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Final Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions	
Virginia Administrative Code (VAC) citation	18 VAC 85-40-10 et seq.	
Regulation title	Regulations Governing the Practice of Respiratory Care	
Action title	Standards of Conduct	
Document preparation date	7/15/05	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

In this regulatory action, the Board proposes to establish standards for professional conduct including maintenance, retention and release of patient records; patient confidentiality; practitioner-patient communication and termination of that relationship; solicitation or remuneration for referrals; sexual contact and practitioner responsibilities.

In the submission and publication of the agency background document describing the need to adopt regulations for ethical standards of practice, all chapters under the Board of Medicine were included as secondary actions under Chapter 20, regulations for doctors of medicine, osteopathy, podiatry and chiropractic. However, in the development and promulgation of the proposed regulations, it became necessary to adopt individually unique regulations addressing the practice-specific issue for each profession.

Statement of final agency 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 July 14, 2005, the Board of Medicine adopted a final regulation for 18VAC85-40-10 et seq. (Regulations Governing the Practice of Respiratory Care) to establish the ethical standards of practice.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe 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 Medicine the authority to promulgate regulations to administer the regulatory system:

§ 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. …

In addition, section 54.1-2915 of the Code of Virginia (as cited below) establish grounds by which the Board may refuse to license or certify an applicant or take disciplinary action against a current license or certificate holder. While regulations on standards of conduct do not duplicate standards set forth in law, they do supplement and interpret the statutory provisions.

§ 54.1-2915. Unprofessional conduct; grounds for refusal or disciplinary action.

A. The Board may refuse to admit a candidate to any examination; refuse to issue a certificate or license to any applicant; reprimand any person; place any person on probation for such time as it may designate; suspend any license for a stated period of time or indefinitely; or revoke any license for any of the following acts of unprofessional conduct:

1. False statements or representations or fraud or deceit in obtaining admission to the practice, or fraud or deceit in the practice of any branch of the healing arts;

2. Substance abuse rendering him unfit for the performance of his professional obligations and duties;

3. Intentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients;

4. Mental or physical incapacity or incompetence to practice his profession with safety to his patients and the public;

5. Restriction of a license to practice a branch of the healing arts in another state, the District of Columbia, a United States possession or territory, or a foreign jurisdiction;

6. Undertaking in any manner or by any means whatsoever to procure or perform or aid or abet in procuring or performing a criminal abortion;

7. Engaging in the practice of any of the healing arts under a false or assumed name, or impersonating another practitioner of a like, similar, or different name;

8. Prescribing or dispensing any controlled substance with intent or knowledge that it will be used otherwise than medicinally, or for accepted therapeutic purposes, or with intent to evade any law with respect to the sale, use, or disposition of such drug;

9. Violating provisions of this chapter on division of fees or practicing any branch of the healing arts in violation of the provisions of this chapter;

10. Knowingly and willfully committing an act that is a felony under the laws of the Commonwealth or the United States, or any act that is a misdemeanor under such laws and involves moral turpitude;

11. Aiding or abetting, having professional connection with, or lending his name to any person known to him to be practicing illegally any of the healing arts;

12. Conducting his practice in a manner contrary to the standards of ethics of his branch of the healing arts;

13. Conducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public;

14. Inability to practice with reasonable skill or safety because of illness or substance abuse;

15. Publishing in any manner an advertisement relating to his professional practice that contains a claim of superiority or violates Board regulations governing advertising;

16. Performing any act likely to deceive, defraud, or harm the public;

17. Violating any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing, or administration of drugs;

18. Violating or cooperating with others in violating any of the provisions of Chapters 1 (§ 54.1-100 et seq.), 24 (§ 54.1-2400 et seq.) and this chapter or regulations of the Board;

19. Engaging in sexual contact with a patient concurrent with and by virtue of the practitioner and patient relationship or otherwise engaging at any time during the course of the practitioner and patient relationship in conduct of a sexual nature that a reasonable patient would consider lewd and offensive;

20. Conviction in any state, territory, or country of any felony or of any crime involving moral turpitude; or

21. Adjudication of legal incompetence or incapacity in any state if such adjudication is in effect and the person has not been declared restored to competence or capacity.

B. The commission or conviction of an offense in another state, territory, or country, which if committed in Virginia would be a felony, shall be treated as a felony conviction or commission under this section regardless of its designation in the other state, territory, or country.

C. The Board shall refuse to admit a candidate to any examination and shall refuse to issue a certificate or license to any applicant if the candidate or applicant has had his certificate or license to practice a branch of the healing arts revoked or suspended, and has not had his certificate or license to so practice reinstated, in another state, the District of Columbia, a United States possession or territory, or a foreign jurisdiction.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of regulatory action is to establish in regulation the standards by which practitioners of the healing arts must conduct their practice. In § 54.1-2914 (A) (7), the Code of Virginia defines one grounds for a finding of unprofessional conduct as “Conducts his practice in a manner contrary to the standard of ethics of his branch of the healing arts.” The Board has used the code of ethics of the American Medical Association and other organizations as guidance but has not specifically adopted ethical standards in regulation. Amended rules will provide standards relating to ethical behavior in the care and treatment of patients, maintenance and disclosure of records, and in the responsibility of a practitioner for delegation of services to subordinates under their supervision. Throughout the substance of these rules, there are measures that will benefit patient health and safety. For example, a patient’s health and safety may benefit from a requirement for the practitioner to communicate and involve the patient in his care, to fully inform the patient and to maintain patient information with confidentiality.

While the vast majority of practitioners conduct their practices ethically, there are those who have not followed professional standards for communicating and informing patients, for maintaining accurate and legible records, for providing records in a timely manner, or for sexual contact with patients. Others who seek to act professionally and ethically have been desirous of specific guidance from the Board on matters such as the retention of records and prescribing for self and family. With adoption of these rules, the Board’s intent is to not only protect the health, welfare and safety of the public against inappropriate and unethical actions by its licensees but also to give regulatory guidance for practice in a professional manner.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the “All changes made in this regulatory action” section.

The substantive provisions of this regulatory action include the following Standards of Professional Conduct:

18VAC85-40-85. Confidentiality.

The proposed regulation prohibits a practitioner from willfully or negligently breaching the confidentiality between a practitioner and a patient. If a breach of confidence is required or permitted by applicable law or beyond the control of the practitioner, it is not considered negligent or willful.

18VAC85-40-86. Patient records.

Proposed regulations set requirements for confidentiality and disclosure of patient records, for maintenance of accurate, timely records, for record retention for a minimum of six years with certain exceptions, and for appropriate destruction of records.

18VAC85-20-87. Practitioner-patient communication; termination of relationship.

Subsection A sets out the standards for ethical communication with patients to include provision of accurate information to patients in terms that are understandable and encourage participation. It would be unethical for a practitioner to deliberately make a false or misleading statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.

Before any invasive procedure is performed, there is a requirement for informed consent in accordance with the policies of the health care entity and a requirement to inform patients of the risks, benefits, and alternatives. Provisions allow for consent from a legally authorized representative in lieu of the patient under certain circumstances and for an exception to the requirement for consent prior to performance of an invasive procedure in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient. For the purposes of this provision, "invasive procedure" is defined. Practitioners must adhere to requirements of § 32.1-162.18 of the Code of Virginia for obtaining informed consent from patients prior to involving them in research activities.

Subsection B provides the professional standard for termination of the practitioner/patient relationship by either party and requires the practitioner to make a copy of the patient record available.

18VAC85-40-88. Practitioner responsibility.

This section lists practitioner actions that are considered irresponsible and unethical, including knowingly allowing subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility; engaging in an egregious pattern of disruptive behavior or interaction in a health care setting that interferes with patient care; or exploiting the practitioner/patient relationship for personal gain.

18VAC85-40-89. Solicitation or remuneration in exchange for referral.

Proposed regulations are identical to current requirements for licensees regulated under Chapter 20 (doctors of medicine, osteopathic medicine, podiatry and chiropractic). There is a prohibition

on knowingly and willfully soliciting or receiving any remuneration for referral of an individual to a health care facility or institution.

18VAC85-40-90. Sexual contact.

Proposed regulations define in subsection A what is meant by sexual contact for purposes of interpreting statutory prohibitions in § 54.1-2915. Subsection B specifies the prohibition against sexual contact with a patient, and subsection C sets the rule concerning a former patient.

Subsections D and E set the conditions under which sexual contact between a practitioner and a key third party or between a medical supervisor and a medical trainee could constitute unprofessional conduct.

18VAC85-40-91. Refusal to provide information.

The proposed regulation is identical to current requirements for licensees regulated under Chapter 20; it makes it unprofessional conduct to refuse to provide information or records as requested or required by the board or one of its investigators in the enforcement of law and regulation.

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 there are no disadvantages to the public or the Commonwealth, please indicate.

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1) There are numerous advantages to the public associated with the proposed regulatory action. By having standards of conduct more clearly stated in regulation, all consumers of services provided by licensees should benefit from specific rules on communication with patients, maintenance of accurate records, access to patient records, confidentiality, and informed consent. In addition, the public is better protected by amendments to rules on advertising, pharmacotherapy for weight loss and sexual contact.
There are no disadvantages to the public of the proposed standards of conduct for licensees of the board.

2) The primary advantage to the agency comes from a more definitive set of standards of professional conduct for licensees. For example, a standard for maintenance of patient records and for prescribing for self and family will be available to practitioners, who often call the Board office for guidance on these issues. Additionally, the Board will be able to rely on a clearer standard to cite in a disciplinary case in which a practitioner may be guilty of unprofessional conduct. In the past, the Board has cited § 54.1-2915, which states that: "Any practitioner of the healing arts regulated by the Board shall be considered guilty of unprofessional conduct if he …conducts his practice in a manner contrary to the standards of ethics of his branch of the healing arts." Without fully setting out the standards in regulation, it could be argued that a

licensee was expected to conduct himself and his practice according to a standard that had not been adopted by the regulatory board and was unknown to the licensee. More explicit regulations on standards of professional conduct will provide guidance for certain situations and more specific grounds for disciplinary action if the standards are violated.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Changes to the proposed regulation since publication are as follows:

18VAC85-40-85. Confidentiality.

A phrase was added to clarify that a breach of confidentiality that is permitted by applicable law is not be considered negligent or willful.

18VAC85-40-86. Patient records.

Authorized representative was changed to personal representative to distinguish between the person who can be given permission to have access to records and the person who is legally designated to make health care decisions.

The provision on maintenance of records for a minor child was rewritten for greater clarity and understanding that the minimum time for record retention is six years from the last patient encounter regardless of the age of the child.

The provision on records that are required by contractual obligation or federal law was restated to indicate that those records may need to be maintained for a longer period of time, but the Board does not require that.

18VAC85-40-87. Practitioner-patient communication; termination of relationship.

An amendment to the requirement for informed consent from patients prior to involving them as subjects in human research was amended to delete the exception of research "that affects their care" and replace it with the exception of "retrospective chart reviews."

18VAC85-40-90. Sexual contact.

Amendments correct the Code cites to reflect changes effective July 1, 2005.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations were published in the Virginia Register of Regulations on November 29, 2004. Public comment was requested for a 60-day period ending January 27, 2005. There were no

specific comments on changes to Chapter 40, but comments on similar sections in Chapter 20 were considered.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	85	n/a	Section 85 prohibits a willful or negligent breach of patient confidentiality but relieves the practitioner of responsibility if the breach is required or permitted by law or beyond his control.
n/a	86	n/a	Section 86 set standards of conduct in regard to patient records. Subsection A requires practitioners to comply with provisions of § 32.1-127.1:03 related to the confidentiality and disclosure of patient records. *(Section 54.1-2914 makes it unprofessional conduct to violate any provision of Chapter 29 or laws relating to prescription drugs but does not specifically allow the Board to take action against a practitioner for a violation of law relating to patient records. Therefore, there was a need to include such a provision in regulations on ethical conduct.)* Subsection B requires practitioners to provide patient records to another practitioner or to the patient or his authorized representative in a timely manner and in accordance with applicable law. *(Both state and federal laws specifically set out the requirements for disclosure of records and providing a record upon request. The regulation requires a practitioner to comply with such laws.)* Subsection C requires practitioners to

			properly manage patient records and maintain timely, accurate, legible and complete patient records. (*In disciplinary cases, the Board has seen evidence of records that were so poorly maintained, illegible or inaccurate that they were effectively useless and provided no record of the patient's care.)* Subsection D applies to the majority of respiratory care practitioners who are employees of a health care institution and do not have ownership of patient records. It requires the licensee to adhere to the policies and procedures of the employing entity in the maintenance of records. Subsection E applies to respiratory care practitioners who are self-employed or do have ownership of patient records. It sets the time limit for maintenance of a patient record at a minimum of six years following the last patient encounter with the following exceptions: a. Records of a minor child, including immunizations, which have to be maintained until the child reaches the age of 18 or becomes emancipated with the minimum time for record retention of six years regardless of the age of the child at the last patient encounter; or b. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or his legally authorized representative; or c. Records that are required by contractual obligation or federal law that may need to be maintained for a longer period of time. *(For a number of years, practitioners have requested some rule on the maintenance of records. The rules established provide a minimal standard for record-keeping; practitioners may choose to maintain patient records for longer periods of time, if so required by a malpractice carrier or other contractual obligation.)*

			Subsection E also requires practitioner (from the effective date of regulations) to post information or in some manner inform all patients concerning the time frame for record retention and destruction. Patient records shall only be destroyed in a manner that protects patient confidentiality, such as by incineration or shredding. *(In order for patients to know the record retention policy, practitioners will be required to post that information in their offices or include it in some informed consent document given to patients. The purpose of such a requirement is to make patients aware that a record might be destroyed and no longer available after a period of time, so if the patient has a need to refer to earlier treatment, the record may no longer exist. This will give patients the opportunity to request a copy of their records before they are destroyed. The rule also requires destruction of records in a manner that protects confidentiality.)*
n/a	87	n/a	Section 87 sets the professional standards for practitioner-patient communication and for termination of a relationship. Subsection A provides rules for communication with patients as follows: 1. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately present information to patients or their legally authorized representative. A practitioner shall not deliberately make a false or misleading statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition. *(The proposed rule protects patients by requiring practitioners to accurately inform patients and to not deliberately mislead them about their care.)* 2. Practitioners shall present information relating to the patient's care to a patient or his legally authorized representative in

			understandable terms and encourage participation in the decisions regarding the patient's care. (*If information is not provided in a manner and in terms that a patient should reasonably be expected to understand, the practitioner is not accurately informing patients or giving them an opportunity to make decisions regarding their care and treatment.)* 3. Before any invasive procedure is performed, informed consent shall be obtained from the patient in accordance with the policies of the health care entity. Practitioners shall inform patients of the risks, benefits, and alternatives of the recommended invasive procedure that a reasonably prudent practitioner practicing in Virginia would tell a patient. a. In the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder, the legally authorized person available to give consent shall be informed and the consent documented. b. An exception to the requirement for consent prior to performance of an invasive procedure may be made in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient. c. For the purposes of this provision, "invasive procedure" shall mean any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decision-maker prior to proceeding. *(Rules on informed consent prior to performance of surgery or an invasive procedure are consistent with those set out in guidance adopted by the Board and with the*

			policies and procedures of most hospitals. It is not intended that informed consent must be obtained before any routine procedure, such as drawing blood in a lab, is performed.) 4. Practitioners shall adhere to requirements of § 32.1-162.18 of the Code of Virginia for obtaining informed consent from patients prior to involving them in research activities. *(There are specific requirements already in the Code for informed consent for patients in research, so that provision of law is referred.)* Subsection B sets out the requirements for termination of the practitioner/patient relationship, as follows: 1. The practitioner or the patient may terminate the relationship. In either case, the practitioner shall make a copy of the patient record available, except in situations where denial of access is allowed by law. 2. A practitioner shall not terminate the relationship or make his services unavailable without documenting notice to the patient that allows for a reasonable time to obtain the services of another practitioner.
n/a	88	n/a	Section 88 establishes certain responsibilities and rules of conduct for practitioners Subsection A provides that a practitioner shall not: 1. Perform procedures or techniques that are outside the scope of his practice for which he is not trained and competent. 2. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised; 3. Engage in an egregious pattern of disruptive behavior or interaction in a health

			care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient; 4. Exploit the practitioner/patient relationship for personal gain. (*All of the behaviors or conducts listed under subsection A have been relevant to disciplinary cases before the Board. The practitioner's ultimate responsibility is to the health and safety of his patients, and behaviors that interfere with care may be unprofessional.)* Subsection B specifies that advocating for patient safety or improvement in patient care within a health care entity does not constitute disruptive behavior provided the practitioner does not engage in behavior prohibited in A 3 of this section. *(The Medical Society specifically requested the language in subsection B to give practitioner some assurance that "whistle-blowing" would not be interpreted as disruptive behavior.)*
n/a	89	n/a	Section 89 provides that a practitioner shall not knowingly and willfully solicit or receive any remuneration, directly or indirectly, in return for referring an individual to a facility or institution. Remuneration is defined as compensation, received in cash or in kind, but shall not include any payments, business arrangements, or payment practices allowed the United States Code or any regulations promulgated thereto. *(This language is identical to the current rule in section 80 of Chapter 20.)*
n/a	90	n/a	Section 90 provides for the following: Subsection A defines, for the purposes of unprofessional conduct set forth in the Code of Virginia, what is meant by "sexual contact."

			Subsection B sets out the rules prohibiting sexual contact with a current patient. The fact that a patient is not actively seeing the practitioner or that there was consent to the contact does not negate the prohibition. Subsection C sets out the rules regarding sexual contact between a practitioner and a former patient, which may still constitute unprofessional conduct if the contact is based on exploitation of the patient in some way. Subsection D addresses sexual contact between a practitioner and a key third party. It provides that such contact shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. For purposes of this section, key third party of a patient shall mean: spouse or partner, parent or child, guardian, or legal representative of the patient. Subsection E addresses sexual contact between a supervisor and a trainee. It provides that such contact shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. *(The Board examined the possibility of a prohibition for such contact – as with current patients – but decided that would be too restrictive and unreasonable. The keys to determining whether such contact constitutes unprofessional conduct is the effect of patient care and the way in which the practitioner has used his or her position of power and superiority to initiate the sexual contact.)*
n/a	91	n/a	Section 91prohibits a practitioner from willfully refusing to provide information or records as requested or required by the board or its representative pursuant to an investigation or to the enforcement of a

			statute or regulation. *(This language is identical to the current rule in section 105 of Chapter 20.)*

Family impact

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

There is no impact of the proposed regulatory action on the institution of the family and family stability.