



[townhall.virginia.gov](http://townhall.virginia.gov)

## Periodic Review and Small Business Impact Review Report of Findings

<b>Agency name</b>	State Board of Health
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12 VAC 5-221
<b>VAC Chapter title(s)</b>	Regulations Governing Cooperative Agreements
<b>Date this document prepared</b>	February 15, 2024

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.*

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"OLC" means the VDH Office of Licensure and Certification.

"TAP" means the Technical Advisory Panel,

"VDH" means the 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.*

The Board is granted responsibility pursuant to Va. Code § 32.1-12 to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Clause 2 of Chapter 741 of the 2015 Acts of Assembly required the Board to promulgate regulations that address (i) the review of applications for proposed collaborative agreements, (ii) the process by which applications for proposed collaborative agreements shall be approved or denied, (iii) post-approval monitoring, and (iv) a schedule establishing the amount of the annual fee.

Va. Code § 15.2-5384.1 sets forth the requirements governing the review and monitoring of cooperative agreements by the Commissioner.

### 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.*

No alternative was considered because the Code of Virginia requires the Board to adopt regulations governing cooperative agreements and amending regulation is the least burdensome method to accomplish the statutory mandate.

### 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.*

This periodic review of the Regulations Governing Cooperative Agreements was published and the public comment period opened on January 30, 2023. The comment period ended on February 20, 2023. During that time, one comment was received.

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Jerry W. Kilgore, on behalf of Ballad Health	<p><b>General Statements</b></p> <p>(i) 12VAC5-221 should be amended</p> <p><b>Section 12VAC5-221-100</b></p> <p>(ii) Comment recommends amending subsection F by adding (i) that “any individual who is tasked with investigating a complaint of noncompliance be properly trained in how to conduct</p>	<p><b>General Statements</b></p> <p>(i) The Board notes the request to amend the regulation.</p> <p><b>Section 12VAC5-221-100</b></p> <p>(ii) The Board notes the suggestion. While self-investigation by the facility itself is an integral and necessary part of the complaint process, it is equally as important for the regulating entity to conduct an outside investigation as well. As to the proper training of investigators, VDH OLC staff are</p>

	<p>investigations”, and (ii) that “the department... request the compliance officer within an organization operating under a cooperative agreement... perform the initial investigation...”, allowing Ballard to conduct initial investigations of complaints at their facility.</p> <p>(iii) Commentor seeks to add a subsection (H) which outlines a required timeline for the department to meet for the review of plans: 30 days after receipt to request additional information, and 60 days after all information is received to accept, decline, or propose modifications.</p> <p><b>12VAC5-221-110</b></p> <p>(iv) Commentor requests to amend subsection B to require that the Plan for Separation be updated and reviewed by an independent organization annually be removed, and instead a review of the plan only be conducted when significant modification occurs. Any updates would be submitted to the department, but may not be “significant” enough to warrant review by an independent organization.</p> <p>(v) Commentor requests the numbered list describing the requirements of the annual report be removed in subsection A and replaced with</p>	<p>already required to possess training and/or experience conducting similar investigations in a healthcare setting.</p> <p>(iii) The Board notes the suggestion and will take this under consideration when amending 12VAC5-221.</p> <p><b>12VAC5-221-110</b></p> <p>(iv) The Board notes the suggestion and will take this under consideration when amending 12VAC5-221.</p> <p>(v) The Board notes the suggestion; however, the items contained in subdivisions A 1 to A 4 of 12VAC5-221-110 are required by subsection G of Va. Code § 15.2-5384.1, and therefore cannot be</p>
--	--	---

	<p>“The report shall include all of the information required to be submitted annually as set forth in the terms and conditions placed on the letter authorizing the cooperative agreement.”</p> <p>(vi) Commentor requests the requirement for audits of the Annual Report be removed from subsection D, and instead have the report be “certified by the Chief Executive Office and Chief Financial Officer of the organization as true and correct to the best knowledge of such person.”</p> <p><b>Section 12VAC5-221-120</b></p> <p>(vii) Comment requests amendment that the TAP (i) not be required to meet annually, and (ii) not be required to provide ongoing input to the commissioner on the evolution and development of new measures, and achievement of commitments</p>	<p>removed from the required submission list. The Board will take remaining submission requirements suggestion under consideration when amending 12VAC5-221.</p> <p>(vi) The Board notes the suggestion. An independent auditor ensures the audit is performed free of bias or conflicts of interest.</p> <p><b>Section 12VAC5-221-120</b></p> <p>(vii) The Board notes the suggestion; while the TAP has not met annually in recent years due to the COVID-19 pandemic and the demands that this public health crisis placed on VDH and the TAP’s membership, the TAP is still integral to the supervision of the cooperative agreement.</p>
--	--	---

**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.*

The regulation is necessary for the protection of public health, safety, and welfare because it governs cooperative agreements between health systems that create healthcare monopolies and the active supervision of those agreements. Without oversight of these agreements, citizens in those areas covered

by the cooperative agreement would be unprotected against abuse of the monopoly’s powers, such as price gouging and the reduction or removal of resources. The regulation is clearly written and understandable; however, the language needs to be updated in order to conform to the *Form, Style and Procedure Manual for Publication of Virginia Regulations* maintained by the Virginia Registrar of Regulations.

**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 has decided to amend the regulation to bring the text into compliance with the *Form, Style and Procedure Manual for Publication of Virginia Regulations* maintained by the Virginia Registrar of Regulations, to address the public comment received regarding ongoing supervision of already-approved cooperative agreements, and to consider regulatory reductions where possible.

**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.*

---

There is a continued need for the regulation as there is a current cooperative agreement in Virginia, and the Board is mandated to actively supervise cooperative agreements. The nature of the comment received concerning the regulation was focused on the ongoing active supervision of current cooperative agreements and was submitted by Ballad Health, the hospital system for which a cooperative agreement is currently in place. The regulation is not complex, nor does it overlap, duplicate, or conflict with federal or state law or regulation. The regulation has not been reviewed since 2018 when a final action was used to conform 12VAC5-221 to mandates from the General Assembly; the current periodic review is the first conducted since the initial promulgation of the regulation in 2017. Ballad Health, the hospital system involved in the current cooperative agreement does not qualify as a small business, and VDH is not aware of any entities that could enter into a cooperative agreement and qualify as a small business.