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Proposed Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC85-160
VAC Chapter title(s)	Regulations Governing the Licensure of Surgical Assistants and Registration of Surgical Technologists
Action title	Amendments for change from registration to licensure
Date this document prepared	7/15/21

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Legislation passed by the 2020 General Assembly changed regulation of surgical assistants from registration to licensure, and amendments that conformed to the statute were enacted. Additional amendments are necessary to provide for consistency with other licensed allied professions regulated by the Board of Medicine in the fee structure, continuing competency, inactive licensure, and standards of practice. Additionally, the Board is amending regulations for renewal of registration for surgical technologists.

Legislation passed in the 2021 General Assembly changed regulation of surgical technologists from registration to certification. Amendments that conform to the statute are being promulgated in another action.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this action is the need to incorporate requirements in regulations appropriate for professions that are now licensed or certified, especially those related to continuing competency and standards of practice, for the protection of the public.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

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:

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions, and the health regulatory boards.

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

Regulations on surgical assistants and surgical technologists are promulgated in accordance with:

§ 54.1-2956.12. Registered surgical technologist; use of title; registration.

A. No person shall hold himself out to be a surgical technologist or use or assume the title of "surgical technologist" or "certified surgical technologist," or use the designation "C.S.T." or "S.T." or any variation thereof, unless such person is certified by the Board.

B. The Board shall certify as a surgical technologist any applicant who presents satisfactory evidence that he (i) has successfully completed an accredited surgical technologist training program and holds a current credential as a certified surgical technologist from the National Board of Surgical Technology and Surgical Assisting or its successor, (ii) has successfully completed a training program for surgical technology during the person's service as a member of any branch of the armed forces of the United States, or (iii) has practiced as a surgical technologist at any time in the six months prior to July 1, 2021, provided he registers with the Board by December 31, 2021.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

Currently, regulations do not provide standards of practice relating to confidentiality and responsibilities of practitioners to their patients. Amendments are necessary to ensure there are standards for confidentiality, patient records, dual relationships, and informed consent to protect public health and safety. Additionally, there are currently no requirements for maintaining competency or continuing education for surgical assistants was were licensed by a grandfather provision nor for surgical technologists. To protect patients who receive services during surgical procedures, it is essential for these practitioners to stay abreast of new techniques and information.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

In 2020, the level of regulation for surgical assistants was elevated by action of the General Assembly from voluntary registration to licensure. Amendments to regulation were adopted under an exemption to conform to changes in the Code, and a NOIRA was also published to announce the intent to adopt additional amendments to make regulations consistent with other licensed professions under the Board of Medicine.
Amendments will: 1) add definitions as necessary; 2) conform fees for licensure to other professions under the Board; 3) add requirements for continuing competency for surgical assistants licensed under a grandfathering provision; 4) provide for an inactive license and for reactivation or reinstatement of a license; 5) provide for a restricted volunteer license or voluntary practice by out-of-state practitioners; and 6) provide for renewal of certification of surgical technologists, including requirements for continuing education. Finally, the Board will adopt standards of practice similar to those for other licensed professions under its jurisdiction and will also consider the code of ethics specific to surgical assistants.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) The primary advantages to the public are the addition of continuing education requirements for all surgical assistants and surgical technologists to ensure competency for continuation in practice and the standards of conduct by which licensees or certificate holders could be held accountable for unprofessional acts. There are no disadvantages.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety in the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale

for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no costs to the state for implementation or enforcement; all funding for the Board is derived from fees charged to applicants and licensees.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs to other agencies
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits to agencies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs to localities

Benefits the regulatory change is designed to produce.	No benefits

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Licensed surgical assistants and certified surgical technologists
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	As of the end of the third quarter of FY2021, there were 333 surgical assistants and 231 surgical technologists. With the change in status for surgical technologists (as of July 1, 2021) from voluntary registration to certification with title protection, the number of technologists is likely to increase. These practitioners are not small businesses and typically practice in large hospital systems.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	The cost of obtaining a new license for a surgical assistant will increase from $75 to $130. The cost for biennial renewal of a surgical assistant license will increase from $70 to $135. Late renewal fees are set at approximately 1/3 the cost of renewal; so that fee will increase from $25 to $50 for assistants. Other fees not currently in regulation but consistent with those for other professions under the Board include fees for reinstatement and a letter of verification of licensure or certification.
Benefits the regulatory change is designed to produce.	The fee structure will be identical to all the other allied professions regulated under the Board and will support its functions of licensing and discipline.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board can only enforce fees and standards of practice that are set forth in regulation. There is no alternative to regulation.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the

objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

The Advisory Board on Surgical Assisting recommended the proposed regulations to the full Board of Medicine. There are no alternative methods consistent with public health and safety to regulate these health care professions.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This action is not being used to conduct a periodic review.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

There was a 30-day comment period from March 1, 2021 to March 31, 2021; no public comment was received.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Medicine is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Henrico, VA 23233; phone: (804) 367-4688; Fax: (804) 527-4434; email: Elaine.yeatts@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
40	n/a	Sets out fees charged to surgical assistants and surgical technologists	The fees in subsection A for surgical assistants are: $130 for initial licensure $135 for biennial renewal $50 for late renewal $70 for an inactive license $180 for reinstatement of license lapsed for more than two years $10 for letter of verification $2,000 for reinstatement after revocation

			Fees for surgical technologists remain unchanged because they are certified rather than licensed. *Prior to 2020, surgical assistants were registered by the Board. As a registered profession, they were not subject to disciplinary action under 54.1-2915 or regulations adopted by the Board. A large percentage of fees collected by the agency is used to cover the costs of investigations and disciplinary proceedings, so fees for the licensed allied professions under the Board of Medicine are consistent.* *For each category in which there is a lower level of the profession, the fees are approximately half of the licensed profession. For example – occupational therapist and occupational therapy assistant; and radiologic technologists and radiologic technologist-limited. Therefore, fees for surgical technologists are set at half of those for surgical assistants.*
60		Sets out the requirements for renewal of licensure for a surgical assistant	Subsection B is added to require a surgical assistant licensed based on completion of a training program in the military or based on a grandfathering provision of practice prior to July 1, 2020 to complete 38 hours of CE recognized by the National Surgical Assistant Association for biennial renewal. *The Code of Virginia requires a surgical assistant who was licensed based on a national credential to maintain that credential in order to renew licensure. However, a person licensed based on completion of a training program in the military or based on a grandfathering provision has no statutory requirement for maintaining continuing competency. The Advisory Board strongly supports continuing competency requirements for all its licensees, so subsection B is added to specify the same number of hours as is required for maintenance of certification with the national board.* *The National Surgical Assistant Association (NSAA) is recognized by the National Commission for the Certification of Surgical Assistants (NCCSA) as the responsible authority for the approval of CEU programs, so all surgical assistants would go through the same approval body for their CE. There are numerous options available to licensees through the NSAA.* *CEU credits can be earned through the following methods:* *1. Health care facility mandatory education* *2. Health care facility sponsored in-services*

			3. Attending professional physician organization programs *4. Writing for health-related publications* *5. Instruction of health professionals* *6. College credit* *7. Lecture* *8. Clinical demonstration* *9. Completion of enduring material activities. Enduring material is non-live and includes but is not limited to hard-copy or electronically delivered CEU articles that have a post-article CEU exam; online health care facility tests; online CEU lectures, or any electronic means that has post-article CEU exams.* *Over the biennium, a licensee should be able to access continuing education for little or no cost through in-service trainings, on-line courses or other types of learning activities.*
n/a	65	Sets out the renewal requirements for certification of a surgical technologist	The renewal requirements for continuing education for surgical technologists are similar to those for surgical assistants. Those who were certified based on their national credential will be required to maintain that credential. Those who were certified based on military training or grandfathering will be required to attest to completion of 30 hours of CE recognized by the Association of Surgical Technologists. As with the surgical assistants, the AST is the organization recognized by the National Board of Surgical Technology and Surgical Assisting (NBSTSA) for maintenance of competency through continuing education credits. For assistants, maintenance of certification requires 38 hours every two years; for technologists, 30 hours is required – so the CE requirement for renewal of licensure is identical and can be met with or without continued certification by the NBSTSA.
n/a	70	Sets out the requirements for reinstatement or reactivation of licensure	Subsection A allows a surgical assistant to obtain an inactive license by payment of an inactive fee. An inactive licensee is not authorized by practice and is not required to maintain continued competency hours. Subsection B sets out the requirements for reactivation of licensure, which include payment of the difference between the inactive and active renewal fee and evidence of continued competency hours. Subsection C sets out the requirements for reinstatement of a license that has been lapsed for more than two years (one renewal cycle). Subsection D states the right of the board to deny reactivation or reinstatement upon evidence that a person has violated provisions of law or regulation.

			Subsection E sets out the requirement for reinstatement of a license that has been revoked.
n/a	80	Sets out a standard for confidentiality between practitioner and patient.	*The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-85 for example)*
n/a	90	Sets out the standard for maintenance and disclosure of patient records, consistent with professions in which practitioners may be self-employed or may be employed by a health care entity that owns the records	*The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-86 for example)*
n/a	100	Sets out the standard for practitioner-patient communication and informed consent and sets the standard for termination of a practitioner-patient relationship.	*The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-87 for example)*
n/a	110	Sets the standard for practitioner responsibility for performance of procedures, delegation to subordinates and exploitation of the relationship for personal gain.	*The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-88 for example)*
n/a	120	Sets the standard for sexual contact with a patient, a former patient or a key third party in the relationship.	*The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-89 for example)*
n/a	130	Sets the standard for refusing to provide information as requested or required by the Board or its representative.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-91 for example)