

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 Proposed 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 profile of information to be made available to the public by the Board.

2. Statement of Purpose:

The purpose of the proposed amendments is to establish a physician 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 proposed regulations are mandated by Chapter 744 of the 1998 Acts of the Assembly and are intended to provide greater protection for the health and safety of the public.

3. Substance of Regulations:

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, proposed 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 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 practicing in Virginia. (The profile form lists specialties from which to choose, or the physician may designate general medicine or unspecified.)
- In #8, the Board has specified that the publications to be listed are not to exceed ten in number.
- In #10, the physician 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.

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, whenever there is a change in information which has been provided and is on record with the profile system.

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

The proposed 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 proposed 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. 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 - 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:

All 26,902 doctors of medicine and surgery and 753 doctors of osteopathy 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 profile system will be integrated into the new computer system at DHP. Once that is fully functional, it will be possible for a physician 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 profile system will likely result in a fee increase. Biennial fees may have to be increased from \$125 to \$138 or \$150.

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: (To be attached)

III. Agency Response:

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

18 VAC 85-20-10 et seq. Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture were promulgated under the general authority of Title 54.1 of the Code of Virginia.

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 issue an inactive license.

§ 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.

Specific statutory authority for collection of data requirements (Effective July 1, 1998).

§ 54.1-2910.1 Certain data required.

The Board of Medicine shall require all physicians of medicine or osteopathy to report and shall make available the following information:

- 1. The names of medical schools and dates of graduation;*
- 2. Any graduate medical education at any institution approved by the Accreditation Council for Graduation Medical Education or the American Osteopathic Association;*
- 3. Any specialty board certification or eligibility for certification as approved by the American Board of Medical Specialities;*
- 4. The number of years in active, clinical practice as specified by regulations of the Board;*
- 5. Any insurance plans accepted, managed care plans in which the physician participates, and hospital affiliations;*
- 6. Any appointments, within the most recent ten-year period, of the physician to a medical school faculty and any publications in peer-reviewed literature within the most recent five-year period and as specified by regulations of the Board;*

7. *The location of any primary and secondary practice settings and the approximate percentage of the physician's time spent practicing in each setting;*

8. *The access to any translating service provided to the primary practice setting of the physician;*

9. *The status of the physician's participation in the Virginia Medicaid Program;*

10. *Any final disciplinary or other action required to be reported to the Board by health care institutions, other practitioners, insurance companies, health maintenance organizations, and professional organizations pursuant to §§ 54.1-2906, 54.1-2908, and 54.1-2909 that results in a suspension or revocation of privileges or the termination of employment or a final order of the Board relating to disciplinary action; and*

11. *Other information related to the competency of physicians as specified in the regulations of the Board*

The Board shall promulgate regulations to implement the provisions of this section, including, but not limited to, the release, upon request from a consumer, of such information relating to a physician. The regulations promulgated by the Board shall provide for reports to include all paid claims in categories indicating the level of significance of each award or settlement.

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

See attached.

e. Summary of Public Comment received in response to the Notice of Intended Regulatory Action.

The Notice of Intended Regulatory Action was published on September 28, 1998 and subsequently sent to the Public Participation Guidelines Mailing List of the Board. The deadline for comment was October 28, 1998 and there was no comment received.

f. Changes to existing regulations.

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, proposed 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 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 practicing in Virginia. (The profile form lists specialties from which to choose, or the physician may designate general medicine or unspecified.)
- In #8, the Board has specified that the publications to be listed are not to exceed ten in number.
- In #10, the physician 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.

Subsection B provides that the physician may include other information on the profile, which 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 whenever there is a change in information which has been provided and is on record with the profile system.

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

The proposed regulations set forth the information which must be reported and 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 he 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 proposed 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.

g. Statement of reasoning for the regulations.

The Code of Virginia specifically sets the mandate for promulgation of this regulation in § 54.1-2910.1. 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. The legislation mandates the promulgation of regulations and specifies information which is to be required and made available upon request from a consumer. The **data to be collected is specified**, but there are a few provisions of the law in which the Board had some discretion through its regulatory authority.

The public will benefit from having a great deal of information on the education, practice, and disciplinary status of a physician. In implementing the system, the Board intends to make information available by the Internet, the telephone, fax, or regular mail, 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 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.

h. Alternatives considered.

In order for the Board of Medicine to be in compliance with the law, there is no non-regulatory solution to be considered. **It is mandated to proceed with promulgation of regulations for a physician profile in accordance with § 54.1-2010.1.** The Board had some discretion through its regulatory authority 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”. Years spent practicing after completion of medical training within and/or outside the United States or Canada would be reportable.
- Identification of a specialty for the purpose of calculating the relative significance of paid malpractice claims for that specialty among physicians practicing in Virginia.
- Information on publications in peer-reviewed literature within the most recent five-year period. - Since some physicians, particularly those associated with medical centers contribute to a large number of journal and textbook articles each year, the Board thought it was appropriate to set a limit of ten as the number of publications to be reported.
- Other information related to the competency of physicians - 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.

- The proposed regulations also set forth the requirements for how the information on all paid malpractice claims will be reported in categories indicating the level of significance of each award or settlement. Practitioners and entities (malpractice insurance carriers) are already required by law to report malpractice payments. These regulations establish how those payments will be reported to the public in terms the date of the payment, 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.

i. Statement of clarity.

Prior to the adoption of proposed regulations by the Board, the Ad Hoc Committee of the Board met to discuss the provisions of the law and the regulations necessary for implementation. That committee, the Legislative Committee and the Board has discussed the changes in open sessions. The clarity and reasonableness of the language that was adopted had the approval of the licensees, the Assistant Attorney General who worked with the Committee in drafting regulatory language, and members of the Board, including its citizen members.

j. Schedule for review of regulation.

The proposed amendments to these regulations will be reviewed following publication in the Register and the 60-day public comment period. If there are any oral or written comments received, the Board will consider revisions to the proposal prior to adoption of final regulations.

Public Participation Guidelines of the Board of Medicine (18 VAC 85-10-10 et seq.) require a thorough review of regulations each biennium. Therefore, the Legislative Committee of the Board will review this regulation in 2001 and will bring any recommended amendments to the full board for consideration.

In addition, the Board receives public comment at each of its meetings and will consider any request for amendments. Petitions for rule-making also receive a response from the Board during the mandatory 180 days in accordance with its Public Participation Guidelines.

As the profile system is implemented, the Board will continued to review the information that is required by regulation and the profiling format being used to present that information to the public. If changes are needed in the format of the profile, the Board can modify its forms without engaging in a regulatory process. If changes are needed in the information that is required, the Board would consider publication of a Notice of Intended Regulatory Action or, if necessary, initiation of legislation.

k. Anticipated Regulatory Impact

Projected cost to the state to implement and enforce:

(i) Fund source:

As a special fund agency, the Board of Medicine 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.

Since the budget bill passed by the 1998 General Assembly contained no funds to support the data collection and dissemination, the fiscal impact analysis prepared on SB 660 at the time 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.

The Attorney General's Office has advised the agency in writing that the activity of collecting and releasing information to consumers is within the regulatory authority of the Board of Medicine and therefore may be supported by licensing fees.

(ii) Budget activity by program or subprogram:

There is a change required in the budget of the Commonwealth as a result of this program; the Department has submitted a request for an increased allocation of \$245,000 for the Board of Medicine.

(iii) One-time versus ongoing expenditures: 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.

In its Fiscal Impact Statement on SB 660, the Department of Planning and Budget acknowledged that fees for physicians would need to be increased from \$125 a biennium to approximately \$150 per biennium. (See attached copy of FIS) It also acknowledged the need

for 4 FTE's for the program and stated that the DPB can authorize the agency to exceed its upper limit for employment during the fiscal year in order to fulfill the mandate of the General Assembly to collect and disseminate the data.

As a result of SB 660, the agency submitted a revised budget for the Board of Medicine for FY 2000 which reflects the need for additional personnel, for contracting the data collection and entry functions and for data processing in order to get the physician profile system operational. Personnel costs are estimated to be \$83,290, contractual costs are \$112,100 and data processing estimated at \$50,000 for costs to the Board of \$245,000 in fiscal year 2000.

The economic impact analysis prepared on SB 660 at the time 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 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 cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be doctors of medicine and osteopathy who hold an active license in Virginia.

Estimate of number of entities to be affected:

All 26,902 doctors of medicine and surgery and 753 doctors of osteopathy will be affected by these regulations

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 profile system will be integrated into the new computer system at DHP. Once that is fully functional, it will be possible for a physician 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.

Biennial renewal fees for physicians may need to be increased from \$125 to approximately \$150.