



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	Virginia Department of Health
VAC Chapter Number:	12 VAC 5-475
Regulation Title:	Virginia Organ and Tissue Donor Registry
Action Title:	Donor Registry
Date:	April 3, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This regulatory action creates a state-wide organ and tissue donor registry which shall maintain, and update as needed, pertinent information on all Virginians who have indicated a willingness to donate their organs, eyes, and tissues for transplantation or research. The registry shall record the donor's full name, address, sex, birth date, age, driver's license number or unique identifying number, and other pertinent identifying personal information. The Virginia Transplant Council shall analyze registry data to promote and increase donation within the Commonwealth. Also, any Virginian may have his name removed from the registry by filing an appropriate form with the Virginia Transplant Council.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

According to the Code of Virginia §32.1-292.2, an Organ and Tissue Donor Registry for the Commonwealth is to be administered by the Department of Health. The Board of Health, in consultation with the Virginia Transplant Council, shall promulgate regulations to administer the organ and tissue donor registry.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this action is to establish regulations to administer the newly established Virginia Organ and Tissue Donor Registry in order to: 1) provide a means of recovering an anatomical gift for transplantation or research and 2) collect data to develop and evaluate the effectiveness of educational initiatives promoting organ, eye and tissue donation.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The regulations regarding the creation of the donor registry as proposed are identical to the emergency regulations approved by the Board of Health in January 2001.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

These regulations will create a legitimate donor registry which will expedite the identification of potential organ and tissue donors. These regulations will also provide the agency with data to evaluate the effectiveness of VTC's educational initiatives. Although the registry will maintain data that includes unique identifiers of individuals, inclusion in the registry is voluntary and provisions are in place for the removal of names from the registry at the request of the individual.

The agency has long recognized the problem of citizens not being aware of their right/opportunity to become a donor, the confusion of how individuals may legitimately and legally declare their decision to donate, and the difficulty of identifying individuals who have now consented to be a donor.

Presently, citizens may designate to be a donor on a donor card, through an advance medical directive, or on their driver's license when they go to a DMV Customer Service Center to either obtain or renew a Virginia license. While the population is most easily reached through contact with DMV, the driver's license/record is not advertised as being part of a recognized Virginia Donor Registry. Any change to the license results in a \$5.00 charge to the citizen, which does not allow for easy entry or exit in making a donor decision.

The Code of Virginia does not permit DMV to release the name, address, or specific age of the citizen--only the gender and age group category in which the citizen is placed. These data are too vague to be utilized for educational purposes by the agency. Also, at the hospital setting and in the absence of a license, an organ procurement organization (OPO) must contact the State Police to access the driver's record to discover if the citizen was a donor. No other information, such as an address, may be obtained from the driver's record.

These regulations will enable a one-stop shop for donor registration and designation with easy entry and exit for citizens and easy access to donation intent by OPOs and eye banks. The registry as established by these regulations would allow for quicker, more streamlined donor identification, an increase in organ and tissue recovery, improvements in organ and tissue usage, and better targeted education efforts by the agency. Both the public and the Commonwealth will greatly benefit from these regulations.

One disadvantage to the agency could be the public perception of the state attempting to create a database that further invades the right of privacy for citizens. However persons entered into the registry will be done so according to their wishes and in a voluntary basis. Persons in the registry will have the option to have their name removed at any time.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget

activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The total budget for one-time design, development, initial training, and implementation for the registry is \$75,000. The total cost for the on-going expense of web-based hosting and supporting the registry annually would be \$21,588. This on-going cost also includes the necessary Oracle licenses, data management, network connectivity, access to a toll free hotline and up to 80 hours of additional programming for new reports, enhancements, and additional training. VDH currently has \$40,000 in general funds appropriated for FY 01 for the initial start-up and \$35,000 for FY 02 and beyond under source code 601-547E.

This registry, as administered by VDH and the VTC, would be considered confidential and would only be available to authorized members of the VTC that procure organs, eyes, and tissues. These members include LifeNet, Washington Regional Transplant Consortium, Mountain Donor Region Services, Carolina Donor Services, Lions Eye Bank and Research Center of Virginia, Inc., and Old Dominion Eye Foundation, Inc. According to the regulations, these members are required to report data regarding their use of the registry. Cost of these reports cannot be determined at this time.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

There are no changes being proposed.

Alternatives

Please describe the specific 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.

There are no relevant alternatives to the proposed regulatory action required by Virginia statutory law.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

Members of the transplant community including transplant centers, organ procurement organization (OPOs), eye banks, Virginia’s only tissue bank, the blood services center, the Virginia Hospital and Healthcare Association, and the South-Eastern Organ Procurement Foundation, support these regulations. The Department of Motor Vehicles also supports these regulations. There are no known opponents to these regulations.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency has drafted these regulations without use of excessive technical terms and jargon so that all points may be clearly understood.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The agency will review these regulations within three years of the date on which they become effective.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

As currently stated in the Code of Virginia §46.2-342, E and F, §54.1-2984, and §54.1-2986, the donor designation shall be sufficient legal authority for procurement without additional authority from the donor or his family or estate. The decision of the donor to donate cannot be revoked upon his or her death, and the family or agent may not refuse to honor the donor designation or to thwart the procurement of the donation.

This regulatory action strongly encourages self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It likewise seeks to honor the individual donor's intent and, thus, reinforce a growing national trend to honor what is called "Donation by Donor Designation" or "First Person Consent." Donation by Donor Designation means that an individual, while living, makes the final decision regarding his body upon death whether to allow use of his remains for the purpose of transplantation. This decision is legally binding and to be followed without hindrance or interference from the next of kin, guardian, or agent.

This action does not erode the authority and rights of parents in the education, nurturing, and supervision of their children, as any individual under the age of 18 must have parental consent before designating to be a donor and thus joining the registry. It is possible as with any decision, that the individual making a decision to donate may not have informed his or her family or power of attorney; upon that individual's death, the family or agent, unknown to the decision, may have objections out of personal fear or an unfavorable personal opinion toward organ and tissue donation. However, it is essential that Virginia maintain the integrity of the Uniform Anatomical Gift Act and defend and support an individual's right and choice to be a donor.

This regulatory action in no way effects a family's disposable income as all donations of organs, eyes and tissue are considered gifts and acts of charity. It is against federal and state law to buy and sell organs and tissues.