



Virginia

Regulatory
Town Hall

townhall.virginia.go

V

Final Regulation Agency Background Document

Agency name	State Board of Health (Virginia Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-475 et seq.
Regulation title	Virginia Organ and Tissue Donor Registry
Action title	Amend the Virginia Organ and Tissue Donor Registry regulation for clarity, efficiency and effectiveness
Date this document prepared	March 4, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

The final amendments update and clarify the current regulations regarding the Virginia Organ and Tissue Donor Registry to more closely reflect current registry practice and to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the registry or the public. The amendments include changing the references to the Virginia Organ and Tissue Donor Registry to the "Virginia Donor Registry" as determined by the 2006 General Assembly amendments to §§ 32.1-292.2 and 32.1-297.1 of the Code of Virginia. The amendments will also replace references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with references to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.).

Changes have been made in Section 10 (Definitions) to make definitions consistent with the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.); to delete definitions no longer required or used in the text; and to amend or add definitions to include donor registration processes available the DonateLifeVirginia.org website and clarify other functions and entities. Section 30 (Administration) will be amended to cite data requirements to be maintained and annually reported to the Board of Health. Section 40 (Access) will be moved and become a new Section 75. This Section will be amended to

include that designees may assist individuals to complete a signed application and that persons may indicate their willingness to donate through a donor registration process or mail-in form available on the DonateLifeVirginia.org website. The proposed amendment to Section 60 (Data to be recorded) will eliminate the recording of the telephone number in the Registry. References to the registry forms (VTC 1 and VTC 0) have been deleted.

No public comments were submitted during the 60-day comment period, and there are no changes between the proposed amendments and the final amendments.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The Virginia State Board of Health approved the text of the final amendments for the Regulations Implementing the Virginia Organ and Tissue Donor Registry, 12VAC5-475 on September 18, 2014.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Section 32.1-292.2 of the Code of Virginia provides the authority for the State Board of Health, in consultation with the Virginia Transplant Council, to promulgate regulations necessary to create, compile, maintain, modify as necessary, and administer the Virginia Donor Registry. The imperative form of the verb "shall" is used in § 32.1-292.2, making the Board's authority to regulate mandatory rather than discretionary.

Purpose

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

The amendments will assist in ensuring the public health, safety and welfare of the citizens of the Commonwealth. Several aspects of the regulations regarding the Virginia Donor Registry need updating and clarifying. The current regulations were the first to be promulgated under statutory authority granted by the 2000 session of the Virginia General Assembly and have been in effect since March 27, 2002 without amendment. The passing of more than ten years since the initial promulgation and review of the current regulations have led the Board to conclude that it is appropriate to amend the regulations to provide clarity; improve efficiency and effectiveness; and bring the regulations in line with current practice.

Substance

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

The final amendments to the regulations include:

- 1) Changing the references from the "Virginia Organ and Tissue Donor Registry" to the "Virginia Donor Registry."
- 2) Replacing references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with references to the Revised Uniform Anatomical gift Act (§32.1-291.1 et seq.).
- 3) Updating definitions in Section 10 for "anatomical gift"; "decedent"; "document of gift"; "donor"; "eye bank"; "guardian"; "organ procurement organization"; "part"; and "tissue bank" to be consistent with the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.).
- 4) Amending the definition of "Document of gift" to reference the donor registration form available on the DonateLifeVirginia.org website and amending the definition of "Registry" to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry.
- 5) Adding a definition for "designee" which has been used throughout the regulation to refer to a person who is designated to use the Virginia Donor Registry for certain limited purposes.
- 6) Adding "DonateLifeVirginia.org" to the definition section to identify the official website that provides information on organ and tissue donation and provides a registration form to indicate a willingness to donate.
- 7) Clarifying data requirements that the Virginia Transplant Council shall maintain and annually report to the Board of Health in Section 30 (Administration).
- 8) Designating that persons may indicate their willingness to donate by completing the Donor Registration form available on the DonateLifeVirginia.org website and eliminating the necessity for the Virginia Transplant Council to contact persons who identify their willingness to be a donor through the Department of Motor Vehicles to complete a registration form (VTC 1).
- 9) Deletion of Sections 20 (Purpose) and movement of 40 (Access) to 75 (Access). The last paragraph of this section has been deleted.

Issues

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

- 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

- 1) There are no disadvantages to the public. The identification of the DonateLifeVirginia.org website as an available resource on organ and tissue donation and the ability to complete an online registration to indicate a willingness to donate are advantages for the public.
- 2) There are no disadvantages to the agency or the Commonwealth. An advantage to both the Board of Health and the Virginia Transplant Council is that the amended regulations will provide greater clarification of the information that the Council must annually report to the Board.
- 3) There are no other pertinent matters of interest related to this action.

Changes made since the proposed stage

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

No changes have been made to the text of the proposed regulation since the publication of the proposed stage.

Section number	Requirement at proposed stage	What has changed	Rationale for change
N/A	N/A	N/A	N/A

Public comment

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

No comments were received during the public comment period following the publication of the proposed stage.

Commenter	Comment	Agency response
N/A	N/A	N/A

Enter any other statement here

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 10 through 90	N/A	Current regulations refer to “Virginia Organ and Tissue Donor Registry”.	Change references to the “Virginia Donor Registry.”
Section 10 through 90	N/A	Current regulations reference §§ 32.1-289 et seq. and 32.1-290.	Replace references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with updated references to the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.)
Section 10: Definitions	N/A	Current regulations do not identify the DonateLifeVirginia.org	Amends definition of “Document of gift” to reference the donor registration form now available on the DonateLifeVirginia.org

		website and do not include 'DonateLifeVirginia.org' in the definition section.	website; amends definition of "Registry" to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry; and adds "DonateLifeVirginia.org" to the definition section to identify the official website that provides information on organ and tissue donation and provides a registration form to indicate a willingness to donate.
Section 10: Definitions	N/A		Addition of definition of "designee" as this term is used throughout the text of the regulation as person designated to use the registry and perform certain functions.
Section 10: Definitions	N/A	Definitions for "agent"; "Commissioner"; "disseminate"; "informed consent"; and "UNOS"	Removes these definitions as they are no longer used in the final regulatory text.
Section 10: Definitions	N/A	Definitions for "anatomical gift or organ donation"; "decedent"; "document of gift"; "donor"; "eye bank"; "guardian"; "organ procurement organization"; "part"; and "tissue bank"	These definitions are amended to be consistent with the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.).
Section 10: Definitions	N/A	Definitions for "procurement" and "VTC"	These definitions are updated for clarity.
Section 20: Purpose	N/A	Defines purpose of regulation.	Section deleted as not needed.
Section 30: Administration	N/A	Subsection A states the board has responsibility for promulgating the regulations. Subsection B contains language stating that the State Health Commissioner is the executive office for the State Board of Health.	Removes subsections A and B as this language is not needed.
Section 30: Administration	N/A	Subsection D contains catchline "Confidentiality".	This becomes subsection B. The catchline "Confidentiality" is removed and specific reference to §32.1-292.2 B is added.
Section 30: Administration	N/A		New subsection C clarifies eight data requirements that the Virginia Transplant Council shall collect and maintain and annually report to the Board of Health (e.g. number of recovered organ donors).
Section 40: Access	Section 75: Access	This section currently identifies who shall have access to the registry; the time frame for access; the terms for which access shall be granted; and specific registry monitoring data elements required to be reported to the Virginia	This section is moved to new Section 75 under Part III. The third paragraph which lists specific monitoring data (e.g. the number of times the registry is accessed or results in an unsuccessful search) is deleted.

		Transplant Council.	
Section 50: Registry Membership	N/A	Current regulations require the Virginia Transplant Council to contact persons who identify their willingness to be a donor through the Department of Motor Vehicles to complete a registration form (VTC 1).	Designates that persons may indicate their willingness to donate by completing the Donor Registration form now available on the DonateLifeVirginia.org website and eliminates the use of the VTC1 form.
Section 60: Data to be recorded	N/A	Current regulations require the donor's telephone number be recorded in the registry and information recorded by completing the VTC 1 form	Deletes the requirement that the donor's telephone number be recorded in the Registry and eliminates the use of the Registry Form (VTC1).
Section 70: removal from the registry	N/A	Current regulations require an individual to complete VTC 0 form to remove name from registry.	Eliminates the required VTC 0 form and adds that a person may have his name removed in accordance with the Revised Uniform Anatomical Gift Act.
Section 80: Use	N/A	Current regulations address the use of the Registry data	Removes excess use of term "decedent" and repetitive language forbidding searches on persons other than the decedent. Substitutes proper terminology for document of gift. Removes term "accredited" from organ procurement organization as this is not required.
Section 90: Dissemination	N/A	Current regulations address dissemination of Registry data.	Substitutes proper terminology for document of gift and anatomical gift. Removes term "accredited" from organ procurement organization as this is not required. Updates references to Code of Virginia. Removes last paragraph for disclosure from Virginia Transplant Council to Department of Motor Vehicles.