

Statement of Final Agency Action

18 VAC 85-20-10 et seq.

Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture

On November 19, 1999, the Board of Medicine reviewed comments received during the 60-day comment period on proposed regulations governing requirements for physician profiling. In response to the comments, the Board recommended several amendments and adopted final regulations.

SUMMARY OF COMMENTS ON PROPOSED REGULATIONS

Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture 18 VAC 85-20-10 et seq.

Regulations for Physician Profile System

Proposed regulations were published in the Virginia Register of Regulations on August 16, 1999. Public comment was requested for a 60-day period ending October 15, 1999. A Public Hearing before the Board of Medicine was held on September 24, 1999 at which the following comment was received:

Dr. David Selig, representing the Community Care Network of Virginia, spoke of his concern about the impact of proposed regulations on their physicians, administrators and patients. He noted several specific concerns: 1) much of the information required for the profile already exists on other databases, so it is redundant and a waste of time. Board should allow physicians to provide data elements from those sources; 2) it is unrealistic to require a physician to list all insurance plans; in a large PPO, there may be 40 or 50 companies; 3) information on malpractice history should be consistent with National Practitioner Databank; 4) proposed regulations will create significant administrative burden if required to manually complete a lengthy form; should be available electronically; and 5) the updating requirement is vague and creates potential for physician to be unintentionally non-compliant; board should designate certain fields as critical and others may be updated annually. Dr. Selig suggested a task force of practice and network administrators to develop options in the adoption of final regulations.

Board response:

- 1) The information that the Board of Medicine must require all physicians to report on the profile is specified by law (§ 54.1-2910.1). While information may exist on other databases, the intent of the law was to make the required information easily accessible to the consumer.
- 2) The Code of Virginia specifically requires the reporting of "any insurance plans accepted, managed care plans in which the physician or podiatrist participates"; there is no discretion in requiring compliance with the law.
- 3) Since the National Practitioner Databank will be the source for information on malpractice payments, it will be consistent except that the profile will not report the actual dollar figure paid but instead the relative frequency of paid claims in a specialty and the relative amount of the claim in terms of average, above average or below average.

4) In the implementation of the law, the Board intends to provide the capability for practitioners to submit and update their profile electronically.

5) The updating requirement in the regulation has been modified for clarification, but the information must be kept as current and accurate as possible in order to be compliant with the law and useful to consumers.

The Agency Regulatory Coordinator and the attorney for the Board recently attended a workshop on the format and implementation of other such reporting systems, so there is a great deal of information available. In addition, the Department is in the process of recruiting a profile administrator whose responsibility will be to oversee the start-up and implementation of the system in Virginia.

In addition, there were 15 written comments received within the 60-Day Comment Period. They are summarized as follows:

9 persons or groups expressed some opposition or concern about the collection and dissemination of information of malpractice payments. Several people commented that it was not required by the statute and therefore should not be included in the Board's regulations. Others recognized that it was mandated by law but felt that the Board should support legislation to amend the Code of Virginia to eliminate all malpractice reports. Those who commented felt that many suits are frivolous and payments are unwarranted with the insurance carriers settling just to avoid costs - the format and presentation of the information should reflect that fact so as not to mislead consumers. One person commented that collection of malpractice information is unnecessary since the National Practitioner Data Bank has disciplinary information available. One person suggested changing the time frame for reporting of malpractice payments to those within the past five years rather than those within the past ten years. One person requested that publication of all relevant data, including transcripts of testimony, so it could be scrutinized by peers of the persons who testified.

Board response:

The collection and dissemination of malpractice payment information is required by the Code. Whether or not the Board would support legislation to eliminate the requirement is not germane to rule-making which must proceed under a statutory mandate. The format and presentation of the malpractice information will include explanatory statements to assist consumers in their understanding of the relative significance of such claims in judging the practice of a physician.

Information on the National Practitioner Databank is not currently available to the general public and would contain actual amounts of payments or awards, which will not be a part of the physician profile in Virginia. If the reporting timeframe was amended to five versus the current ten years of malpractice payments, the numbers in a specialty might be too small to be useful in determining averages, which could be detrimental to the practitioner who has had a claim. It is not possible to publish all relevant data since

much of it is protected by confidentiality laws. Physicians have the option of releasing information in a malpractice suit themselves.

4 persons of groups commented that the information should not be made available to the public on the Internet because it is too costly and not mandated by the statute. The public should have to submit a request in writing or by phone and should be charged a fee for the process of releasing information by mail or fax. Doctors should not have to pay increased fees in order to cover the costs of a profiling system.

Board response: It is not accurate to assume that providing information via the Internet would be more costly than hiring additional staff to respond to phone and mail requests. In addition, all agencies of the state are under an Executive Order from the Governor to incorporate Internet access and electronic commerce wherever practical. The Internet will provide instant access to consumers and will allow them to customize their requests for information to match their unique needs (i.e., all podiatrists within a certain zip code that accept a certain insurance plan). The intent of the law is consumer access to important information on health care providers; it was not contemplated that the consumer be charged for that information. According to the Assistant Attorney General who provides counsel to the Board, the collection and dissemination of information on physicians is a part of the Board's statutory responsibility and may be covered by fees as is provided by the Code for all duties of the Board. The amount of renewal fees necessary to cover this and all activities of the Board is a matter for separate rule-making currently in process and not germane to this promulgation.

4 persons or groups commented that the practitioner should be allowed to write in the name of his specialty or sub-specialty since all are not included on the listing. Two persons specifically requested the addition of their specialties.

Board response: The physician will be able to write in the specialty in which he practices; the reporting form has been modified accordingly. The specialties listed on the form are those recognized by the ABMS, the ABOMS or the ABPS, the certifying bodies specified in the Code.

4 persons or groups opposed the requirement that insurance and managed care plans which the practitioner accepts be listed on the profile. Several said that they saw no purpose to the collection and publication of such information and asked why it was needed. Others commented about the rapid changes that take place in that business and the inability of the practitioner to keep the information current.

Board response: In addition to the fact that insurance and managed care plans accepted is information of vital importance to the inquiring consumer, it is information specifically required by the Code of Virginia. The practitioner has up to 30 days in which to modify the profile whenever changes in required information occur.

3 persons or groups indicated that requiring a physician to indicate that he accepts Medicaid could actually force some practitioner away from participation. Those that would accept a reasonable number of Medicaid patients might be afraid to advertise that fact for fear they would be inundated by those patients.

Board response: The Board has modified the regulations and the reporting form to require the practitioner to indicate whether he is accepting any more Medicaid patients. That will allow him to continue accepting a reasonable number without being "inundated".

3 persons or groups commented that the information required by the Board is redundant of information, such as medical school and primary practice address that the Board already has on file.

Board response: Information that the Board already has on file will be pre-printed on the profile and will not have to be provided by the practitioner. The address of record with the Board is not always the primary practice address, so that information will have to be completed.

1 group requested that the Board withhold implementation until legislation is passed to require all medical doctors who work for insurers as medical directors or consultants to be licensed in Virginia. The consumer is entitled to have information on the credentials of these decision-makers. If the profiling is implemented, it should contain a statement that insurance companies are not required to have Virginia physician as medical directors or consultants.

Board response: The position of the Board on any such legislation is not relevant to the promulgation of these regulations.

The Richmond Academy of Medicine has most of the data elements in its Centralized Credentials Verification Service, so it requested that the Board utilize the Academy to provide data to reduce the hassle and costs to doctors - they are prepared to make service available to all physicians in Virginia.

Board response: The actual process for collection of data is not an issue for the promulgation of these regulations, which specify the requirements for reporting as mandated by the law.

Miscellaneous comments and questions:

- Requirement on translating services should specify "non-English speaking"; otherwise the practitioner may be liable for "translating" for the hearing impaired, etc.

Board response: The Code and the regulations are specific in reference to translating services for non-English speaking patients. However, the physician may have an obligation under the Americans with Disabilities Act to provide certain services which are not the subject of this rule.

- Question about the purpose of being required to list medical faculty appointment.

Board response: It is a reporting element required by law.

- Question about the reporting of malpractice payments - what are the sources for such reports and will the practitioner have an opportunity for review prior to disclosure to the public.

Board response: The source of the reporting of malpractice payments is the National Practitioner Databank. That information will not be reviewable by the practitioner prior to disclosure to the public, but there is a mechanism for appeal with the Databank. In addition, the profile will not report actual settlements but only relative frequency and averages.

- Question about the reporting of sanctions by hospitals and other entities - would the sanctions on licenses held by Virginia doctors in other states also be reported; if a practitioner turned in his license while under investigation, would that be reported and what would the record show; and how will disciplinary actions by hospital and other entities be reported to the Board and will the practitioner have an opportunity for review prior to disclosure to the public?

Board response: Those entities will be required to report to the extent there are reports being made to the National Practitioner Databank or as mandated by Virginia law, which requires reporting of disciplinary actions resulting in termination of employment or in revocation or suspension. Hospitals and other entities must provide due process to allow the practitioner an opportunity for review prior to the report to the Board and the Databank. In addition, a practitioner would have the opportunity to file a request for a review of information on the profile under the provisions of the Administrative Process Act. A physician cannot unilaterally turn in a license to practice; it could only be surrendered for cause as the result of a disciplinary action by the Board. A clarification of the reporting requirements for the Board has been added to section 290 of the regulations.

- There is an omission of a requirement to report criminal convictions; public should know if it is related to services provided.

Board response: A felony conviction is automatically reported to the Board and results in a mandatory suspension of a license, which would be reported on the profile. Misdemeanor convictions would be reported in the context of a disciplinary action that might result thereof.

- Newsletter stated that the requirements also applied to podiatrists, but proposed regulations do not include them.

Board response: Since the profiling law was amended in 1999 to include podiatrists, the Board has added them to these regulations. They were not required to report when the regulations were initially proposed.

- Insurance companies will be able to report practitioners based on their suspicions and the onus of proof will be on the practitioner.

Board response: The Code requires that the profile contain only those actions that result in suspension or revocation of privileges or the termination of employment for causes as stated in § 54.1-2909 to include a reasonable probability that the practitioner is professionally incompetent, guilty of unprofessional conduct or mentally or physically unable to engage safely in practice.

- The percentage of time spent at different location can vary from week to week, so reporting that information would be very confusing and is also irrelevant.

Board response: The Code allows for reporting of approximate time spent at each location. The profiling form will allow the practitioner to indicate that the patient should check with the physician's office for additional information.

- The Board should eliminate the requirements for reporting insurance plans, medical school faculty appointments and publications - information is irrelevant to practice.

Board response: That information is required by the law.

Summary of Final Amended Regulations

18 VAC 85-20-10 et seq. Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture

The Board of Medicine has adopted amendments to regulations in order to comply with the mandate in § 54.1-2910.1 of the Code of Virginia establishing a physician/podiatrist profile system by which information on the education, practice and disciplinary actions on physicians would be available to the public. Regulations of the Board specify the information which a physician or podiatrist is required to report and provide that failure to comply with a request for information may subject the licensee to a disciplinary action. Willfully providing false information will subject a physician or podiatrist to disciplinary action and may jeopardize his license to practice.

Changes to Proposed Regulations

In order to comply with Chapter 573 of the 1999 Acts of the Assembly, the Board amended the proposed regulations to include podiatrists in the requirements for reporting certain information as mandated by § 54.1-2910.1 of the Code of Virginia.

In addition, the following amendments were adopted:

In 18 VAC 85-20-280, amendments were added to specify that the physician or podiatrist should also indicate whether he is accepting new patients for the insurance plans, health maintenance organizations or Virginia Medicaid Program in which he participates. Subsection C was rewritten for greater clarity.

In 18 VAC 85-20-290, amendments were adopted to add language specifying that the Board will make information on disciplinary actions available on the profile.

REGISTRAR'S SUBMISSION PACKAGE

BOARD OF MEDICINE

18 VAC 85-20-10 et seq.

Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture

Analysis of Final Amendments to Regulation

1. Basis of Regulation:

Title 54.1, Chapter 24 and Chapter 29 of the Code of Virginia provide the basis for these regulations.

Chapter 24 establishes the general powers and duties of health regulatory boards including the power to establish qualifications for licensure and renewal, to promulgate regulations and to issue inactive licensees.

Chapter 29 establishes the definitions and the requirements for the establishment of a physician/podiatrist profile of information to be made available to the public by the Board.

2. Statement of Purpose:

The purpose of the amendments is to establish a physician/podiatrist profile which will include information on education, training, practice and disciplinary actions to be made available to the consuming public in seeking the services of a medical professional. The final amended regulations are mandated by Chapter 744 of the 1998 Acts of the Assembly and by Chapter 573 of the 1999 Acts of the Assembly and are intended to provide greater protection for the health and safety of the public.

3. Substance of Regulations:

The proposed regulations were amended in the final adoption to also require podiatrists to report certain information as mandated by the 1999 General Assembly in amendments to § 54.1-2910.1.

Part VII. Practitioner Profile System.

18 VAC 85-20-280. Required information.

The information to be required of the practitioner and made available to the public is primarily set forth in § 54.1-2910.1 of the Code of Virginia. In subsection A, amended regulations restate those requirements and provide additional specification where it is required by statute that the Board do so in regulation.

- In #4, the Board has specified that the years in active, clinical practice shall be those spent practicing in the United States or Canada and/or those years in active clinical practice outside the United States or Canada following completion of medical training.
- In #5, the physician or podiatrist is required to specify the specialty in which he practices for the purpose of calculating the relative significance of paid malpractice claims for that specialty among physicians or podiatrists practicing in Virginia. (The profile form lists specialties from which to choose, or the practitioner may designate general medicine or specify a specialty.)
- In #6, the Board has added an amendment to the requirement for reporting insurance or managed care plan participation. The practitioner will also be required to indicate whether he is accepting new patients under such plans.
- In #8, the Board has specified that the publications to be listed are not to exceed ten in number.
- In #10, the physician or podiatrist is required to indicate whether translating services are available at the primary practice setting, and which, if any foreign language is spoken in the practice.
- In #11, the Board has added an amendment to the requirement for reporting participation in the Virginia Medicaid Program. The practitioner will also be required to indicate whether he is accepting new Medicaid patients; and the profile will also allow the practitioner to indicate that he does not participate but will accept Medicaid patients.

Subsection B provides that the physician may include other information on the profile that is not required by law or regulation but which may be useful to the consumer, such as continuing education earned or honors and awards received.

Subsection C states that the licensee is required to update the profile within 30 days, whenever there is a change in information which has been provided and is on record with the profile system. It was amended for greater clarity.

18 VAC 85-20-290. Reporting of malpractice paid claims.

The Board has added a subsection B to section 290 to set the requirement for reporting relative information concerning disciplinary notices and actions. Regulations set forth the information which is to be used by the Board to calculate the level of significance of a malpractice award or settlement. Each report on the profile will state: the number of years of practice in Virginia; the specialty in which the physician practices; the number of physicians practicing in that specialty in Virginia and the percentage that have made malpractice payments within the last ten-year period; the date of the claim; and the relative amount of the paid claim described as average, below average or above average. Definitions for those relative levels of payment are also stated in section 290.

18 VAC 85-20-300. Non-compliance or falsification of the profile.

The final regulation stipulates that failure to provide information within 30 days of the request from the Board may constitute unprofessional conduct and may subject the licensee to disciplinary action. Intentionally providing false information does constitute unprofessional conduct and shall subject the licensee to disciplinary action.

4. Issues of the Regulations

ISSUE 1:.

In the 1998 General Assembly, Senate Bill 660 (Chapter 744) was introduced by Senator John Watkins to require the collection and release of certain data on physicians. Chapter 573 of the 1999 General Assembly added podiatrists to the profiling requirements. The legislation mandates the promulgation of regulations and specifies information that is to be required and made available upon request from a consumer. While **the data to be collected is statutorily specified**, there are several provisions of the law in which the Board had some discretion through its regulatory authority. Those are as follows:

- Information on the number of years in active, clinical practice - The Board considered a definition for “active” (number of hours, months per year, etc.) and a definition for “clinical”. It is proposing that anyone who holds an active license to practice would be considered to be “in active, clinical practice”. Those years spent practicing after completion of medical training within and/or outside the United States or Canada would be reportable.
- Information on publications in peer-reviewed literature within the most recent five-year period - The Board considered ten to be an appropriate limitation to the number of publications to be reported.
- Other information related to the competency of physicians or podiatrists - The Board sought comment on the need for information other than that specified in § 54.1-2910.1.

Some physicians want an opportunity to include other pertinent information on their training or abilities – such as honors and awards or hours of continuing education.

- While the Code of Virginia requires reporting of all paid malpractice claims, the regulations provide the information necessary to report those payments in categories indicating the level of significance of each award or settlement. Those reports will be made in terms of the date paid, whether it was a judgment or a settlement, whether it was above average, average or below average for similar cases, the number of practitioners with the same specialty in Virginia, and the percentage of practitioners with paid claims.
- In the development of regulations, the Board considered the consequences for failure to report in a timely fashion or for the reporting of false information. The proposed regulation sets a reasonable time limit of 30 days for providing information after a request from the Board or after a change in the current information has occurred. Failure to report may subject the licensee to disciplinary action, but intentionally providing false information shall subject the licensee to disciplinary action. The Board considered but rejected specified, graduated monetary penalties designated for failure to report within 30, 60 or 90 days.

Advantages and disadvantages

There are no disadvantages for the public, which will benefit from the law requiring the establishment of a profile and specifying the information to be included. Having a great deal of information on the education, practice, and disciplinary status of a physician will assist patients in choosing competent and ethical doctors. In implementing the system, the Board intends to make information available by the Internet, fax, mail, or by telephone so that all Virginians will have access to the data. Consumers of medical care will have the data necessary to make more informed choices about their physicians.

The law requires that physicians provide initial information upon request; they will also have to update that information as it changes. For those physicians who have had malpractice awards or settlements, who have been disciplined by the hospitals in which they have privileges, or who have had disciplinary action taken by the Board of Medicine, the physician profile system may have a detrimental effect on their practice, if consumers become concerned about the pattern of negative findings. The Board does intend to attach disclosures, similar to those on the Massachusetts profile, to state such things as: a) studies have shown that there is not necessarily a correlation between malpractice history and a physician's competence; and b) a payment of a malpractice claim should not be construed as creating a presumption that medical malpractice has occurred.

ISSUE 2: Penalties for non-compliance or for providing false information

The Board determined that penalties for non-compliance should not be specified by regulation, but that it should be stated that such action may be considered unprofessional conduct and may

subject the licensees to disciplinary action. Therefore, the Board has the ability of handling non-compliance in a variety of ways, depending on the circumstances and the severity of the problem. Providing false information is definitely considered unprofessional conduct and will subject the licensee to a disciplinary action.

Advantages and disadvantages

There are no disadvantages to the public or to the licensees. The Board has clearly stated that providing accurate information for the physician profile system is part of the professional responsibility of a licensee and to do otherwise may place his license to practice in jeopardy.

5. Estimated Fiscal Impact of the Regulations

I. Fiscal Impact Prepared by the Agency:

Number of entities affected by this regulation:

Approximately 26,900 doctors of medicine and surgery, 750 doctors of osteopathy, and 500 doctors of podiatry will be affected by these regulations.

Projected cost to the agency:

The agency will incur some costs (approximately \$5000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

The fiscal impact analysis prepared on SB 660 at the time the legislation was under consideration stated that regulations would likely have to be amended to provide for an increase in the renewal fees for physicians in accordance with the Board's authority in § 54.1-2400. To that end, the Board has also submitted a request for publication of a Notice of Intended Regulatory Action to increase fees during the renewal cycle beginning in January of 2000.

Projected costs to the affected entities:

Other than the time it takes to provide the initial data and then to keep it updated, there would be no costs for compliance with these regulations for the licensees. The physician/podiatrist profile system will be integrated into the new computer system at DHP. Once that is fully functional, it will be possible for a physician or podiatrist to electronically update the self-reported information. The initial collection of information will be accomplished by use of a mailed survey followed by data entry into the system. Thereafter, updating may be done electronically, by written request, or by telephone. Of course, certain information on disciplinary actions will be verified by the Board and may not be altered by the doctor.

The overall costs of initiating and operating the physician/podiatrist profile system will likely result in a fee increase, which is the subject of a separate rule-making process.

Citizen input in development of regulation:

In the development of the proposed regulations, notices were sent to persons on the public participation guidelines mailing list of every meeting of the Legislative Committee of the Board, and of the Board itself. A Notice of Intended Regulatory Action was also sent to persons on the list; no comment was received on the NOIRA. Public comment was also received at each meeting.

Localities affected:

There are no localities affected by these regulations in the Commonwealth.

II. Fiscal Impact Prepared by the Department of Planning and Budget: (attached)

III. Agency Response: The agency concurs with the analysis of the Department of Planning and Budget.