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Notice of Intended Regulatory Action Agency Background Document

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

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Basis

Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

Section 32.1-292.2 of the *Code of Virginia* provides for 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.

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Substance

Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. 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 citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

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, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.

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 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.

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.

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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 martial 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.