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Periodic Review Report of Findings

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-475
Regulation title	Regulations Implementing the Virginia Donor Registry
Date this document prepared	November 28, 2018

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Acronyms and Definitions

Please define all acronyms used in this Report. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

VDH – Virginia Department of Health

DBA – Doing Business As

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Section 32.1 – 292.2 of the Code of Virginia gives authority to the Virginia Department of Health (Board), in consultation with the Virginia Transplant Council, 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.

Alternatives

Please 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.

The Virginia Department of Health consulted the Virginia Transplant Council (DBA Donate Life Virginia) to determine if any amendments were needed. No viable alternatives for achieving the purpose of the existing regulations could be determined. The regulations are mandated under law and are administered in the least burdensome method.

Public Comment

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

No comments were received during the public comment period following publication of the periodic review.

Effectiveness

Pursuant to § 2.2-4017, please indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

The regulations meet the criteria set out in Executive Order 14 (2018) as they are clearly mandated by law and are necessary for the protection of public health, safety, and welfare in that they reflect current donor registry practice. The regulations are clearly written and understandable.

Decision

Please explain the basis for the rulemaking entity’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

VDH is recommending the regulations remain in effect without change. The Virginia Department of Health consulted the Virginia Transplant Council (DBA Donate Life Virginia) and determined that no amendments are needed at this time. The regulations, in their current form, provide for the ongoing existence of an important public health resource.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (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 the stated objectives of applicable law, will minimize the economic impact of regulations on small businesses.

There is a continued need for the regulations as they are mandated by law. No public comments were received during the public comment period. The regulations are clearly written and easily understandable. The regulations do not overlap, duplicate or conflict with any known federal or state law or regulation. Regulations are evaluated on an ongoing basis and these regulations were last amended in July 2015. Retaining the regulations in their current form does not appear to cause an adverse economic impact on small businesses in the Commonwealth of Virginia.