



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 et seq. |
| Regulation title | Regulations Governing the Practice of Nurse Practitioners |
| Action title | Practice in patient care teams |
| Date this document prepared | 8/6/13 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed regulation revises requirements for practice of nurse practitioners consistent with a model of collaboration and consultation with a patient care team physician working under a mutually agreed-upon practice agreement within a patient care team. The goal of the amended regulation is to revise terminology and criteria for practice, consistent with changes to the Code in Chapter 213 of the Acts of the Assembly.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CNM = certified nurse midwife
 CRNA = certified registered nurse anesthetist
 NP = nurse practitioner

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Boards of Nursing and Medicine the authority to promulgate regulations to 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:

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 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

The specific mandate to promulgate regulations for the practice of nurse practitioners is found in § 54.1-2957 of the Code of Virginia:

§ 54.1-2957. Licensure and practice of nurse practitioners; practice agreements.

A. 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 the Commonwealth unless he holds such a joint license.

B. A nurse practitioner shall only practice as part of a patient care team. Each member of a patient care team shall have specific responsibilities related to the care of the patient or patients and shall provide health care services within the scope of his usual professional activities. Nurse practitioners practicing as part of a patient care team shall maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician. Nurse practitioners who are certified registered nurse anesthetists shall practice under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry. Collaboration and consultation among nurse practitioners and patient care team physicians may be provided through telemedicine as described in § 38.2-3418.16. Practice of patient care teams in all settings shall include the periodic review of patient charts or electronic health records and may include visits to the site where health care is delivered in the manner and at the frequency determined by the patient care team.

Physicians on patient care teams may require that a nurse practitioner be covered by a professional liability insurance policy with limits equal to the current limitation on damages set forth in § 8.01-581.15.

Service on a patient care team by a patient care team member shall not, by the existence of such service alone, establish or create liability for the actions or inactions of other team members.

C. The Board of Medicine and the Board of Nursing shall jointly promulgate regulations specifying collaboration and consultation among physicians and nurse practitioners working as part of patient care teams that shall include the development of, and periodic review and revision of, a written or electronic practice agreement; guidelines for availability and ongoing communications that define consultation among the collaborating parties and the patient; and periodic joint evaluation of the services delivered. Practice agreements shall include a provision for appropriate physician input in complex clinical cases and patient emergencies and for referrals. Evidence of a practice agreement shall be maintained by a nurse practitioner and provided to the Boards upon request. For nurse practitioners providing care to patients within a hospital or health care system, the practice agreement may be included as part of documents delineating the nurse practitioner's clinical privileges or the electronic or written delineation of duties and responsibilities in collaboration and consultation with a patient care team physician.

D. 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 the Commonwealth.

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

F. As used in this section:

"Collaboration" means the communication and decision-making process among members of a patient care team related to the treatment and care of a patient and includes (i) communication of data and information about the treatment and care of a patient, including exchange of clinical observations and assessments; and (ii) development of an appropriate plan of care, including decisions regarding the health care provided, accessing and assessment of appropriate additional resources or expertise, and arrangement of appropriate referrals, testing, or studies.

"Consultation" means the communicating of data and information, exchanging of clinical observations and assessments, accessing and assessing of additional resources and expertise, problem-solving, and arranging for referrals, testing, or studies.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

A team care approach emphasizing collaboration and consultation will allow for more creative and fuller utilization of nurse practitioners while ensuring appropriate setting-specific physician

input. The law and regulations also embrace technological and communications advances such as telemedicine not envisaged under the earlier statutes. Nurse practitioner mobility and geographic outreach into underserved areas can be facilitated by the revised practice paradigm. Collaboration and consultation on patient care within a patient care team protects public health and safety by utilizing the strengths and expertise of nurse practitioners and physicians.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

The following changes are proposed:

- The definitions of “collaboration” and “consultation” are added and are identical to the definitions specified in subsection F of § 54.1-2957. The term “licensed physician” is deleted and replaced by the term “patient care team physician,” which is the term now used in the Code and similarly defined in § 54.1-2900. Likewise, the requirement for a protocol has been replaced in the law with a practice agreement, as specified in subsection C of § 54.1-2957.
- The requirement for supervision of the practice of a nurse practitioner is replaced with a requirement for collaboration and consultation with a patient care team physician as part of a patient care team. The CRNA is omitted from this section because the revisions to the Code retained the supervisory requirement for that category of nurse practitioners.
- The requirements for a practice agreement (which was described as the “protocol” for practice of an NP) are established consistent with elements of a practice agreement are found in Subsection C of § 54.1-2957.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

- 1) The most significant benefit is to the patients/clients in Virginia who may benefit from an expansion of care by nurse practitioners since they are not required to practice in the same location as the patient care team physician and are able to deliver care in a collaborative approach in which each member of the team practices to the extent of his training. There are no disadvantages to the public.
- 2) There are no specific advantages to the agency or the Commonwealth except possibly better utilization of nurse practitioners throughout underserved parts of the state. There are no disadvantages.

- 3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

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| Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board | The individuals affected are nurse practitioners and the physicians with whom they practice. |
| Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million. | There are 7408 persons who hold a current license as a nurse practitioner. Each of the NP’s would have <i>at least</i> one patient care team physician with whom he has a practice agreement (or in the case of a CRNA, who supervises his practice). The number of persons who would constitute a small business is unknown. Some NP’s establish their own practice; some practice within a physician practice; others practice in large medical centers. |
| Benefits expected as a result of this regulatory proposal. | The benefit of the regulatory proposal is consistency with the Code, which was amended in 2012 to allow for practice by NP’s in collaboration and consultation, rather than under supervision. |
| Projected cost to the <u>state</u> to implement and enforce this regulatory proposal. | There are no projected costs to implement and enforce the proposal. Notification of statutory and regulatory changes has been done electronically through the website or email. The promulgation of regulations and conducting a public hearing are accomplished during regularly scheduled meetings of the Boards of Nursing and Medicine |
| Projected cost to <u>localities</u> to implement and enforce this regulatory proposal. | There are no costs to localities. |
| All projected costs of this regulatory proposal for <u>affected individuals, businesses, or other entities</u>. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development. | There are no costs to affected entities. |

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.

There are no alternatives that will achieve the essential purpose of the action.

After working together for two years, the leadership at the Medical Society of Virginia (MSV) and the Virginia Council of Nurse Practitioners (VCNP) reached an agreement that outlined a team-based care model designed to help improve access to MD and NP care and reduce paperwork. In response to recommendations emerging out of the Virginia Health Reform Initiative (VHRI) to explore solutions that address systemic challenges to access to care in the Commonwealth, the legislation passed by the General Assembly emphasizes a consultative and collaborative approach between physician and NPs with the physician providing leadership and management of the care team.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Since the promulgation of regulations for collaboration and consultation by a nurse practitioner with a patient care team physician under a written or electronic practice agreement is specified by the Code of Virginia, there are no alternative methods that will accomplish the objectives of applicable law.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

The NOIRA and emergency regulation were published in Vol. 29, Issue 30 of the Register of Regulations on June 3, 2013; comment was requested until July 3, 2013. There were no comments on the Virginia Regulatory Townhall. Comments sent to the Boards are summarized as follows:

| Commenter | Comment | Agency response |
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| Russell C. Libby, M.D., President of the Medical Society of Virginia | MSV supports the nurse practitioner regulations as drafted. | The agency acknowledges the support of MSV. |
| Tine Hanse-Turton Chief Executive Officer, National Nursing Centers | Requests elimination of requirement for "appropriate physician input in complex clinical cases" in a practice agreement. There is no clear definition of a complex clinical case | Subsection C of § 54.1-2957 of the Code of Virginia specifies that: "Practice agreements shall include a provision for appropriate physician input in complex clinical cases and patient emergencies and for referrals." The |

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| Consortium | and the requirement for physician input limits patient access to care. | Boards have adopted a regulatory requirement which is identical to the statutory requirement and therefore do not have the discretion for its elimination. To define “complex clinical cases” in regulation would be inconsistent with the commenter desire for more discretion and flexibility in the practice of an NP. A “complex clinical case” might be quite different in specialty practices versus primary care. |
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Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.

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

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

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

There are no changes from the emergency regulation currently in effect.

| Current section number | Proposed new section number, if applicable | Current requirement | Proposed change, intent, and likely impact of proposed requirements |
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| 10 | | Establishes definitions for words and terms used in the regulations | The definitions of “collaboration” and “consultation” are identical to the definitions specified in subsection F of § 54.1-2957. The terms “controlling institution” and “preceptor” are deleted because they are not currently used in the chapter. The term “licensed physician” is deleted and replaced by the term “patient care team physician,” which is the term now used in the Code and similarly defined in § 54.1-2900. Likewise, the requirement for a protocol has been replaced in the law with a practice agreement, as specified in subsection C of § 54.1-2957. |

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| | | | <i>The likely impact of the proposed changes in definitions is minimal since terms are also used and defined in the Code.</i> |
| 90 | | Sets out the list of professional credentialing bodies acceptable for licensure by examination for nurse practitioners | The list of credentialing bodies has been amended because three of the names have been changed since this section was last amended. <i>The impact is additional clarity in the regulation to eliminate any possible confusion about the names of the credentialing bodies.</i> |
| 100 | | Sets out the requirements for renewal of licensure | The word “mailed” is changed to “sent” to allow the board to send initial notices for renewal electronically. <i>While Nursing has not adopted that process as yet, other boards at the Department of Health Professions have done so, and this change in regulation will make it clear that email notification is authorized for nurse practitioner renewal.</i> |
| 105 | | Sets out the requirements for continuing competency | An obsolete date in subsection B is deleted. |
| 120 | | Sets out the criteria for practice of all nurse practitioners, except certified registered nurse anesthetists (CRNA) | Subsection A is revised for consistency with A 3 in § 54.1-2901. <i>The requirement for supervision of the practice of a nurse practitioner is replaced with a requirement for collaboration and consultation with a patient care team physician as part of a patient care team. The CRNA is omitted from this section because the revisions to the Code retained the supervisory requirement for that category of nurse practitioners.</i> Subsection B is amended to clarify that all NP practice is based on specialty education preparation as “an advanced practice registered nurse.” <i>While the term “nurse practitioner” continues to be used in law and regulation, such person is defined in the Code as an “advanced practice registered nurse,” and it is the term used in the consensus model advocated by nursing groups.</i> The specific standards for practice of a certified nurse midwife (CNM) are currently found in subsection D of section 121, which has been amended to reference CRNA’s instead of CNM’s. |
| 121 | | Sets out the criteria for practice of certified registered nurse anesthetists (CRNA) | While other nurse practitioners practice in collaboration and consultation with a patient care team physician, the legislation retains the requirement of supervision for CRNA’s. (See subsection B of § 54.1-2957). Therefore, a separate section on practice was established which includes the requirement to practice according to specialty education preparation, which are currently found in subsection D of section 120. <i>Prior to 2012 amendments to the Code, a nurse practitioner licensed as a certified nurse midwife (CNM)</i> |

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| | | | <p><i>was allowed to practice in “collaboration and consultation” with a licensed physician. (§ 54.1-2901 A 31). Since all categories of nurse practitioner (except CRNA’s) may now practice in collaboration and consultation, there was no need for a separate practice section for CNM’s.</i></p> |
| n/a | 122 | n/a | <p>Section 122 sets out the requirements for a practice agreement (which was described as the “protocol” for practice of an NP).</p> <p>Subsection A reiterates the requirement in Code for practice in accordance with a practice agreement, which may be developed and “signed” in writing or electronically.</p> <p>Subsection B sets out the basic content of a practice agreement to include periodic review of patient records, appropriate physician input in complex cases and emergencies, and the authority for the NP to sign certain documents. The practice agreement may also include provisions for visits to the site where the NP is delivering care in a manner and at a frequency determined by the team.</p> <p><i>Required elements of a practice agreement are found in Subsection C of § 54.1-2957.</i></p> <p>Subsection C of the regulation requires the practice agreement to be maintained by the nurse practitioner and provided upon request. Nurse practitioners providing care to patients within a hospital or health care system can include the practice agreement as part of documents delineating the nurse practitioner's clinical privileges or the electronic or written delineation of duties and responsibilities; however, the nurse practitioner is responsible for providing a copy to the boards upon request. <i>Requirements for maintenance, provision upon request, and inclusion of the practice agreement in hospital documents are found in Subsection C of § 54.1-2957.</i></p> |