Form: TH- 02

Virginia Regulatory Town Hall

Proposed 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:	3/22/02

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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 proposed 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 proposed 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 providing detail of the regulatory action's changes.

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. 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.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

Advantages or disadvantages to the public:

Amendments to allow a less stringent schedule for site visits to be established in the practice agreement may free up some time for the supervising physicians and the nurse practitioners to be engaged in direct patient care. The schedule of site visit will be set in the practice agreement and may depend on factors such as geography, acuity of patient population, and practice setting, but that there will be an outside limit on the frequency, i.e., not less than quarterly. Since the more important element of supervision is the regular chart review, which is not being amended, the public is protected by the current and revised regulation. Specificity about the site visit being necessary for consultation and direction for appropriate patient management may provide clearer direction and supervision – which would also be of benefit to patients. There are no disadvantages to the public.

Advantages or disadvantages to the agency:

Clarification of questions related to the number or numbers required for a written prescription by a nurse practitioner or to whether a nurse practitioner may dispense drugs under a license held by the physician from the Board of Pharmacy may relieve the Board staff of phone inquiries currently being received. In addition, there may be further clarification about the purpose of a site visit, which will be helpful to both the LNP and the supervising physicians. Many of the settings in which nurse practitioners practice without on-site collaboration and supervision by physicians are public health clinics throughout the Commonwealth. To the extent the site visit is burdensome for physicians who serve those clinics, these amendments may alleviate some of that burden.

There are no disadvantages to the agency; there are no new requirements to be interpreted and enforced.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board 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 one-time costs (less than $2,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There should be no on-going expenditures related to the proposed amendments.

Projected cost on localities:

There are 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 persons licensed as nurse practitioners who hold authorization to prescribe controlled substances and the physicians who provide supervision for their practice. Public health clinics may experience a modest benefit from less restrictive requirements for site visits. Some time spent by physicians in those activities may be redirected to other patient care functions.

Estimate of number of entities to be affected:

Currently, there are approximately 1,800 nurse practitioners who hold authorization to prescribe controlled substances. Each of them has at least one supervising physician, and in most cases, there are multiple supervisors within a practice or hospital setting.

Projected costs to the affected entities:

There should be no costs to the affected entities for compliance with these amended regulations.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed 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.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The Boards have considered the following alternatives in the review of these regulations:

- Amendments to reduce the burden of monthly site visits and chart reviews. Since both are required by law, the options available to the Boards would include: 1) a requirement for a "periodic review" with the physician left to interpret the frequency requires by the word "periodic;" 2) a requirement for a visit and review on a set schedule, such as quarterly; 3) a requirement to specify the frequency and purpose in the practice agreement signed by the supervising physicians and nurse practitioners; or 4) a combination of flexibility by having it specified in the practice agreement with an outside limitation on the frequency.

  The Board did recommend that a minimal standard of quarterly visits and monthly chart reviews be established. There are certain differences among the practice settings mandated by statute that would need to be preserved, such as a requirement for private practices that the supervising physician regularly practice in any location in which the nurse practitioner exercises prescriptive authority.

- Clarification of parts of the regulation that have not been clearly understood by the regulated entities such as: 1) an interpretation of the requirement that a physician may only supervise four nurse practitioners at any one time; 2) the reference to an "authorization number" on a prescription or drug dispensed, which could be interpreted as the nurse practitioner's license number, the DEA number or the CSR number (see Substance section, 18 VAC 90-40-110); and rules on dispensing to include the distribution of manufacturer's sample drugs.

  The Boards determined that the provision for a physician to supervise no more than four nurse practitioners at any one time was being clearly and properly interpreted by the regulated entities, so no amendment was proposed.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the Board's intention to amend its regulations pursuant to recommendations of the periodic review was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the Boards (which is approximately 1100 persons on the PPG mailing list for the Board of Nursing and 250 persons on the list for the Board of Medicine). Public comment was accepted until March 1, 2001.

During the 30-day comment period, no comments were received from members of the public on the Notice of Intended Regulatory Action. The Boards did consider the comment that was received following the notice of a periodic review; those comments requested a less restrictive rule on chart reviews and site visits.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Committee of the Joint Boards, representing various categories of nurse practitioners and physicians who supervise nurse practitioners, has reviewed these regulations for consistency and clarity. The Assistant Attorney General who provides counsel to the Board of Nursing has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation. Since the regulations were drafted and approved by the practitioners who will have to comply with the stated requirements, the Boards are satisfied that the regulation is clearly written and will be easily understandable by the individuals affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Boards to review regulations each biennium or as required by Executive Order. Regulations governing prescriptive authority for nurse practitioners will be reviewed again during the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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 proposed 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 proposed 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.