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Fast Track Regulation Agency Background Document

Agency name	Board of Health Professions, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC75-20-10 et seq.
Regulation title	Regulations Governing Practitioner Self-Referral
Action title	Hearing conducted by agency subordinate
Document preparation date	4/23/07

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

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

Part IV is added to regulations governing practitioner self-referral in order to set out criteria for delegation of an informal conference to an agency subordinate. The criteria for delegation would be those applications for an advisory opinion or an exception to the Practitioner Self-Referral Act that are deemed by the executive director and the chairman of the Board to be appropriate for a conference with a subordinate who is qualified by his training and experience in the organizational structure of the entity providing the health care service. The Board would delegate the choice of the subordinate to the executive director.

Sections 60 and 70 are also amended to accurately reflect the process currently followed by a committee of the board that hears an application for an advisory opinion or an exception. The committee does not issue the opinion or grant the exception until its recommendation is presented to the board for ratification.

Statement of agency final action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On April 20, 2007, the Board of Health Professions took action to amend 18VAC75-20-10 et seq., Regulations Governing Practitioner Self-Referral, through the fast-track regulatory process.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Health Professions the authority to promulgate regulations to administer the regulatory system and to delegate to an agency subordinate:

§ 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. ...

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 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 30 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 30-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 § 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019, upon receipt of information

that a practitioner may be subject to a disciplinary action. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

The specific statutory mandate for regulations necessary for administration of the Practitioner Self-Referral Act are in § [54.1-2412](#):

§ [54.1-2412](#). *Board to administer; powers and duties of Board; penalties for violation.*

A. In addition to its other powers and duties, the Board of Health Professions shall administer the provisions of this chapter.

B. The Board shall promulgate, pursuant to the Administrative Process Act (§ [2.2-4000](#) et seq.), regulations to:

1. Establish standards, procedures, and criteria which are reasonable and necessary for the effective administration of this chapter;

2. Establish standards, procedures, and criteria for determining compliance with, exceptions to, and violations of the provisions of § [54.1-2411](#);

3. Establish standards, procedures, and criteria for advising practitioners and entities of the applicability of this chapter to activities and investments;

4. Levy and collect fees for processing requests for exceptions from the prohibitions set forth in this chapter and for authorization to make referrals pursuant to subsection B of § [54.1-2411](#);

5. Establish standards, procedures, and criteria for review and referral to the appropriate health regulatory board of all reports of investigations of alleged violations of this chapter by practitioners and for investigations and determinations of violations of this chapter by entities;

6. Establish standards, procedures, and criteria for granting exceptions from the prohibitions set forth in this chapter; and

7. Establish such other regulations as may reasonably be needed to administer this chapter.

C. Upon a determination of a violation by the Board, pursuant to the Administrative Process Act, any entity, other than a practitioner, that presents or causes to be presented a bill or claim for services that the entity knows or has reason to know is prohibited by § [54.1-2411](#) shall be subject to a monetary penalty of no more than \$20,000 per referral, bill, or claim. The monetary penalty may be sued for and recovered in the name of the Commonwealth. All such monetary penalties shall be deposited in the Literary Fund.

D. Any violation of this chapter by a practitioner shall constitute grounds for disciplinary action as unprofessional conduct by the appropriate health regulatory board within the Department of Health Professions. Sanctions for violation of this chapter may include, but are not limited to, the monetary penalty authorized in § [54.1-2401](#).

The Administrative Process Act authorizes delegation of informal fact-finding to a subordinate.

§ 2.2-4019. *Informal fact finding proceedings.*

A. Agencies shall ascertain the fact basis for their decisions of cases through informal conference or consultation proceedings unless the named party and the agency consent to waive such a conference or proceeding to go directly to a formal hearing. Such conference-consultation procedures shall include rights of parties to the case to (i) have reasonable notice thereof, (ii) appear in person or by counsel or other qualified representative before the agency or its subordinates, or before a hearing officer for the informal presentation of factual data, argument, or proof in connection with any case, (iii) have notice of any contrary fact basis or information in the possession of the agency that can be relied upon in making an adverse decision, (iv) receive a prompt decision of any application for a license, benefit, or renewal thereof, and (v) be informed, briefly and generally in writing, of the factual or procedural basis for an adverse decision in any case.

B. Agencies may, in their case decisions, rely upon public data, documents or information only when the agencies have provided all parties with advance notice of an intent to consider such public data, documents or information. This requirement shall not apply to an agency's reliance on case law and administrative precedent.

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.

The intent of the proposed action is to amend the regulations governing practitioner self-referral to allow the Board to delegate an informal conference to consider the issuance of an advisory opinion or exception from provisions of the law.

In the Practitioner Self-Referral Act (Chapter 24.1 of Title 54.1), the Code sets out certain exceptions to the prohibition against self-referral and authorizes the Board of Health Professions to grant other exceptions to entities or practitioners who meet statutory criteria for an exception. The Board is also authorized to administer the chapter by issuing advisory opinions on the applicability of the law to a proposed referral arrangement between or among practitioners.

An entity seeking an advisory opinion or an exception must file an application and submit a fee, along with sufficient documentation to support the position that the business relationship proposed does not constitute a violation of the Act. Since the issues involved in rendering a decision are typically financial and business in nature, rather than practice or professional in nature, the Self-Referral Committee of the Board (acting as an informal conference committee) generally depends on the review of the documents by and opinions of legal and/or financial experts to render its decision following an informal fact-finding proceeding.

In the Administrative Process Act, § 2.2-4019 sets out the rights of parties to the case in informal fact-finding and includes the authority of the agency to have the case heard by its subordinates or before a hearing officer for the informal presentation of factual data, argument, or proof in connection with any case. Any recommendation from the subordinate would have to be ratified by the Board of Health Professions, so the authority to make decisions relative to the

applicability of the Self-Referral Act would remain with the Board in order to ensure that consumers of health care services are being appropriately referred without jeopardizing their health and safety.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendments because this is strongly recommended by the Self-Referral Committee of the Board, and there is agreement among citizen and professional members with the changes proposed. The action is not controversial and is expected to facilitate decisions on applications for advisory opinions or exceptions.

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.)

A new section of regulation is added to set out the criteria and process for delegation of conferences on advisory opinions and requests for exceptions to the practitioner self-referral prohibition, including authorization to delegate, criteria for delegation, and the qualifications of individuals who may be designated as agency subordinates. Any recommendation by the subordinate must be ratified or may be reversed by the Board in rendering its decision on an application.

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.

There are no disadvantages to the public of these amendments. For those entities seeking an advisory opinion or an exception to the Act, the process should be less cumbersome and a decision may be more timely.

There are no advantages or disadvantages to the agency or the Commonwealth. There would be an advantage to the members of the Board of Health Professions who would not be required to give up a day of practice to attend an informal conference on an application relating to the Practitioner Self-Referral Committee.

There are no other pertinent matters of interest.

Economic impact

<p>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</p>	<p>The agency will incur some one-time costs (less than \$1,000) for mailings and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings or distribute notices by email. There are no ongoing expenditures related to this amendment. 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.</p>
<p>Projected cost of the regulation on localities</p>	<p>None</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>The individuals, businesses or entities that may be affected would be those seeking an advisory opinion on the applicability of the Self-Referral Act or an exception to the provisions of the Act.</p>
<p>Agency’s best estimate of the number of such 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.</p>	<p>The agency has no estimate of the number of entities that will be affected. The Board typically receives one or two applications per year.</p>
<p>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.</p>	<p>There would be no additional costs to the affected entities. The same documents would need to be submitted with the application, and the conference would be conducted in the same manner.</p>

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.

There were no viable alternatives to the proposed regulatory action. The Board could continue to utilize a committee of the board to conduct the hearings, but the expertise needed for making decisions that are essentially legal or financial would continue to be missing. Currently, the Board relies heavily on the analysis of the Administrative Proceedings Division of the Department and on advice from other experts as needed. The ability to delegate a hearing to an appropriately-trained subordinate would facilitate the process, reduce the workload of board members who are often healthcare professionals with busy practices, and enable the applicant to receive an answer to the applicability of the Act on the contemplated referral arrangement after ratification by the Board. If the arrangement for health care services does not constitute a violation of the Act or an exception is warranted, those services could be made available to consumers in a more timely manner.

Family impact

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

There is no potential 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.

Current section number	Current requirement	Proposed change and rationale
60	Sets out the process for considering an application for an advisory opinion on the applicability of the Act.	Subsection D is amended to clarify that applicant is notified by the board, not the committee, about when his application will be heard. Subsection E clarifies that at the conclusion of an informal conference, the advisory opinion issued by the committee must be presented for ratification by the board.
70	Sets out the process for considering an application for an exception to the provisions of the Act.	Subsection D is amended to clarify that applicant is notified by the board, not the committee, about when his application will be heard. Subsection E clarifies that at the conclusion of an informal conference, the decision regarding the request for except issued by the committee must be presented for ratification by the board.
n/a		Adds Part IV on delegation to an agency subordinate Section 120 states that, in accordance with § 54.1-2400 (10)

		<p>of the Code of Virginia, the board may delegate an informal conference to an agency subordinate to consider an application for an advisory opinion or an exception to the provisions of the Act.</p> <p><i>The regulation states the statutory authority for the Board to delegate its responsibility to delegate.</i></p>
		<p>Section 130 sets out the criteria for delegation, to include applications that may be delegated would be those approved by the chairman and executive director of the board.</p> <p><i>The decision of whether to delegate an application would be made by the chairman and executive director after they have received a completed application, all necessary documentation and a legal analysis from the Administrative Proceedings Division (APD) of the Department.</i></p>
		<p>Section 140 sets out the criteria for an individual who may be authorized to serve as agency subordinate, to include current or past board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in the organizational structure of entities providing the health care services identified in the application.</p> <p><i>Since the issues surrounding an application for an advisory opinion or an exception are largely legal and business-related, the person who would conduct the conference should be someone who has knowledge and experience with such arrangements and structures. That person could be a member of staff, a current or former board member, or another individual with whom the Board contracts for serving as the agency subordinate.</i></p> <p>Subsection B delegates to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a conference based on the qualifications of the subordinate and the type of case being heard.</p> <p><i>After a review of the application and analysis from APD, the executive director would be authorized to select the appropriate individual to serve as the subordinate to conduct the informal conference.</i></p>