REGISTRAR'S SUBMISSION PACKAGE

BOARD OF MEDICINE 18 VAC 85-50-10 et seq.

Regulations Governing the Practice of Physician Assistants

Analysis of Proposed Amendments to Regulation

1. Basis of Regulation:

Title 54.1, Chapter 24 and Chapter 29 of the Code of Virginia provide the basis for these regulations.

Chapter 24 establishes the general powers and duties of health regulatory boards including the power to establish qualifications for licensure and renewal, to promulgate regulations and to issue inactive licensees.

§§ 54.1-2949 through 54.1-2953 establish the requirement for licensure of physicians' assistants, the requisite training and supervision, and the authority to prescribe certain prescription drugs.

2. Statement of Purpose:

The purpose of the proposed amendments is to establish inactive licensure for physician assistants pursuant to the specific authority granted in the Code of Virginia by Chapter 469 of the 1998 Acts of the Assembly. The amended regulations set forth the qualifications, fees and requirements for reactivation of an inactive license which are consistent with protection of the public health and safety.

3. Substance of Regulations:

18 VAC 85-50-58. Inactive licensure

The proposed regulations would add a section establishing a category of inactive licensure and specifying that such a license holder is not required to maintain certification by the NCCPA, but is likewise not entitled to practice as a physician assistant.

To reactivate an inactive license, the physician assistant is required to provide documentation of having renewed or maintained NCCPA certification and to pay the difference between the current inactive and active renewal fee.

The Board reserves the right to deny a request for reactivation to any person determined to have committed a violation of these regulations or of § 54.1-2914 of the Code of Virginia.

18 VAC 85-50-170. Fees.

Amendments are proposed in this section to: a) establish a lesser fee for renewal of an inactive license (\$60 per biennium versus \$80 for an active license); b) to increase the penalty fee for late renewals from \$10 to \$25, consistent with other professions (physical therapists, occupational therapists, radiologic technologists and licensed acupuncturists); and c) to establish a fee and required submission for information on practice for persons who want to reinstate an expired license after two or more years.

4. <u>Issues of the Regulations</u>

ISSUE 1: Establishment of an inactive license.

The Department of Health Professions sought legislation in the 1998 General Assembly to give authorization to all boards to issue an active license. Some boards within the Department already had such authority in the practice act for the particular professions regulated, but an amendment to § 54.1-2400 granted general authority to set out the qualifications, fees and conditions for reactivation of inactive licensure.

The Board of Medicine currently requires a physician assistant to maintain current certification by the National Commission on Certification of Physician Assistants (NCCPA) in order to renew a license. NCCPA requires a minimum of 100 hours of continuing medical education for a 2-year renewal period; 40 of those hours must be classified as Category I or pre-approved programs recognized by the American Academy of Physician Assistants. For someone who is not planning to actively practice for a period of time, it may be unnecessarily burdensome to have to take the continuing education hours required by NCCPA to maintain certification. By taking an inactive status, the licensee is not required to maintain certification but is not permitted to practice. If the licensee wants to reactivate a license, it would be necessary to provide documentation that he has first taken the continuing education hours necessary to reactivate his certification with NCCPA.

Advantages and disadvantages

There are no disadvantages for the public which remains protected by requirements that assure that physician assistants are current in their skills and knowledge. By requiring an inactive licensee to be certified by the NCCPA, the Board is providing assurance of minimal competency as it does in initially granting a license to practice. For persons who do not want to actively practice for a period of time, these regulations will allow them to maintain an

inactive license and eliminate the need to reapply for reinstatement of an expired license. Renewal of an inactive license is also less expensive than renewal of an active license.

ISSUE 2: Requirements for reinstatement of an expired license.

In proposing regulations for an inactive license, the Board determined that it was also necessary to set forth the requirements for reinstatement of a license expired for two years or more. Within the two years after expiration, a licensee may renew by payment of the renewal fee and an administrative fee (proposed to be \$25), provided the licensee is qualified for renewal.

After two years, the expired license may only be reinstated by submission of a reinstatement application which includes information on practice and licensure in other states during the period in which the license was lapsed in Virginia and payment of a reinstatement fee of \$125.

Advantages and disadvantages

The proposed regulation provides a means for a licensee who has allowed his license to lapse to reinstate, but it also protects the public by requiring that the applicant provide complete information on practice and licensure in other jurisdictions during that period. The Board maintains its authority to deny reinstatement to anyone who has committed acts in violation of law or regulation.

5. <u>Estimated Fiscal Impact of the Regulations</u>

I. Fiscal Impact Prepared by the Agency:

Number of entities affected by this regulation:

There are 523 physician assistants licensed in Virginia; 46 of those list an out-of-state address. Some of those who live out-of-state may choose an inactive license if they are not actively practicing in Virginia.

Projected cost to the agency:

The agency will incur some costs (less than \$1000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities. Since these regulations are being amended simultaneously with other regulations of the Board, the costs of mailings, meetings and hearings will be shared by several professions. In addition, every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

The potential loss of income to the Board from persons who choose inactive licensure is minimal. It is estimated that only 15 - 20 licensees will become inactive at a cost of \$300 to

\$400 per biennium in reduced revenue to the Board. If an inactive licensure status is not available, it is not known how many of those 15-20 persons would choose to let their Virginia license lapse at a loss of income of \$1200 to \$1600 per biennium. Therefore, rather than resulting in a loss of income, inactive licensure may in fact result in preservation of revenue to the Board.

Projected costs to the affected entities:

There would be no additional costs for compliance with these regulations for the vast majority of physician assistants. For a small number (2-3 per renewal cycle) who do not renew their licenses on time, there will be an additional cost of \$15 for an administrative fee to process a late renewal in house. For those who allow their licenses to expire for more than two years (estimated to be 2 or 3 in number), there will be a cost of \$125 to reinstate the license.

For those persons who are not actively practicing in Virginia but who want to maintain a license, there would be a savings of \$20 biennially.

Citizen input in development of regulation:

In the development of regulations, notices were sent to persons on the public participation guidelines mailing list of every meeting of the Advisory Board on Physician Assistants, the Legislative Committee of the Board, and of the Board itself. A Notice of Intended Regulatory Action was also sent to persons on the list; no comment was received on the NOIRA. Public comment was also received at each meeting.

Localities affected:

There are no localities affected by these regulations in the Commonwealth.

II. Fiscal Impact Prepared by the Department of Planning and Budget:

(To be attached)

III. Agency Response:

c. Source of the legal authority to promulgate the contemplated regulation.

18 VAC 85-50-10 et seq. Regulations Governing the Practice of Physician Assistants was promulgated under the general authority of Title 54.1 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and issue an inactive license.

- § 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:
 - 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.
 - 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.
 - 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.
 - 4. To establish schedules for renewals of registration, certification and licensure.
 - 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
 - 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title.
 - 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.
 - 8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.
 - 9. To take appropriate disciplinary action for violations of applicable law and regulations.

- 10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.
- 11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.
- 12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.
- **18 VAC 85-50-10 et seq.: Regulations Governing the Practice of Physician's Assistants** was promulgated under the general authority of § 54.1-2949 through § 54.1-2953 of the Code of Virginia.
- § 54.1-2949. License required.--It shall be unlawful for a person to practice or to hold himself out as practicing as a physician's or podiatrist's assistant unless he holds a license as such issued by the Board.
- § 54.1-2950. Requisite training and educational achievements of assistants.--The Board shall establish a testing program to determine the training and educational achievements of the assistant or the Board may accept other evidence, such as experience or completion of an approved training program, in lieu of testing and shall establish this as a prerequisite for approval of the licensee's application.

Pending the outcome of the next examination administered by the National Commission for Certification of Physicians' Assistants, the Board may grant provisional licensure to graduates of physicians' or podiatrists' assistants curricula which are approved by the Committee on Allied Health Education and Accreditation of the American Medical Association or the Committee on Education of the American Podiatry Association. Such provisional licensure shall be granted at the discretion of the Board.

§ 54.1-2951. Application to supervise assistants.--The Board shall formulate guidelines for the consideration of applications to supervise and employ assistants. Each application shall include the following:

- 1. The qualifications, including related experience, possessed by the assistant;
- 2. The professional background and specialty of the licensee who will supervise the assistant;
- 3. A description of the practice and the way in which the assistant is to be utilized.

§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.

A. A physician, or a podiatrist licensed under this chapter may apply to the Board to supervise assistants and delegate certain acts which constitute the practice of medicine to the extent and in the manner authorized by the Board.

No licensee shall be allowed to supervise more than two assistants at any one time. However, a licensee, in the performance of his duties with the Department of Corrections, may supervise more than two assistants under the terms and conditions of supervision and control prescribed by the Board.

Any professional corporation or partnership of any licensee, any hospital and any commercial enterprise having medical facilities for its employees which are supervised by one or more physicians, or podiatrists may employ one or more assistants in accordance with the provisions of this section.

Activities shall be delegated in a manner consistent with sound medical practice and the protection of the health and safety of the patient. Such services shall be limited to those which are educational, diagnostic, therapeutic or preventive in nature, but shall not include the establishment of a final diagnosis or treatment plan for the patient or the prescribing or dispensing of drugs, except as provided in § 54.1-2952.1.

- B. No assistant shall perform any delegated acts except at the direction of the licensee and under his supervision and control. Every licensee, professional corporation or partnership of licensees, hospital or commercial enterprise that employs an assistant shall be fully responsible for the acts of the assistant in the care and treatment of human beings.
- C. In order to ensure adequate and proper medical treatment to inmates of Virginia correctional institutions and facilities, the Board shall have the authority to promulgate regulations permitting the employment of assistants by the Virginia Department of Corrections.

§ 54.1-2952.1. Prescription of certain controlled substances and devices by licensed physician's assistant.

A. A licensed physician's assistant shall have the authority to prescribe Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title upon the provision to the Board of Medicine of such evidence as it may require that the assistant has entered into and is, at the time of writing a prescription, a party to a

written agreement with a licensed physician or podiatrist which provides for the direction and supervision by such licensee of the prescriptive practices of the assistant.

- B. It shall be unlawful for the assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensee and the assistant.
- C. The Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of assistants as are deemed reasonable and necessary to ensure an appropriate standard of care for patients. The regulations promulgated pursuant to this section shall include, at a minimum, (i) a formulary of the specific Schedule VI drugs and devices that the assistant is eligible to prescribe pursuant to this section to the extent, and in the manner, authorized in a written protocol between the assistant and the supervising licensee; (ii) requirements for periodic site visits by supervising licensees who supervise and direct assistants who provide services at a location other than where the licensee regularly practices; and (iii) a requirement that the assistant disclose to his patients the name, address and telephone number of the supervising licensee and that he is a physician's assistant. A separate office for the assistant shall not be established.

In order to maintain a current and appropriate list of specific Schedule VI drugs and devices, the Board of Medicine, in consultation with the Board of Pharmacy, may, from time to time, amend the formulary required by this subsection and, as provided in § 9-6.14:4.1, shall be exempted from the Administrative Process Act (§ 9-6.14:1 et seq.) when so doing. The Boards shall, however, jointly conduct public hearings prior to making such amendments to the formulary. Thirty days prior to conducting such hearing, the Boards shall give written notice by mail of the date, time, and place of the hearings to all currently licensed assistants and any other persons requesting to be notified of the hearings and publish notice of their intention to amend the formulary in the Virginia Register of Regulations. Interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any amendments. Proposed and final amendments of the list shall also be published, pursuant to § 9-6.14:22, in the Virginia Register of Regulations. Final amendments to the formulary shall become effective upon filing with the Registrar of Regulations.

- D. This section shall not prohibit a licensed physician's assistant from administering Schedule VI controlled substances in compliance with the definition of "administer" in § 54.1-3401. However, this section shall not authorize the dispensing or the sale of Schedule VI controlled substances by a licensed physician's assistant unless pursuant to the lawful order of a physician.
- § 54.1-2953. Renewal, revocation, suspension and refusal.--The approval of the Board for the employment of an assistant shall expire at the end of one year. A new application shall be submitted for approval, supplying such information as the Board may require, at the time and in the manner prescribed by the Board.

The Board may revoke, suspend or refuse to renew an approval for any of the following:

- 1. Any reason stated in this chapter for revocation or suspension of the license of a practitioner;
- 2. Failure of the supervising licensee to supervise the assistant or failure of the employer to provide a licensee to supervise the assistant;

- 3. The assistant's engaging in acts beyond the scope of authority as approved by the Board;
- 4. Negligence or incompetence on the part of the assistant or the supervising licensee in his use of the assistant;
- 5. Violating or cooperating with others in violating any provision of this chapter or the regulations of the Board; or
- 6. A change in the Board's requirements for approval with which the assistant or the licensee does not comply.

d. Letter of assurance from the office of the Attorney General.

See attached.

e. Summary of Public Comment received in response to the Notice of Intended Regulatory Action.

The Notice of Intended Regulatory Action was published on September 28, 1998 and subsequently sent to the Public Participation Guidelines Mailing List of the Board. The deadline for comment was October 28, 1998 and there was no comment received.

f. Changes to existing regulations.

Section 58 is added to the existing regulations, and section 170 is amended as follows:

18 VAC 85-50-58. Inactive licensure

The proposed regulations would add a section establishing a category of inactive licensure and specifying that such a license holder is not required to maintain certification by the NCCPA but is likewise not entitled to practice as a physician assistant.

To reactivate an inactive license, the physician assistant is required to provide documentation of having renewed or maintained NCCPA certification and to pay the difference between the current inactive and active renewal fee.

The Board reserves the right to deny a request for reactivation to any person determined to have committed a violation of these regulations or of § 54.1-2914 of the Code of Virginia.

18 VAC 85-50-170. Fees.

Amendments are proposed in this section to a) establish a lesser fee for renewal of an inactive license (\$60 per biennium versus \$80 for an active license); b) to increase the penalty fee for late renewals from \$10 to \$25 consistent with other professions (physical

therapists, occupational therapists, radiologic technologists and licensed acupuncturists); and c) to establish a fee and required submission for information on practice for persons who want to reinstate an expired license after two or more years.

g. Statement of reasoning for the regulations.

The Department of Health Professions sought legislation in the 1998 General Assembly to give authorization to all boards to issue an active license. Some boards within the Department already had such authority in the practice act for the particular professions regulated, but an amendment to § 54.1-2400 granted general authority to set out the qualifications, fees and conditions for reactivation of inactive licensure.

The Board of Medicine currently requires a physician assistant to maintain current certification by the National Commission on Certification of Physician Assistants (NCCPA) in order to renew a license. NCCPA requires a minimum of 100 hours of continuing medical education for a 2-year renewal period; 40 of those hours must be classified as Category I or pre-approved programs recognized by the American Academy of Physician Assistants. For someone who is not planning to actively practice for a period of time, it may be unnecessarily burdensome to have to take the continuing education hours required by NCCPA to maintain certification. By taking an inactive status, the licensee is not required to maintain certification but is not permitted to practice. If the licensee wants to reactivate a license, it would be necessary to provide documentation that he has first taken the continuing education hours necessary to reactivate his certification with NCCPA. There needs to be some assurance that a practitioner with an inactive license has maintained or relearned some of the minimal knowledge and skills necessary to practice with safety. Certification by the NCCPA is the standard by which the Board judges such competency.

In proposing regulations for an inactive license, the Board determined that it was also necessary to set forth the requirements for reinstatement of a license expired for two years or more. Within the two years after expiration, a licensee may renew by payment of the renewal fee and an administrative fee (proposed to be \$25), provided the licensee is qualified for renewal. After two years, the expired license may only be reinstated by submission of a reinstatement application which includes information on practice and licensure in other states during the period in which the license was lapsed in Virginia and payment of a reinstatement fee of \$125. A reinstatement application is necessary in order for the Board to have assurance that the applicant has been practicing safely or has been licensed without disciplinary action in another jurisdiction. The Board maintains the authority (stated in § 54.1-2953) to refuse to reinstate or renew a license of someone who has violated provisions of law or regulation.

h. Statement on alternatives considered.

In considering requirements for reactivation of an inactive license, the Board determined that the public remains protected by requirements that assure that physician

assistants are current in their skills and knowledge. By requiring an inactive licensee to be recertified by the NCCPA, the Board is providing assurance of minimal competency as it does in initially granting a license to practice. For persons who do not want to actively practice for a period of time, these regulations will allow them to maintain an inactive license and eliminate the need to reapply for reinstatement of an expired license.

In considering the appropriate renewal fee for an inactive license, the Board determined that the fee should be less expensive than renewal of an active license. The difference is similar to the proportional difference proposed for other professions regulated by the Board of Medicine and similar to other professions within the Department who currently have an inactive licensure option.

The Board also determined that the proposed regulation should provide a means for a licensee who has allowed his license to lapse to reinstate, but it should foremost protects the public by requiring that the applicant provide complete information on practice and licensure in other jurisdictions during that period. The Board maintains its authority to deny reinstatement to anyone who has committed acts in violation of law or regulation.

i. Statement of clarity.

Prior to the adoption of proposed regulations by the Board, the Advisory Board on Physician Assistants and the Legislative Committee discussed the changes in open sessions. The clarity and reasonableness of the language which was adopted had the approval of the physician assistants, the Assistant Attorney General who worked with the Advisory Board in drafting regulatory language, and members of the Board, including the citizen members and those who supervise physician assistants.

j. Schedule for review of regulation.

The proposed amendments to these regulations will be reviewed following publication in the <u>Register</u> and the 60-day public comment period. If there are any oral or written comments received, the Board will consider revisions to the proposal prior to adoption of final regulations.

Public Participation Guidelines of the Board of Medicine (18 VAC 85-10-10 et seq.) require a thorough review of regulations each biennium. Therefore, the Advisory Board and the Legislative Committee of the Board will review this set of regulations in 2001 and will bring any recommended amended regulations to the full board for consideration.

In addition, the Board receives public comment at each of its meetings and will consider any request for amendments. Petitions for rule-making also receive a response from the Board during the mandatory 180 days in accordance with its Public Participation Guidelines.

k. Anticipated Regulatory Impact

Projected cost to the state to implement and enforce:

- (i) Fund source: As a special fund agency, the Board of Medicine must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.
- (ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.
- (iii) One-time versus ongoing expenditures: The agency will incur some costs (less than \$1000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities. Since these regulations are being amended simultaneously with other regulations of the Board, the costs of mailings, meetings and hearings will be shared by several professions. In addition, every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

If an inactive licensure status is not available, it is not known how many of those 15-20 persons would choose to let their Virginia license lapse at a loss of income of \$1200 to \$1600 per biennium. Therefore, rather than resulting in a loss of income, inactive licensure may in fact result in preservation of revenue to the Board.

Projected cost on localities:

There is no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be physician assistants who are not now or who may choose to not actively practice in Virginia. Those persons who have allowed their licenses to lapse for more than two years would also be affected if they want to reinstate.

Estimate of number of entities to be affected:

There would be no additional costs for compliance with these regulations for the vast majority of physician assistants (523 licensed in Virginia). For a small number (2-3 per renewal cycle) who do not renew their license on time, there will be an additional cost of \$15 for an administrative fee to process a late renewal in house. For those who allow their license to expire for more than two years (estimated to be 2 or 3 in number), there will be a cost of \$125 to reinstate the license.

For those persons who are not actively practicing in Virginia but who want to maintain a license, there would be a savings of \$20 biennially for an inactive license.