Virginia Regulatory Town Hall

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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 85-20-10 et seq.	
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic	
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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 expand the current regulations on professional conduct to include standards for treating and prescribing for self and family; maintenance, retention and release of patient records; patient confidentiality; practitioner-patient communication and termination of that relationship; and practitioner responsibilities. In addition, substantive amendments are proposed for advertising ethics, the recommendation for vitamins and minerals, pharmacotherapy for weight loss, and sexual contact.

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 18VAC85-20-10 et seq. (Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic) 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 § 54.1-2915, 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. This regulatory action expands the current regulations on standards of professional conduct, which already included rules for advertising, recommending vitamins and minerals, prescribing for weight loss, solicitation or remuneration in exchange for referral, and sexual contact. Amended rules will also 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 additions to Part II, Standards of Professional Conduct:

18VAC85-20-21. Treating and prescribing for self or family.

This section specifies the conditions under which it would be ethical for a practitioner to prescribe for self or family, including adherence to the law that requires a bona fide practitioner-patient relationship and maintenance of a patient record. Practitioner can prescribe Schedule VI drugs but should not prescribe other scheduled drugs unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.

18VAC85-20-22. Patient records.

Requirements for patient records include compliance with provisions of § 32.1-127.1:03 related to the confidentiality and disclosure of patient records; provision of records in a timely manner and in accordance with applicable law; proper management and completion of records; maintenance of records for a minimum of six years following the last patient encounter with several exceptions; informing all patients concerning the time frame for record retention and destruction; and destruction in a manner that protects patient confidentiality, such as by incineration or shredding.

18VAC85-20-23. 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 be considered negligent or willful.

18VAC85-20-24. 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 surgery or 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 surgery or 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.

18VAC85-20-25. 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.

In most of the current regulations for ethical standards, it is stated that "it shall be unprofessional conduct for a licensee to…" In its review of the regulations, the Board determined that the standard of conduct should be stated and then a violation of the regulation, as determined in a case decision by the Board, would provide grounds for disciplinary action. Accordingly, changes in terminology are applied to current regulations.

Additionally, substantive changes were made in the following sections:

18VAC85-20-30. Advertising ethics.

There is a new requirement for practitioner responsibility and accountability for the validity and truthfulness of the content of an advertisement to ensure that it is not deceptive, misleading or false.

18VAC85-20-40. Vitamins, minerals and food supplements.

Rather than requiring that the rationale for use of vitamins, minerals or food supplements be therapeutically proven and not experimental, the amended regulation requires that recommendation or direction for such be based upon a reasonable expectation that use will result in a favorable patient outcome, including preventive practices, and that a greater benefit will be achieved than that which can be expected without such use. The amended regulation is more reasonable and in keeping with the accepted standard for a recommendation.

The current rule prohibits recommending "toxic" doses, which is problematic and ill-defined. The amended rule would prohibit a recommended dose that would be contraindicated based on the individual patient's overall medical condition and medications.

18VAC85-20-90. Pharmacotherapy for weight loss.

The rules for prescribing "anorectic" drugs are amended to refer to all "controlled substances," Schedules III through VI, used for the purpose of weight reduction or control in the treatment of obesity, since many of the current drugs are not "anorectics." The conditions that must be met include performance of an appropriate history and a review of laboratory work, as indicated, including testing for thyroid function. Rather than requiring an EKG for every patient, the amended rule requires an electrocardiogram to be performed and interpreted within 90 days of initial prescribing for treatment of obesity, if the drug could adversely affect cardiac function.

Rather than weighing the patient at least once a month as is currently required, the amended rule requires that the patient be seen within the first 30 days following initiation of pharmacotherapy for weight loss and that the treating physician direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy. The prohibition against prescribing amphetamine-like substances for use as an anorectic agent in children under 12 years of age is eliminated.

18VAC85-20-100. Sexual contact.

The amended regulation defines 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 are new language and 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.

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.

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:

18VAC85-20-26. 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.

18VAC85-20-27. 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.

18VAC85-20-28. Practitioner-patient communication; termination of relationship.

Grammatical changes were made in subsection A.

There was an amendment to the requirement for practitioners to inform patients of the risks, benefits, and alternatives of the recommended surgery or invasive procedure to clarify that the standard for informed consent was what a reasonably prudent practitioner in similar practice in Virginia would tell a patient.

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."

18VAC85-20-30. Advertising ethics.

Subsection D was rewritten for clarification; the requirement continues to be that a licensee must disclose the complete name of the specialty board which conferred the certification when using or authorizing the use of the term "board certified" or any similar words or phrase calculated to convey the same meaning in any advertising for his practice.

18VAC85-20-100. Sexual contact ~~with patients~~.

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; during that period, the following comments were received:

Fourteen persons posted comment on the Regulatory Townhall requesting an amendment to require a physician to obtain a patient's informed consent before prescribing the off-label use of a medication. Such consent would include disclosure of all warnings, contraindications or adverse reactions that appear in FDA-approved package inserts. Specific concerns about the use of the drug Cytotec (misoprostol) to induce or augment labor were cited.

Two persons posted comment opposing such a requirement for informed consent for every off-label use of a drug. The issue is the judicious and appropriate use of a medication and not the medication itself.

Board response: The Board concurs with the two commenters who stated that the issue is not the off-label use of a drug, which is often medically-appropriate and beneficial to a patient. Such a decision must be made on a case-by-case basis and is dependent on the professional knowledge and judgment of the prescriber based on available research and recommendations for the drug's use. All warnings, contraindications or adverse reactions are described on package inserts, which must be made available to a consumer by the person dispensing the drug. Therefore, no change to the regulation was made in response to the persons who wanted the rules to require informed consent to be obtained prior to prescribing the off-label use of a drug.

Joan Resk, D.O. provided the following comment:
Section 26 *– Definition needed for "properly" and "complete"- subject to interpretation. Need more detail about "posting" requirement.*

Board response: The Board did not amend proposed regulations based on the comment. A requirement for records to be maintained properly is an accepted standard of practice and is intended to ensure that a patient, a health care facility or another provider has crucial information available about the patient's history, treatment and prognosis. The "posting" requirement in subsection E is intentionally subjective to permit the practitioner to determine the most efficient and cost-effective manner for informing patients about the policy on destruction of records. That may be accomplished by posting a sign in the waiting room and/or examination rooms or by making that a part of the informed consent forms signed by each patient.

Section 27 *– Should include language about unintentional breach of confidentiality by release of records to a state agency or board; regulation only allows a breach by applicable law – patients*

have their confidentiality breached by this type of release as well as to insurance companies. "Beyond the control of the practitioner" is vague.

> **Board response:** The Board concurs that a release of patient information that is permitted by law (to a state agency, insurance company, etc.) would not be unprofessional conduct; an amendment is adopted accordingly. If there was a complaint to the Board about an unauthorized breach of confidentiality, it would be determined in a case decision whether the breach was beyond the control of the practitioner, and therefore not considered negligent or willful.

Section 28 *– Regulation should include "impression" or "assessment" in addition to "diagnosis" as most patients are given a term for their illness without knowing that it is merely a working diagnosis.*

> **Board response:** The intent of the regulation is set a standard for communication of practitioners with their patients. It does not preclude a practitioner giving from additional information about his/her impressions or assessment of the patient's condition or from explaining that he/she has made a working diagnosis. No change was made based on the comment.

Section 29 *– Questioned what constitutes "properly trained and supervised" in delegation of care to subordinates. What could "reasonably be expected to adversely impact the quality of care" is subjective and open to interpretation. Also, the term "egregious pattern of disruptive behavior" needs to be defined.*

> **Board response:** The Board believes the standard is clearly stated as to the manner in which a reasonable practitioner would delegate care to persons under his supervision. An egregious pattern of disruptive behavior may be subjective but the standard is further defined as behavior that interferes or adversely impacts patient care. Again, if there was a complaint to the Board about a practitioner's failure to appropriately train and supervise persons to whom he has delegated patient care or about an egregious pattern of behavior, it would be determined in a case decision whether or not the practitioner has been negligent in his/her practice.

Section 30 *– Responsibility for advertising more burdensome for solo practitioners than for group practice. Questioned when the responsibility for the content of an advertisement ends for solo practitioners; creates a double standard.*

> **Board response:** The intent of the amendment is to ensure that there is one responsible licensee in a multi-practitioner practice who assumes responsibility for the content of an advertisement. With a solo practitioner, that line of responsibility clearly leads to the licensee. There is not a double standard; in both cases there is an obligation to ensure that the advertisement is not false, misleading or deceptive.

Section 40 *– Objects to the requirement that the recommendation for vitamins and minerals be based on an expectation that a greater benefit can be achieved – requirement is more stringent that*

what is required for approval of a prescription drug. In her opinion, compliance with subsection B should be required for all prescriptions if it is required for vitamins and minerals.

> **Board response:** The proposed standard for recommending vitamins or minerals is less restrictive than the current standard, which requires that the rationale for use must be "therapeutically proven and not experimental." The proposed language was recommended by a subcommittee of practitioners who are familiar with such use, and no change from the proposed was recommended.

William Hall, Esquire, provided the following comment:
Section 26 *– Recommends deletion of subsection A as isolated instances of disclosure of patient records should not be considered unprofessional conduct.*

> **Board response:** The Board does not concur with the comment that it should be permissible to violate a provision of law relating to patient confidentiality.

Subsection D should be amended to state that failure to maintain patient records for a minimum period of six years would not be deemed unprofessional conduct and to delete language stating a physician should maintain a patient record longer if required by contractual obligation. Subsection F should be deleted; practitioner should not be required to post information on destruction of records.

> **Board response:** The commenter noted that it should not be unprofessional conduct to fail to maintain a single patient record if there was no harm to the patient. The Board believes the standard for maintaining patient records is reasonable and necessary for protection of the health of patients. Whether a practitioner would be disciplined for a single violation of the rule would depend on a complaint being filed and on the facts presented. The Board concurs with the comment that a practitioner should not be disciplined because he did not maintain records as required by contractual obligation. Accordingly, the rule has been restated to point out to practitioners that records may need to be maintained longer. On the requirement for posting or informing patients about record destruction, the Board believes that it is important for patients to understand the policy for destruction of their record. Giving appropriate notification and information then places the obligation on the patient to ensure that he/she requests a copy of the record for future reference prior to the destruction date. Simply placing a sign in a waiting room or examination rooms or including that information on forms signed by the patient is not overly burdensome.

Section 27 *– It should not be unprofessional conduct unless a practitioner willfully breaches confidentiality or breaches in a manner that constituted gross negligence.*

> **Board response:** The proposed regulation does provide that the practitioner shall not "willfully and negligently" breach confidentiality. To insert a "gross negligence" standard to the breach of confidentiality would be inconsistent with § 54.1-2915 which was amended to replace the gross negligence standard with "intentional and negligent conduct."

Section 28 *– The standard for informing patient should be a good faith effort in describing the risks and benefits to patients. Practitioner should be able to proceed with treatment if the patient or an alternative decision-maker cannot give consent. Regulations for termination should not apply if care of the patient is transferred to another practitioner within the group practice.*

> **Board response:** The Board believes that standard is clearly stated to require the practitioner to inform patients or their legally authorized representative information about risks and benefits that a reasonable prudent practitioner in similar practice in Virginia would tell a patient. According to representatives of the three medical centers in Virginia, the standard set for proceeding with treatment without consent is consistent with the hospital standards in which there must be a likelihood of imminent harm. Finally, a transfer to another practitioner within a group practice would not be a termination provided there is patient consent for the transfer and a continuum of care.

David F. Boleyn, Esquire, on behalf of a subcommittee of the Health Law Section of the Virginia Bar Association, provided the following comment:

Section 25 *– Questions the criteria for a practitioner-patient relationship set in § 54.1-3303 and acknowledges that the comment is outside the scope of the regulation. Questions what constitutes an "emergency situation" or an" isolated setting" or a "single episode" – suggests adding "unless he has reason to believe" that it is an emergency situation, etc.*

> **Board response:** The Board believes the rule is adequate for the understanding of practitioners who may have the need to prescribe a drug other than a schedule VI under the conditions set forth in subsection B. No change was recommended by the Ad Hoc Committee or adopted by the Board.

Section 26 *– Subsection A is subsumed in subsection B and can be deleted. HIPAA uses the term "personal representative" so that should be substituted for "legally authorized representative". Requirement for a medical record to be "complete" is subjective – suggests insertion of the word "materially."*

> **Board response:** While subsection B appears to be redundant, the Board determined that there are differences and both are necessary. The Board concurred with the recommendation to change the term to "personal representative" in this section relating to patient records. The Board did not amend proposed regulations relating to the maintenance of records. A requirement for a record to be "complete" is an accepted standard of practice and is intended to ensure that a patient, a health care facility or another provider has crucial information available about the patient's history, treatment and prognosis.

In subsection D, 1) recommends deletion of the term "or the age of emancipation, whichever comes first" since an emancipated child, while responsible for making his own health care decisions, remains a child; 2) a practitioner who has transferred a patient record should be required to maintain a record of that transfer for six years; 3) it should not be grounds for unprofessional conduct for a practitioner to violate a contractual obligation to maintain a record; 4) Requirement for destruction of records should be amended to include "in a manner <u>reasonably calculated</u> to protect patient confidentiality"; and 5) recommends stating the provisions of §54.1-2405 in the

regulation to increase practitioner awareness of requirements for notification to patients if selling or moving a practice.

> **Board response:** In subsection D: 1) the Board has amended the record-keeping provision of D 1 to make it clear that the minimum time is 6 years; 2) there is an exception from the 6-year rule in D 2 for any record that has been transferred; 3) the Board concurs with the comment that a practitioner should not be disciplined because he did not maintain records as required by contractual obligation. Accordingly, the rule has been restated to point out to practitioners that records may need to be maintained longer; 4) the Board does not concur that destruction of records should be in a manner that is "reasonably calculated" to protect confidentiality; and 5) in the publication of the Virginia Administrative Code, there is a link for any section of the Code that is cited, so it is not necessary to quote the statute.

Section 27*- Commented that "willfulness" and "negligence" can occur in degrees; suggested use of phrases "willful misconduct" and "gross negligence". The language about breach of confidentiality should extend to those situations in which release of patient records is permitted by law.*

> **Board response:** The proposed regulation does provide that the practitioner shall not "willfully and negligently" breach confidentiality. To insert a "gross negligence" standard to the breach of confidentiality would be inconsistent with § 54.1-2915 which was amended to replace the gross negligence standard with "intentional and negligent conduct." The Board concurs that a release of patient information that is permitted by law (to a state agency, insurance company, etc.) would not be unprofessional conduct; an amendment is adopted accordingly.

Section 28 – *Commenter suggested some grammatical changes.*
Subsection A - Suggested that subsection A2 be amended to avoid the absolute language and require that the practitioner present information in terms that "the practitioner believes will be readily understandable."

> **Board response:** The Board considered amending subsection A but concluded that there should be a requirement for the practitioner to communicate in understandable terms and encourage participation in one's care.

In subsection A3, the informed consent provisions are directed at specialty practice and should be expanded to include general practitioners by including language such as "to an extent or degree reasonably comparable to that which a prudent Virginia practitioner would inform patients."

> **Board response:** To eliminate the confusion about the applicability of the rule, the Board has amended the language to cover information that a reasonably prudent practitioner "in a similar practice" in Virginia would tell a patient.

In subsection A3a, the language should include the possibility that informed consent may be withheld. In subsection A3b, the determination of whether an emergency exists or harm will result from failure to treat is subjective, and the word "imminent" is misapplied.

Board response: According to representatives of the three medical centers in Virginia who served on the Ad Hoc Committee, the standard set for proceeding with treatment without consent is consistent with the hospital standards in which there must be a likelihood of imminent harm.

In subsection A4, the last four words ("that affects their care") should be deleted as it is a subjective judgment on the part of the practitioner.

Board response: The intent of the proposed regulation was to exempt from informed consent requirements research that consists of a retrospective review of a patient's chart to determine the effectiveness of a particular treatment or medication. While the institution conducting the research must typically give consent, it is not required that informed consent be obtained from every patient for the purpose of gathering statistical information. An amendment to the section on research clarifies the intent.

Subsection B – Suggested additional clarity in the provisions for termination of a practitioner-patient relationship to include language about "patient abandonment," specific citations of Virginia Code related to provision of patient records and a requirement for documenting the advanced notice for termination. Suggested separating the exception provided in §54.1-2962.2 into another subdivision of subsection B to increase practitioner awareness of the law.

Board response: The Board considered the comment and suggestions for inclusion of other specific citations relating to termination of the patient-practitioner relationship but determined that the rule, as stated, was sufficient to ensure that the patient is protected and that it was not necessary to repeat provisions of the Code in regulation.

***Section 29** – The use of the word "egregious" in A2 is superfluous and should be deleted.*

Board response: The Board does not concur that the word "egregious" should be deleted; it is necessary to describe the type of disruptive behavior that may constitute unprofessional conduct.

***Section 30** – The commenter provided comment on subsections B, C, and D, which were not amended in the proposed action.*

Board response: Since the comments were not related to the proposed amendments, there was no response adopted.

***Section 40** – Recommended the deletion of the last two words in subsection A and replacement with "the use of the vitamins, minerals or food supplements so recommended."*

Board response: The Board did not believe the rule would be clearer with the substitution of the language suggested.

A Public Hearing before the Board was held on January 21, 2005, at which time the following comment was received:

Sammy Johnson, Deputy Director for Enforcement at the Department of Health Professions suggested the Board consider a definition for "family member" to clarify the rule on prescribing.

> **Board response:** While the Board appreciated the desire for clarity, it determined that it was too restrictive to try to specify who should constitute a "family member" and chose to leave the term undefined.

Note: In the proposed regulations posted on the Regulatory Townhall and adopted by the Board, new subsections were numbered 21 through 25. Commenters referred to those numbers in providing comment. In the publication of proposed regulations, the Registrar of Regulations re-numbered those sections as 25 though 29. Therefore, the responses to comments refer to the section numbers as found in the official publication of proposed regulations found in the Register of Regulations.

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	25	n/a	Section 25 sets the appropriate standard for treating and prescribing for self or family to include that it should be based on a bona fide practitioner-patient relationship and meet the criteria set forth in § 54.1-3303 of the Code of Virginia. *(The components of a bona fide practitioner-patient relationship for the purpose of prescribing controlled substances are already set in the Code, so the regulation refers those criteria as the basis for any such relationship.)* Subsection B requires that a practitioner not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner

			available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication. *(The vast majority of prescribing for self or family members involves a Schedule VI prescription, which has no potential for abuse, so the Board did not place any prohibitions on such prescribing. Under very limited circumstances and for a single episode, it would also be appropriate to prescribe Schedule II-V drugs.)* Subsection C requires the practitioner, when treating or prescribing for self or family, to maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship. *(This provision is intended to clarify that even prescribing Schedule VI drugs requires compliance with the law in regard to patient records and establishment of a bona fide practitioner-patient relationship.)*
n/a	26	n/a	Section 26 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 54.1-2915 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 personal 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 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: 1. Records of a minor child, including immunizations, shall be maintained until the child reaches the age of 18 or becomes emancipated, with a minimum time for record retention six years from the last patient encounter regardless of the age of the child; or 2. Records that have previously been transferred to another practitioner or provided to the patient or his legally authorized representative; or 3. Records that are required by contractual obligation or federal law 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 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	27	n/a	Section 27 provides that a practitioner shall not willfully or negligently breach the confidentiality between a practitioner and a patient. A breach of confidence that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful. *(The Medical Society requested language stating that a breach of confidentiality that was beyond the control of the practitioner should not be considered willful or negligent, which makes the rule more reasonable.)*
n/a	28	n/a	Section 28 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 inform a patient or his legally authorized representative of any medical diagnoses, prognosis and prescribed treatment or plan of care. 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 surgery or 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 surgery or invasive procedure that a reasonably prudent practitioner in a similar practice 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 surgery or 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. Except as provided in § 54.1-2962.2, a practitioner shall not terminate the relationship or make his services unavailable without notice to the patient that allows for a reasonable time to obtain the services of another practitioner. (*The 2004 General Assembly placed in law specific provisions for termination of a relationship in the emergency department of a hospital. It is necessary to specify that rules requiring notice do not apply to those situations.)*
n/a	29	n/a	Section 29 establishes certain responsibilities

			and rules of conduct for practitioners Subsection A provides that a practitioner shall not: 1. 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; 2. 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; 3. 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 2 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.)*
30	n/a	Section 30 sets out rules for advertising ethics: Subsection A requires any statement specifying a fee must include all the cost of all related procedures, services and products	

		which, to a substantial likelihood, will likely be necessary for the completion of the advertised service. Subsection B prohibits charging for care performed within 72 hours of the initial office visit in response to an advertisement for a free service, unless rendered as a result of a bonafide emergency. Subsection C requires an advertisement of discounts to disclose the full fee that has been discounted and documented evidence to substantiate the discounted fees. Subsection D requires a practitioner to disclose the complete name of the specialty board which conferred a certification used in an advertisement. Subsection E states that it shall be considered unprofessional conduct for a licensee of the board to publish an advertisement which is false, misleading, or deceptive.	Subsection D is amended to require the disclosure of the complete name of the specialty board which conferred the certification when using or authorizing the use of the term "board certified" or any similar words or phrase calculated to convey the same meaning in any advertising for his practice. Subsection E is amended to eliminate the term "advertisement" and insert "advertise information" to clarify that the prohibition applies to advertisements that are not "published" but may be provided to consumers in another format. There is also an additional requirement for a practitioner who is a solo practitioner to be presumed to be responsible and accountable for the validity and truthfulness of an ad's content. For an advertisement for a practice in which there is more than one practitioner, the name of the practitioner or practitioners responsible and accountable for the content of the advertisement must be documented and maintained by the practice for at least two years.
40	n/a	Section 40 sets out the rules for use or recommendation	

		for use of vitamins, minerals and food supplements.	
		Subsection A provides that the use or recommendation of vitamins, minerals or food supplements and the rationale for that use or recommendation must be documented by the practitioner and that the rationale for said use must be therapeutically proven and not experimental.	Subsection A is amended to use the terminology "recommendation or direction for the use," rather than "use or recommendations." It is not the "use" of vitamins and minerals that is being addressed; it is the direction or recommendation for such use. Also, the requirement that the rationale for said use must be therapeutically proven and not experimental is unreasonable and is eliminated. The recommendation or direction should be based upon a reasonable expectation that such use will result in a favorable patient outcome, including preventive practices, and that a greater benefit will be achieved than that which can be expected without such use.
		Subsection B requires that vitamins, minerals, or food supplements, or a combination of the three, cannot be sold, dispensed, recommended, prescribed, or suggested in toxic doses	Subsection B is amended to clarify that the dose recommended should not be contraindicated based on the individual patient's overall medical condition and medications. The word "toxic" is eliminated, as it is not clear and would differ with different patients.
		Subsection C requires the practitioner to conform to the standards of his particular branch of the healing arts in the therapeutic application of vitamins, minerals or food supplement therapy.	
50	n/a	Section 50 states that it shall be considered unprofessional conduct for a licensee of the board to sell, prescribe, or administer anabolic steroids to any patient for other than accepted therapeutic purposes.	An amendment will state what the conduct should be, and if a practitioner is found to be in violation of the regulation, it would be considered unprofessional conduct and grounds for disciplinary action under the law.
80	n/a	Section 80 states that it shall be unprofessional conduct for a licensee of	A similar amendment was made in section 80.

90	n/a	the board to knowingly and willfully solicit or receive any remuneration, directly or indirectly, in return for referring an individual to a facility or institution. Section 90 establishes the rules for use of pharmacotherapy for weight loss. Subsection A prohibits a practitioner from prescribing amphetamine, Schedule II, for the purpose of weight reduction or control. Subsection B states that it is unprofessional conduct for a physician to prescribe anorectic drugs, Schedules III through VI, for the purpose of weight reduction or control in the treatment of obesity, unless the following conditions are met: 1. A comprehensive history, physical examination, and interpreted electrocardiogram are performed and recorded at the time of initiation of treatment for obesity by the prescribing physician; 2. A diet and exercise program for weight loss is prescribed and recorded;	An amendment to subsection B eliminates the term "anorectic drugs" and replaces it with the term "controlled substances," since no all weight loss drugs are anorectics. 1. The word "comprehensive" is replaced with "appropriate" before history. The requirement for an "interpreted electrocardiogram" is now found in subdivision 2. The term "treatment" is replaced with "pharmacotherapy," and there is an additional requirement for the physician to review the results of laboratory work, as indicated, including testing for thyroid function (which should be a part of an examination for obesity). 2. If prescribing a weight loss drug that could adversely affect cardiac function, the physician is required to review the results of an electrocardiogram performed and interpreted within 90 days of initial prescribing for treatment of obesity. The current rule requires that the prescribing physician perform the EKG and that it must be performed at the time of initiating

			treatment. The revised rule would not require an EKG if the prescribed drug has no effect on cardiac function and would allow the EKG to be performed and interpreted by another practitioner within the past 90 days.
		3. The patient is weighed at least once a month , at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy;	Number 3 is now number 4 and requires that the patient be seen within the first 30 days following initiation of pharmacotherapy for weight loss, by the prescribing physician or a licensed practitioner with prescriptive authority working under the supervision of the prescribing physician, at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy.
		4. No more than a 30-day supply of such drugs shall be prescribed or dispensed at any one time;	Current number 4 is eliminated; the duration of the prescription should be patient-specific and based on a number of factors.
		5. No such drugs shall be prescribed or dispensed for more than 90 days unless the patient: a. Has a recorded weight loss of at least 12 pounds in the first 90 days of therapy; b. Has continued progress toward achieving or maintaining a target weight~~;~~ and c. Has no significant adverse effects from the prescribed program.	Current number 5 is amended to eliminate the limitation on a 90-day prescription unless the patient has lost a certain amount of weight in that time period. Again, treatment regimens and prescribing varies depending on the response of the individual patient. An amendment will require that the treating physician direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy.
		Subsection C makes it unprofessional conduct for a physician to prescribe amphetamine-like substances for use as an anorectic agent in children under 12 years of age.	Subsection C is eliminated as it is considered overly restrictive by bariatic physicians who treat children with morbid obesity.
100	n/a	Section 100 establishes rules regarding sexual contact by practitioners.	

		Subsection A references the Code sections on unprofessional conduct and sexual contact and defines sexual contact between a practitioner and a patient includes, but is not limited to, sexual behavior or involvement with a patient including verbal or physical behavior which: 1. May reasonably be interpreted as intended for the sexual arousal or gratification of the practitioner, the patient, or both; or 2. May reasonably be interpreted as romantic involvement with a patient regardless of whether such involvement occurs in the professional setting or outside of it. Subsection B sets out the rules regarding any sexual contact with a patient. 1. The determination of when a person is a patient for purposes of §54.1-2914 A 16 of the Code of Virginia is made on a case-by-case basis with consideration given to the nature, extent, and context of the professional relationship between the practitioner and the person. The fact that a person is not actively receiving treatment or professional services from a practitioner is not determinative of this issue. A person is presumed to remain a patient until the patient-practitioner	Amendments to subsection A 1) correct the Code cite, and 2) clarify that the definition of "sexual contact" applies generally to this section and not solely to contact with current patients. Subsection B is amended to include the language that is currently in subsection C.

		relationship is terminated. 2. The consent to, initiation of, or participation in sexual behavior or involvement with a practitioner by a patient does not change the nature of the conduct nor negate the statutory prohibition. Subsection C states that a patient's consent to, initiation of, or participation in sexual behavior or involvement with a practitioner does not change the nature of the conduct nor lift the statutory prohibition. Subsection C also states that sexual contact between a practitioner and a former patient after termination of the practitioner-patient relationship may still constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge, or influence of emotions derived from the professional relationship.	Subsection C is amended to only reference sexual contact between a practitioner and a former patient. Subsection D is added to address 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 is added to address sexual contact between a medical supervisor and a medical 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

105	n/a	Section 105 states that it is unprofessional conduct for a licensee to willfully refuse 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.	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.)* An amendment in 105 will state what the conduct should be, and if a practitioner is found to be in violation of the regulation, it would be considered unprofessional conduct and grounds for disciplinary action under the law.

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.