Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Boards of Pharmacy and Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-40-10 et seq.
Regulation title	Regulations Governing Collaborative Practice Agreements
Action title	Regulatory review
Document preparation date	11/30/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Boards of Pharmacy and Medicine intend to amend requirements for collaborative practice agreements between doctors of medicine, osteopathy or podiatry and pharmacists directly involved in patient care in order to clarify certain provisions and modify others that are unnecessarily cumbersome or burdensome.

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 Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18 VAC 110-40-10 et seq. Regulations Governing Collaborative Practice Agreements are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

> ***§ 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 statutory authority for the Board to promulgate regulations for collaborative practice agreements between doctors of medicine or osteopathic medicine and pharmacists is found in § 54.1-3300.1.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions and/or limitations, for the purpose of improving patient outcomes. No patient shall be required to participate in a collaborative procedure without such patient's consent.

Collaborative agreements may include the modification, continuation or discontinuation of drug therapy pursuant to written, patient-specific protocols; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

(1999, cc. 895, 1011.)

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Without a regulatory action to make the process for collaborative practice agreements less cumbersome and more clear to practitioners and pharmacists, the restrictions that may impede collaborative agreements will remain in effect. Any impediment to the implementation of collaborative agreements without an accompanying benefit to patient health, safety and welfare should be eliminated to encourage a process that enables patients to have disease states and conditions monitored and treated in a manner that is less costly and more accessible. By using local pharmacists as participants in patient care, the patient is better served and the physician can concentrate on other aspects of practice.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The boards intend to amend those regulations that are confusing and modify others that are unnecessarily cumbersome or burdensome without achieving a greater degree of patient safety. The advisory committee reviewing the regulation has recommended changes in the following regulations:

1) Alternate practitioners/pharmacists
   - Virginia Law indicates that a collaborative practice can exist between "one pharmacist and his designated alternate pharmacists involved directly in patient care at a location where patients receive services" and "a practitioner…and his designated alternate practitioners involved directly in patient care."
   - The regulations assert that practitioners and pharmacists may designate alternate practitioners and pharmacists "provided the alternates are also signatories to the agreements."
   - For compliance with the law, it is not necessary to require the "signatures" of the designated alternate pharmacists and practitioners in the agreement. This would be especially beneficial in cases in which practitioners or pharmacists are filling in at a practice location for a short time or in the case of transfers between practice sites on the part of practitioners or pharmacists.
2) Patient informed consent
   - Virginia Law states that "[n]o patient shall be required to participate in a collaborative procedure without such patient's consent."

- The regulations stipulate that the practitioner must obtain "written" informed consent from the patient and provide a copy to the pharmacist.
- In practice, the order by the practitioner for a patient to participate in a collaborative agreement may come after he has seen the patient and ordered certain tests. Based on the results of those tests, he may feel the patient would benefit from follow-up with his local pharmacist and suggest participate in a collaborative agreement. In that scenario, the informed consent could be documented by the pharmacist and sent to the practitioner for inclusion in the patient's medical record. Amendments to the section on signed authorization are necessary to affect those changes.

3) Length of agreement
   - Virginia Law does not impose a restriction on the length of a collaborative practice agreement. However, the regulations only allow an agreement to be valid for "a period not to exceed two years."
   - This constraint is not necessary under the definition of the law and a less restrictive approach would consider an agreement valid until terminated by either the practitioner or the pharmacist that entered in to the agreement, or at a time when the treatment plan is no longer current or is no longer considered to be the standard of care. The boards may want to require periodic reviews of the agreement as appropriate.
4) Approval of Protocols
   - Regulations may be causing confusion under the heading of "Approval of Protocols." The approval process, and application fee, only applies to the rare protocols that are outside the clinically accepted standard of care. By changing the title of the section to "Approval of Protocols Outside the Standard of Care" or an equally clarifying title, some confusion would be eliminated as to which protocols are required to undergo an approval process by the Committee of practitioners of medicine and pharmacy.
   - There could also be confusion about the provision that allows an agreement in which the practitioner wants to increase monitoring beyond what is an acceptable standard of care without board approval.
   - A requirement for an applicant to submit documentation that the protocol "follows an acceptable standard of care" is an impossibility, since the reason for seeking board approval is that the protocol is "outside the standard of care." The criteria should be whether the protocol is safe and effective for the particular condition or disease to be managed or treated by a collaborative agreement.
5) Notification requirements
   - The boards may add a requirement for notice to the collaborating parties and to the patient if there is a change in ownership or in location of one of the practices. Such a change may affect patient care and the patient's choice about participation in the collaborative agreement.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

Regulations for collaborative practice agreements were adopted following the enabling legislation passed by the 1999 General Assembly and have not been reviewed or revised since the effective date of January 17, 2001. Since that time, experience with collaborative agreements has shown that some of the requirements may be more restrictive than necessary and may be inhibiting full implementation. To explore changes that would eliminate barriers and review regulations for effectiveness, the Boards published a Notice of Periodic Review and request for comment beginning April 18, 2005 for a 30-day comment period. There were no written comments as a result of the Notice, but the Virginia Pharmacists Association (VPHA) developed discussion points on the regulations.

Subsequently, an advisory committee was appointed to conduct the review and make recommendations for change, which are reflected in the substance section of this document. Members of the advisory committee included two members of the Board of Medicine, three members of the Board of Pharmacy, a former member of the Medicine board and a pharmacy professor who participated in the development of the initial regulations, a family practitioner who utilizes collaborative agreements in his practice, and the Executive Director of VPHA, who has an interest in collaborative agreements.

The recommendations of the advisory committee will go to the Boards of Pharmacy and Medicine following publication of the Notice of Intended Regulatory Action. Without a regulatory action, the restrictions that may impede collaborative agreements will remain in effect.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The Board is also 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 for the public comment file may do so by mail, email or fax to Elaine Yeatts at 6603 W. Broad Street, Richmond, VA 23230 or to 80-662-9114 or **elaine.yeatts@dhp.virginia.gov** . Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency/board is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.}

A public hearing will be held after publication of the proposed regulations. Notice of the hearing will be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency/board has already used an ad hoc advisory committee to develop recommended language. The primary function of the advisory committee was to develop recommended regulation amendments for consideration through the collaborative approach of regulatory negotiation and consensus.

Family impact

Assess the potential 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 potential impact on the family and family stability.

Periodic review

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section*. If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 21, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

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1) There was no comment on the notice of periodic review.

2) The regulation meets the criteria set out in EO21 and is necessary for the protection of public health, safety and welfare. It is being revised to be less restrictive and more clearly written.