Form: TH- 03

Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Boards of Pharmacy and Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 110-40-10 et seq.
Regulation Title:	Regulations Governing Collaborative Practice Agreements
Action Title:	Establishment of initial permanent rules governing collaborative practice
Date:	11/28/00

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The Boards of Pharmacy and Medicine have adopted new regulations, 18 VAC 110-40-10 et seq., entitled Regulations Governing Collaborative Practice Agreements. These regulations will replace emergency regulations and are identical to those regulations which became effective on January 20, 2000. Regulations are promulgated pursuant to a mandate in Chapter 1101 of the 1999 Acts of the Assembly and are intended to set forth provisions for signatories of an agreement, informed consent to the agreement, content of an agreement and treatment protocol, record retention, and an approval process for a protocol outside the accepted standard of care.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On November 17, 2000, the Board of Medicine and on November 27, 2000, the Board of Pharmacy adopted 18 VAC 110-40-10 et seq., Regulations Governing Collaborative Practice Agreements, in order to implement new regulations replacing emergency regulations which have been in effect since January 20, 2000.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

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

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*

12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.

Chapter 1101 of the 1999 Acts of the Assembly amended § 54.1-3300 by adding a definition of a "collaborative agreement" and added § 54.1-3300.1 that mandates promulgation of regulations by the Boards of Pharmacy and Medicine for collaborative practice agreements.

§ 54.1-3300. (Effective until July 1, 2004) Definitions.

As used in this chapter, unless the context requires a different meaning:
"Board" means the Board of Pharmacy.
"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 which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.
"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for delivery.
"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.
"Pharmacy" means every establishment or institution in which the practice of pharmacy is conducted; drugs, medicines or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.
"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records ; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.
Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) of this title unless the context requires a different meaning.

§ 54.1-3300.1. (Effective until July 1, 2004) 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.

The Assistant Attorney General who provides counsel to the Board has certified that the Board has the authority to promulgate the amended regulations and that they do not conflict with existing state or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

In response to legislation introduced in the General Assembly in 1998, 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 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 regulations being promulgated by the Boards are those initially recommended by the Ad Hoc Committee of the Boards and adopted as emergency regulations. They are essential to protect patients who will participate in collaborative practice agreements with physicians and pharmacists.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

18 VAC 110-40-10 et seq. is being promulgated as a new regulation, replacing the emergency regulation on collaborate practice agreements currently in effect. In addition to definitions necessary for implementation of the regulation, it contains provisions for who may signed such an agreement, the required consent from the patient to participate, the essential content of an agreement and the treatment protocol. Regulations further provide for an approval process and an application fee for an entity or entities that want to enter into an agreement with a protocol

outside the accepted standard of care. Finally, regulations provide for rescindment or alteration of the agreement and clarify that any collaborative agreement must be governed by current law.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

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 regulations follow the provisions of law which state 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 is 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 involved directly in patient care, and be at a location where patients regularly receive services.

- The patient has the authority and ability to not participate 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 amended 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. Regulations 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 using a collaborative agreement would have to comply with the current law. A pharmacist may only dispense a drug which is ordered by a prescriber for a specific patient. This is still the case with a collaborative agreement.

- 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" 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 a chemically dissimilar drug requires the physician's authorization. The same authorization by the prescriber is required in order for a pharmacist to "switch" a patient to a different drug than the one originally prescribed.

- 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 adopted 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.

1) The primary advantages and disadvantages to the public are as follows:

The Boards do not believe that there are any disadvantages to the public, which is fully protected by current law on prescribing and provisions of the collaborative practice regulations. Participation is entirely voluntary and may be altered or rescinded by the patient at any time. Advantages of collaborate practice agreements to the public may include: closer monitoring of their disease state or condition, more effective drug treatment, and reduced cost by a reduction in the number of patient visits to a physician. By a collaborative agreement that actively involves the pharmacist with the physician in patient care, the patient may be better served by being able to take advantage of the expertise of the pharmacist in drug therapies and pharmacology.

2) There are no advantages or disadvantages to the agency or the Commonwealth. A collaborative agreement will be drawn between or among a group of practitioners without the need for specific approval from the Boards. Costs for approval of a treatment protocol that is outside the accepted standard of care should be recovered from a fee charged to the applicants.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public hearing was held before the Board of Pharmacy at the Department of Health Professions in Richmond on October 10, 2000. No comment was presented at that time nor was any written or electronically submitted comment received during the 60-Day Comment Period from August 28, 2000 to October 27, 2000.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

This is a new set of regulations; the 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.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

The agency has reviewed the regulation in relation to its impact on the institution of the family and family stability. There would be no effect of the regulation on the authority and rights of parents, economic self-sufficiency or the martial commitment. Since some patients may be able to have their diseases or conditions co-managed by their physicians and pharmacists, the regulation may result in fewer visits to the physician resulting in a minimally positive effect on disposable family income. The primary purpose of collaborative agreements is more attentive management of medications with better compliance on the part of the patients. If the intent is achieved, patients with chronic health problems may stay healthier and more productive.