Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Boards of Nursing and Medicine/Department of Health Professions
VAC Chapter Number:	18 VAC 90-40-10 et seq.
Regulation Title:	Regulations Governing Prescriptive Authority for Nurse Practitioners
Action Title:	Periodic Review
Date:	10/11/02

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

18 VAC 90-40-10 et seq. establishes the qualifications for licensed nurse practitioners to be approved by the Joint Boards of Nursing and Medicine for prescriptive authority, the requirements for a practice agreement with supervising physicians, and standards for supervision, site visits and chart reviews. Regulations also set forth application, renewal and other fees as necessary to support the regulatory and disciplinary functions of the Joint Boards and establish grounds and a process for disciplinary action. The Boards of Nursing and Medicine are recommending the regulation be amended to provide less burdensome requirements for site visits by supervising physicians, to make certain changes related to expanded prescriptive authority, and to clarify requirements or terminology which are not easily understood.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On September 24, 2002, the Board of Nursing and on October 10, 2002, the Board of Medicine adopted final amendments to 18 VAC 90-40-10 et seq., Regulations Governing Prescriptive Authority for Nurse Practitioners, pursuant to a periodic review of regulations.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

18 VAC 90-40-10 et seq. 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 discipline regulated professionals.

§ 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.

Statutes governing prescriptive authority for licensed nurse practitioners are in §§ 54.1-2957 and 54.1-2957.01 of the Code of Virginia.

§ 54.1-2957. Licensure of nurse practitioners.

The Board of Medicine and the Board of Nursing shall jointly prescribe the regulations governing the licensure of nurse practitioners. It shall be unlawful for a person to practice as a nurse practitioner in this Commonwealth unless he holds such a joint license.

The Boards may issue a license by endorsement to an applicant to practice as a nurse practitioner if the applicant has been licensed as a nurse practitioner under the laws of another state and, in the opinion of the Boards, the applicant meets the qualifications for licensure required of nurse practitioners in this Commonwealth.

Pending the outcome of the next National Specialty Examination, the Boards may jointly grant temporary licensure to nurse practitioners.

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title, a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2000; (ii) Schedules IV through VI on and after January 1, 2002; and (iii) Schedules III through VI controlled substances on and after July 1, 2003. Nurse practitioners shall have such prescriptive authority upon the provision to the Board of Medicine and the Board of Nursing of such evidence as they may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician which provides for the direction and supervision by such physician of the prescriptive practices of the nurse practitioner. Such written agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician providing direction and supervision.

B. It shall be unlawful for a nurse practitioner to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensed nurse practitioner and the licensed physician.

C. The Board of Nursing and the Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of nurse practitioners as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.

The Board of Medicine and the Board of Nursing shall be assisted in this process by an advisory committee composed of two representatives of the Board of Nursing and one nurse practitioner appointed by the Board of Nursing, and four physicians, three of whom shall be members of the Board of Medicine appointed by the Board of Medicine. The fourth physician member shall be jointly appointed by the Boards of Medicine and Nursing. Regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued nurse practitioner competency which may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients, and (ii) requirements for periodic site visits by physicians who supervise and direct nurse practitioners who provide services at a location other than where the physician regularly practices.

D. This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any nurse practitioners which are otherwise authorized by law or regulation.

E. The following restrictions shall apply to any nurse practitioner authorized to prescribe drugs and devices pursuant to this section:

1. The nurse practitioner shall disclose to his patients the name, address and telephone number of the supervising physician, and that he is a licensed nurse practitioner.

2. Physicians, other than physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners. In the case of nurse practitioners, other than certified nurse midwives, the supervising physician shall regularly practice in any location in which the nurse practitioner exercises prescriptive authority pursuant to this section. A separate office for the nurse practitioner shall not be established. In the case of certified nurse midwives, the supervising physician either shall regularly practice in the location in which the certified nurse midwife practices, or in the event that the certified nurse midwife has established a separate office, the supervising physician shall be required to make periodic site visits as required by regulations promulgated pursuant to this section.
3. Physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners who provide services on behalf of such entities. Such physicians either shall regularly practice in such settings or shall make periodic site visits to such settings as required by regulations promulgated pursuant to this section.
F. This section shall not prohibit a licensed nurse practitioner from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the amended regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

During the periodic review of regulations, two professional organizations commented that the monthly chart review and site visit may not be necessary and overly burdensome in some practices. While the Boards did recommend amendments to regulations, they did not recommend that chart reviews or site visits be discretionary. In those settings in which the physician does not regularly practice with the nurse practitioner, the amendment will require site visits for consultation and direction to occur in accordance with the practice agreement but no less frequently than quarterly. Consideration was given to modifying the requirement for a review of charts from a monthly, random review to a quarterly review. However, since it is not required that all charts be reviewed, the Boards decided that the current requirement for a monthly review should remain to provide greater assurance that patient health and safety is being protected by the care of the nurse practitioner with prescriptive authority. The collaboration of a supervising physician in the practice of the nurse practitioner is believed to be essential to the continued protection of the public's health and safety in receiving services delivered by a nurse practitioner.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

Amendments to regulations will eliminate unnecessary duplication and clarify provisions for the supervision of nurse practitioners who practice in public and private settings. The only substantive change is a less burdensome requirement for the site visit in a setting where the physician does not regularly practice with the nurse practitioner. The amended rule will change a required monthly site visit to a visit no less than quarterly on a schedule set forth in the protocol. Other amendments will clarify: 1) that the prescription from a nurse practitioner should show the authorization number from the Board of Nursing and the DEA number, if applicable; and 2) that a nurse practitioner is authorized to dispense manufacturer's samples in accordance with the practice agreement on file with the Board.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on June 3, 2002. A Public Hearing before the Board of Nursing was held on July 16, 2002 at which no comment was received. Public comment was requested for a 60-day period ending August 2, 2002; during that period the Board received the following written comment:

The Virginia Council of Nurse Practitioners supports the proposed changes to the prescriptive authority of nurse practitioners. The amendments clarify requirements and modifications to the site visit requirements remove an unnecessary barrier to practice and will promote the utilization of nurse practitioners in various settings.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

18 VAC 90-40-10 et seq., Regulations for Prescriptive Authority for Nurse Practitioners is amended as follows:

18 VAC 90-40-100. Supervision and site visits.

- The proposed amendments will combine subsections A and B to provide for more consistency between practice in public or non-profit clinics and other types of practice

settings. However, since the Code provides certain exceptions to the requirement that the supervising physician regularly practice in the same location as the nurse practitioner, the regulations must address those differences among the practice settings.

- Amendments to current requirements for a "monthly" site visit are proposed. The Committee of the Joint Boards noted that a review of patient charts should not be tied to the site visit, since in fact, a more thorough review might be possible in a different setting or environment. If the site visit is not conducted for the purpose of chart review, there needed to be some clarification as to its purpose, which is for consultation and direction on patient management.
- Amendments are also recommended to provide more flexibility in the scheduling of site visits to permit the frequency to be determined by the physician and nurse practitioner as outlined in the practice agreement. The frequency of the site visit may depend on factors such as the practice settings, proximity of the physician to the practice of the nurse practitioner, acuity of the patient population, and others to be determined. The Boards recommend that a minimal standard of quarterly visits be established.

18 VAC 90-40-110. Disclosure.

- An amendment is proposed to clarify the "authorization number" to be included on each prescription written or dispensed. Most nurse practitioners have been using their license number on prescription. However, nurse practitioners are now authorized by law to prescribe schedule V drugs; those who have those drugs included in their protocol are required by federal law to have an authorization number from the Drug Enforcement Administration (DEA). Some nurse practitioners are still only authorized by their practice to prescribe only schedule VI drugs, so they will not have a DEA number. Therefore, the regulation specifies the nurse practitioner must include on every prescription the Prescriptive Authority number issued by the boards and if applicable, the DEA number.

18 VAC 90-40-120. Dispensing.

- Amendments are proposed to clarify the rules about dispensing of drugs. Nurse practitioners with prescriptive authority are now authorized by law to dispense manufacturers' samples of any drugs which they are authorized to prescribe.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulatory action does not have any impact on the institution of the family or the rights of parents, does not encourage or discourage economic self-sufficiency or affect the marital commitment. While amendments to make the supervision requirements less restrictive should

have no effect on family income, they could potentially ease the burden of physicians and nurse practitioners who provide services in public and non-profit health clinics.