Form: TH- 06

Virginia Regulatory Town Hall

Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Nursing
VAC Chapter Number:	18 VAC 90-40-10 et seq.
Regulation Title:	Regulations for Prescriptive Authority for Nurse Practitioners
Action Title:	Periodic review
Date:	

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

18 VAC 90-40-10 et seq. establish 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.

Basis

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is found in § 54.1-2400 and Chapter 29 of Title 54.1 of the Code of Virginia.

Section 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to establish qualifications for licensure, to set fees and schedules for renewal, to establish requirements for an inactive license and to promulgate regulations, in accordance with the Administrative Process Act, which are reasonable and necessary to effectively administer the regulatory system.

§ 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.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the boards' review of regulations governing the prescriptive authority for nurse practitioners was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the Public Participation Guidelines mailing list for the board. Public comment was received until July 1, 2000. During the 30-day comment period, two e-mail and two written comments were received from members of the public. They are summarized as follows:

One person wrote to request that the regulations be developed as simple and burden-free as possible to ensure a smooth transition to the expanded prescriptive authority permitted by law. (*Amendments related to the expanded prescriptive authority and repeal of the formulary requirement have already been promulgated under an exemption from the APA to conform regulations to the Code of Virginia.)*

One person wrote to ask the boards to assist in getting prescriptive authority expanded to include schedules III through VI. (*That is a statutory change and has already occurred with the passage of HB 818 in the 2000 Session of the General Assembly.)*

The Virginia Chapter of the American College of Nurse-Midwives and the Virginia Council of Nurse Practitioners made the following recommendations: 1) revise the requirement for a monthly chart review by a supervising physician in a public or nonprofit clinic to something less burdensome, such as a quarterly review; 2) revise the requirement for a monthly site visit to a less burdensome requirement as outlined in the practice agreement and proportionate to factors such as practice setting, acuity of patient population and geography; and 3) permit the chart review to be conducted at any location, not necessarily at the practice site. (*Amendments to regulations are being recommended to accomplish the changes requested by these groups.)*

On August 30 the Committee of the Joint Boards of Nursing and Medicine and the Advisory Committee on Nurse Practitioners met to review the comments that had been received on regulations and the recent legislative changes to prescriptive authority resulting from passage of HB 818 (Chapter 924 of the Acts of the Assembly). An Advisory Committee, established in the Code to ensure representation of the broad scope of practice and to assist the Joint Boards in the development of regulations, joined the Committee of the Joint Boards for that meeting. Members of the Boards of Medicine and Nursing and members of the committee who are licensed nurse practitioners, licensed nurse midwives, licensed nurse anesthetists, and physicians who supervise nurse practitioners were present for the meeting. In addition, representatives of nurse practitioner groups were in attendance and participated in the discussion of comments and regulations. Regulations were thoroughly reviewed and recommendations for amendments to 18 VAC 90-40-10 et seq. were adopted.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The specific goals of the regulations were included with the Notice for Periodic Review and request for comment. The goals are:

1) Establish criteria for prescriptive authority which are reasonable, consistent with statutes and sufficient to assure minimal competency.

Criteria for initial approval of prescriptive authority are reasonable, consistent with statutes and sufficient to assure minimal competency. (See #3 below) The Boards have determined that evidence of continued competency, as now mandated in the amendments to § 54.1-2957.01, has not been provided through regulations for renewal and reinstatement. Therefore, the Boards have already published a Notice of Intended Regulatory Action to address the issue of continuing competency with a comment period from September 11th to October 11th. Proposed regulations are being developed by the Committee of the Joint Boards with assistance from the Advisory Committee. A sub-committee of those groups has scheduled a meeting after the 30-day comment period in order to have a proposal for the boards' consideration at their meetings in November (Nursing) and December (Medicine).

2) Review the requirements to remove unnecessary barriers to practice.

Judging from the comments received on the regulations, there may be an unnecessary barrier to practice in public or non-profit clinics. Two professional organizations commented that the monthly chart review and site visit may not be necessary and overly burdensome in some practices. Since the law requires both chart reviews and periodic site visits by the supervising physician who does not regularly practice in the same location as the nurse practitioner, a less restrictive requirement is requested. While the Committee of the Joint Boards is recommending amendments to regulations, it is not recommending that chart reviews or site visits be

discretionary. It is likely that the requirement will be amended to allow a schedule for reviews and site visits to be established in the practice agreement, depending on factors of geography, acuity, and practice setting, but that there will be an outside limit on the frequency, i.e., not less than quarterly. 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.

3) Ensure submission of required documentation for prescriptive authority by licensees.

Qualifications for prescriptive authority established in 18 VAC 90-40-40 have been reviewed by the Committee of the Joint Boards and the Advisory Committee, and no amendments were recommended. The practice agreement between supervising physicians and nurse practitioners must be submitted for review and approval by the board prior to initiating the practice of prescribing. It requires a detailed listing of the categories of drugs and devices which the nurse practitioner is and is not authorized by his supervising physician to prescribe and the signatures of all physicians who will be providing supervision and chart reviews for the nurse practitioner.

Requirements established have been sufficient to ensure minimal competency as evidenced by the number of nurse practitioners who enter into practice agreements with supervising physicians and by the lack of disciplinary cases involving prescriptive authority.

Likewise, regulations are generally clearly written and understandable by the public and regulated entities. With expanded prescriptive authority, there may be a need to clarify certain terms or words, such as "authorization number." There are also questions about the meaning of the term "at any one time" as it is used to limit the number of nurse practitioners with prescriptive authority who may be supervised by a physician. Clarification in regulation may be advisable.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

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.

- 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.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The Boards of Nursing and Medicine are recommending the regulation governing prescriptive authority for nurse practitioner be amended to provide less burdensome requirements for site visits and chart reviews by supervising physicians, to make certain changes related to expanded prescriptive authority, and to clarify requirements or terminology which are not easily understood.

Substance

Please detail any changes that would be implemented.

Amendments have been recommended in the following sections of regulations:

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

- The Boards will consider combining subsections A and B to provide for more consistency between practice in public or non-profit clinics and other types of practice settings. 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.
- Amendments to current requirements for a monthly site visit and review of patient charts are recommended. 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 may need to be some clarification as to its purpose.
- Amendments are also recommended to provide more flexibility in the scheduling of site visits and chart reviews to permit the frequency to be determined by the physician and nurse practitioner as outlined in the practice agreement and to occur according to 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. There is precedence for basing the frequency proportionate to those factors in that they are now included in the definition of "medical direction and supervision" in regulations governing the practice of nurse practitioners. The Committee does recommend that a minimal standard of quarterly visits and chart reviews be established.

- Consideration will be given to a clarification of the requirement that a physician may supervised no more than four nurse practitioners *at any one time*. Practitioners are occasionally confused about the boards' interpretation of that terminology, so a clarification will be sought.

18 VAC 90-40-110. Disclosure.

- An amendment is recommended to clarify the "authorization number" to be included on each prescription written or dispensed. Nurse practitioners have been using their license number on prescription. However, since nurse practitioners are now authorized by law to prescribe schedule V drugs, they are required by federal law to have an authorization number from the Drug Enforcement Administration (DEA) and by state law to have a Controlled Substance Registration (CSR) issued by the Virginia Board of Pharmacy. Some nurse practitioners are not seeking expanded prescriptive authority in their practice and therefore will not a DEA number or a CSR. There may be some confusion about the "authorization number" to be used, so regulations should clarify that requirement.

18 VAC 90-40-120. Dispensing.

- Amendments are recommending clarifying 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. Some change in this section may be necessary to clarify that authority.

Family Impact Statement

Please provide a preliminary 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 affect on family income, they could potentially ease the burden of physicians and nurse practitioners who provide services in public and non-profit health clinics.