Virginia Regulatory Town Hall

townhall.virginia.gov

# Proposed 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, Osteopathy, Podiatry and Chiropractic |
| **Action title** | Standards of Conduct |
| **Document preparation date** | 7/2/04 |

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

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

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.

## 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 number(s), if applicable, and (2) promulgating entity, i.e., the 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 (6) 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, sections 54.1-2914, 54.1-2915, and 54.1-2916 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.

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-2914

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-2915

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+54.1-2916

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.*

---

The 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. 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

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 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 §§ 54.1-2914. 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so 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 § 54.1-2914 (7), 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.

## Economic impact

*Please identify the anticipated economic impact of the proposed regulation.*

| | |
|---|---|
| **Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures** | a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than $3,000) for mailings to the Public Participation Guidelines mailing lists and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled; there will be on on-going expenditures associated with the fee increase. |
| **Projected cost of the regulation on localities** | None |
| **Description of the individuals, businesses or other entities likely to be affected by the regulation** | The entities that are likely to be affected by these regulations would be doctors of medicine, osteopathy, podiatry and chiropractic and interns and residents |
| **Agency's best estimate of the number of such entities that will be affected** | Doctors of Medicine 29,106<br>Doctors of Osteopathic Medicine 1085 |

| | |
|---|---|
| | Doctors of Podiatry 488<br>Doctors of Chiropractic 1589<br>Interns & Residents 2750 |
| **Projected cost of the regulation for affected individuals, businesses, or other entities** | There should be no cost for compliance with the proposed regulations, as they reflect the current standard for ethical practice and professional conduct. |

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

The necessity for regulatory action arose from a decision by the Virginia Court of Appeals that reversed a disciplinary decision by the Board of Medicine. A licensed physician was charged with ethical violations related to his inappropriate behavior toward female medical students while serving as a resident. He was placed on probation by the residency program and eventually dismissed. Subsequently, he was noticed to appear before an informal conference committee of the Board where he received a reprimand for ethical violations. Upon request from the physician for a formal hearing, the order of the committee was vacated. After the formal hearing, the physician was placed on indefinite probation with terms, including a requirement to complete hours of AMA-approved continuing education in professional boundaries.

Following the formal hearing, the physician appealed the order of the Board to the Circuit Court, where the Board's ruling was upheld. The physician then appealed that ruling to the Virginia Court of Appeals. At the formal hearing, the Commonwealth's case referenced the AMA Code of Ethics, but the Court of Appeals ruled that the Board had never established that as the standard by regulation and had not disseminated that standard to its licensees, so therefore could not take action against a practitioner on that basis.

Following this decision by the Court, the Board determined that it must initiate regulatory action to incorporate rules for ethical conduct into its regulations in order to have a standard of conduct for all practitioners that could be consistent, appropriate and understandable. Since adoption of a standard of professional conduct is a complex process, the began the regulatory action with the creation of an ad hoc committee that included citizen members of the board, representatives of professional groups as well as practitioners or licensees. The committee considered a variety of alternatives for establishing ethical standards in regulation, including:

A) Incorporation by reference of codes of ethics established by professional bodies, such as the American Medical Association. Initially, that approach was favored by the Medical Society of Virginia and others. However, several problems were presented: 1) the code of the AMA is a constantly-evolving document, lengthy document (almost 300 pages of opinions and annotations), so the licensees would be challenged to stay abreast of the code; 2) the changes in the code would have to be frequently re-examined to determine continued approval for

incorporation, and the Board would have no control over its content; 3) the code contains opinions and guidance on social issues affecting medicine that should not become the standard of conduct upon which a Virginia licensee could be held accountable; 4) the AMA advised that its code was never intended to become a standard used by a regulatory board to regulate and discipline doctors; and 5) each professional licensed by the Board has its own professional code of ethics, so the AMA code could not generically apply to chiropractors, acupuncturists, etc.

B) Incorporation by reference of parts of the codes of ethics established by professional bodies. The AMA Principles of Medical Ethics is a general statement of ethical principles that is augmented by specific opinions relating to ethical decisions or dilemmas. The Board considered adoption the Principles but realized that they were aspirational statements, rather than concrete rules to which a practitioner could be held accountable.

C) Creation of a new standard of ethics that would be applicable to all professions regulated under the Board that would be an assimilation of principles and codes from other sources. After examining all the options and reviewing availability professional documents, the Board concluded that it was appropriate to amend Part II of Chapter 20, which already contained standards of professional conduct for such situations as advertising, sexual contact, and prescribing for weight loss. Regulations for the professions overseen by advisory boards did not previously contain standards of professional conduct, so those standards that were appropriate and applicable were added to each.

On the advice of board counsel, the Board voted in June 2003 to proceed with a regulatory action. Comment on the NOIRA concluded in August 2003, and the Board then included the issue as a major part of its agenda for a board workshop in September 2003. The various options and issues were reviewed by the Board at its meeting in October 2003, and a committee was appointed to develop regulatory language. The Ad Hoc Committee on Ethical Standards of Conduct met five times between December 2003 and April 2004 to review a variety of source material, including model regulations from the Federation of State Medical Boards, the Code of Medical Ethics of the AMA, and ethical standards from other professional organizations. The ad hoc committee was composed of board members (both licensees and citizen), representatives of the Medical Society of Virginia, the Old Dominion Medical Society, the advisory boards under Medicine. Invited guests were encouraged to freely participate in the discussions and proposals; they included representatives of the Richmond Academy of Medicine, the Virginia Chiropractic Association, the Richmond Chapter of the American Academy of Pediatrics, and the Virginia Society for Respiratory Care.

In addition to the primary Ad Hoc Committee, two subcommittees were appointed to consider issues related to the current regulations for ethical practice in prescribing for treatment of obesity and for vitamins, minerals & food supplements. Participating on those committees were doctors who have particular expertise in their training and practice in the treatment of obesity and in the use of supplements.

The proposed regulations contain elements and language drawn from a number of other documents – including the Guide to the Essentials of a Modern Medical Practice of the Federation of State Medical Boards, the Code of Virginia, standards of conduct found in regulations of other professions within the Department, the AMA Code of Ethics and codes from all professions regulated by the

Board. Starting with the Guide of the Federation, the committee reviewed the 42 recommended grounds for disciplinary action by a state medical board and identified those that were not already addressed in law or regulation in Virginia. Where gaps were noted, the Board developed regulatory language to deal with such issues as confidentiality, disruptive behaviors, retention of records and informed consent.

Throughout the process, the Board was kept informed and received drafts of regulations. The Legislative Committee received the recommended draft of the ad hoc committee, and with minor changes recommended its adoption by the Board.

## Public comment

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

The NOIRA was published on July 28, 2003 and comment closed on August 27, 2003. During that period, there was no public comment.

However, throughout the development of these regulations, drafts were widely circulated and numerous people commented informally at meetings, through emails, and in telephone conversation. There was a general misunderstanding about the process with a number of persons believing that there would be no further opportunity for comment once the draft was adopted by the Board in June. A few individuals had specific comments and concerns, which were appropriately addressed by the ad hoc committee. For example, one doctor felt that retention of immunization records indefinitely was overly burdensome, and the committee concurred. Another felt that an absolute prohibition on sexual contact between a medical supervisor (resident) and a trainee (4$^{th}$ year med student) was not workable and likely to have unintended consequences. The committee concurred and amended its original proposal.

Initially, the Medical Society of Virginia expressed concern that the draft regulations were unnecessary and expressed a preference for incorporation of the Code of Ethics of the AMA. After discussions with MSV, its members concurred with the rationale for development of regulations for Virginia practitioners. In addition to the MSV representation on the Ad Hoc Committee of the Board, MSV chose to appoint its own committee to work on draft language. In an effort to resolve lingering differences and questions, staff of the Board met with the MSV committee. As a result, some suggested amendments were incorporated into the Ad Hoc Committee's recommended draft. Consequently, the governing board of the Medical Society voted to support the draft proposed regulations recommended by the Committee and adopted by the Board with minor changes.

## Family impact

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

The proposed regulatory action would not have a direct impact on the institution of the family and family stability.

## Detail of changes

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

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

| Current section number | Proposed new section number, if applicable | Current requirement | Proposed change and rationale |
|---|---|---|---|
| n/a | 21 | n/a | Section 21 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.<br><br>*(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.)*<br><br>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.<br><br>*(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.)* |

| | | | |
|---|---|---|---|
| n/a | 22 | n/a | 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.<br><br>*(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.)*<br><br>Section 22 set standards of conduct in regard to patient records.<br><br>Subsection A requires practitioners to comply with provisions of § 32.1-127.1:03 related to the confidentiality and disclosure of patient records.<br><br>*(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.)*<br><br>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.<br><br>*(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.)*<br><br>Subsection C requires practitioners to properly manage patient records and maintain timely, accurate, legible and complete patient records.<br><br>(*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.)*<br><br>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, which have to be maintained until the child reaches the age of 18 or the age of emancipation, whichever comes first, except the minimum time for record retention shall be six years regardless of the age of the child at the last patient encounter; or<br><br>2. Records that have previously been transferred to another practitioner or provided to the patient or his legally authorized representative; or<br><br>3. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.<br><br>*(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.)*<br><br>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.<br><br>*(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 | 23 | n/a | Section 23provides that a practitioner shall not willfully or negligently breach the confidentiality between a practitioner and a patient. A breach of confidence that is required by applicable law or beyond the control of the practitioner shall not be |

| | | | |
|---|---|---|---|
| n/a | 24 | n/a | considered negligent or willful.<br><br>*(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.)*<br><br>Section 24 sets the professional standards for practitioner-patient communication and for termination of a relationship.<br><br>Subsection A provides rules for communication with patients as follows:<br><br>1. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately inform patients or their 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.<br><br>*(The proposed rule protects patients by requiring practitioners to accurately inform patients and to not deliberately mislead them about their care.)*<br><br>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.<br><br>(*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.)*<br><br>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 practicing in Virginia in the same or a similar specialty 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.<br><br>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.<br><br>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.<br><br>*(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.)*<br><br>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.<br><br>*(There are specific requirements already in the Code for informed consent for patients in research, so that provision of law is referred.)*<br><br>Subsection B sets out the requirements for termination of the practitioner/patient relationship, as follows:<br><br>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. |

| | | | |
|---|---|---|---|
| n/a | 25 | n/a | 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.<br><br>(*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.)*<br><br>Section 25 establishes certain responsibilities and rules of conduct for practitioners<br><br>Subsection A provides that a practitioner shall not:<br><br>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;<br><br>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;<br><br>3. Exploit the practitioner/patient relationship for personal gain.<br><br>(*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.)*<br><br>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.<br><br>*(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:<br><br>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.<br><br>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.<br><br>Subsection C requires an advertisement of discounts to disclose the full fee that has been discounted and documented evidence to substantiate the discounted fees.<br><br>Subsection D requires a practitioner to disclose the complete name of the specialty board which conferred a certification used in an advertisement.<br><br>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 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.<br>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.<br>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<br>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. | 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.<br>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.<br>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. |
| 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 | A similar amendment was made in section 80. |

| | | | |
|---|---|---|---|
| 90 | n/a | be unprofessional conduct for a licensee of 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.<br><br>Section 90 establishes the rules for use of pharmacotherapy for weight loss.<br><br>Subsection A prohibits a practitioner from prescribing amphetamine, Schedule II, for the purpose of weight reduction or control.<br><br>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:<br><br>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; | 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.<br><br>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).<br><br>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. |

| | | | |
|---|---|---|---|
| | | 2. A diet and exercise program for weight loss is prescribed and recorded;<br><br>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;<br><br>4. No more than a 30-day supply of such drugs shall be prescribed or dispensed at any one time;<br><br>5. No such drugs shall be prescribed or dispensed for more than 90 days unless the patient:<br><br>a. Has a recorded weight loss of at least 12 pounds in the first 90 days of therapy;<br><br>b. Has continued progress toward achieving or maintaining a target weight~~;~~ and<br><br>c. Has no significant adverse effects from the prescribed program. | 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.<br><br>Current number 4 is eliminated; the duration of the prescription should be patient-specific and based on a number of factors.<br><br>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.<br><br>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. |
| 100 | n/a | 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.<br><br>Section 100 establishes rules regarding sexual contact by practitioners.<br><br>Subsection A references the | Subsection C is eliminated as it is considered overly restrictive by bariatic physicians who treat children with morbid obesity.<br><br>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. |

| | | | |
|---|---|---|---|
| | | 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:<br><br>1. May reasonably be interpreted as intended for the sexual arousal or gratification of the practitioner, the patient, or both; or<br><br>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.<br><br>Subsection B sets out the rules regarding any sexual contact with a patient.<br><br>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 relationship is terminated.<br><br>2. The consent to, initiation | Subsection B is amended to include the language that is currently in subsection C. |

| | | | |
|---|---|---|---|
| | | 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.<br><br>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.<br><br>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.<br><br>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.<br><br>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 on patient care.<br><br>*(The Board examined the possibility of a prohibition for such contact – as with current patients – but decided that would be too restrictive* |

| | | | |
|---|---|---|---|
| 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. | *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.)*<br><br>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. |