



Proposed Regulation Agency Background Document

Agency name	State Board of Health (Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-475 <i>et seq.</i>
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	August 3, 2012

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed 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 proposed amendments include changing the references to the Virginia Organ and Tissue Donor Registry to the "Virginia Donor Registry" as determined by the 2006 amendments to §§ 32.1-292.2 and 32.1-297.1 of the Code of Virginia and to replace references to §§ 32.1-289 *et seq.* and 32.1-290, which were repealed by the 2007 General Assembly, with references to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 *et seq.*).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 on 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.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

VTC means the Virginia Transplant Council

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.

The legal basis for this action is § 32.1-292.2 of the Code of Virginia. This statute 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 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, the environmental benefits, and the problems the proposal is intended to solve.

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 briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

The proposed 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 definition of "Document of gift" to reference the donor registration form available on the DonateLifeVirginia.org website and amending 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 the regulatory action poses 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.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities that bear any identified disproportionate material impact from these amended regulations.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Dev Nair, Virginia Department of Health, 109 Governor Street, 10th Floor, Richmond, VA 23219, TEL: (804) 864-7662, FAX: (804) 864-7670, or email: Dev.Nair@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	The board does not anticipate any additional incurred cost to implement or enforce this proposed regulation.
Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.	No additional impact on individuals, businesses or other entities.
Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	N/A
All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs	No additional costs will be incurred related to clarifying the Virginia Donor Registry regulation.

<p>required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The amendments to the current regulation are designed to enhance its clarity, efficiency and effectiveness.</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. 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 regulation.

The two alternatives to the present action are to leave the current regulations intact or to make fewer changes to the regulations. However, in reviewing these regulations it has been decided to make all the changes included in this package to provide greater clarity and bring the regulations in line with current practice.

Regulatory flexibility analysis

Please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

The regulatory change impacts the Virginia Donor Registry, which does not meet the statutory definition of a small business. Therefore, the adverse impact on small businesses does not apply in the development of this regulatory action.

Public comment

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

The Department of Health’s Notice of Intended Regulatory Action was published in the June 9, 2008 Virginia Register (VR 24:20) for the public comment period from June 9, 2008 to July 9, 2008.

There were no public comments during the Notice of Intended Regulatory Action (NOIRA) process.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or encourage or discourage economic self-sufficiency, self pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents. It does not strengthen or erode the marital commitment and is not expected to affect disposable family income.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this 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, intent, rationale, and likely impact of proposed requirements
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 <i>et seq.</i> and 32.1-290.	Replace references to §§ 32.1-289 <i>et seq.</i> and 32.1-290, which were repealed by the 2007 General Assembly, with updated references to the <i>Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.)</i>
Section 10: Definitions	N/A	Current regulations do not identify the DonateLifeVirginia.org website and do not include ‘DonateLifeVirginia.org’ in the definition section.	Amends definition of “Document of gift” to reference the donor registration form now available on the DonateLifeVirginia.org 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 proposed 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 <i>et seq.</i>).
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 officer 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 Transplant Council.	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.
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:	N/A	Current regulations require	Deletes the requirement that the donor’s

Data to be recorded		the donor's telephone number be recorded in the registry and information recorded by completing the VTC 1 form	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.