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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-221
Regulation title(s)	Virginia's Rules and Regulations Governing Cooperative Agreements
Action title	Establishes standards for the review of applications for proposed Cooperative Agreements and post-approval monitoring
Date this document prepared	August 26, 2015

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

House Bill 2316, enacted by the 2015 General Assembly, mandates the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applications for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement. http://lis.virginia.gov/cgi-bin/legp604.exe?151+ful+CHAP0741+pdf. HB2316 further specified that the regulations must be effective within 280 days of enactment. For that reason, the Board is utilizing the emergency rulemaking process authorized by the Administrative Process Act. The regulations contain

provisions pertaining to definitions, a fee schedule, procedures for the Commissioner's request for information, the Commissioner's review, ongoing monitoring and annual reporting.

In drafting the Emergency Regulations the Virginia Department of Health consulted other jurisdictions, convened a regulatory advisory panel, and held a public hearing. Tennessee has a program which is similar to the program envisioned by HB2316 and is a neighboring jurisdiction to Southwest Virginia. For these reasons, the Virginia Department of Health utilized regulations issued by Tennessee as a framework to build upon in drafting the Emergency Regulations. The Virginia Department of Health convened a regulatory advisory panel of stakeholders consisting of hospital providers, health plans, physicians, and representatives from the Southwest Virginia Health Authority. The regulatory advisory panel met twice and provided feedback to a framework document that the Virginia Department of Health incorporated into the Emergency Regulations. Finally the Virginia Department of Health, held a public hearing in Abingdon, Virginia. Public comment received at the hearing was considered and where appropriate incorporated into the Emergency Regulations.

Acronyms and Definitions

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

No acronyms are utilized within this Agency Background Document.

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

HB2316 of 2015 specified that the regulations must be effective within 280 days of enactment. For that reason, the Board is utilizing the emergency rulemaking process authorized by the Administrative Process Act.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

The regulatory chapter 12VAC5-221 is promulgated under the authority of HB2316 of the 2015 General Assembly and § 32.1-12 of the Code. HB2316 of the 2015 General Assembly Session enacted as Chapter 741 of the 2015 Virginia Acts of Assembly contains an enactment clause which mandates the State Board of Health to promulgate regulations to implement the provisions of the Act and requires those regulations contain at a minimum provisions regarding i) the review of applications for proposed cooperative agreements; ii) the process by which applications for proposed cooperative agreements shall

be approved or denied; iii) post-approval monitoring; and iv) a schedule establishing the amount of the annual fee that the Commissioner is authorized to assess from the parties to a cooperative agreement. Section 32.1-12 of the Code of Virginia authorizes the Board of Health to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of Title 32.1 of the Code and other laws of the Commonwealth administered by it, the Commissioner or the Department.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

In order to address the unique healthcare challenges that exist in the Southwest Virginia region, the General Assembly through HB2316 of 2015 has authorized the Commissioner to approve Cooperative Agreements that are beneficial to individuals served by the Southwest Virginia Health Authority, and to actively supervise Cooperative Agreements to ensure compliance with the provisions that have been approved. The intent of this regulatory action is to promote and protect the health and safety of individuals within the Southwest Virginia Health Authority's geographic area by ensuring any Cooperative Agreements entered into by hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvements in population health status in the Southwest Virginia Health Authority's geographic area. HB2316 of 2015 mandates that this regulatory action include at a minimum provisions regarding i) the review of applications for proposed cooperative agreements; ii) the process by which applications for proposed cooperative agreements shall be approved or denied; iii) post-approval monitoring; and iv) a schedule establishing the amount of the annual fee that the Commissioner is authorized to assess from the parties to a cooperative agreement. The proposed Emergency Regulations contain provisions which meet these requirements.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

This regulatory action is mandated by HB2316 enacted by the 2015 General Assembly. It is the intent of the Virginia Department of Health, the State Health Commissioner and the Board of Health to implement regulations which promote and protect the health and safety of individuals within the Southwest Virginia Health Authority's geographic area by ensuring any Cooperative Agreements entered into by hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvements in population health status in the Southwest Virginia Health Authority's geographic area.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10 – Purpose	This section of the regulations lays out the purpose of the regulatory chapter which is derived from HB 2316 (2015) and § 15.2-5368 of the Code of Virginia.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To provide members of the public a better understanding of the reason for the regulatory chapter and the program. Likely impact: Notice to the public and parties to a Cooperative Agreement.
20 – Definitions	This section of the regulations defines key terms utilized within the regulatory chapter.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure members of the public and regulated entities have a clear understanding of the vocabulary utilized within the regulatory chapter. Likely impact: Clear understanding of terms used in the regulations.
30 – Separate Applications	This section of the regulations requires that each cooperative agreement entered into requires its own Letter Authorizing Cooperative Agreement. The section states that amendments to existing Cooperative Agreements require submission of a new application.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure the Commissioner and the Authority have notice of all activities taking place under the Cooperative Agreement program. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
40- Application	This section of the regulations specifies the process for applying for a Letter Authorizing Cooperative Agreement. The section states that applications shall be submitted simultaneously to the Authority, Commissioner and the Office of the Attorney General. The section also lays out the method for submitting information considered to be confidential.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure that applicants submit applications in the manner consistent with the Code of Virginia. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
50-Fee Schedule	This section of the regulations lays out the method for submitting application fees, establishes the application fee, method for the Department to refund	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: The Cooperative Agreement program is an unfunded mandate. Therefore the Department shall require application fees to effectively run the program.

	the applicant should it be necessary and establishes that the Department may charge additional fees beyond the application fee should the cost to the Department be greater than the application fee.		Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
60- Public Hearing	This section of the regulations lays out the requirements of the public hearing required by § 15.2-5384.1 (D) of the Code of Virginia. This section states that the public hearing shall be held by the Authority in conjunction with the Virginia Department of Health, shall be open to the public and shall be recorded by the Virginia Department of Health.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To establish the requirements of the public hearing which is a statutory mandate required by § 15.2-5384.1 (D) of the Code of Virginia. Ensure the public and regulated entities are aware that public hearings held in accordance with this section shall be recorded. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
70 – The Commissioner's Request for Information	This section of the regulations lays out that information the Commissioner shall request from an applicant provided that information is not already included within the application. The Commissioner is permitted to request further information not specified by regulation.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure the applicants have adequate notice of the information to be requested by the Commissioner. Placing this information in regulation provides the applicant the opportunity to gather the listed information while the Authority is reviewing their application, provided any of the information is not included within the Authority's application process. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.
80 – The Commissioner's Review	This section of the regulations lays out the process the Commissioner shall follow when reviewing an application for a Letter Authorizing Cooperative Agreement. The Commissioner shall Consult with the Attorney General's	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure an applicant is notified of the method of the Commissioner's review. Transparency. Likely impact: Effective oversight of Letters Authorizing Cooperative

	Office and other affected agencies of the Commonwealth and may consult with the Federal Trade Commission and other affected jurisdictions. This section specifies what materials the Commissioner shall consider, when the Commissioner shall issue his decision, and the circumstances under which the Commissioner shall approve an application.		Agreement. Notice to the public and parties to a Cooperative Agreement.
90- Action on an application	This section of the regulations provides the framework for the Commissioner's decision including the timeframe a decision will be rendered, as required by § 15.2-5384.1 (F) of Virginia, and laying out potential conditions which may be placed on a Letter Authorizing Cooperative Agreement.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure an applicant is aware of the timeframe a decision will be rendered and aware prior to a decision that the Letter Authorizing Cooperative Agreement may have conditions. Also ensuring the applicant is aware of their rights under the Administrative Process Act. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
100- Ongoing and Active Supervision	This section of the regulations lays out the process for ongoing monitoring should a Letter Authorizing Cooperative Agreement be issued, including ongoing reporting to the Department. Further, the section lays out how the Department will evaluate continued reporting to determine if the Letter Holder is compiling with the terms of the Letter Authorizing Cooperative Agreement including conditions. That process includes the creation of an index. The index will be created utilizing the Technical Advisory Panel established in Section 120 of these Regulations. This section permits the Virginia Department of Health to	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure that Letter Holders are aware of the requirements of ongoing supervision and the method the Department will use to evaluate ongoing supervision. This will ensure transparency. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.

	make on-site inspections if necessary and requires an investigation of any complaints regarding non-compliance with the Cooperative Agreement or the Letter Authorizing Cooperative Agreement. The regulation also provides for other methods of monitoring provided the Commissioner and the Department provides advance notice to the Parties.		
110 – Annual Reporting	This section of the regulations details the requirements of the annual report each Letter Holder is required to submit. This section lays out the fee due to be submitted with the annual report.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: Notice to Letter Holders regarding the requirements of Annual Reporting and the amount of the annual filing fee. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
120- Technical Advisory Panel	This section of the regulations states that the Commissioner shall appoint a Technical Advisory Panel which will provide recommendations to the Commissioner regarding the creation of an Index which will be utilized to track the benefits of a Cooperative Agreement. The section further lays out the requirements of the membership of the Technical Advisory Panel, when it shall meet and the metrics it shall identify.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: Specify the process for the appointment of a Technical Advisory Panel and the task of that panel. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
130 – Enforcement Procedures	This section of the regulations lays the procedures that the Commissioner is to follow should there be reason to believe that a Cooperative Agreement no longer meets the requirements of the Code of Virginia. The section also lays out the circumstances in which the Commissioner may revoke a Letter Authorizing	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: Specify the process in the event the Letter Holder is no longer in compliance with the Letter Authorizing Cooperative Agreement. Transparency. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.

	Cooperative Agreement.		
140- Voluntary Termination of Cooperative Agreement	This section of the regulations states that Letter Holder shall file notice with the Department should they terminate a Cooperative Agreement and return the Letter Authorizing Cooperative Agreement.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: Specify the process in the event the Letter Holder wishes to voluntarily terminate a Cooperative Agreement. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
150 – Official Records	This section of the regulations clarifies that the Commissioner and the Department shall maintain all Cooperative Agreements, all records collected pursuant to the regulatory chapter and all annual reports as official records. The section also states which records shall be available on the Department's website.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: Specify requirements regarding records collected by the Department and the Commissioner in administering the program. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

HB2316 enacted by the 2015 General Assembly mandates that the Board of Health promulgate these regulations. Therefore, there are no alternatives to this regulatory action.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative

costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to **Susan Puglisi, 9960 Mayland Drive, Henrico Virginia 23233, phone: 804-367-2157, fax: 804-527-4502, and susan.puglisi@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Family impact

Please assess the impact of this 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.

It is not anticipated that the proposed regulatory action will have any direct impact on the institution of the family and family stability. However, should a Cooperative Agreement be entered into the regulatory chapter shall ensure that the Cooperative Agreement hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvement in population health status in the Southwest Virginia Health Authority's geographic area, all of which may help to increase disposable family income.