Virginia Regulatory Town Hall

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Proposed Regulation
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	6/22/06

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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Boards of Pharmacy and Medicine have proposed amendments to 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., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18VAC110-40-10 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.

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 and the problems the proposal is intended to solve.

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. Proposed amendments preserve the practitioner-patient-pharmacist relationship but modify some of the procedures to facilitate collaborative agreements.

Substance

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

The boards amended those regulations that are confusing and modified others that are unnecessarily cumbersome or burdensome and did not achieve a greater degree of patient safety. The advisory committee reviewing the regulation recommended changes that were subsequently adopted by the two boards 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. Additionally, word "regularly" is not needed in the description of where a patient receives services. For example, a pharmacist may designate an alternate pharmacist working at a different pharmacy where the patient does not normally go, but could consent to go if the regular pharmacist is absent for some reason.

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 participation in a collaborative agreement. In this and in other situation, it may be more practical for the informed consent to be documented by the pharmacist and sent to the practitioner for inclusion in the patient's medical record rather than making the patient go back to the practitioner's office. Amendments to the section on signed authorization are necessary to affect this change.
3) Length of agreement
   - Virginia Law does not impose a restriction on the length of a collaborative practice agreement. However, the current 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 and better approach would consider an agreement valid until terminated by either the practitioner or the pharmacist that entered into the agreement, or at a time when the treatment plan is no longer current or no longer considered to be the standard of care. The regulation change requires that the parties establish a plan for periodic review and revision of the agreement and treatment protocol.
4) Approval of Protocols
   - Current regulations are causing confusion under the heading of "Approval of Protocols" as some pharmacists and practitioners have been reluctant to initiate such programs because they feel the approval process if cumbersome and do not realize that they do not need approval if they are using protocols that are already within the accepted standard of care. The approval process, and application fee, would only apply to a rare protocol that is 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, this confusion may be eliminated.
   - There may also be confusion that approval is required for management of a disease state for which there is an accepted standard of care, but for which a practitioner may want to increase monitoring and oversight above the level required by the accepted standard. Amended language clarifies that increased oversight does not require 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
   - A requirement was added 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.

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 so indicate.

1) As noted by the National Association of Chain Drug Stores in a comment to the Board, the primary advantage to the public would be an increase in efficiencies and reduction of unnecessary burdens by reducing the paperwork and simplifying the process of implementing a collaborative agreement. Patients could be monitoring for a chronic disease state by their local pharmacist in accordance with an agreed-upon protocol with their physician, reducing cost to the patient and improving the opportunity for compliance with a treatment regime. There are no disadvantages to the patients, since informed consent would still be required and the patient would continue to have the option to not participate or to withdraw at any time.

2) There are no advantages to disadvantages to the agency or the Commonwealth.

3) There are no other pertinent matters of interest.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals that will be affected by this regulation are doctors of medicine or osteopathic medicine and pharmacists who would enter into a collaborative practice agreement to monitor certain patients with chronic health conditions.
Agency's best estimate of the number of such	There is no estimate of the entities affected because

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.	the Board does not require registration of such agreements. Anecdotally, the boards are aware that there are some practice agreements being utilized. With passage of these amendments, it is anticipated that the number of collaborative agreements could increase. There have been no applications for approval of an agreement that is outside the accepted standard of care and none are expected.
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 are no projected costs of the regulation.

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.

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. The original enabling legislation had an expiration provision of July 2004 which was removed by the 2004 General Assembly. Experience with collaborative agreements has shown that some of the requirements may be more restrictive than necessary and may be inhibiting full implementation of the legislation. 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 were adopted by the Boards of Pharmacy and Medicine following publication of the Notice of Intended Regulatory Action with only editorial revisions. Without a regulatory action, the restrictions that may impede collaborative agreements will remain in effect.

Public comment

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

Following publication of a Notice of Periodic Review, an Ad Hoc Committee on Collaborative Agreements met on November 2, 2005 to conduct a periodic review of regulations and draft recommended changes to the regulations. Taking the recommendations of the Committee, the Boards adopted a Notice of Intended Regulatory Action which was published on March 6, 2006 with comment until April 5, 2006.

During the comment period, the National Association of Chain Drug Stores (NACDS) commented on behalf of approximately 982 chain pharmacies in Virginia. While NACDS noted that the Virginia Board was a national leader in ensuring that regulations are consistent with pharmacy practice and patient care and safety, they commented that simplifying the process for initiation of a collaborative agreement as recommended by the Ad Hoc Committee could have a positive effect on the number of practitioners and pharmacists willing to engage in collaborative agreements for patient care. NACDS also recommended a reduction in the fee for approval of a protocol for situations in which the agreement is outside the clinically accepted standard of care. The Boards declined to amend the fee but did clarify that any exception to the clinical standard of care that increases patient monitoring and oversight does not require an application to and approval by the Board. A collaborative agreement that otherwise deviates from the clinical standard would necessitate review by a committee, preparation of documentation by staff and likely would include the use of experts to advise the boards on the safety and effectiveness of the altered protocol. Therefore, the cost is reasonable for such an application.

The draft regulations were presented to the Board of Pharmacy at its meeting on June 5, 2006 and to the Board of Medicine on June 22, 2006.

Family impact

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

There is no impact of the proposed regulatory action on the institution of the family and 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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Establishes definitions for words and terms used in the regulation	A proposed amendment to section 20 eliminates the requirement for all alternate pharmacists or practitioners to be signatories to the agreement, so that part of the definition of a pharmacist is also eliminated.
20	n/a	Establishes the requirements for signed authorization for an agreement	Subsection A. Proposed amendments would eliminate the requirement that all alternate pharmacists or practitioners be signatories on the agreement. In addition, eliminating the requirement for the alternate pharmacists or practitioners to be at a location where patients "regularly" receive services will allow for more flexibility in meeting the needs of the patient in accordance with the agreement. The law does not require the alternates to be signatories, so the amendments will allow practitioners and pharmacists to designate alternates with a practice or a pharmacy group who are involved directly in patient care. Subsection B. Amendments will allow informed consent to be obtained by the practitioner or by the pharmacist and documented in the patient record. A written consent form is not required as long as the patient's consent is documented in the patient record. Again, the Code requires that the patient consent to participate in such an agreement but it does not require a written consent form. This change allows for more flexibility in the use of electronic medical records. An amendment will also allow the pharmacist or the practitioner to explain the agreement and protocol to the patient and obtain the consent from the patient. Such a change may enable a patient to participate in a more timely fashion rather than waiting for a return visit to the doctor only for the purpose of agreeing to participate.

30	n/a	Sets out the application process and fee for approval of a protocol outside the accepted standard of care	Amendments in the title clarify that only those protocols outside the standard of care must be approved by the Board. Subsection B is rewritten to further inform the regulated that a protocol that increases patient oversight and monitoring does not need to be approved and does not require an application. Another amendment will change the requirement that an applicant submit documentation that the protocol follows an acceptable standard of care. Since the protocol has been identified as "outside the standard of care", the evidence that is necessary for approval would be documentation that the protocol is safe and effective.
40	n/a	Sets out the requirements for the content of an agreement and treatment protocol	An amendment to subsection D changes the two-year limitation on an agreement to a requirement for periodic review. Some protocols for monitoring chronic disease are long-standing and do not change in a two-year period, so periodic review is more appropriate. With the amended language, the schedule for review will depend on the nature of the agreement and the participants.
50	n/a	Sets out the requirements for record retention	Since the requirement for a written consent form is being eliminated, an amendment to subsection C of this section will require that the patient's consent be documented and retained in the patient record.