



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health (Department of Health)
Virginia Administrative Code (VAC) citation	12 VAC 5 – 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	September 10, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

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 Virginia Donor 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 General Assembly 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and 32.1-297.1 of the *Code of Virginia* and to replace references to §§ 32.1-289 *et seq.* and 32.1-290, which were repealed by the 2007 General Assembly, with references to the *Revised Uniform Anatomical Gift Act* (§ 32.1-291.1 *et seq.*). The regulatory action will also amend the definition for “Document of gift” to reference the donor registration form available on the save7lives.org website; amend the definition of “Registry” to refer to the Virginia Donor Registry; and add a definition for “save7lives.org.” 12VAC5-475- 40 will be amended to clarify data requirements that will be maintained and annually reported to the Board of Health. 12VAC5-475-50 will be amended to include that designees may assist individuals who complete a signed application and that persons may indicate their willingness to donate by completing the Donor Registration form available on the save7lives.org website. The proposed amendment to 12VAC5-475-60 would eliminate the recording of the telephone number in the Registry and eliminate the reference to the Registry Form (VTC 1) which has been replaced by registration via the save7lives.org website.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The state 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 are in need of updating and clarification. 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 five years since the initial promulgation and the Board’s and Virginia Transplant Council’s experience with the current regulations lead the Board to conclude that it is an 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 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 proposed amendments to the regulations include:

- 1) Changing the references to 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) Amending definition of “Document of gift” to reference the donor registration form available on the save7lives.org website; amending definition of “Registry” to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry; and adding the “save7lives.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.
- 4) Clarifying data requirements that the Virginia Transplant Council shall maintain and annually report to the Board of Health.
- 5) Designating that persons may indicate their willingness to donate by completing the Donor Registration form available on the save7lives.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).

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 no disadvantages to the public. The identification of the save7lives.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 requirement of the proposal which are more restrictive than applicable federal requirements. Include 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 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 by mail, email or fax to Janice M. Hicks, Virginia Department of Health, 109 Governor Street, 7th Floor, Richmond, VA 23219, TEL: (804) 864-7662, EMAIL: Janice.hicks@vdh.virginia.gov, FAX: (804) 864-7670. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	The Board does not anticipate any additional incurred cost to implement or enforce this proposed regulation.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	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 regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	No additional costs will be incurred related to clarifying the Donor Registry regulation.

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 the Agency 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 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 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.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if	Current requirement	Proposed change and rationale
------------------------	---------------------------------	---------------------	-------------------------------

	applicable		
12VAC5-475-10 thru 12VAC5-475-90	N/A	Current regulations refer to Virginia Organ and Tissue Donor Registry	Change the references to the Virginia Organ and Tissue Donor Registry to the "Virginia Donor Registry."
12VAC5-475-10 thru 12VAC5-475-90	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 references to the <i>Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.)</i>
12VAC5-475-10	N/A	Current regulations do not identify the save7lives.org website and do not include 'save7lives.org' in the definition section	Amends definition of "Document of gift" to reference the donor registration form now available on the save7lives.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 the "save7lives.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.
12VAC5-475-40	N/A	Current regulations identify data that the organ procurement organizations, eye and tissue banks are required to report to the VTC, but do not identify data that must be provided to the Board of Health	Clarifies data requirements that the Virginia Transplant Council shall collect and maintain and annually report to the Board of Health.
12VAC5-475-50	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 save7lives.org website and eliminates the use of the VTC1 form.
12VAC5-475-60	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).
12VAC5-475-70	N/A	Current regulations require an individual to complete VTC 0 form to remove name from registry.	Eliminates the required VTC0 form and adds that a person may have his name removed in accordance with the Revised Uniform Anatomical Gift Act.
12VAC5-475-80 and 90	N/A	Current regulations addresses the use and dissemination of the Registry data	Language clarification/cleanup

