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Fast-Track Regulation
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	March 22, 2017

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 applicants 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. HB2316 further specified that the regulations must 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 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 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 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 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.

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Virginia Board of Health approved these amendments to the Regulations Governing Cooperative Agreements in Virginia on March 16, 2017.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulatory chapter 12VAC5-221 is promulgated under the authority of HB 2316 of the 2015 General Assembly and § 32.1-12 of the Code of Virginia. HB2316 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 explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health,

safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

In order to address the unique healthcare challenges that exist in the Southwest Virginia region, the General Assembly through HB2316 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 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 Regulations contain provisions which meet these requirements.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

HB2316 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 applicants 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 within 280 days. The emergency regulations that were promulgated have been utilized since 2015. Furthermore, the Code of Virginia (§15.2-5384.1) is very specific in regards to the review of cooperative agreements, with the regulatory language closely tracking the statutory requirements. Therefore, the Virginia Department of Health believes the proposed regulation will be noncontroversial, allowing use of the fast-track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

A chart describing the proposed new regulation

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 et.seq. 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 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.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: To ensure that authorized fees are assessed and collected. 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 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.	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 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 within which 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 qualitative measures. The qualitative measures will be created utilizing the Technical Advisory Panel established in Section 120 of these Regulations. This section permits the Virginia Department of Health to make on-site inspections if necessary and requires an investigation of any complaints regarding noncompliance with the Cooperative Agreement or the Letter Authorizing	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.

	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 qualitative measures 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 Cooperative Agreement.	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.
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.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages to the public, the agency and the Commonwealth is in meeting the stated policy of the Commonwealth as included in Va Code §15.2-5384.1 "to encourage cooperative, collaborative, and integrative arrangements, including mergers and acquisitions among hospitals, health centers, or health providers who might otherwise be competitors. To the extent such cooperative agreements, or the planning and negotiations that precede such cooperative agreements, might be anticompetitive within the meaning and intent of state and federal antitrust laws, the intent of the Commonwealth with respect to each participating locality is to supplant competition with a regulatory program to permit cooperative agreements that are beneficial to citizens served by the Authority, and to invest in the Commissioner the authority to approve cooperative agreements recommended by the Authority and the duty of active supervision to ensure compliance with the provisions of the cooperative agreements that have been approved." The proposed regulatory action poses no disadvantage to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this proposal that exceed federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

Those localities within the jurisdiction of the Southwest Virginia Health Authority, specifically those with the Lenowisco and Cumberland Plateau Planning District Commissions, as well as the Counties of Smyth and Washington, and the City of Bristol.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

HB2316 mandates the Board of Health to promulgate regulations governing cooperative agreements. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by HB2316.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	A minimum $87,000 for the initial review of a cooperative agreement, with the likelihood that this is a conservative estimate. A minimum of $75,000 annually for ongoing, active State supervision and monitoring of the cooperative agreement, with the likelihood that this is a conservative estimate. A maximum of $75,000 for initial review and $75,000 annually for supervision is authorized, by statue, for reimbursement from the applicants.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Wellmont Health System, Mountain States Health Alliance, as well as all competitors, health insurance carriers and consumers of health care services in those localities within the jurisdictions of the Southwest Virginia Health Authority.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	258,101 health care consumers. 3,253 physicians. 11 hospitals. At least 8 health insurance carriers plus Medicare and Medicaid.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	Beyond the $75,000 reimbursements to the State it is unknown and impossible to estimate the cost applicants may incur to apply for a cooperative agreement as allowed in the regulations, to maintain records and to comply with annual record keeping and reporting and any other requirements of active supervision by the State.
Beneficial impact the regulation is designed to produce.	Provides the criteria by which cooperative agreements are to be considered, approved or denied, and continuously supervised.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

HB 2316 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 notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.

Current Section Number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
	12VAC5-221-10. Purpose		To address the unique healthcare challenges that exist in the Southwest Virginia community, the

			General Assembly authorized the Commissioner to approve or deny an Application for a Cooperative Agreement following receipt of a recommendation for approval by the Authority. To the extent an approved Cooperative Agreement might be anticompetitive within the meaning and intent of state and federal antitrust laws, it is the intent of the Commonwealth with respect to each Participating Locality to supplant competition with a regulatory program to permit Cooperative Agreements that are beneficial to citizens served by the Authority. The Commissioner is authorized to issue a Letter Authorizing Cooperative Agreement if he determines by a preponderance of the evidence that the benefits likely to result from the Cooperative Agreement outweigh the disadvantages likely to result from a reduction in competition. The Commissioner is responsible for actively supervising the Parties that receive the Letter Authorizing Cooperative Agreement to ensure compliance with the provisions that have been approved. Such intent is within the public policy of the Commonwealth to facilitate the provision of quality, cost-efficient medical care to residents of a Participating Locality. 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.
	12VAC5-221-20. Definitions		"Applicant" means a Party to a proposed Cooperative Agreement who submits an Application to the Authority pursuant to § 15.2-5384.1 of the Code of Virginia. "Application" means the written materials submitted to the Authority and the Department in accordance with § 15.2-5384.1 of the Code of Virginia by Applicants. "Authority" means the political subdivision organized and operated pursuant to Chapter 53.1 of Title 15.2 of the Code of Virginia, or if such Authority is abolished, the board, body, authority, Department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law. "Attorney General" means the Attorney General for the Commonwealth of Virginia. "Commissioner" means the State Health Commissioner. "Cooperative Agreement" means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals. "Day" or "Days" means calendar days. "Department" means the Virginia Department of Health. "Hospital" includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches

			thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including, without limitation, hospitals, nursing homes, assisted living facilities, continuing care facilities, self-care facilities, mental health facilities, wellness and health maintenance centers, medical office facilities, clinics, outpatient surgical centers, alcohol, substance abuse and drug treatment centers, dental care clinics, laboratories, research facilities, sanitariums, hospices, facilities for the residence or care of the elderly, the handicapped or the chronically ill, residential facilities for nurses, interns, and physicians and any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability), together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including, without limitation, kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public. "Letter Authorizing Cooperative Agreement" means a document that is issued by the Commissioner approving a Cooperative Agreement. "Measure" means some number of factors or benchmarks, which may be binary, a range or continuous factors. "Participating Locality" means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the Authority will function. "Party" means a hospital entering into a Cooperative Agreement. "Plan of Separation" means the written proposal submitted with an Application to return the parties to a pre-consolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, employee benefits, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the

			consolidation occurs or thereafter. "Primary Service Area" or "PSA" means the geographic area from which a hospital draws 75% of its patients as measured by the residential zip code of each patient. "Secondary Service Area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient. 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.
	12VAC5-221-30. Separate Applications		A Party shall submit an Application for a Letter Authorizing Cooperative Agreement for each Cooperative Agreement the Party is applying to enter into. This provision applies even in the event that the Parties have an existing Letter Authorizing Cooperative Agreement issued by the Commissioner. An amendment to a Cooperative Agreement shall require submission of a new Application. 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.
	12VAC5-221-40. Application		A. Parties within any Participating Locality may submit an Application for a Letter Authorizing Cooperative Agreement to the Authority. Information regarding the requirements of an Application for a Letter Authorizing Cooperative Agreement submitted to the Authority should be obtained through the Authority. B. At the time of submission to the Authority, Parties shall simultaneously submit a copy of the Application to the Commissioner and the Attorney General. C. If the Authority requires the Applicant to submit additional information before determining that the Application is complete, the Parties shall simultaneously submit a copy of the additional information to the Authority, the Commissioner, and the Attorney General. D. If the applicants believe the materials submitted contain proprietary information that are required to remain confidential, such information must be clearly identified and the applicants shall submit duplicate applications, one with full information for the Commissioner's use and one redacted application available for release to the public. Proprietary information that is clearly identified by the Applicants will be kept confidential by the Department pursuant to § 2.2-3705.6 (3) of the Code of Virginia. 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.

	12VAC5-221-50. Fee Schedule		A. Fees shall be remitted only by certified check, cashier's check, bank money order or other methods approved by the department. Fees shall be made payable to the Department. B. The Application fee shall be $50,000 and shall be due to the Department upon its receipt of a recommendation for approval from the Authority. C. If the Commissioner should determine after review of the Application that the actual cost incurred by the Department is less than $50,000, the Applicant shall be reimbursed the amount that is greater than the actual cost. If the Commissioner should determine that the actual cost incurred by the Department is greater than $50,000, the Applicant shall pay any additional amounts due as instructed by the Department. The Application fee shall not exceed $75,000. Intent: To ensure that the application and monitoring fee structure is clear in the manner consistent with the Code of Virginia. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
	12VAC5-221-60. Public Hearing		A. The Authority shall, in conjunction with the Commissioner, schedule a public hearing for each completed Application submitted. The hearing shall be held no later than 45 days after the receipt of a complete Application by the Authority. B. The Authority will publish and issue notice of the hearing in accordance with § 15.2-5384.1 (C) of the Code of Virginia. C. The public hearing shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et. seq.) of the Code of Virginia. D. The public hearing shall be recorded by the Virginia Department of Health. 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 Agreements.
	12VAC5-221-65. Public Comment to the Commissioner		The public may submit written comments regarding the Application to the Commissioner. To ensure consideration by the Commissioner, written comments must be received no later than 14 days after the Authority adopts its recommendation on the Application. Intent: Assure public participation is the cooperative agreement review process. Likely impact: Improved information and transparency in the review of requests for letters authorizing Cooperative Agreements.
	12VAC5-221-70. The Commissioner's Request for Information		A. Upon receipt of the Authority's recommendation for approval, the Commissioner and Department may request supplemental information from the Applicants.

			B. To the extent the information is not present within the Application, the Commissioner shall request the following information: 1. A report(s) used for public information and education about the proposed Cooperative Agreement prior to the Parties' submission of the Application. The Applicants shall document the efforts used to disseminate the report(s). The report(s) shall include, but are not limited to: a. A description of the proposed Primary Service Area (PSA) and Secondary Service Areas (SSA) and the services and facilities to be included in the Cooperative Agreement; b. A description of how health services will change if the Letter Authorizing Cooperative Agreement is issued; c. A description of improvements in patient access to health care including prevention services for all categories of payers and advantages patients will experience across the entire service area regarding costs, availability, and accessibility upon implementation of the Cooperative Agreement and/or findings from studies conducted by hospitals and other external entities, including health economists, and clinical services and population health experts, that describe how implementation of the proposed Cooperative Agreement will be effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including, but not limited to, eliminating duplicative services; and equitable with respect to maintaining quality and competition in health services within the service area and assuring patient access to and choice of insurers and providers within the health care system; d. A description of any plans by the Parties regarding existing or planned facilities that will impact access for patients to the services currently offered by the Parties at their respective facilities, including expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services; e. A description of the findings from community or population health assessments for the service areas regarding major health issues, trends, and health disparities, including comparisons to measures for the state and similar regional areas, and a description of how the health of the population will change if the Letter Authorizing Cooperative Agreement is issued; and f. A description of the impact on the health professions workforce including long-term employment, wage levels, retirement, benefits, recruitment, and retention of health professionals. 2. A record of community stakeholder and consumer views of the proposed Cooperative Agreement collected through a public participatory process including meetings and correspondence. Transcripts or minutes of any meetings held during the public participatory process shall be included in the report. 3. A summary of the nature of the proposed Cooperative Agreement between the parties; 4. A signed copy of the Cooperative Agreement and a copy of the following: a. A description of any consideration passing to any Party, individual or entity under the Cooperative Agreement including the amount, nature, source, and recipient;

			b. A detailed description of any merger, lease, operating or management contract, change of control or other acquisition or change, direct or indirect, in ownership of any Party or of the assets of any Party to the Cooperative Agreement; c. A list of all services and products and of all hospitals and other service locations that are a subject of the Cooperative Agreement including those not located or provided within the boundaries of the Commonwealth of Virginia, and including, but not limited to, hospitals or other inpatient facilities, insurance products, physician practices, pharmacies, accountable care organizations, psychiatric facilities, nursing homes, physical therapy and rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer centers or services, imaging centers or services, support services, and any other product, facility, or service; and d. A description of each Party's contribution of capital, equipment, labor, services, or other contribution of value to the transaction. 5. A detailed description of the current and proposed PSA and SSA for the Parties, including the PSA and SSA of each of the Parties' hospitals, not limited to the boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from the service areas where the Parties have conducted business over the five (5) years preceding the Application, a description of how and why the proposed PSA or SSA differ and why changes are proposed; 6. A description of the prior history of dealings between the Parties for the last five (5) years including but not limited to, their relationship as competitors and any prior joint ventures, affiliations or other collaborative agreements between the Parties. 7. Documents sufficient to show the financial performance of each Party to the transaction for each of the preceding five (5) fiscal years including tax returns, debt, bond rating, and debt service, and copies of offering materials, subsequent filings such as continuing disclosure agreements and material event disclosures, and financial statements prepared by external certified public accountants, including management reports; 8. A copy of the current annual budget and budgets for the last five (5) years for each Party to the Cooperative Agreement. The budgets shall be in sufficient detail so as to determine the fiscal impact of the Cooperative Agreement on each Party. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented; 9. Projected budgets, including project costs, revenues, profit margins, and operating ratios, of each Party for each year for a period of five years after a Letter Authorizing Cooperative Agreement is issued. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented; 10. A detailed explanation of the projected effects including expected change in volume, price, and revenue as a result of the Cooperative Agreement, including:

			a. Identification of all insurance contracts and payer agreements in place at the time of the Application and a description of pending or anticipated changes that would require or enable the parties to amend their current insurance and payer agreements; b. A description of how pricing for provider insurance contracts are calculated and the financial advantages accruing to insurers, insured consumers and the parties to the Cooperative Agreement, if the Letter Authorizing Cooperative Agreement is issued including changes in percentage of risk-bearing contracts; and c. Identification of existing and future business plans, reports, studies or other documents of each party that: (1) Discuss each Party's projected performance in the market, business strategies, capital investment plans, competitive analyses, and financial projections, including any documents prepared in anticipation of the Cooperative Agreement; and (2) Identify plans that will be altered, eliminated, or combined under the Cooperative Agreement. 11. A copy of the following policies under the proposed Cooperative Agreement: a. A policy that assures no restrictions to Medicare and/or Medicaid patients; b. Policies for free or reduced fee care for the uninsured and indigent; c. Policies for bad debt write-off; and d, Policies that require the Parties to the Cooperative Agreement to maintain or exceed the existing level of charitable programs and services. 12. A description of the plan to systematically integrate health care and preventive health services among the Parties to the Cooperative Agreement in the proposed geographic service area that addresses the following: a. A streamlined management structure, including a description of a single board of directors, centralized leadership, and operating structure; b. Alignment of the care delivery decisions of the system with the interests of the community; c. Clinical standardization; d. Alignment of the cultural identities of the Parties to the Cooperative Agreement e. Any planned expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services; f. Any plan for integration regarding health professions workforce development and the recruitment and retention of health professionals; and g. Any plan for implementation of innovative or value-based payment models. 13. A description of the plan, including economic metrics, that details anticipated efficiencies in operating costs and shared services that can be gained only through the Cooperative Agreement including: a. Proposed use of any cost saving to reduce prices borne by insurers and consumers; b. Proposed use of cost savings to fund low or no-cost services designed to achieve long-term population health improvements; and c. Other proposed uses of savings to benefit advancement of health and quality of care and outcomes. 14. A description of the market and the

			competitive dynamics for health care services in the Parties' respective service areas, including at a minimum: a. The identity of any non-Party hospital located in the PSA and SSA and any non-Party hospital outside of the PSA and SSA that also serves patients in the Parties' PSA and SSA; b. Estimates of the share of hospital services furnished by each of the Parties and any non-Party hospitals; c. Identification of whether any services or products of the proposed Cooperative Agreement are currently being offered or capable of being offered by any non-Party hospitals in the PSA and SSA and a description of how the proposed Cooperative Agreement will not exclude such non-Party hospitals from continued competitive and independent operation in the PSA and SSA; d. A listing of the physicians employed by or under contract with each of the Parties' hospitals in the PSA and SSA, including their specialty and office location(s); e. The identity of any potential entrants in the Parties' PSA and SSA and the basis for any belief that such entry is likely within the two calendar years immediately following the date of the Letter Authorizing Cooperative Agreement is issued by the Department; and f. A list of each Party's top 10 commercial insurance payers by revenue within the PSA and SSA. 15. A detailed description of each of the benefits that the Parties propose will be achieved through the Cooperative Agreement. For each benefit include: a. A description specifically describing how the Parties intend to achieve the benefit; b. A description of what the Parties have done in the past with respect to achieving or attempting to achieve the benefits independently or through collaboration and how this may change if the Cooperative Agreement is granted; c. An explanation of why the benefit can only be achieved through a Cooperative Agreement and not through other less restrictive arrangements; and d. A description of how the Parties propose that the Commissioner measure and monitor achievement of the proposed benefit including: (1) Proposed measures and suggested baseline values with rationale for each measure to be considered by the Commissioner in developing a plan to monitor achievement of the benefit; (2) The current and projected levels, and the trajectory, for each measure that would be achieved over the next five years under the Cooperative Agreement; (3) The projected levels for each measure in five years in the absence of the Cooperative Agreement; and (4) A plan for how the requisite data for assessing the benefit will be obtained. 16. A description of any potential adverse impact of the proposed Cooperative Agreement on population health, or quality, availability, cost, or price of health care services to patients or payers; 17. A description of any commitments the Parties are willing to make to address any potential adverse impacts resulting from the Cooperative Agreement. Each such commitment shall at a

			minimum include: a. The Parties' proposed benchmarks and metrics to measure achievement of the proposed commitments; b. The Parties' proposed plan to obtain and analyze data to evaluate the extent to which the commitments have been met, including how data shall be obtained from entities other than the Parties; and c. The Parties' proposed consequences if they do not meet a commitment. 18. A Plan of Separation. The parties shall provide an independent opinion from a qualified organization verifying the Plan of Separation can be operationally implemented without undue disruption to essential health services provided by the Parties. 19. A statement regarding the requirements for any Certificate(s) of Public Need resulting from the Cooperative Agreement; 20. A detailed description of the total cost to the Parties resulting from the Application for the Cooperative Agreement. Cost estimates should include costs for consultant, legal and professional services, capital costs, financing costs, and management costs. The description should identify costs associated with the implementation of the Cooperative Agreement, including documentation of the availability of necessary funds. The description should identify which costs will be borne by each Party. 21. An explanation of the reasons for the exclusion of any information set forth in this section. If the Parties exclude an item because it is not applicable to the proposed Cooperative Agreement, an explanation of why the item is not applicable shall be provided; 22. A timetable for implementing all components of the proposed Cooperative Agreement and contact information for the person(s) authorized to receive notices, reports, and communications with respect to the Letter Authorizing Cooperative Agreement; 23. Records, reports, and documentation to support the information submitted pursuant to this section, including any additional supplemental information requested by the Commissioner. C. All supplemental information submitted to the Commissioner shall be accompanied by a verified statement signed by the Chairperson of the Board of Directors and Chief Executive Officer of each Party; or if one or more of the Parties is an individual, signed by the individual attesting to the accuracy and completeness of the enclosed information. 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.
	12VAC5-221-80.		A. The Commissioner shall consult with the

	The Commissioner's Review		Attorney General when reviewing an Application. B. The Commissioner may consult with the Federal Trade Commission when reviewing an Application. C. The Commissioner may consult and coordinate with other affected jurisdictions when reviewing an Application. D. The Commissioner shall consult with all other affected agencies of the Commonwealth when reviewing an Application. E. The Commissioner in his review shall examine the record developed by the Authority, the Authority's recommendation for approval, and any additional information received from the Parties. In addition, the Commissioner may consider any other data, information, or advice available to him. F. The Commissioner shall not render a decision on the Application until all supplemental information requested has been received. G. The Commissioner shall consider the following factors when conducting a review of an Application: 1. Advantages: a. Enhancement of the quality of hospital and hospital-related care, including mental health services and treatment of substance abuse, provided to citizens served by the Authority, resulting in improved patient satisfaction; b. Enhancement of population health status consistent with the regional health goals established by the Authority; c. Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities to ensure access to care; d. Gains in the cost-efficiency of services provided by the hospitals involved; e. Improvements in the utilization of hospital resources and equipment; f. Avoidance of duplication of hospital resources; g. Participation in the state Medicaid program; and h. Total cost of care. 2. Disadvantages: a. The extent of any likely adverse impact of the proposed Cooperative Agreement on the ability of health maintenance organizations, preferred provider organizations, managed health care organizations, or other health care payers to negotiate reasonable payment and service arrangements with hospitals, physicians, allied health care professionals, or other health care providers; b. The extent of any reduction in competition among physicians, allied health care professionals, other health care providers, or other persons furnishing goods or services to, or in competition with, hospitals that is likely to result directly or indirectly from the proposed Cooperative Agreement; c. The extent of any likely adverse impact on patients in the quality, availability, and price of health care services; and d. The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition likely to result from the proposed Cooperative Agreement. H. The Commissioner shall approve the Application if he finds by a preponderance of the

			evidence that the benefits likely to result from the proposed Cooperative Agreement outweigh the disadvantages likely to result from a reduction in competition from the proposed Cooperative Agreement. I. In the selection and application of the measures for reviewing the proposed benefits of the Cooperative Agreement, as well as during the monitoring and active supervision of any approved Cooperative Agreement, the Commissioner shall: 1. Draw from consensus health and health care metrics, such as those being developed pursuant to the Virginia state innovation model development initiative and state population health improvement plan, to ensure the validity and consistency of the measure; 2. Use historical actual experience in the region to establish baseline performance and evaluate progress over time; 3. Consider recommendations on the measures and goals from the Technical Advisory Panel pursuant to 12VAC5-221-120; and 4. Allow for flexibility, to the extent quantifiable goals or targets are specified, should environmental factors that are outside the control of the Parties change significantly. Intent: To ensure an applicant is notified of the method of the Commissioner's review. Transparency. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.
	12VAC5-221-90. Action on an application		A. The Commissioner shall issue his decision in writing within 45 days of receipt of the Authority's recommendation. However, if the Commissioner has requested supplemental information from the Applicants, the Commissioner shall have 15 days, following receipt of the supplemental information, to issue a decision. B. At the request of the Applicants, the Commissioner may delay issue of his decision to provide additional time to review the record. C. The Commissioner may condition approval of the Letter Authorizing Cooperative Agreement upon the Applicants' commitment to achieving the improvements in population health, access to health care services, quality, and cost efficiencies identified by the Applicant in support of their Application. Such conditions may include, but are not limited to: 1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by product. The method for calculating such a case-mix shall be published on the Virginia Department of Health's Office of Licensure and Certification's website in a guidance document. The Department may rely on third-party auditors to assist in determining the method for determining such caps, their level, and a plan for monitoring compliance; 2. A commitment to return a portion of the cost savings and efficiencies gained through the Cooperative Agreement to residents in the Participating Localities through specific proposed mechanisms; 3. An agreement that the Parties shall not prevent or discourage health plans from directing or incentivizing patients to choose certain providers;

			the Parties shall not have any contractual clauses or provisions which prevent health plans from directing or incentivizing patients; 4. An agreement that the Parties shall not engage in the tying of sales of the health system's services with the health plan's purchase of other services from the health system; 5. An agreement that the Parties shall not restrict a health plan's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan; and 6. A commitment that the Parties shall not refuse to include certain provisions in contracts with health plans that have been utilized in health plan contracts in other parts of the Commonwealth in order to promote value-based health care, including but not limited to, bundled payments, pay for performance, utilization management, and other processes that reward improvements in quality and efficiency. D. The Commissioner's decision to approve or deny an Application shall constitute a case decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et. seq.). Intent: To ensure an applicant is aware of the timeframe a decision will be rendered and to be 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.
	12VAC5-221-100. Ongoing and Active Supervision		A. The Commissioner shall maintain active and continuing supervision of the Parties in accordance with the terms under this subsection and to ensure compliance with the Cooperative Agreement and the Letter Authorizing Cooperative Agreement. . B. Any Party who receives a Letter Authorizing Cooperative Agreement shall submit any additional information that is requested by the Department to establish benchmarks for ongoing monitoring and supervision. The Department's request may include, but is not limited to, information on patient satisfaction, employee satisfaction, a charge master, and information reflecting the contracted rates negotiated with non-physician providers, allied health professionals, and other providers. C. The Department shall establish quantitative measures that will be used to evaluate the proposed and continuing benefits of the Cooperative Agreement. 1. The quantitative measures shall include measures of the cognizable benefits from the Cooperative Agreement in at least the following categories: a. Population health; b. Access to health services; c. Economic; d. Patient safety; e. Patient satisfaction; and f. Other cognizable benefits. 2. Each category may be comprised of measures for subcategories.

			3. The Technical Advisory Panel and the Parties to the Cooperative Agreement may make recommendations for the creation and evaluation of quantitative measures, but the Department shall have the exclusive authority to add, modify, accept, or reject recommendations when creating or interpreting the quantitative measures. D. A Department representative may make periodic unannounced on-site inspections of the Parties' facilities as necessary. If the Department finds, after inspection, noncompliance with any provision of this chapter, any applicable state regulations, or the elements of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement, the Commissioner shall begin enforcement procedures in accordance with 12VAC5-221-130. E. The Parties shall make available to the Department representative any requested records and shall allow access to interview the agents, employees, contractors, and any other person under the Parties' control, direction, or supervision. F. Complaints received by the Department with regard to noncompliance with the Cooperative Agreement or the Letter Authorizing Cooperative Agreement shall be investigated. When the investigation is complete, the Parties, and the complainant, if known, shall be notified of the findings of the investigation. G. The Commissioner may develop other mechanisms of monitoring the Parties to determine compliance with the Cooperative Agreement and whether compliance continues to meet the requirements of Code of Virginia § 15.2-5384.1. The Commissioner may modify the mechanisms of monitoring the Parties upon notice to the Parties. 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.
	12VAC5-221-110. Annual Reporting		A. Parties shall report annually to the Commissioner on the extent of the benefits realized and compliance with any terms and conditions placed on their Letter Authorizing Cooperative Agreement. The report shall: 1. Describe the activities conducted pursuant to the Cooperative Agreement; 2. Include any actions taken in furtherance of commitments made by the Parties or terms imposed by the Commissioner as a condition for approval of the Cooperative Agreement; 3. Include information related to changes in price, cost, quality, access to care, and population health improvement; 4. Include actual costs, revenues, profit margins, and operating costs; 5. Include a charge master; 6. Include information reflecting the contracted rates negotiated with non-physician providers, allied health professionals, and others; 7. Include any measures requested by the Department based on the recommendations of the

			Technical Advisory Panel appointed pursuant to 12VAC5-221-120; and 8. Include the current status of the quantitative measures established under 12VAC5-221-100(C) and the information requested by the Department for benchmarks established in 12VAC5-221-100(B). B. The Parties shall be required to update the Parties' Plan for Separation annually and submit the updated Plan of Separation to the Department. The Parties shall provide an independent opinion from a qualified organization that states the Plan of Separation may be operationally implemented without undue disruption to essential health services provided by the Parties. C. The Commissioner may require the Parties to supplement the annual report with additional information to the extent necessary to ensure compliance with the Cooperative Agreement and the Letter Authorizing Cooperative Agreement. D. All annual reports submitted pursuant to this subsection shall be certified audited by a third-party auditor. E. The fee due with the filing of the annual report shall be $20,000. If the Commissioner should determine that the actual cost incurred by the Department is greater than $20,000, the Parties shall pay any additional amounts due as instructed by the Department. The annual filing fee shall not exceed $75,000. F. The Commissioner shall issue a written decision and the basis for the decision on an annual basis as to whether the benefits of the Cooperative Agreement continue to outweigh any disadvantages attributable to a reduction in competition that have resulted from the Cooperative Agreement. 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.
	12VAC5-221-120. Technical Advisory Panel		A. The Commissioner shall appoint a Technical Advisory Panel to provide initial recommendations to the Commissioner as to the quality, cost, and access measures and benchmarks to be considered to objectively track the benefits and disadvantages of a Cooperative Agreement, and to provide ongoing input to the Commissioner on the evolution of these and other new measures and the progress of the Parties with respect to achievement of commitments with respect to these measures. B. The Technical Advisory Panel shall consist of: 1. A representative of the Commissioner of Health who shall serve as Chair of the panel; 2. The Chief Medical or Quality Officer(s) of the Parties; 3. A Chief Medical or Quality Officer of a hospital or health system from other state market areas with no affiliation with the Parties; 4. A Chief Medical or Quality Officer of a health plan that has subscribers in the affected area; 5. Experts in the area of health quality measurement and performance; 6. A consumer and employer representative from the affected area;

			7. A representative from the Board of Insurance; 8. The Chief Financial Officer(s) of the Parties; 9. A Chief Financial Officer of a hospital or health system from other state market areas with no affiliation with the Parties; and 10. A Chief Financial Officer of a health plan that has subscribers in the affected area. C. The Technical Advisory Panel shall meet at least on an annual basis. D. The Technical Advisory Panel shall identify evidence-based cost, quality, and access measures in areas including, but not limited to, population health, patient safety, health outcomes, patient satisfaction, access to care, and any other areas identified by the panel. The panel shall also make recommendations regarding how to best report performance on quality metrics. E. The Technical Advisory Panel meetings shall be staffed by the Virginia Department of Health Office of Licensure and Certification. 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.
	12VAC5-221-130. Enforcement Procedures		A. If the Commissioner has reason to believe that compliance with a Cooperative Agreement no longer meets the requirements of the Code of Virginia § 15.2-5384.1 or this chapter, the Commissioner shall initiate a proceeding to determine whether compliance with the Cooperative Agreement no longer meets the requirements of Code of Virginia § 15.2-5384.1 or this chapter. B. In the course of such a proceeding, the Commissioner is authorized to seek reasonable modifications to a Letter Authorizing Cooperative Agreement. Such modifications shall be with the consent of the Parties. C. The Commissioner may revoke a Letter Authorizing Cooperative Agreement upon a finding that: 1. The Parties are not complying with the terms or conditions of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement; 2. The Cooperative Agreement is not in substantial compliance with the terms of the Parties' Application or the Letter Authorizing Cooperative Agreement; 3. The benefits resulting from the Cooperative Agreement no longer outweigh the disadvantages attributable to the reduction in competition resulting from the Cooperative Agreement; 4. The Commissioner's approval was obtained as a result of intentional material misrepresentation to the Commissioner or as the result of coercion, threats, or intimidation toward any Party to the Cooperative Agreement; or 5. The Parties have failed to pay any fee required by the Department or the Authority. D. The proceeding initiated by the Commissioner under this section, and any judicial review thereof, shall be held in accordance with and governed by the Virginia Administrative Process Act (§ 2.2-4000). 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.
	12VAC5-221-140. Voluntary Termination of Cooperative Agreement		A. Any Party shall file notice with the Department within 30 days after terminating its participation in a Cooperative Agreement. The notice shall be sent in writing to the attention of the director of the Office of Licensure and Certification. B. In the event of a termination of a Cooperative Agreement, the Parties shall return the Letter Authorizing Cooperative Agreement to the Office of Licensure and Certification. 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.
	12VAC5-221-150. Official Records		A. The Commissioner shall maintain on file all Cooperative Agreements that the Commissioner has approved. B. All records collected pursuant to this regulatory chapter shall be maintained in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et. seq.) and the Library of Virginia's record management program (§ 42.1-85). C. All approved Cooperative Agreements and Letters Authorizing Cooperative Agreement shall be published on the Virginia Department of Health's Office of Licensure and Certification website. D. All reports collected pursuant to 12VAC5-221-110 shall be published on the Virginia Department of Health's Office of Licensure and Certification website. E. The Commissioner shall make public his annual determination of compliance with a Letter Authorizing the Cooperative Agreement. 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.

Changes from the Emergency Regulations:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-221-20. Definitions		"Applicant" means a Party to a proposed Cooperative Agreement who submits an Application to the Authority pursuant to § 15.2-5384.1 of the Code of Virginia. "Application" means the written materials submitted to the Authority	"Day" or "Days" means calendar days. The Intent: Clarify that since the Code of Virginia does not specify business days, "days" is read to mean calendar days. Likely Impact: The definition will mean the total time of review will be shortened.

		and the Department in accordance with § 15.2-5384.1 of the Code of Virginia by Applicants. "Authority" means the political subdivision organized and operated pursuant to Chapter 53.1 of Title 15.2 of the Code of Virginia, or if such Authority is abolished, the board, body, authority, Department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law. "Attorney General" means the Attorney General for the Commonwealth of Virginia. "Commissioner" means the State Health Commissioner. "Cooperative Agreement" means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals. "Day" or "Days" means calendar days. "Department" means the Virginia Department of Health. "Hospital" includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including, without limitation, hospitals, nursing homes, assisted living facilities, continuing care facilities, self-care facilities, mental health facilities, wellness and health maintenance centers, medical office facilities, clinics, outpatient surgical centers, alcohol, substance abuse and drug treatment centers, dental care clinics, laboratories, research facilities, sanitariums, hospices, facilities for the residence or care of the elderly, the handicapped or the chronically ill, residential facilities for	"Plan of Separation" includes employee benefits. The Intent: To assure employee benefits are addressed in any separation of merged entities. Likely impact: The definition will include employee benefits.

		nurses, interns, and physicians and any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability), together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including, without limitation, kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public. "Letter Authorizing Cooperative Agreement" means a document that is issued by the Commissioner approving a Cooperative Agreement. "Measure" means some number of factors or benchmarks, which may be binary, a range or continuous factors. "Participating Locality" means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the Authority will function. "Party" means a hospital entering into a Cooperative Agreement. "Plan of Separation" means the written proposal submitted with an Application to return the parties to a pre-consolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, employee benefits, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the consolidation occurs or thereafter. "Primary Service Area" or "PSA"	

		means the geographic area from which a hospital draws 75% of its patients as measured by the residential zip code of each patient. "Secondary Service Area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient.	
12VAC5-221-70. The Commissioners Request for Information		A. Upon receipt of the Authority's recommendation for approval, the Commissioner and Department may request supplemental information from the Applicants. B. To the extent the information is not present within the Application, the Commissioner shall request the following information: 1. A report(s) used for public information and education about the proposed Cooperative Agreement prior to the Parties' submission of the Application. The Applicants shall document the efforts used to disseminate the report(s). The report(s) shall include, but are not limited to: a. A description of the proposed Primary Service Area (PSA) and Secondary Service Areas (SSA) and the services and facilities to be included in the Cooperative Agreement; b. A description of how health services will change if the Letter Authorizing Cooperative Agreement is issued; c. A description of improvements in patient access to health care including prevention services for all categories of payers and advantages patients will experience across the entire service area regarding costs, availability, and accessibility upon implementation of the Cooperative Agreement and/or findings from studies conducted by hospitals and other external entities, including health economists, and clinical services and population health experts, that describe how implementation of the proposed Cooperative Agreement will be effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including, but not limited to, eliminating duplicative services; and equitable with respect to maintaining quality and competition in health services within the service area and assuring patient access to and choice of insurers and providers within the health care system;	Section B(1)(f) includes retirement benefits in the description of the impact on the health professions workforce. The Intent: To assure retirement benefits are addressed in any separation of merged entities. Likely impact: Retirement benefits will be included in the description of the impact on the health professions workforce.

		d. A description of any plans by the Parties regarding existing or planned facilities that will impact access for patients to the services currently offered by the Parties at their respective facilities, including expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services; e. A description of the findings from community or population health assessments for the service areas regarding major health issues, trends, and health disparities, including comparisons to measures for the state and similar regional areas, and a description of how the health of the population will change if the Letter Authorizing Cooperative Agreement is issued; and f. A description of the impact on the health professions workforce including long-term employment, wage levels, retirement, benefits, recruitment, and retention of health professionals. 2. A record of community stakeholder and consumer views of the proposed Cooperative Agreement collected through a public participatory process including meetings and correspondence. Transcripts or minutes of any meetings held during the public participatory process shall be included in the report. 3. A summary of the nature of the proposed Cooperative Agreement between the parties; 4. A signed copy of the Cooperative Agreement and a copy of the following: a. A description of any consideration passing to any Party, individual or entity under the Cooperative Agreement including the amount, nature, source, and recipient; b. A detailed description of any merger, lease, operating or management contract, change of control or other acquisition or change, direct or indirect, in ownership of any Party or of the assets of any Party to the Cooperative Agreement; c. A list of all services and products and of all hospitals and other service locations that are a subject of the Cooperative Agreement including those not located or provided within the boundaries of the Commonwealth of Virginia, and including, but not limited to, hospitals or other inpatient facilities, insurance products, physician practices, pharmacies, accountable	

		care organizations, psychiatric facilities, nursing homes, physical therapy and rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer centers or services, imaging centers or services, support services, and any other product, facility, or service; and d. A description of each Party's contribution of capital, equipment, labor, services, or other contribution of value to the transaction. 5. A detailed description of the current and proposed PSA and SSA for the Parties, including the PSA and SSA of each of the Parties' hospitals, not limited to the boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from the service areas where the Parties have conducted business over the five (5) years preceding the Application, a description of how and why the proposed PSA or SSA differ and why changes are proposed; 6. A description of the prior history of dealings between the Parties for the last five (5) years including but not limited to, their relationship as competitors and any prior joint ventures, affiliations or other collaborative agreements between the Parties. 7. Documents sufficient to show the financial performance of each Party to the transaction for each of the preceding five (5) fiscal years including tax returns, debt, bond rating, and debt service, and copies of offering materials, subsequent filings such as continuing disclosure agreements and material event disclosures, and financial statements prepared by external certified public accountants, including management reports; 8. A copy of the current annual budget and budgets for the last five (5) years for each Party to the Cooperative Agreement. The budgets shall be in sufficient detail so as to determine the fiscal impact of the Cooperative Agreement on each Party. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented; 9. Projected budgets, including project costs, revenues, profit margins, and operating ratios, of each Party for each year for a period of five years after a Letter	

		Authorizing Cooperative Agreement is issued. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented; 10. A detailed explanation of the projected effects including expected change in volume, price, and revenue as a result of the Cooperative Agreement, including: a. Identification of all insurance contracts and payer agreements in place at the time of the Application and a description of pending or anticipated changes that would require or enable the parties to amend their current insurance and payer agreements; b. A description of how pricing for provider insurance contracts are calculated and the financial advantages accruing to insurers, insured consumers and the parties to the Cooperative Agreement, if the Letter Authorizing Cooperative Agreement is issued including changes in percentage of risk-bearing contracts; and c. Identification of existing and future business plans, reports, studies or other documents of each party that: (1) Discuss each Party's projected performance in the market, business strategies, capital investment plans, competitive analyses, and financial projections, including any documents prepared in anticipation of the Cooperative Agreement; and (2) Identify plans that will be altered, eliminated, or combined under the Cooperative Agreement. 11. A copy of the following policies under the proposed Cooperative Agreement: a. A policy that assures no restrictions to Medicare and/or Medicaid patients; b. Policies for free or reduced fee care for the uninsured and indigent; c. Policies for bad debt write-off; and d, Policies that require the Parties to the Cooperative Agreement to maintain or exceed the existing level of charitable programs and services. 12. A description of the plan to systematically integrate health care and preventive health services among the Parties to the Cooperative Agreement in the proposed geographic service area that addresses the following:	

		a. A streamlined management structure, including a description of a single board of directors, centralized leadership, and operating structure; b. Alignment of the care delivery decisions of the system with the interests of the community; c. Clinical standardization; d. Alignment of the cultural identities of the Parties to the Cooperative Agreement e. Any planned expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services; f. Any plan for integration regarding health professions workforce development and the recruitment and retention of health professionals; and g. Any plan for implementation of innovative or value-based payment models. 13. A description of the plan, including economic metrics, that details anticipated efficiencies in operating costs and shared services that can be gained only through the Cooperative Agreement including: a. Proposed use of any cost saving to reduce prices borne by insurers and consumers; b. Proposed use of cost savings to fund low or no-cost services designed to achieve long-term population health improvements; and c. Other proposed uses of savings to benefit advancement of health and quality of care and outcomes. 14. A description of the market and the competitive dynamics for health care services in the Parties' respective service areas, including at a minimum: a. The identity of any non-Party hospital located in the PSA and SSA and any non-Party hospital outside of the PSA and SSA that also serves patients in the Parties' PSA and SSA; b. Estimates of the share of hospital services furnished by each of the Parties and any non-Party hospitals; c. Identification of whether any services or products of the proposed Cooperative Agreement are currently being offered or capable of being offered by any non-Party hospitals in the PSA and SSA and a description of how the proposed Cooperative Agreement will not exclude such non-Party hospitals from continued	

		competitive and independent operation in the PSA and SSA; d. A listing of the physicians employed by or under contract with each of the Parties' hospitals in the PSA and SSA, including their specialty and office location(s); e. The identity of any potential entrants in the Parties' PSA and SSA and the basis for any belief that such entry is likely within the two calendar years immediately following the date of the Letter Authorizing Cooperative Agreement is issued by the Department; and f. A list of each Party's top 10 commercial insurance payers by revenue within the PSA and SSA. 15. A detailed description of each of the benefits that the Parties propose will be achieved through the Cooperative Agreement. For each benefit include: a. A description specifically describing how the Parties intend to achieve the benefit; b. A description of what the Parties have done in the past with respect to achieving or attempting to achieve the benefits independently or through collaboration and how this may change if the Cooperative Agreement is granted; c. An explanation of why the benefit can only be achieved through a Cooperative Agreement and not through other less restrictive arrangements; and d. A description of how the Parties propose that the Commissioner measure and monitor achievement of the proposed benefit including: (1) Proposed measures and suggested baseline values with rationale for each measure to be considered by the Commissioner in developing a plan to monitor achievement of the benefit; (2) The current and projected levels, and the trajectory, for each measure that would be achieved over the next five years under the Cooperative Agreement; (3) The projected levels for each measure in five years in the absence of the Cooperative Agreement; and (4) A plan for how the requisite data for assessing the benefit will be obtained. 16. A description of any potential adverse impact of the proposed Cooperative Agreement on population health, or quality, availability, cost, or price of health	

		care services to patients or payers; 17. A description of any commitments the Parties are willing to make to address any potential adverse impacts resulting from the Cooperative Agreement. Each such commitment shall at a minimum include: a. The Parties' proposed benchmarks and metrics to measure achievement of the proposed commitments; b. The Parties' proposed plan to obtain and analyze data to evaluate the extent to which the commitments have been met, including how data shall be obtained from entities other than the Parties; and c. The Parties' proposed consequences if they do not meet a commitment. 18. A Plan of Separation. The parties shall provide an independent opinion from a qualified organization verifying the Plan of Separation can be operationally implemented without undue disruption to essential health services provided by the Parties. 19. A statement regarding the requirements for any Certificate(s) of Public Need resulting from the Cooperative Agreement; 20. A detailed description of the total cost to the Parties resulting from the Application for the Cooperative Agreement. Cost estimates should include costs for consultant, legal and professional services, capital costs, financing costs, and management costs. The description should identify costs associated with the implementation of the Cooperative Agreement, including documentation of the availability of necessary funds. The description should identify which costs will be borne by each Party. 21. An explanation of the reasons for the exclusion of any information set forth in this section. If the Parties exclude an item because it is not applicable to the proposed Cooperative Agreement, an explanation of why the item is not applicable shall be provided; 22. A timetable for implementing all components of the proposed Cooperative Agreement and contact information for the person(s) authorized to receive notices, reports, and communications with respect to the Letter Authorizing Cooperative Agreement; 23. Records, reports, and documentation to support the	

		information submitted pursuant to this section, including any additional supplemental information requested by the Commissioner. C. All supplemental information submitted to the Commissioner shall be accompanied by a verified statement signed by the Chairperson of the Board of Directors and Chief Executive Officer of each Party; or if one or more of the Parties is an individual, signed by the individual attesting to the accuracy and completeness of the enclosed information.	