Regulatory Review Package

Emergency Regulations

Board of Pharmacy
Board of Medicine
18 VAC 110-40-10 et seq.

1. Proposed emergency regulation - See attached.

2. Source of the legal authority to promulgate the contemplated regulation.

The proposed emergency regulations are being promulgated to comply with statutory provisions of HB 2428 passed by the 1999 General Assembly. House Bill 2428 (Chapter 1101) has an enactment clause requiring the Boards of Pharmacy and Medicine to promulgate regulations to implement the act to be effective within 280 days of the enactment. (See attached copy of Chapter 1101)

Rulemaking is mandatory in order for the Board to comply with statutory language in which it is stated that the Board shall promulgate regulations within 280 days of enactment.

b. Letter of assurance from the office of the Attorney General.

See attached.

c. Statement of necessity.

Promulgation of the Emergency Regulation, 18 VAC 110-40-10 et seq., is necessary to conform to statutory provisions of Chapter 1101 of the 1999 Acts of the Assembly. In accordance with the Administrative Process Act, the "emergency situation" which exists is specified in § 9-6.14:4.1 (C)(5)(ii) of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law. The proposed regulations are not exempt from provisions of subdivision C of § 9-6.14:4.1. **Since the date of enactment was April 15, 1999, the final date for the regulations to be in effect is January 20, 2000**.

d. Statement of changes which the regulations will implement.

This is a new set of regulations; the proposed sections are as follows:

18 VAC 110-40-10. Definitions.

There are four terms defined as necessary for the understanding of and ease of compliance with these rules; they are "agreement", "committee", "pharmacist", and "practitioner". Definitions are essential because each of the terms defined has a meaning unique to these regulations.

18 VAC 110-40-20. Signed authorization for an agreement.

Subsection A states the parties who may be signatories to a collaborative practice agreement and that each must be directly involved in patient care at the location where the patient regularly receives services.
Subsection B clearly states that an agreement for a patient may be implemented only pursuant to an order for that patient and only with the written informed consent from that patient obtained by the practitioner who has authorized patient participation. The regulation further specifies that the patient may decline participation and shall be fully informed as to the procedures to be followed. The practitioner and pharmacist are also required to disclose any financial incentive they may have which may impact participation in the agreement.

18 VAC 110-40-30. Approval of protocols.

Subsection A requires that the practitioner and pharmacist who intend to manage or treat a condition through a practice agreement, for which there is not a clinically accepted standard of care, must submit the proposed protocol for approval by a committee of the two boards.
Subsection B states that if the proposed treatment protocol increases practitioner oversight beyond the accepted standard of care, approval by the committee is not required.
Subsection C establishes the fee for review and approval of a protocol and states the information which must be submitted.

18 VAC 110-40-40. Content of an agreement and treatment protocol.

Subsection A specifies that the agreement must contain a treatment protocol that is clinically accepted as the standard of care within the medical and pharmaceutical professions.
Subsection B summarizes what information must be contained in the protocol.
Subsection C requires that the protocol describe the activities in which the pharmacist is allowed to engage and the procedures which are to be followed.
Subsection D states that the agreement is only valid for a period of not more than two years, after which the signatories shall review the procedures and protocols.

18 VAC 110-40-50. Record retention.

Subsection A requires the signatories to keep a copy of the agreement on file at their practice location.
Subsection B requires that the order from the prescribing practitioner authorizing drug therapy management pursuant to an agreement be noted in the patient's medical record and also kept on file by the pharmacist.
Subsection C specifies that a copy of the written informed consent must be maintained in the patient's medical record and kept on file by the pharmacist in a readily retrievable manner.

18 VAC 110-40-60. Rescindment or alternation of the agreement.

Subsection A provides that a signatory or the patient may rescind the agreement at any time.
Subsection B provides that a practitioner may override the agreement whenever he deems such action to be appropriate or necessary.

18 VAC 110-40-70. Compliance with statutes and regulations.

This section specifies that any agreement or referral under an agreement must also be in compliance with the Practitioner Self-Referral Act and with applicable chapters of Title 54.1 of the Code of Virginia.

e. Statement of reasoning for the regulations.

In response to legislation introduced in the General Assembly in1998, the Medical Society of Virginia and the Virginia Pharmacists Association signed a memorandum of agreement "for the purpose of determining the necessary guidelines for establishing collaborative practice agreements between physicians and pharmacists." A Joint Collaborative Practice Committee, consisting of five physicians and five pharmacists was formed to gather information on collaborative agreements and address concerns raised on particular issues. A literature search was conducted, data was gathered, and a presentation was made on collaborative agreements that are currently in use. Its research indicated that collaborative practice agreements are being successfully utilized in many other states and in hospital and community settings in Virginia. Furthermore, the Committee found that collaborative practice agreements allow "physicians and pharmacists to more efficiently optimize patient care by providing higher quality health care and drug therapy outcomes. Studies consistently show that collaborative practice agreements result in a reduction of morbidity and mortality associated with medication misadventures and improve patients' drug therapy outcomes by increasing compliance." It was the study report of the Committee (submitted to the General Assembly December 1, 1998), that formed the basis for the legislation patroned by Delegate Chris Jones.

Also, the Committee developed draft definitions and language for collaborative agreement guidelines, which became the basis for these proposed regulations.

Prior to adoption of emergency regulations, the Board of Medicine and the Board of Pharmacy appointed an Ad Hoc Committee on Collaborative Practice to consider the requirements of the law, receive public comment and develop draft regulations accordingly. The Ad Hoc Committee, composed of two physician members of the Board of Medicine, two members of the Board of Pharmacy, two physicians recommended by the Medical Society of Virginia (MSV), and two pharmacists recommended by the Virginia Pharmacists Association (VPHA), was chaired by Karen E. Knapp, M.D., a member of the Board of Medicine, who had also served on a Joint Collaborative Practice Committee. The two groups (MSV and VPHA) were asked to suggest practitioners with particular knowledge about collaborative practice to join the task force and provide expertise and advice.

The Ad Hoc Committee held three meetings at which all interested parties were invited to present comments and offer amendments and were fully included in the discussion of the regulations. Notice of the task force meeting was sent to approximately 270 consumers and groups on the mailing lists of the Boards of Pharmacy and Medicine. All meetings were open to the public, and everyone was encouraged to participate by attempting to seat all attendees at the table for full participation. Representatives of the Pharmaceutical Research and Manufacturers' Association (PhRMA), the Virginia Academy of Family Physicians, the Medical Society of Virginia, the Virginia Pharmacists Association, MCV/VCU, and a number of drug companies attended the meetings and had ample opportunity for input in the process.

The emergency regulations being promulgated by the Board are those recommended by the Ad Hoc Committee of the Boards and are those which are essential to protect patients who will participate in collaborative practice agreements with physicians and pharmacists.

f. Statement on alternatives considered.

The Boards did not consider alternatives to the promulgation of regulations as they were mandated to adopt regulations to implement the statute. They did consider and adopt the least burdensome regulation consistent with the specific provisions of the statutes and with their concern for public health and safety. In the development of regulations, the Board considered regulatory content and language from a variety of sources including:

1) Draft language for Collaborative Practice Agreements from the MSV-VphA Committee - including a statement of purpose, definitions, written guideline or protocol, required components of a protocol, patient notification, review of the protocol, and exceptions to the protocol.

2) Collaborative practice agreements and protocols for care currently in use in Virginia and elsewhere, including:

- The Outpatient Anticoagulation Clinic Protocol - Williamsburg Community Hospital
- Ambulatory Care Oral Anticoagulation Guidelines - Martha Jefferson Hospital
- Adult immunization clinics and hyperlipidemia clinics - Ukrop's Pharmacy and Richmond family practitioners
- The Asheville Project for Diabetes Management - Asheville, NC

3) Regulations of other states, particularly those of Idaho, which the National Association of Boards of Pharmacy suggested as "model regulations".

ISSUES RELATED TO THE REGULATIONS

Throughout the course of developing regulations and having them adopted by the two boards, several issues were raised by members of the Committee or representatives of some interested party; all issues were explored and fully deliberated. Those issues or concerns included:

Issue #1. Any pharmacist and any practitioner may become part of the patient-specific agreement just by signing the agreement.

- The draft regulations follow the provisions of law which states that a collaborative agreement means a voluntary, written arrangement between "one pharmacist *and his designated alternate pharmacists* involved directly in patient care at a location where patients receive services and a practitioner of medicine, osteopathy, or podiatry and *his designated alternate practitioners* involved directly in patient care…" It is clear that it is the pharmacist and the practitioner who are to designate their alternates in the agreement - just as it is in a protocol between a physician and a nurse practitioner. The agreement is between one pharmacist and one physician, but it essential (and mandated by law) that each be allowed to designate one or more alternates who could be available to the patient.

- Every pharmacist and every practitioner who participates in the agreement must be a signatory to the agreement with the treatment protocol included, must be <u>involved directly</u> in patient care, and be at a location where patients regularly receive services.

- The patient has the authority and ability to <u>not participate</u> or to withdraw from participation at any time if he or she is uncomfortable with the signatories or any part of the agreement.

Issue #2. *Certain conditions cannot be safely managed via a collaborative agreement, yet neither the bill nor the proposed regulations clearly define which diseases can be managed via an agreement and which cannot.*

- The "standard of care" is not spelled out in law or regulation for procedures and treatments performed by practitioners. It is the physician who has the ultimate responsibility for his/her patient and for providing treatment in accordance with an appropriate standard of care. That is also the case with a collaborative practice agreement.

- The law specifically provides two scenarios under which a collaborative practice agreement may be used: 1) for conditions which have protocols that are clinically accepted as the standard of care (e.g., proven in clinical trials); or 2) for conditions for which there is no clinically accepted standard of care but which have been approved by the boards. (§ 54.1-3300.1)

- The draft regulations set up a process for such approval, by which a case decision would be rendered from an informal conference committee comprised of two members of each board. The Administrative Process Act would apply to such a proceeding with the right of the applicants to appeal any decision of the committee to the boards. (18 VAC 110-40-30)

- Since the professional licenses of the practitioner and the pharmacist are at stake, the expectation is that both would approach an agreement as a team working in the best interest of the patient. Any party to an agreement (a physician, a pharmacist or a patient) could opt out of the agreement at any time the party was dissatisfied with the any aspect of the agreement.

- A practitioner, who is responsible for the care of his/her patient, would have no reason to push his/her patient into the care of a pharmacist with a questionable ability to provide care. The procedures to be followed for reporting to the physician are to be clearly spelled out in the protocol, and physician oversight may be increased at any time, if the situation warrants it. (18 VAC 110-40-40)

- The task force uniformly agreed that it was unnecessary and unwise to spell out in regulation which conditions or diseases could be managed under a collaborative agreement. Protocols for managing certain disease states or conditions are already in use in many hospitals with well-established standards of care.

- In recognition of the growing utilization of disease management protocols, the American Pharmaceutical Association has published a book entitled "The American Pharmaceutical Association Drug Treatment Protocols" which contains 44 drug treatment protocols written and peer-reviewed by pharmacists, physicians and nurses. On average, 15 health care professionals were involved in the development of each protocol, which begins with a diagnosis made by the physician and then describes pharmacotherapeutic and pharmaceutical-care choices. Current national guidelines, along with additional scientific literature, were used in developing the therapeutic protocols. The protocols may be used or modified by practitioners and pharmacists on the local level to meet the specific needs of their patients.

Issue #3. Proposed regulation do not assure that patients' drug therapy will not be switched by pharmacists based on monetary or other non-clinical interests.

- Regulations do clearly provide that the drugs, drug categories, or drug therapies must be described in the treatment protocol contained in the agreement. The physician writes the order for a patient to participate in that protocol; the pharmacist has no independent authority to switch a patient to a drug that is not specified in the protocol. (18 VAC 110-40-40 B)

- Regulations also require that any collaborative agreement must comply with requirements of Chapter 33 (the Pharmacy Act) and Chapter 34 (The Drug Control Act), which require that a pharmacist fill a prescription only on the valid order of a practitioner. In addition, the Code states that "No prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship." (§ 54.1-3303) (18 VAC 110-40-70)

- Among the acts prohibited in the Drug Control Act is "Dispensing or causing to be dispensed, except as provided in § 32.1-87 relating to the Virginia Voluntary Formulary, a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing." [§ 54.1-3457 (16)] As is stated above, any practitioner or pharmacist treating a patient by a protocol under a collaborative agreement would have to comply with the current law.

- Additionally, the use of collaborative agreements and protocols may be written or adjusted based on the needs of the individual patient. If the protocol normally allows the pharmacist to change from a specific drug to another specific drug following the procedure in the agreement, a practitioner may specify that such a switch would not be in the best interest of an individual patient and may disallow that aspect of the protocol in the order written for the patient.

- Participation in a collaborative practice agreement is entirely voluntary; the procedures and the protocol to be followed must be agreed to by all parties to the agreement - the patient, the physician and the pharmacist.

- "Drug-switching" commonly occurs now, usually at the recommendation of the pharmacy benefits manager for an insurer or a health maintenance organization. However, the switching of a patient to another drug requires the physician to agree to the change. Since the prescriber's order is always required for a pharmacist to fill a prescription, that would also be the case for prescription filled under a collaborative agreement.

- The Ad Hoc Committee and the Boards reviewed and rejected the amendments proposed by PhRMA, concluding that they were both unnecessary and unduly restrictive.

- Delegate Chris Jones, chief patron of HB 2428, wrote to John Hasty, Director of the Department, that "the proposed regulations, as drafted by the Ad Hoc Committee on Collaborative Practice meet the spirit and intent of HB 2428." He had looked at a draft amendment that would have addressed the drug-switching issue and recommended against any amendments to the draft regulations adopted by the Committee. Delegate Jones further stated emphatically that this was not a drug-switching bill, but a collaborative practice bill. He went on to say that he had followed the process and commended all of the involved parties for their efforts on behalf of the citizens of the Commonwealth.

Issue #4. Fee for Review of a Protocol by the Committee of the Joint Boards.

In the proposed regulation, the process for review and approval of a protocol which does not follow the accepted standards of care is established. Given that only those protocols which are outside the standards of care will need to be approved by the Boards, it is expected that there will be very few if any applications for approval. There was concern that the fee be sufficient to cover the expenditures that would be incurred but would not be excessive or prohibitive. Since the protocols which will be submitted for approval will be those that are out of the ordinary, it is expected that the informal conference committee will have to contract with one or more consultants who have expertise or knowledge in the related fields of medicine and pharmacology. The Boards would have to compensate them for their time (current rate is $90 to $150 per hour) in studying the content of the protocol, reviewing the treatment plan, and testifying before the committee. If the applicants are not satisfied with the findings of the committee, they would have the right to appeal that decision to a joint hearing of the two boards. Without any history of applications for approval of protocols or of holding such informal conference committee hearings, it is difficult to project the actual costs, but the Boards determined that a fee of $750 was both reasonable and minimal.

g. Publication of a NOIRA to replace emergency regulations

The Boards of Medicine and Pharmacy hereby request permission to publish a Notice of Intended Regulatory Action to replace the Emergency Regulations with permanent regulations. (NOIRA form to be submitted is attached.)