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Regulatory
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Proposed Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 85-101-10 et seq.
Regulation title	Regulations Governing the Practice of Radiologic Technology
Action title	Standards of Conduct
Document preparation date	7/26/04

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 establish standards for professional conduct including maintenance of patient records; patient confidentiality; practitioner-patient communication; sexual contact and practitioner responsibilities.

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

Legal basis

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. Amended rules will provide standards relating to ethical behavior in the care and treatment of patients, maintenance and disclosure of records, and in the responsibility of a practitioner for delegation of services to subordinates under their supervision. Throughout the substance of these rules, there are measures that will benefit patient health and safety. For example, a patient’s health and safety may benefit from a requirement for the practitioner to communicate and involve the patient in his care, to fully inform the patient and to maintain patient information with confidentiality.

While the vast majority of practitioners conduct their practices ethically, there are those who have not followed professional standards for communicating and informing patients, for maintaining accurate and legible records, for providing records in a timely manner, or for sexual contact with patients. 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 Standards for Professional Conduct:

18VAC85-101-161. 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 considered negligent or willful.

18VAC85-101-162. Patient records.

Proposed regulations set requirements for confidentiality and disclosure of patient records, and for maintenance of accurate, timely records. Since rad techs are always employed by a health care institution or other entity, they are required to maintain records in accordance with the policies of that entity.

18VAC85-101-163. Practitioner-patient communication; termination of relationship.

Section 163 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. Practitioners are also required to refer or consult with other health care professionals, if indicated and to adhere to provisions of the Code if involving a patient in research activities.

18VAC85-101-164. Practitioner responsibility.

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

18VAC85-101-165. Sexual contact.

Proposed regulations define in subsection A what is meant by sexual contact for purpose 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 set the conditions under which sexual contact between a practitioner and a key third party or between a medical supervisor and a medical trainee could constitute unprofessional conduct.

18VAC85-101-166. Refusal to provide information.

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

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If 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, sexual contact and informed consent.

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 retention of patient records 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.

<p>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</p>	<p>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.</p>				
<p>Projected cost of the regulation on localities</p>	<p>None</p>				
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>The entities that are likely to be affected by these regulations would be radiologic technologists and radiologic technologists, limited</p>				
<p>Agency’s best estimate of the number of such entities that will be affected</p>	<table style="width: 100%; border: none;"> <tr> <td style="width: 80%;">Radiologic technologists</td> <td style="text-align: right;">2614</td> </tr> <tr> <td>Radiologic technologists, limited</td> <td style="text-align: right;">939</td> </tr> </table>	Radiologic technologists	2614	Radiologic technologists, limited	939
Radiologic technologists	2614				
Radiologic technologists, limited	939				
<p>Projected cost of the regulation for affected individuals, businesses, or other entities</p>	<p>There should be no cost for compliance with the proposed regulations, as they reflect the current standard for ethical practice and professional conduct.</p>				

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 or the American Society of Radiologic Technologists. 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 "ASRT Code of Ethics" of the American Society of Radiologic Technologists is aspirational and guiding rather than an enforceable document or 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 regulations for the professions overseen by advisory boards. Those regulations did not previously contain standards of professional conduct, so 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.

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 (4th 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.

The draft regulations were reviewed and discussed by the Advisory Board on Radiologic Technology at several of its meetings. The Advisory Board recommended that the proposed regulations be consistent with current and amended regulations for professional standards of practice adopted for doctors, provided the rule was applicable to the practice of occupational therapy. For example, rules relating to prescribing of drugs and retention of records were omitted as Rad Tech’s do not have prescriptive authority and do not own the patient records.

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	161	n/a	Section 161 prohibits a willful or negligent breach of patient confidentiality but relieves the practitioner of responsibility if the breach is required by law or beyond his control.

n/a	162	n/a	<p>Section 162 set standards of conduct in regard to patient records.</p> <p>Subsection A requires practitioners to comply with provisions of § 32.1-127.1:03 related to the confidentiality and disclosure of patient records.</p> <p><i>(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.)</i></p> <p>Subsection B requires practitioners to properly manage patient records and maintain timely, accurate, legible and complete patient records.</p> <p><i>(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.)</i></p> <p>Subsection C requires rad techs who are employees of a health care institution or other entity and do not have ownership of patient records. It requires the licensee to adhere to the policies and procedures of the employing entity in the maintenance of records.</p>
n/a	163	n/a	<p>Section 163 sets the professional standards for practitioner-patient communication and for termination of a relationship.</p> <p>Subsection A states that except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately present information to patients or their legally authorized representative. 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.</p> <p><i>(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</i></p>

<p>n/a</p>	<p>164</p>	<p>n/a</p>	<p><i>informing patients or giving them an opportunity to make decisions regarding their care and treatment.)</i></p> <p>Subsection B provides that 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.</p> <p><i>(The proposed rule protects patients by requiring practitioners to accurately inform patients and to not deliberately mislead them about their care.)</i></p> <p>Subsection C requires practitioners to refer or consult with other health care practitioners if so indicated.</p> <p><i>(The proposed rule is part of the ASRT Code of Ethics and was strongly recommended by the Advisory Board for inclusion in regulation.)</i></p> <p>Subsection D requires practitioners to 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.</p> <p><i>(There are specific requirements already in the Code for informed consent for patients in research, so that provision of law is referred.)</i></p> <p>Section 164 establishes certain responsibilities and rules of conduct for practitioners</p> <p>Subsection A provides that a practitioner shall not:</p> <ol style="list-style-type: none"> 1. Perform procedures or techniques that are outside the scope of his practice for which he is not trained and competent. 2. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate’s scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised; 3. Engage in an egregious pattern of disruptive behavior or interaction in a health care setting that interferes with patient care or could reasonably be
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<p>n/a</p>	<p>165</p>	<p>n/a</p>	<p>expected to adversely impact the quality of care rendered to a patient;</p> <p>4. Exploit the practitioner/patient relationship for personal gain.</p> <p><i>(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.)</i></p> <p>Subsection B specifies that advocating for patient safety or improvement in patient care within a health care entity does not constitute disruptive behavior provided the practitioner does not engage in behavior prohibited in A 3 of this section.</p> <p><i>(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.)</i></p> <p>Section 165 provides for the following:</p> <p>Subsection A defines, for the purposes of unprofessional conduct set forth in the Code of Virginia, what is meant by “sexual contact.”</p> <p>Subsection B sets out the rules prohibiting sexual contact with a current patient. The fact that a patient is not actively seeing the practitioner or that there was consent to the contact does not negate the prohibition.</p> <p>Subsection C sets out the rules regarding sexual contact between a practitioner and a former patient, which may still constitute unprofessional conduct if the contact is based on exploitation of the patient in some way.</p> <p>Subsection D addresses sexual contact between a practitioner and a key third party. It provides that such contact shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. For purposes of this section, key third party of a patient shall mean: spouse or partner, parent or child, guardian, or legal</p>
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n/a	166	n/a	<p>representative of the patient.</p> <p>Subsection E addresses sexual contact between a supervisor and a trainee. It provides that such contact shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care.</p> <p><i>(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 key 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.)</i></p> <p>Section 166 prohibits a practitioner from willfully refusing to provide information or records as requested or required by the board or its representative pursuant to an investigation or to the enforcement of a statute or regulation.</p> <p><i>(This language is identical to the current rule in section 105 of Chapter 20.)</i></p>
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