



Virginia  
Regulatory  
Town Hall

## Emergency Regulation Agency Background Document

<b>Agency Name:</b>	Department of Health (State Board of)
<b>VAC Chapter Number:</b>	12 VAC 5-475
<b>Regulation Title:</b>	Regulations Implementing the Virginia Organ and Tissue Donor Registry
<b>Action Title:</b>	Adopt regulations to administer the Donor Registry
<b>Date:</b>	August 30, 2000

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

### Emergency Preamble

*Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).*

*Please include a brief summary of the emergency action. There is no need to state each provision or amendment.*

The emergency regulation is necessary, as Virginia statutory law requires that the regulation be effective with 280 days or less from its enactment. The regulation is not otherwise exempt under the provisions of §9-6.14:4.1 (C) (4). The Board of Health, in consultation with the Virginia Transplant Council shall promulgate regulations to administer the organ and tissue donor registry.

## Basis

*Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.*

*Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.*

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In accordance with 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.

## Substance

*Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.*

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The registry 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.

## Alternatives

*Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.*

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

### Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the 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.

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As currently stated in the *Virginia Code* under §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 "First Person Consent": an individual, while living, may make the final decision regarding his body upon death as to use of his remains for the purpose of transplantation and that the decision be followed without hindrance.

This action in no way erodes 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. With respect to one's marital commitment, it is probable as with any decision that the individual making a decision to donate may not have informed his or her family or power of attorney. And that 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.