Virginia Regulatory Town Hall

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# Fast Track Proposed Regulation
# Agency Background Document

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| **Agency name** | Boards of Nursing and Medicine; Department of Health Professions |
| **Virginia Administrative Code (VAC) citation** | 18VAC90-30-10<br>18VAC90-40-10 |
| **Regulation title** | Regulations Governing the Licensure of Nurse Practitioners<br>Regulations Governing Prescriptive Authority for Nurse Practitioner |
| **Action title** | Periodic review recommendations |
| **Date this document prepared** | 7/2/08 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The proposed amendments to regulations for nurse practitioners are the result of a periodic review of regulations. The changes to Chapter 30 will: 1) clarify certain provisions and requirements; 2) include category 1 continuing medical education in the approved courses for continuing competency requirements; and 3) allow submission of continuing education as evidence of competency for reinstatement. The changes to Chapter 40 will: 1) clarify and update regulations; 2) modify the definition of supervision and allow for "regular" rather than "monthly" chart reviews; and 3) clarify that the current rules for prescribing for self and family by supervising doctors are also applicable to the nurse practitioners with prescriptive authority.

## Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

The Board of Nursing adopted the amendments to 18VAC90-20-10 et seq., Regulations Governing the Licensure of Nurse Practitioners and 18VAC90-40-10 et seq., Regulations Governing Prescriptive Authority for Nurse Practitioners on May 20, 2008, and the Board of Medicine adopted the amendments on June 26, 2008.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

**Chapter 24 of Title 54.1** establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations.

*§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:*

*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…*

**Chapter 29 of Title 54.1** establishes the requirements for supervision of physicians for nurse practitioners:

*§ 54.1-2901. Exceptions and exemptions generally.*
*A. The provisions of this chapter shall not prevent or prohibit:…*
*3. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;*

*§ 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; (iii) Schedules III through VI controlled substances on and after July 1, 2003; and (iv) Schedules II through VI on and after July 1, 2006. 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.*
*G. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife and holding a license for prescriptive authority may prescribe Schedules II through VI controlled substances without the requirement for either medical direction or supervision or a written agreement between the licensed nurse practitioner and a licensed physician while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.*

## Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

The purpose of the action is to clarify and update requirements pursuant to a periodic review of regulations and to reflect the collaborative nature of the practice arrangement between licensed nurse practitioners (LNP) and supervising physicians. Amendments to more clearly specify the evidence of educational qualification in a specialty category, to accept continuing medical education and to allow continuing education hours as evidence of competency to resume practice after one's license has lapsed are all intended to ensure that a nurse practitioner has the appropriate knowledge and skills to practice safely. The amendments also make the requirements for maintaining a written protocol setting out the scope of the LNP's practice and for submitting a current practice agreement whenever there are significant changes in prescriptive authority. Such changes are intended to encourage compliance with law and regulation to make nurse practitioners more competent and safer in their practice.

## Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

The Boards have determined that a fast-track process is appropriate because the action is primarily clarifying rather than substantive. Amendments have been drafted by a committee of nurse practitioners and physicians, approved by the Committee of the Joint Boards, the Board of Nursing and the Board of Medicine and are not expected to be controversial.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)*

The changes to Chapter 30 will: 1) clarify certain provisions and requirements; 2) specify the evidence of coursework leading to specialty licensure that must be submitted with an initial application; 2) include category 1 continuing medical education in the approved courses for continuing competency requirements; 3) allow submission of continuing education as evidence of competency for reinstatement; and 4) clarify that a copy of the written protocol must be maintained.

The changes to Chapter 40 will: 1) provide a definition of a "nonprofit health care clinic" and modify the definition of "supervision" to reflect that both the LNP and the supervising physician are responsible for the patient and for collaboration on his or her course of treatment; 2) allow for "regular" rather than "monthly" chart reviews; and 3) clarify rules for prescribing for self and family.

## Issues

*Please identify the issues associated with the proposed regulatory action, including:*
*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 indicate.*

1) There is an advantage to the public of clarifying the requirements for initial licensure, renewal and reinstatement to ensure competency to practice in a specialty category of licensure. Rules that reinforce the need to maintain a written protocol and a current practice agreement for prescriptive authority also ensure collaboration with supervising physicians on patient care. There are no disadvantages to the public.
2) The primary advantage to the agency and the Commonwealth is greater clarity of the regulations and consistency with the Code to reduce the confusion and misinterpretation.
3) The only pertinent matter of interest to the regulated community is the desire to eliminate or modify the supervisory relationship of nurse practitioners and physicians to allow nurse practitioners to practice more independently. The committee that reviewed the regulations considered that issue and modified the regulation within the context of the statute. The regulated community understands that any significant changes necessitate amendments to the Code of Virginia.

## Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities particularly affected.

## Economic impact

*Please identify the anticipated economic impact of the proposed regulation.*

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| **Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures** | a) 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; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.<br><br>There will be no on-going expenditures related to this action. |
| **Projected cost of the regulation on localities** | There are no costs to localities. |
| **Description of the individuals, businesses or other entities likely to be affected by the regulation** | The individuals affected by this regulation would be nurse practitioners. Amendments to Chapter 40 would affect nurse practitioners with prescriptive authority and the supervising physicians with whom they have practice agreements. |
| **Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.** Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | There are currently 5504 licensed nurse practitioners, 3184 with prescriptive authority; each LNP would have a practice agreement with at least one physician. There is no estimate of the number that would fall within the definition of small businesses because the Board does not categorize or keep data on practice sites. |
| **All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.** | There should be no costs associated with this action. There may be some cost reduction inherent in an indefinite time requirement for chart reviews for nurse practitioners with prescriptive authority. The acceptance of category 1 CME may allow some nurse practitioners to obtain continuing education hours at no cost through hospitals or other health care institutions. |

## Alternatives

*Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

Proposed amendments are the result of a periodic review of 18VAC90-30 and 18VAC90-40. The review and request for comment was sent to interested parties, posted on the Townhall and published in the Register of Regulations on March 3, 2008 with comment until April 2, 2008. Comments were received from the Virginia Council of Nurse Practitioners (VCNP) and the Virginia Association of Nurse Anesthetists (VANA).

The VCNP generally requested that the boards balance the need to regulate against the realities of the current practice environment and to lessen regulatory burden wherever possible. It specifically requested that written protocols include authorization to refer patients to physical therapy. The VANA made similar recommendations.

To conduct the review of the regulations, the Committee of the Joint Boards formed a subcommittee comprised on nurse practitioners and physicians. Staff from the Boards of Nursing and Medicine participated in the review to bring information on regulatory provisions that have raised questions or concerns or have been misunderstood by applicants or licensees. The Regulation Review Committee met on April 24, 2008, reviewed the comment on the notice of periodic review, and then went over the regulations section by section.

The requests from VCNP and VANA were considered and changes made to foster a more collaborative model of practice and to less the supervisory burden of physicians. Based on issues that are discussed within the nurse practitioner community, there were two suggested amendments that the committee considered but did not recommend: 1) adding action taken against a licensee by a certifying board to the grounds for disciplinary action; and 2) defining the meaning of "regularly practice in the same location," which is required by law and regulation.

The committee did not adopt the first suggestion because the underlying reason for dismissal or action by a certifying board would likely be grounds for disciplinary action under the current law or regulation. However, if the cause for losing one's certification was failure to pay a fee to the organization, that should not constitute grounds for disciplinary action against a license because retention of specialty board certification is not a requirement for renewal of a license. The committee did not recommend an amendment to further specify or define the meaning of "regularly practice" because there is currently some flexibility for licensees to determine the meaning of that requirement depending on the nature of the practice and other such factors. To create a definition for the term might be too limiting or prescriptive.

## Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

There is no impact on the institution of the family or family stability.

## Detail of changes

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

### *Amendments to Chapter 30: Regulations Governing the Licensure of Nurse Practitioners*

| Current section number | Current requirement | Proposed change and rationale |
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| Section 10 | Sets out definitions of words and terms used in the regulation | In the definitions and throughout the chapters, the word "osteopathy" is changed to reflect the current terminology of "osteopathic medicine." |
| Section 20 | Sets out the delegation of authority to the executive director of the Board of Nursing | An amendment adds the granting of exemptions for compliance with continuing competency requirements to those actions that may be delegated to facilitate the regulation of nurse practitioners. |
| Section 30 | Sets out the composition of the Committee of the Joint Boards of Nursing and Medicine | Since the Nurse Practice Act was amended in 2008 to require at least one member of the Board of Nursing to be a nurse practitioner, the composition was also amended to specify that at least one appointee from that Board be a nurse practitioner. |
| Section 80 | Specifies the qualifications for initial licensure | Currently, an applicant is required to submit evidence of a graduate degree in nursing or nurse practitioner specialty. Sometimes, it is difficult to discern from the evidence presented whether the applicant qualifies for licensure in a specialty. The amendment will assure that the transcript provides sufficient information about coursework to determine qualification. |
| Section 85 | Specifies the qualifications for licensure by endorsement | Same amendment as section 80. |
| Section 100 | Specifies the requirements for renewal of licensure | Amendments to subsection B are consistent with on-line renewal notices by the agency. An additional provision specifies that failure to receive the renewal notice does not relieve the licensee of responsibility for renewal. That is currently the policy of this board and all boards at DHP, but this chapter did not have that provision stated. |

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| | | Amendments to subsection C are clarifying.<br><br>A new subsection D includes language found in other nursing regulations clarifying that the license automatically lapses if not renewed and practice on a lapsed license may subject the licensee to disciplinary action. |
| Section 105 | Sets out requirements for continuing competency | Subsection B is amended to allow nurse practitioner to complete hours of CE approved by ACCME as Category 1 continuing medical education. Additional approved courses may facilitate the acquisition of CE for nurse practitioners.<br><br>Subsection D is amended to eliminate the percentage that must be audited to give the boards more flexibility in that process.<br><br>Subsection E is amended to eliminate the extension for "good cause" since that is virtually impossible to regulate and enforce. An extension for circumstances beyond the control of the licensee is added to the exemption provisions in subsection F. |
| Section 110 | Sets out requirements for reinstatement of a lapsed or suspended license | Currently, a person who has allowed his nurse practitioner license in Virginia to lapse must provide evidence of current professional certification (does not specify that the certification must be in your specialty but that is assumed) or, if applicable, licensure or certification in another jurisdiction. Amendments will: 1) allow someone who does not have current certification to provide evidence of continuing education hours instead; and 2) specify that the license in another jurisdiction must be current and unrestricted (again, assumed but not currently specified).<br><br>Amendments in subsection C specify the evidence of competency to resume practice after suspension or revocation. That evidence would be identical to the evidence of current competency for persons who have a lapsed license, except there would be no license in another state to present. |
| Section 120 | Sets out the practice requirements for nurse practitioners, others than certified nurse midwives | An amendment to subsection C specifies that the nurse practitioner must maintain a copy of the written protocol and make it available upon request. Additionally, the law allows a nurse practitioner to make referrals for physical therapy, but only if it is specified in the protocol – so that is specifically stated in what a protocol should include.<br><br>*In 2007, the Board audited protocols and found that some nurse practitioners were unaware that they had to maintain a protocol with a supervising physician. Therefore, the regulation has been amended to clarify that* |

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| | | *responsibility and to emphasize the legal requirement for a written protocol.* |
| Section 121 | Sets out the practice requirements for nurse practitioners licensed as certified nurse midwives | The same language as in section 120 is added to this section. |
| Section 220 | Sets out grounds for disciplinary action | This section has clarifying and housekeeping changes. |
| Section 230 | Sets out the process for conducting administrative proceedings | There is an exception added to clarify that section 240 provides for a hearing to be conducted by an agency subordinate. |

### *Changes to Chapter 40: Regulations Governing Prescriptive Authority for Nurse Practitioners*

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| Section 10 | Sets out definitions for words and terms used in this chapter | Defines "nonprofit health care clinics or programs" consistent with the Code and current interpretation for clarification of the meaning as used in section 100.<br>Clarifies the definition of a "nurse practitioner" as one who is licensed in accordance with Chapter 30.<br>Amends the definition of supervision to clarify that the physician and the nurse practitioner collaborate on the course of treatment and medications prescribed. Both parties have responsibility for a patient's care and well-being. |
| Section 20 | Sets out the statutory authority and the delegation to the executive director of the Board of Nursing certain duties and responsibilities. | An amendment adds the granting of exemptions for compliance with continuing competency requirements to the actions that may be delegated to facilitate the regulation of nurse practitioners. |
| Section 50 | Sets out the requirements for renewal of prescriptive authority | Amendments are necessary to make the regulation consistent with on-line renewals in which a signature is not required to complete the process. Submission of a new practice agreement is required at the time when certain changes occur, as specified in section 90, so it is unnecessary to state the requirement in this section. |
| Section 55 | Specifies the continuing competency requirements for prescriptive authority | Subsection B is amended to clarify that the 8 hours of continuing education in pharmacology or drug therapy is necessary for prescriptive authority and is in addition to the hours or certification required to maintain a nurse practitioner license.<br><br>Subsection D is amended to eliminate the percentage that must be audited to give the boards more flexibility in that process.<br><br>Subsection E is amended to eliminate the extension for "good cause" since that is virtually impossible to regulate and enforce. An extension for circumstances beyond the control of the licensee is added to the exemption |

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| | | provisions in subsection F. |
| Section 60 | Sets out the requirements for reinstatement of prescriptive authority | Amendments are needed for greater clarity in the regulation. |
| Section 90 | Specifies the requirements for a practice agreement | Amendments to subsections A and B clarify when an initial agreement must be submitted to the Board and an amended agreement submitted when there are any subsequent changes in the primary supervising physician, the authorization to prescribe or the scope of practice. |
| Section 100 | Sets out requirements for supervision and site visits by a physician | In accordance with the Code, physicians who supervise must practice regularly in the same location with the nurse practitioner; the Code does not require that the physician be present at all times. Therefore, regulations specify random review of patient charts on which a prescription has been written to ensure some collaboration on patient care. The specific time-frame of monthly reviews has been replaced by a requirement for "regular" reviews. The change should be less burdensome for practices in which there is an on-going collaboration and consultation on patient care, so monthly chart reviews is really not necessary. The frequency and method of review can be spelled out in the practice agreement among practitioners. |
| **New** Section 121 | Sets out the rules for prescribing for self and family | Subsequent to the adoption of Chapter 40, the Board of Medicine has revised its standards of practice for doctors of medicine, osteopathic medicine and podiatry. Included in those standards are rules for prescribing for self and family. The Boards concurred that similar rules are applicable for nurse practitioners, who have the same prescriptive authority and work under the doctor's supervision. The proposed rules are actually more permissive than most prescribers would practice, because they do allow for prescribing of Schedule VI drugs, provided there is adequate documentation. |
| Section 130 | Sets out grounds for disciplinary action | Amendment eliminates an outdated VAC cite. |
| Section 140 | Sets out the process for conducting administrative proceedings | There is an exception added to clarify that section 240 provides for hearing to be conducted by an agency subordinate and clarifies that the grounds for disciplinary action set forth in Chapter 30 also apply to a practitioner's prescriptive authority – i.e., a nurse practitioner whose basic license was suspended on regulatory or statutory grounds would also have his prescriptive authority suspended. |