Dear Mr. Smith,

The Hospital & Healthsystem of Pennsylvania (HAP), on behalf of its members, more than 225 acute and specialty hospitals and health systems, appreciates the opportunity to comment on the Pennsylvania State Board of Medicine’s proposed revisions to the Physician Assistant regulations. The regulations are of particular interest to HAP and its members because of the increased utilization of PAs in acute and specialty hospitals throughout the Commonwealth. On September 27, 2003, the Pennsylvania Department of Health published a statement of policy that allows for the utilization of certified registered nurse practitioners (CRNPs), physician assistants, and certified nurse midwives (CNM) in acute and specialty hospitals provided that hospitals ensure the appropriate utilization of these practitioners consistent with their respective practice acts and regulations. In order to permit appropriate utilization of these practitioners in all care settings, it is important that each profession’s regulations be drafted in such a way as to recognize aspects of their practice unique to institutional settings, as well as, outpatient private practice settings, which is where the majority of physician assistants practice.

In general, HAP supports the proposed revisions to the physician assistant regulations because they broadly define how physician assistants may practice in the Commonwealth, provide for effective utilization of physician assistants to the fullest extent of their education and training, and appear to be more readily adaptable to future changes in medical practice and health care delivery. Before offering specific comments on the proposed physician assistant regulatory revisions, HAP would like to make sure that those reviewing the revisions understand how these regulations relate to other facility regulations with which hospitals must comply and highlight two major areas of the regulations that HAP believe require further consideration before codifying the regulations as final-form regulations.

Limitations of the Written Agreement between the Physician Assistant and Supervising Physician - HAP believes that while the requirements for a written agreement serves as an excellent tool for documenting the agreed to practice parameters between a physician assistant and his/her respective supervising physician, the written agreement in the hospital setting has limited applicability. In a hospital setting, hospital
privileges dictate physician assistant practice and the approved privileges for that particular practitioner is what frontline staff would refer to rather than the written agreement between the physician assistant and supervising physician. In short, the written agreement filed with the State Board of Medicine is not the authoritative document that dictates the physician assistant practice in a licensed acute or specialty hospital. Hospitals may require that it be filed to ensure that such an agreement exists to ensure compliance with Board regulations and to assist/inform in the determination of hospital privileges. However, a hospital may decide to limit the practice of a physician assistant in the hospital compared to what is contained in the executed written agreement between the physician assistant and supervising physician that is filed with the Board of Medicine. In the hospital setting, frontline staff will rely on the document that outlines the privileges that have been accorded the physician assistant and other hospital and medical staff policies, procedures, rules and requirements rather than the written agreement.

**Hospital Authority** – Hospitals may allow practice as dictated by the physician assistant regulations so long as other statute or regulations do not prohibit hospitals to utilize physician assistants as provided for in the proposed physician assistant regulations. Additionally, hospitals through their respective medical and clinical staffs may choose to limit physician assistant practice or require additional oversight of physician assistant practice in the hospital setting based on patient populations served and complexity of services offered. As a result, hospitals may:

- require greater supervision of physician assistant practice than what is required by Board regulations;
- limit which therapeutic, corrective or diagnostic measures may be ordered or administered/executed by physicians assistants for hospitalized patients and/or patients treated in outpatient settings that are under the license of the hospital;
- limits which medications may be ordered or administered for hospitalized patients and/or patients treated in outpatient settings that under the license of the hospital;
- determine how frequently the supervising physician needs to see hospitalized patients and those receiving care and treatment through an outpatient setting that is under the license of the hospital;
- determine how soon after executing, administering, and/or ordering a medical regimen, including medications, the physician assistant must be in contact with the supervising physician;
- mandate how frequently records of patients that have been seen or treated by a physician assistant must be reviewed by the supervising physician;
require countersignature of all physician assistant written or oral orders within 24 hours by the supervising physician in order to comply with DOH facility licensure requirements; and

- decide which health care professionals (taking into consideration other statutes and regulations) in the hospital or outpatient settings under the hospital license may implement an order for a medical regimen or medication from a physician assistant.

**Written and Oral Orders** - HAP supports the inclusion of language that deals directly with the role of physician assistants in issuing written and oral orders in the hospital setting; however, HAP cannot support these revisions as written until the Board more carefully considers and more specifically addresses physician assistant practice in the hospital setting.

Historically, there have been ongoing concerns about whether a physician assistant can issue written and oral orders and whether certain licensed health care practitioners, especially licensed professional nurses, can implement orders issued by a physician assistant. This has resulted in different legal interpretations and variation in practice in licensed health care facilities. The Pennsylvania DOH Statement of Policy on Specified Professional Personnel has greatly assisted in clarifying the role of the physician assistant, certified registered nurse practitioner, and certified nurse midwife in the hospital setting. However, many in the regulated community remain unclear as to whether certain health care professionals licensed in the Commonwealth are permitted to accept and implement orders issued by a physician assistant. HAP recommends that legal counsel for appropriate professional boards consider which licensed health care practitioners may accept written and oral orders from physician assistants in accordance with their respective practice acts and regulations.

**Prescribing and Dispensing of Medications** - HAP strongly encourages the Board with the assistance of a diverse group of practitioners, including pharmacists, nurse practitioners, physician assistants and others to reconcile the differences between the proposed revisions and existing physician assistant and certified registered nurse practitioner prescribing and dispensing regulations and to promulgate those regulations at the same time to avoid confusion and promote patient safety. The Pennsylvania State Board of Nursing is in the process of revisioning the certified registered nurse practitioner regulations and may be amenable to carving out these prescribing and
dispensing requirements as a separate regulatory package to avoid holding up promulgation of the physician assistant regulations.

HAP has attached its specific recommendations for consideration by the Board. HAP has also provided extensive recommendations with respect to written and oral orders that HAP believes need to be considered and addressed in final-form regulations in order to provide for sufficient clarification about physician assistant practice in the hospital environment.

HAP looks forward to revised physician assistant regulations that adequately reflect physician assistant practice in all health care settings. HAP also requests that the association be notified when the Board submits the final-form regulations to the House Professional Licensure and Senate Consumer Protection and Professional Licensure Committees as well as notice of any amendments or changes to the proposed version.

If you have any questions about HAP’s comments, please feel free to contact Lynn Leighton, vice president, professional & clinical services, HAP at (717) 561-5308 or by email at lgleighton@hapoline.org.

Sincerely,

PAULA A. BUSSARD
Senior Vice President
Policy and Regulatory Services

cc: Joanne Sorensen, Chair, Pennsylvania State Board of Nursing
    Teresa Lazo-Miller, Counsel, Pennsylvania State Board of Nursing
    Michael J. Romano, Chair, Pennsylvania State Board of Pharmacy
    Carole L. Clark, Counsel, Pennsylvania State Board of Pharmacy
    John R. McGinley, Jr., Chairman, Pennsylvania Independent Regulatory Review Commission
    Hon. Thomas P. Gannon, Chair, House Professional Licensure Committee
    Hon. Robert M. Tomlinson, Chair, Senate Consumer Protection and Professional Licensure Committee
GENERAL PROVISIONS

§18.122. Definitions. HAP supports the modifications made to several of the definitions contained in the regulations. Specifically, HAP supports:

- the deletion of direct supervision and the changes incorporated under the definition of supervision;
- the clarification made to the definition of medical regimen and the inclusion of a definition of order. An area that has proved problematic for hospitals and health systems with respect to utilization of certified registered nurse practitioners in the hospital setting has been the use of the term prescription which other state agencies and physician groups have interpreted as meaning that certified registered nurse practitioners can only prescribe from the identified formulary in certain ambulatory care settings. This has also been problematic to some degree in the existing physician assistant regulation. Inclusion of definitions for an order as well as prescription help to remedy this confusion and clearly indicate that physician assistants may issue orders in the hospital as well as provide prescriptions to patients ready for discharge from the hospital. In pre-draft CRNP regulations, HAP has recommended that the Board of Nursing consider adopting the same definitions to mark the distinction between an order and a prescription and to clearly identify that certified registered nurse practitioners may issue orders and prescriptions.

HAP recommends some minor modifications to the following definitions contained in the proposed regulations.

**Physician assistant examination** — An examination recognized by the Board to test whether an individual has accumulated sufficient academic knowledge to qualify for licensure as a physician assistant. [The Board recognizes the certifying examination of the NCCPA.] HAP recommends that identification of the certification exam be eliminated as there may be instances in the future where more than one examination or a different examination may be deemed acceptable by the Board.

**Physician assistant program** — A program for the training and education of physician assistants which is recognized by the Board and accredited by [the Committee on Allied Health Education and Accreditation (CAHEA), Commission for Accreditation of Allied Health Education Programs (CAAHEP), Accreditation Review Commission (ARC-PA) or any successor agency] an organization(s) recognized by the United States Department of Education and the Board. It is not clear whether all of the agencies listed currently accredit physician assistant programs or whether it is one agency whose name has been changed over the years. As in the previous recommendation, HAP recommends avoiding where possible the actual naming of accrediting agencies.

**Primary supervising physician** — A medical doctor who is currently licensed in the Commonwealth, registered with the Board, and designated in the written agreement as having primary responsibility for directing and supervising the physician assistant. HAP believes that
the regulations assume that the supervising physician is licensed by the Board of Medicine, but it is not explicitly stated in the physician assistant regulations.

**Substitute supervising physician** – A supervising physician who is *currently licensed in the Commonwealth*, registered with the Board, and designated in the written agreement as assuming primary responsibility for a physician assistant when the primary supervising physician is unavailable.

**Supervising physician** – A physician who is *currently licensed in the Commonwealth* and identified in a written agreement as the physician who supervises a physician assistant.

**Supervision**

(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]. HAP does not believe it is necessary to identify the means by which the two parties need to be in contact with each other; however, it is important that both parties outline the primary means that they will use to communicate with each other in the executed written agreement.

**PHYSICIAN ASSISTANT EDUCATIONAL PROGRAMS**

§18.131. Approved educational programs. – As indicated in previous comments related to the definition of a physician assistant program, HAP questions whether it is prudent to list those agencies currently involved in the accreditation of physician assistant programs, since the names of those agencies may change or there may be changes in the actual list of accrediting bodies. HAP suggests that the Board recognize physician assistant educational programs accredited by an organization recognized by the United States Department of Education and the Board.

**CERTIFICATION OF PHYSICIAN ASSISTANTS AND REGISTRATION OF PHYSICIAN ASSISTANT SUPERVISORS**

§18.142. Written agreements. – HAP supports the proposed revisions to this subsection of the PA regulations. HAP suggests the following revision to §18.142.(a)(1) The agreement must identify and be signed by the physician assistant and each physician acting as a supervising physician. As least one physician shall be a medical doctor *currently licensed in the Commonwealth*.

Since the Board has proposed the elimination of the list of functions and/or procedures that the physician assistant may perform under the supervision of a physician in §18.151 which formed the basis for the written agreement in the past, HAP recommends that the Board consider developing a written agreement template for use by supervising physicians and physician assistants which cues each party to consider what should be addressed and included in the written agreement. Use of a standardized document will assist the Board in ensuring that all relevant areas of interest to the Board are appropriately and thoroughly addressed in the written agreement.
§18.143. Criteria for registration as physician assistant supervisor. - HAP suggests the following revision to §18.143(a)(2). The Board will approve for registration as a physician assistant supervisor an applicant who has filed a completed Board approved registration form accompanied by the written agreement (see §18.142 relating to written agreements) and the required fee under §18.13 (relating to licensure, certification, examination, and registration fees). The 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.

HAP suggests the use of a Board approved registration form to ensure consistency and completeness of information submitted to the Board.

PHYSICIAN ASSISTANT UTILIZATION

§18.151. Role of physician assistant. - The proposed revisions eliminate the lists of functions, tasks or procedures that the physician assistant can perform. The introduction to the revised regulations states that, “As amended, this section would establish as a baseline that the physician assistant should be authorized to perform any medical service delegated by the physician.” As proposed, this regulation suggests that each physician assistant does not possess a baseline scope of practice and competencies, but rather derives his/her scope of practice from the supervising physician. HAP is concerned that in settings where there is not sufficient regulatory oversight that this proposed amendment may compromise patient safety.

HAP suggests that the Board identify a set of baseline skills or core competencies that all physician assistants should possess in order to practice in the Commonwealth. These skills or competencies should be derived from the accredited physician assistant education programs recognized by the Pennsylvania State Board of Medicine. HAP recognizes that physician assistants will be able to perform additional procedures, functions, and tasks once in practice with a supervising physician that the supervising physician may educate and train the physician assistant to perform. However, HAP would suggest that there will always be some procedures and/or functions that will clearly be outside of bounds regardless of an interest on the part of the supervising physician to delegate those procedures, functions or tasks to the physician assistant. As articulated earlier in this comment letter, there are controls that exist in regulated entities such as hospitals that would prevent this from happening, but this is not the case in all health care settings across the Commonwealth.

In addition to specifically identifying the core competencies that form the basis of physician assistant practice, HAP recommends that §18.151(b) be modified to recognize this basic scope of practice. Specifically, HAP recommends that this provision read as follows, The physician assistant may provide [any] selected medical services as directed by the supervising physician when the service is within the physician assistant’s scope of practice, 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 accepted standards of medical practice.

HAP is also concerned with §18.15(e) which suggests that any other licensed, certified, or registered health care practitioner who is not a physician might be compelled to implement the written or oral orders of a physician assistant because the physician assistant is serving as an agent of the supervising physician. HAP suggests that this provision be revised after considering the impact of this requirement on other licensed, certified, or registered health care practitioners, especially those of equal, equivalent or more education and training than the physician assistant.
§18.153. Executing and relaying medical regimens. HAP recommends that this subsection be titled, Executing and relaying medical regimens by written or oral order.

§18.153.(a) - HAP supports the inclusion of language that deals directly with the role of physician assistants in issuing written and oral orders in the hospital setting; however, HAP cannot support these revisions until they consider more carefully the practice of the physician assistant in the hospital setting. Additionally, HAP recognizes that there may be differences in what medications the physician assistant may be permitted to order by the supervising physician in the hospital versus what medications the physician assistant may be permitted to prescribe. If such differences exist, they should be spelled out in the written agreement. The requirements for expressly addressing such differences should be reflected appropriately in §18.142, Written agreements.

Historically, there have been ongoing concerns about whether a physician assistant can issue written and oral orders and whether certain licensed health care practitioners, especially licensed professional nurses, can implement orders issued by a physician assistant. This has resulted in different legal interpretations and variation in practice in licensed health care facilities. The Pennsylvania DOH Statement of Policy on Specified Professional Personnel has greatly assisted in clarifying the role of the physician assistant, certified registered nurse practitioner, and certified nurse midwife in the hospital setting. However, many in the regulated community remain unclear as to whether certain health care professionals licensed in the Commonwealth are permitted to accept and implement orders issued by a physician assistant. HAP recommends that legal counsel for appropriate professional boards consider which licensed health care practitioners may accept written and oral orders from physician assistants in accordance with their respective practice acts and regulations.

§18.153.(b) - HAP agrees with this provision. However, HAP believes that 24 hours rather than 36 hours represents more than sufficient time to reach and communicate with the supervising physician when the physician assistant has executed or relayed a medical regimen by written or oral order. In the case of hospital practice, 24 hours may even be considered too long.

§18.153.(c) - This provision as written does not capture the practice of those physician assistants that practice primarily in the hospital setting. This provision appears to speak to the requirements of the physician assistant who works primarily in an office practice. Specifically, the physician assistant would document any medical regimen executed by the physician assistant in the patient's office chart as well as any order relayed by the physician assistant to another health care practitioner in the patient's office chart. Since the proposed regulations contain other provisions that would essentially eliminate the need for the supervising physician to review and sign-off on all records, HAP questions whether this requirement as written does not conflict with these other recommended revisions in the physician assistant regulations.

As stated earlier, these provisions do not adequately deal with practice in an acute care or specialty hospital and HAP cannot support this regulatory package until these provisions accurately address physician practice in the hospital. HAP recommends that the Board consider the following:

§18.153(c). Written orders.

(i) Physician assistants may write orders necessary for patient management, including admission, discharge, medications, diagnostic tests, and other therapeutic measures or
treatment in accordance with their legally authorized scope of practice, executed agreement with their supervising physician, health care facility clinical privileges and duties, position description, and/or other relevant health care facility policies and procedures.

(ii) Written orders may be issued by facsimile transmission or use of computerized order entry systems. Written orders shall include the date and time that the order was written.

(iii) The orders shall be implemented only by those persons qualified by education, training and demonstrated competency and authorized to perform tests and administer medications and treatment in the facility in accordance with scope of practice standards and health care facility policy.

(iv) The supervising physician will only be executed upon signed order of the physician assistant.

(v) The supervising physician countersignature shall appear on a written order in the medical record within a reasonable time not to exceed 10 days, unless countersignature is required sooner by facility regulation, policy within the medical care facility, or the requirements of a third-party payor.

§18.153(c). Oral orders.

(i) Physician assistants may issue oral orders for admission, discharge, medications, diagnostic tests, and other therapeutic measures or treatment when waiting for a written order would delay appropriate and timely patient management.

(ii) Oral orders shall be accepted, transcribed, and implemented only by persons qualified and authorized to accept and transcribe orders in accordance with scope of practice standards, regulations, and health care facility policy.

(iii) The physician assistant and/or supervising physician shall be required to authenticate those oral orders within a reasonable time not to exceed 10 days, unless countersignature is required sooner by facility regulations, policy within the medical care facility, or the requirements of a third-party payor.

(iv) Physician assistants may accept, transcribe, and implement oral orders from their supervising and/or consulting physicians.

§18.153.(d) – HAP supports immediate access to the written agreement for any practitioner who questions whether a physician assistant may issue a written or oral order for a medical regimen or execute a medical regimen. HAP suggests that in the event the health care practitioner does not believe that the written agreement sufficiently addresses the question or circumstances, then the health care practitioner shall discuss the situation immediately with the physician assistant supervising physician. As already stated in the HAP comment letter, the written agreement is not necessarily the authoritative document that spells out the physician practice in the hospital setting. Additionally, in the hospital environment, other health care professionals who raise questions about a physician assistant order are afforded mechanisms to have those concerns addressed. It therefore seems reasonable that should questions arise, immediate access to the supervising physician should be afforded to the health care professional who has questions or concerns about the order or the physician assistant’s practice and that this should be codified in regulation.

§18.155. Satellite locations. – HAP agrees with the proposed recommended revisions, but believes that the written agreement should spell out the criteria by which the physician assistant and supervising physician will recognize which patients need to be seen by the physician and which patient charts need to be reviewed by the physician. The requirements for expressly addressing such criteria should be reflected appropriately in §18.142. Written agreements.
§18.156. Monitoring and review of physician assistant utilization. - In hospitals, the practice of physician assistants is appropriately monitored by the Pennsylvania DOH during survey and when a complaint may be received by the department. As a matter of course, HAP questions to what extent the Pennsylvania State Board of Medicine monitors the utilization of physician assistant in physician offices and other unregulated health care facilities. HAP would appreciate information related to the monitoring and review of physician assistants by the State Board of Medicine be addressed in the introduction to the regulations. It is unclear whether this enforcement is ongoing or whether monitoring and investigation only occurs on the basis of a complaint made through the Bureau of Professional and Occupational Affairs.

§18.157. Administration of controlled substances and whole blood and blood components. - HAP recognizes that physician assistants may be directed by their supervising physician to administer controlled substances or blood/blood components to specific patients. In these situations, the physician assistant should be required to transcribe the order appropriately in that patient’s medical record in accordance with the practice prescribed by regulations or health care facility policy. HAP also recognizes that physician assistants in practice with certain types of physicians may be more involved in the ordering and/or prescribing of blood products, anticoagulation medications, and pain medications. In these situations, the written agreement should spell out what exactly the physician assistant is permitted to do. As stated previously, the written agreement may not be used exclusively to determine physician assistant practice in the hospital.

§18.158. Prescribing and dispensing drugs. - The proposed revisions to this subsection represent a significant change to current regulation and practice, where the supervising physician must choose those categories of medications that the physician assistant will be allowed to prescribe or dispense and document those medications in the written agreement. As currently proposed, an identified formulary of medications would no longer exist in the regulations and the supervising physician would no longer need to choose which categories of drugs that the physician assistant will be permitted to order, prescribe or dispense. Rather, the supervising physician would identify only those medications that the physician assistant cannot order, prescribe or dispense.

This change as well as several other proposed regulatory changes in this subsection would make the prescribing practice different for physician assistants than what currently exists for certified registered nurse practitioners. HAP is concerned that such differences may create confusion in the health care community and seriously compromise patient safety. HAP supports a standard of practice that applies to physician assistants and certified registered nurse practitioners to avoid confusion and potential error. If this is the direction that the State Board of Medicine wants to pursue, then a common set of regulations related to the prescribing and dispensing of medications should be issued by both Boards simultaneously.

At the present time, HAP supports retaining and/or modifying the categories of medications that a physician assistant may order, prescribe or dispense, including adding anti-coagulation medications to the formulary rather than eliminating the formulary. HAP believes that there are certain high-risk medications that the physician assistant should never routinely prescribe or dispense, including chemotherapy, oxytocics, radioactive agents, inhalation agents, pentothal, or diprivan by regulation. HAP strongly recommends that the Board reconsider these revisions to the proposed physician assistant regulations and that the Board work collaboratively with practicing pharmacists and other health care practitioners to develop a list of those medications that should never be ordered, prescribed or dispensed by physician assistants. This list should be
included in the physician assistant regulations. HAP would also support provisions in the regulations that allow for the inclusion of medications not addressed in the formulary or medications expressly prohibiting for prescription by the physician assistant to be addressed in the written agreement depending on the nature of the practice of the supervising physician and physician assistant.

HAP concurs with several of the other suggested modifications to this subsection, including:

- eliminating the time frame by which a physician assistant may prescribe or dispense a new medication approved by the Food and Drug Administration (FDA). It seems unreasonable to limit access to new medications, unless the supervising physician determines that he/she wants to determine which patients are eligible for a new medication and wants to prescribe the medication before the physician assistant is authorized to renew the prescription for the medication.
- eliminating the requirement that the physician assistant may not prescribe or dispense drugs not approved by the FDA since this is against the law for physicians and others authorized to prescribe medications.
- authorizing physician assistants to receive, sign for, and distribute drug samples.
- eliminating restrictive time frames for the refill of prescribed medications and permitting reasonable clinical judgment and discretion as to how many refills the patient may receive of the original medication prescription.
- permitting the physician to prescribe or dispense Schedule II medications in a manner that is similar to what the certified registered nurse practitioner is permitted by regulation. However, there are some differences between what is proposed for the physician and what exists in regulation for the certified registered nurse practitioner.

HAP strongly encourages the Board with the assistance of a diverse group of practitioners, including pharmacists, nurse practitioners, physician assistants and others to reconcile the differences between the proposed revisions and existing physician and certified registered nurse practitioner prescribing and dispensing regulations and to promulgate those regulations at the same time to avoid confusion and promote patient safety. The Pennsylvania State Board of Nursing is in the process of revising the certified registered nurse practitioner regulations and may be amenable to carving out the prescribing and dispensing requirements as a separate regulatory package to avoid holding up promulgation of the physician assistant regulations.

MEDICAL CARE FACILITIES AND EMERGENCY MEDICAL SERVICES

§18.161. Physician assistant employed by medical care facilities. — HAP supports the proposed revisions to the regulations which would allow hospitals flexibility in staffing and utilization of physician assistants as house staff for more than three physicians. This is particularly beneficial in surgical specialties where physician assistants may rotate among surgical groups and be responsible to multiple surgeons. The current regulations restrict this ability.

§18.162.(a) Emergency medical services. — HAP supports the deletion of the requirement for direct supervision of the physician assistant by the supervising physician in an emergency medical care setting (hospital emergency room, urgent care facility, and/or fast track in a hospital emergency room) and provisions that would allow licensed physician assistants to respond in the case of disaster situations (a declared state of emergency at the state or local level) without having to meet the usual requirements for themselves and physicians working with them provided they render care consistent with relevant standards of care.
IDENTIFICATION AND NOTICE RESPONSIBILITIES

§18.171. Physician assistant identification, and §18.172. Notification of changes in employment. – HAP concurs with the minor revisions that the Board proposes making to the physician assistant regulations.

DISCIPLINE

§18.181. Disciplinary and corrective measures. – HAP concurs with the minor revisions that the Board proposes making to the physician assistant regulations.