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Periodic Review and Small Business Impact Review Report of Findings

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-475
VAC Chapter title(s)	Regulations Implementing the Virginia Organ and Tissue Donor Registry
Date this document prepared	April 1, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

"VTC" means Virginia Transplant Council
"Board" means the State Board of Health
"Department" means Virginia Department of Health

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Section 32.1-292.2 of the Code of Virginia directed the Virginia Transplant Council to establish the Virginia Donor Registry which was to be created, compiled, operated, maintained, and modified by the Virginia Transplant Council in accordance with the regulations of the Board of Health and administration of the Department of Health.

Section 32.1-297.1 of the Code of Virginia established the Virginia Transplant Council with appropriate representation regarding Organ and Tissue Donation to oversee and for management of the Virginia Donor Registry. It also lists the duties of the Virginia Transplant Council as it relates to oversight of the Virginia Donor Registry.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

There are no viable alternatives for this regulation. The regulation establishes the Virginia Donor Registry, who administers it, and who maintains it. The regulation is necessary to maintain Registry in an efficient and cost effective manner while offering the citizens of Virginia opportunities to show their intent to donate organs and tissues in accordance with the Revised Uniform Anatomical Gift Act (§ [32.1-291.1](#)). Amending the regulation will allow for necessary technical changes in order to make the regulation clearer and more understandable.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency's response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

No public comments were submitted during the comment period for this periodic review.

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

In its current form the regulation meets the criteria set out in the ORM procedures and is necessary to offer opportunities to constituents to declare their intent to donate their organs and tissues upon their death. The Registry offers a source for all involved to obtain the necessary information to identify potential donors in a timely manner to facilitate the donation process. The registry also allows for all involved to maintain metrics to assess the availability of viable potential donors located within the Commonwealth. The regulations are necessary for the protection of public health, safety, and welfare. The regulations are also clearly written and easily understandable.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.

The Board recommends amending the chapter to conform the language to the Registrar's Style Manual and correct any technical errors.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

§ 32.1-292.2, Article 2 of Chapter 8 of Title 32.1 of the Code of Virginia establishes the Virginia Donor Registry with the intent of saving lives by reducing the shortage of organs and tissues for transplantation and to implement cost savings for patients and various state agencies by eliminating needless bureaucracy. The Agency considered the following;

1. There is a continued need for the regulation to assure that the death of potential organ and tissue donors are reported in a timely fashion.
2. There have been no known complaints or comments regarding the regulation.
3. The regulation is not complex and specifically states the duties and responsibilities of those involved.
4. There are no observed overlaps or conflicts with federal or state laws or regulations.
5. The regulation was evaluated over a three-month period, ensuring the stakeholders were involved throughout the evaluation process. The Transplant Council is responsible for maintaining and updating the Registry and funds are available to manage it appropriately.

12VAC5-475 outlines the duties of the Virginia Transplant Council in reference to the Virginia Donor Registry, stipulates what information is maintained in the registry, who has access and how it is disseminated. The regulation is effective in its intent and is necessary to continue to offering opportunities for the citizens to donate their organs and tissues upon their death as they intended in a cost effective and timely fashion.
