear Chairman Bush:

Enclosed is a copy of a final 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., M.D., Chairperson
State Board of Medicine

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

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-4916
SUBJECT:	PHYSICIAN ASSISTANTS
AGENCY:	DEPARTMENT OF STATE – STATE BOARD OF 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
2006 SEP 15 AM 11:00
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/15/06	Lisa Seltzammer	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
9/15/06	Charlotte E. Yocum	
9-15-06		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
9-15-06		
9/15/06	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)